



Annual Report

2022 - 2023



**Bharati Vidyapeeth
(Deemed to be
University)**

**INTERACTIVE
RESEARCH SCHOOL
FOR HEALTH AFFAIRS**



IRSHA
INTERACTIVE RESEARCH SCHOOL
FOR HEALTH AFFAIRS

Bharati Vidyapeeth Deemed University
Interactive Research School for Health Affairs (IRSHA)
Annual Report July 2022- June 2023

Index		
S. No	Contents	Page no
1.	Overview of Director	
2.	Organogram	
3.	Research Reports	3-97
4.	Mother and Child Health	3-15
	Cancer Research	16-23
	Obesity and Diabetes Research	24-34
	Herbal Medicine	35-37
	Centre for Innovation in Nutrition, Health and Disease (CINHD)	38-66
	Communicable Diseases	67-97
5.	Other Information	
	Budget	98-103
	Publications, Book/book chapters, Patents	104-106
	Awards and Honors	107-110
	Presentations in Conferences/Seminars, Workshops	110-111, 113-114
	Ph.D. Degree Awarded	116
	Invited talks by faculty	117-118
	collaborations	111-113, 115-116
6.	Other Activities	
	Invited lectures Social outreach activities Extension activities Any other activities Photo gallery	118-121
7.	Staff information	123-132
8.	Institutional Committees	132-134

Overview of Director

It is my privilege to present the Annual report of Interactive Research School for Health Affairs (IRSHA) for the year 2022-2023.. All the departments of IRSHA were successful in receiving financial support of Rs.118.62 Lakhs from national funding agencies for carrying out their research work. This year student fellowships of Rs. 48.67 lakhs were received. In the current year 3 students were awarded PhD degree.

In the year 2022-2023, the external funding through consultancy projects at NIBEC crossed 1000 lakhs. The efforts taken at NIBEC for testing of samples from SARS-CoV-2 clinical trials for determining neutralizing antibody titer were recognized by Dr Jitendra Singh, Minister Incharge Science & Technology, Government of India.

In the year 2022-2023 research work at the institute culminated into 13 publications research articles

Several activities had been organized at the institute and also the staff and students participated in national and international events. A brief summary of these events, activities and achievements by all the staff members has been presented in the current report.

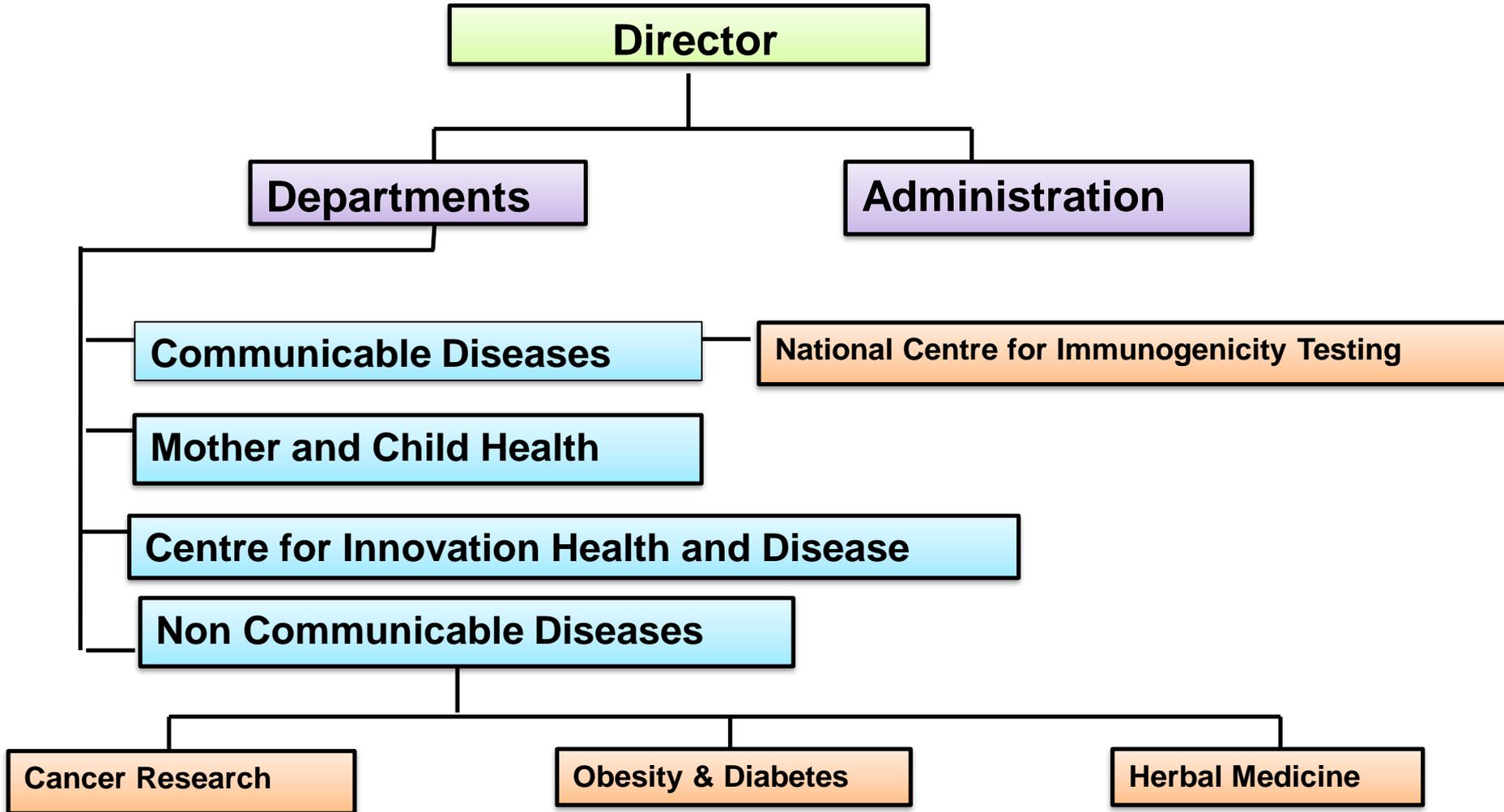
I appreciate the support and hard work of all the scientists, technical and administrative staff for their commendable performance.

Finally I sincerely thank the management for extending all the support for undertaking our research work.

Dr A C Mishra, M Sc, Ph D, LL B, FASc, FNA

Director

Organogram



Name of the Programme: Mother and Child Health

1. **Title:** Investigating Mechanisms Leading to Preeclampsia (**Project ID:** MCH/17/1/E); **Funding:** ICMR, Centre for Advanced Research; **Duration:** March 2017 to March 2022; **Sanctioned Amount:** Rs. 7,55,55,247/- **Investigators:** **PI** - Dr. Sadhana Joshi; **Co PI-** Dr. Girija Wagh, Dr. Sanjay Lalwani, Dr. Sanjay Gupte; **Co-Investigators** - Dr. Giriraj Chandak; Dr. Savita Mehendale, Dr. Arun Kinare, Dr. Priscilla Joshi, Dr. Leena Srivastav, Dr. Hemant Mandke, Dr. Anvita Kale, Dr. Deepali Sundrani, Dr. Nisha Wadhvani; **Ph.D. Students:** Aditi Godhamgaonkar; Vaishali Kasture (DST Inspire-SRF); Juhi Nema (CSIR-JRF); Anjali Jadhav (ICMR-SRF); Kinjal Dave (CSIR-JRF); **Human Ethical Approval:** IEC/2015/37, dated 03.10.2015

Background: The current study aims to follow pregnant women from early pregnancy until delivery, to examine changes across gestation in nutritional, biochemical, and molecular measures and identify the underlying mechanisms which influence the pathophysiology of preeclampsia (PE). This will be useful in development/validation of biomarkers for early prediction of PE. The study will also follow up the children's growth during infancy and their neurodevelopment at the age of 2 years.

Work done:

The project is completed and results are discussed below

- A total number of 1814 pregnant women recruited from two hospitals (Bharati Hospital and Gupte Hospital) of which 1154 women delivered and were included in the study.
- Analysis for this report includes data on 1096 singleton pregnancies of which 112 women had preeclampsia (PE) and 984 were women without preeclampsia (non-PE).
- Maternal blood was collected at each time point; cord blood and placenta were collected at delivery.
- Information on subjects' clinical history, medication, SLI, physical activity, 24 hr dietary recall, FFQ, ultrasonography and color Doppler measures were recorded at each time point.

- Women with PE were older, had a higher SLI score, were professionals and more educated, had higher BMI and systolic and diastolic blood pressure at all the time points, had a higher percentage of nulliparous women, higher percentage of assisted mode of conception and caesarean sections as compared to non-PE women.
- Gestational age at birth was lower in the PE group as compared to the non-PE group.
- Babies born to mothers with PE had a lower birth weight and head circumference as compared to the non-PE group.
- The percent preterm birth and SGA babies in the PE group were higher than the non-PE group.
- TSH levels were higher in women with PE as compared to non-PE women at V1.
- Fetal growth measures such as BPD, HC, AC, and EFW were lower at 18-22 weeks of gestation and FL was lower at 32-35 weeks of gestation in the PE group as compared to the non-PE group
- Mean uterine artery PI was higher at 11-14 weeks and 18-22 weeks of gestation in the PE group as compared to the non-PE group.
- Umbilical artery PI and fetal MCA PI at 32-35 weeks were lower in the PE group as compared to the non-PE group.
- Fetal growth measures such as AC, FL, and EFW at 32-35 weeks were negatively associated while mean uterine artery PI at 11-14 weeks and 18-22 weeks was positively associated with with preeclampsia after adjusting for confounders.
- The placentae of women with PE had a lower thickness at centre, at edge and at cord insertion as compared to the non-PE placentae.
- The percentage of bilobed and irregular shape and percentage of velamentous cord insertion was more in case of PE as compared to the non-PE group.
- Physical activity was lower in women with preeclampsia across pregnancy, but not associated with an increased risk of preeclampsia
- Women with preeclampsia consumed lower millets and green leafy vegetables, whereas higher ghee/butter, milk/milk products and nuts/oilseeds in early pregnancy. However, none of the above were associated with risk for preeclampsia.
- The REVAMP participants gained less weight throughout pregnancy compared to Intergrowth-21st reference.

- Data on maternal erythrocyte fatty acid levels shows that in the PE group at V1, saturated fatty acid levels were higher; at V2, total omega-6 fatty acids and omega-6/omega3 fatty acid ratio were higher; at V3, arachidonic acid was higher as compared to the non-PE group.
- The $\Delta 6$ desaturase index was higher in the PE group at V1, V2, and at delivery while $\Delta 5$ desaturase index was lower at V2, and at delivery.
- $\Delta 6$ desaturase index at 11-14 weeks showed significant predictive power in predicting EOP with the cut-off value of 0.138.
- No significant differences in the maternal and cord levels of folate, vitamin B₁₂ and homocysteine between PE and non-PE groups.
- Maternal serum magnesium levels were lower in the PE group at V2.
- Magnesium levels were negatively associated with the risk of PE at V2 after adjusting for confounders.
- Hs-CRP levels were higher at V1, V2 and V3 in the PE group but not associated with risk of preeclampsia.
- Maternal vitamin D levels were lower in the PE group at V2 and at delivery
- No significant differences were observed in the MDA levels between both the groups.
- Angiogenic factors like PIGF in maternal plasma were lower at all the time points while VEGF was lower only at V1 in the PE group.
- Anti-angiogenic factors like sEng in maternal plasma was higher at all the time points while sFlt-1 was lower at V3 in the PE group.
- sEng/PIGF ratio was higher at V1, V2, and V3 while sFlt-1/PIGF ratio was higher at V2, V3, and V4 in the PE group.
- sEng/PIGF at V2 for prediction of early onset preeclampsia was significant with the cut-off value of 25.90. Maternal factors such as MAP and BMI combined with the sEng/PIGF ratio, increased to AUC, sensitivity and specificity.
- sFlt-1/PIGF at V2 for prediction of early onset preeclampsia was significant with the cut-off value of 33.5. Maternal factors such as MAP and BMI combined with the sFlt-1/PIGF ratio, increased to AUC, sensitivity and specificity.
- Follow up of children - weight of the child remained lower at 6 weeks, 10 weeks, 14 weeks, 6 months (trend, but no significance). Weights were similar in both groups from 9 months upto 2 years.

- There was a lower trend ($p=0.076$) observed for the Developmental Quotient (DQ) levels in the children of PE group.
- Maternal fatty acid status in early pregnancy was associated with placental DNA methylation patterns of angiogenic factors (PlGF and FLT-1) and transcription factors (HIF-1 α and HIF-3 α).

Translational Potential:

Adoption of research outcomes in public health practices resulting in guidelines/programs.

- Weight Gain: Gestational weight gain (GWG) of Indian women is lower than the prescriptive standards of the Intergrowth charts.
- It provides a reference chart for GWG in different BMI categories - will be useful for routine obstetric use.
- Doppler in early pregnancy: higher mean uterine artery PI in women with preeclampsia – useful for clinical diagnosis.

Product/technology Development: Products developed/technology resulted in the outcome of research undertaken.

- Various biochemical measures **predate clinical diagnosis of preeclampsia:**
 - increased saturated fatty acids
 - higher n 6: n 3 fatty acid ratio
 - higher delta 6 desaturase index
 - low magnesium
 - low vitamin D
 - imbalance in angiogenic factors
- Identified Biomarkers for detection of early onset preeclampsia:
 - Delta 6 desaturase index
 - Soluble Endoglin/ Placental growth factor (sEng/PlGF)
 - Soluble fms like tyrosine kinase -1 / Placental growth factor (sFlt-1/PlGF)
- Biomarkers could be validated and used for development of diagnostic kits

- Association of early maternal fatty acid status with DNA methylation of genes - suggests their causal role and provides a target for reversal of the future risk.

Biorepository – A large ICMR CAR biorepository of a total number of ~90 to 95 vials for each subject across the study period are collected (~1,20,000 vials)

Conclusion:

- This study has systematically and comprehensively investigated the key biochemical and molecular mechanisms contributing to preeclampsia.
- We have identified novel circulating proteins [Delta 6 desaturase index, Soluble Endoglin/ Placental growth factor (sEng/PlGF), Soluble fms like tyrosine kinase -1 / Placental growth factor (sFlt-1/PlGF)] which predict the risk of developing preeclampsia. These biomarkers could be validated and used for development of diagnostic kits.
- The study also demonstrates that women with preeclampsia have increased saturated fatty acids, higher n 6: n 3 fatty acid ratio, low magnesium, low vitamin D, imbalance in angiogenic factors before clinical diagnosis of preeclampsia. This provides clues for therapeutic interventions.
- The study also provides insights into novel epigenetic mechanisms in the placenta which may lead to impaired placentation and fetal growth in preeclampsia.
- Women with preeclampsia and their children are suggested to be at increased risk for non-communicable diseases (NCDs) in later life Our findings will help guide development of public health interventions to reduce the burden of NCDs in India.

The project duration is over and project objectives are completed.

2.Title: Early Interventions to Support Trajectories for Healthy Life in India (EINSTEIN). Healthy Life Trajectories Initiative (HeLTI) (**Project ID:** MCH/17/2/E) Multicentric Project; **Funding:** DBT; **Sanctioned Amount:** Total Sanctioned Rs. 743.44 Lakhs; IRSHA Share: Rs.13.50 Lakhs; **Duration:** Dec 2017 to Nov 2025; **Investigator at IRSHA:** Dr. Sadhana Joshi; **Human Ethical Approval:** IEC/2018/34

Background: The study is a community-based, cluster randomized intervention with three arms (pre-conception, pregnancy and control) set in rural Mysore, South India, with individual villages forming the basis for the cluster. The primary outcome at age 5 years in the children across all HeLTI cohorts is adiposity, measured by fat mass index. Other key outcomes at 5 years include; overweight and obesity, glucose metabolism, blood pressure, and infant/child development.

Work done:

Formative work: Mysore Team commenced the formative work in November 2018 in three villages

Community engagement: Extensive community engagement to explain the study and assess the community's interest and willingness to not only participate, but also contribute to the study design and delivery

Qualitative work: Undertook focus group discussions (FGDs) with village women, husbands, mothers/mothers-in-law, village leaders and officials, and local community health staff.

Quantitative work:

Analyses of fatty acids have been undertaken at IRSHA, Bharati Vidyapeeth, Pune

Plasma fatty acid profile revealed a high n6/n3 PUFA ratio (total n6=33.51 g/100g (SD 4.57); total n3=1.51 g/100g (SD 0.60); n6/n3 ratio=26:1

Intervention development: The core members of the India and Canada teams conceptualised the intervention modules and prepared the outline in February 2019. The intervention will be delivered across four phases. The local team then developed six pre-conceptual modules: General Health; Healthy Eating; Health Lifestyle; Keeping Clean; Positive Thinking; and Preparing for Pregnancy.

Harmonisation and governance : All four HeLTI teams have worked together to harmonise data variables and intervention domains and we have achieved a high degree of harmonisation

3. Title: OPTIMISE: Optimal preconception nutrition to offset inflammation and non-communicable disease risk in pregnant women and their children in China, India and South Africa; (Project ID: MCH/22/3/E) **Funding:** Medical Research Council, United Kingdom; **Duration** : 5 years; Project Sanctioned but not initiated; **Investigators:** **Principal Investigator** Dr Kalyanaraman Kumaran University of Southampton Human Development and Health; **Co-Investigator** Professor Caroline Fall University of Southampton Human Development and Health Co-Investigator Professor Philip Calder University of Southampton Human Development and Health Co-Investigator Dr Mark Johnson Imperial College London Surgery and Cancer; Co-Investigator Dr Amanda SferruzziPerri University of Cambridge Physiology Development and Neuroscience; Co-Investigator Professor Shane Norris University of the Witwatersrand Faculty of Health Sciences Co-Investigator Professor Stephen Matthews University of Toronto Physiology; Co-Investigator Dr Stephen Lye University of Toronto Physiology; Co-Investigator Dr Ghattu V Krishnaveni CSI Holdsworth Memorial Hospital Research; Co-Investigator Dr Giriraj Chandak CSIR - Centre for Cellular and Molecular; Co-Investigator Dr catherine birken Hospital for Sick Children (SickKids) Paediatrics and Genetics Co-Investigator Professor Cindy-Lee Dennis University of Toronto Unlisted; Co-Investigator Dr William Fraser University of Sherbrooke Faculty of Medicine and Health Sciences Co-Investigator Professor Hefeng Huang Huang Shanghai Jiao Tong University Medical School; Co-Investigator Professor Luigi Bouchard University of Sherbrooke Faculty of Medicine and Health Sciences; Co-Investigator Dr Fengxiu Ouyang Shanghai Jiao Tong University; Co-Investigator Dr Yanting Wu Shanghai Jiao Tong University Medical School; Co-Investigator Dr SADHANA JOSHI Bharati Vidyapeeth University IRSHA, Pune (School for Health Affairs)

Hypothesis: We propose that inflammation is an important modifiable factor underlying an inter-generational cycle of non-communicable disease (NCD) risk in low- and middle-income countries (LMICs). We hypothesise that recent dietary changes in LMICs (causing the ‘double burden of malnutrition’) set up a chronic inflammatory state which increases the risk of type 2 diabetes (T2DM) and cardiovascular disease (CVD). Among pregnant women, this inflammatory state leads to pregnancy complications (gestational diabetes, hypertensive disorders and pre-term birth) and placental changes that impair fetal growth. These disrupt fetal neurodevelopment and increase fetal adiposity. Optimising maternal diet and nutritional status before and during

pregnancy will reduce inflammation, prevent pregnancy complications and improve newborn body composition. Long term benefits, beyond the scope this project, will be reduced NCD risk in the mother, and improved brain development and reduced cardiometabolic disease in the offspring.

OPTIMISE aims to leverage a unique trio of harmonised randomised controlled trials (RCTs) taking place in China, India and South Africa to:

Determine context-specific nutritional factors influencing inflammatory load among young women and how nutrition interacts with other drivers of inflammation

Elucidate relationships between maternal inflammatory load and common adverse pregnancy outcomes (gestational diabetes, hypertensive disorders, pre-term birth and fetal growth restriction)

Determine if a package of interventions to optimise women's nutrition before and during pregnancy reduces inflammatory load and these adverse pregnancy/birth outcomes

Investigate mechanisms, including altered placental structure, inflammation and nutrient transport capacity, linking inflammatory load with adverse pregnancy outcomes.

Work Done:

The study has been initiated and we are awaiting for samples.

4. Title: Epigenetic regulation of angiogenic factors in assisted reproductive technology (ART) and non-ART derived placentae (**Project ID:** MC/19/4/E); **Funding:** DBT; **Sanctioned Amount:** 59.91 Lakhs; **Duration:** July 2019 to July 2022; **Investigators:** PI- Dr. Deepali P. Sundrani **Co-Investigators:** Dr. Sadhana Joshi; Dr. Sanjay Gupte

Background: In India, the rate of infertility is on the rise thereby increasing the demand for assisted reproductive technology (ART) procedures. ART treatment coincides with several phases of epigenetic programming during gametogenesis and early embryo development. During these stages, *de novo* methylation and chromatin remodeling takes place which influences the placental structure and function by switching on and off various genes. This study aims to examine the placental epigenetic patterns of angiogenic factors in women undergoing ART

procedures and also examine their association with maternal one carbon metabolites and fatty acid profile.

Work Done:

The project is completed and the findings are as follows.

- Recruitment and sample collection for 94 non-ART and 65 ART subjects is completed.
- Subjects history and clinical information and neonatal characteristics have been recorded.
- mRNA expression of VEGF, PIGF, FLT-1, KDR genes and miRNA expression completed on collected samples.
- Methylation levels of VEGF and FLT1 genes completed on 28 non-ART and 26 ART samples

Results and Conclusion

- Maternal age and diastolic blood pressure was higher and gestational age and birth weight of the neonate was lower in ART women as compared to women of the non-ART group.
- Placental mRNA expression levels of FLT-1 and KDR were higher in ART placentae whereas placental mRNA expression of PIGF was lower and VEGF was higher.
- Further, mean methylation at the VEGF promoter was lower in the placenta of ART women as compared to those who conceived naturally. Our data indicates that there is altered angiogenesis in the placentae of women undergoing ART procedure.
- miRNA miRCURY array designed for miRNAs targeting angiogenic factors identified differential miRNAs that were associated with ART procedure.
- Validation experiment showed that miR_30c_5p, miR_140_5p and miR_205_5p are differential expressed in the ART group as compared to non-ART group.
- These miRNAs are known to target PIGF (miR-30c-5p), VEGF (miR_140_5p) and FLT-1 (miR_205_5p) genes suggesting that changes in mRNA expression of angiogenic genes could be regulated by these miRNAs. This is further supported by association of PIGF mRNA expression and FLT expression with expression of miRNAs like miR-30-5p and miR-497-5p respectively.
- Maternal plasma fatty acids were associated with various miRNAs targeting angiogenic factors that were analyzed in this study.

- This study for first time demonstrated altered expression of the angiogenic genes that are possibly epigenetically regulated by miRNAs that are known to target them.

The project duration is over and project objectives are completed.

5. Title: Influence of maternal one carbon metabolites on placental epigenetic patterns (**Project ID:** MCH/18/1/P) **Funding:** CSIR; **Sanctioned Amount:** 22.94 lakhs ; **Duration:** August 2018 – August 2023; **Guide:** Dr. Sadhana Joshi; **PhD Student:** Kinjal Dave (CSIR JRF/SRF) **Ethical Approval:** BVDU/MC/51

Background: Alterations in the one carbon metabolism which supplies methyl group for all biological methylation reactions can result in changes in the DNA methylation patterns. The current study therefore aims to examine the placental CpG methylation and mRNA expression levels of angiogenic factors, *PEMT* and *FADS* in women with preeclampsia and compare it with normotensive women. We also aim to examine the association of the CpG methylation patterns with maternal blood pressure and fetal outcome.

Work done: A total of 200 placental tissues (100 normotensive controls, 100 preeclampsia) were collected from central maternal region and stored at -80°C. Genomic DNA was isolated from placental samples using the DNeasy Blood and Tissue kit.

Gene specific methylation analysis of selected candidate genes PIGF, FLT-1, HIF1A, HIF3A and PEMT was completed. Data showed significant hypomethylation at various CpG sites in the PIGF promoter region and FLT-1 gene and significant hypermethylation on two CpG sites in the HIF3A gene and one CpG site in HIF1A. This data indicates altered methylation of these genes in the preeclampsia placentae may influence angiogenesis, placental growth as well as intrauterine fetal development that may predispose the children to higher risk of cardiometabolic disorders in future.

In conclusion, the findings from the current study reports that DNA methylation and expression patterns of angiogenic genes and fatty acid desaturase gene are altered in the preeclampsia

placentae. Further, the study demonstrates that maternal nutritional status including micronutrients involved in one carbon metabolism and LCPUFA, influences the DNA methylation patterns of the above mentioned genes.

Therefore, this thesis supports the hypothesis that Maternal nutrition influences placental epigenetic patterns of genes involved in angiogenesis and fatty acid metabolism in preeclampsia.

The project objectives are completed.

6. Title: Fatty Acids, Oxidative Stress and Neurotrophins in Gestational Diabetes Mellitus **(Project ID:MCH/18/2/P) Funding:** ICMR; **Sanctioned Amount:** ; **Duration:** August 2018 – August 2023; **Guide:** Dr. Sadhana Joshi; **PhD Student:** Anjali Jadhav (ICMR SRF) **Ethical Approval:** BVDU/MC/51

Background: The present study reports the levels of fatty acids, oxidative stress markers (Protein carbonyl, Malondialdehyde), antioxidant (Glutathione), neurotrophins (BDNF, NGF) in the placenta in the women with GDM and compares them with non GDM women. We also report the levels of fatty acids longitudinally across pregnancy in the above women and their association with birth outcome. The association of fatty acid levels, oxidative stress markers and neurotrophins with birth outcome measures are also reported. Hypothesis: “Long chain polyunsaturated fatty acids, oxidative stress and growth factors will be altered in women with Gestational Diabetes Mellitus”..

Work done: The present study for the first time reports several novel and interesting findings-
1. Altered placental fatty acid levels in women with GDM suggests that fatty acids may have a role in placental development and functioning
2. Absence of oxidative stress in the placentas derived from women with GDM indicating a protective or adaptive mechanism in the placenta that prevents the fetus or neonate from oxidative damage
3. Decreased level of glutathione in the placenta suggests that antioxidant defense mechanism may be impaired in women with GDM
4. Differential effects of neurotrophic factors i.e. BDNF and NGF in the placentae in GDM
5. Positive association of key fatty acids such as DHA and AA with their counterparts in the placenta and cord
6. Negative association of omega 3 fatty acids and positive association of omega 6. fatty acids with lipid peroxidation marker (MDA) highlighting their complementary

role in influencing oxidative stress. This supports the hypothesis that fatty acids, oxidative stress and neurotrophins are altered and play a key role in the pathophysiology of GDM. This has implications for increased risk for neurodevelopmental disorders in children born to mothers with GDM.

10. Title: Placental Telomere Attrition in Women with Preeclampsia. (**Project ID:**MCH/17/3/P); **Funding:** ICMR, Duration: 2017-2022, **Sanctioned Amount:** 22.94 lakhs, **Guide:** Dr. Sadhana Joshi; **PhD Student:** Aditi Godhamgaonkar; **Ethical Approval:** IEC/2015/37, dated 03.10.2015

Background: The current study explores the influence of maternal fatty acid status and oxidative stress profile with placental telomere length in women with preeclampsia.

Work done:

Plasma levels of protein carbonyl were estimated at four different time points across gestation that is 11-13 weeks, 18-22 weeks, 26-28 weeks and at delivery. Placental levels of oxidative stress markers were also estimated (protein carbonyl and 8-oxo-dG). Placental telomere length was estimated using RT-PCR.

Results and Conclusion:

Maternal plasma protein carbonyl levels were comparable between the PE and non-PE group at all timepoints across gestation. Placental 8-oxo-dG levels were lower in the EOP group as compared to non-PE ($p < 0.05$). Placental telomere length, though shorter in PE group, was not statistically different between the groups. Placental protein carbonyl levels were negatively associated with placental telomere length. Early pregnancy (11-14 weeks) omega-3 fatty acid, EPA is positively associated with placental telomere length in the whole cohort. Placental telomere length was negatively associated with cord erythrocyte AA, total omega-6 fatty acid and total PUFA levels in the whole cohort.

11. Title: Role of Maternal Nutrients and its influence on Inflammation and Angiogenesis in women with Gestational Diabetes Mellitus. (**Project ID:**MCH/21/4/P);

Guide: Dr. Sadhana Joshi; **PhD Student:** Shweta D. Madiwale **Ethical Approval:** BVDUMC/IEC/84A, dated 20.04.2023

Background: The study explores the role of maternal supplementation of folate and vitamin B₁₂ in women with GDM and Non-GDM and also observe the folate and vitamin B₁₂ rich food intake longitudinally in GDM and Non-GDM women.

Work done:

Maternal supplementation of folate and vitamin B₁₂ and dietary intake of folate and vitamin B₁₂ rich food intake were estimated on 100 Non-Gestational Diabetes Mellitus women and 100 women with Gestational Diabetes Mellitus which were estimated at three different time points across gestation that is 11-13 weeks, 18-22 weekk and 26-28 weeks.

Results and Conclusion:

This study includes 200 pregnant women (100 Non-GDM and 100 GDM women). GDM women had higher daily consumption of vitamin B₁₂ rich foods at V1 and V3 as compared to non-GDM women. Whereas, the frequency of consumption of folate-rich foods was similar in the GDM and non-GDM groups at all time points. Also, the percentage of GDM women taking vitamin B₁₂ supplements was higher at V1 and folate supplements was higher at V1 and V3 as compared to non-GDM women

Name of the Programme: Cancer Research Lab

1. **Title:** Repurposing of cephalosporin drugs on cervical cancer. (**Project ID:** CR/22/1/E)
Funding: EMR-ICMR **Duration:** Sep 2022- Jun 2023 **Sanctioned Amount:** Rs. Rs.31, 15,500/-
Investigators: PI 1.Dr.Ruchika Kaul-Ghanekar, Cancer Research Lab **Co PI-** 1. Dr. Purna Raina Cancer Research Lab, IRSHA, BVDU 2. Dr. Manali Kulkarni Bioinformatics Centre, Savitribai Phule Pune University **Ph.D. Students:** NA **Project Student:** Rushabh Waghmode
Human Ethical Approval: NA

Background:

Cephalosporin (beta-lactam) antibiotics, used against bacterial infections have been reported to exhibit anti-cancer potential. Ceftriaxone was shown to suppress lung cancer growth in vitro and in vivo. Ceftiofur, a veterinary antibiotic, was reported to target mitogen-activated protein kinase (MAPK) signaling pathway proteins. Few cephalosporins have also exhibited immune regulation. In the present project we aim at evaluating the anti-cancer activity of different generations of cephalosporins against cervical cancer.

Work done:

Evaluating effect of cephalosporin's on viability of cervical cancer and non-cancerous squamous epithelial cells

Preliminary In-silico screening of the selected potent cephalosporin for possible drug target

Detailed meta-analysis to find differentially expressed gene in cervical cancer.

Results:

During the first year, we evaluated the effect of different generations of cephalosporin's on viability of HeLa (HPV 18+), SiHa (HPV16+) C33A (HPV-) and Ca Ski (HPV18+/16+) cervical cancer cell lines. The cervical cancer cell lines were treated with the first generation cephalosporins, cephalexin and cefazolin for 24-72 h. At 72h, compared to cephalexin, cefazolin was found to be more potent against HeLa and SiHa with IC50 of 632.6 and 418.9 µg, respectively. Interestingly, at 800 µg/ml dose, cefazolin reduced the viability of CaSki to 56 % in 24 h and not at 48 or 72h. Further, the cervical cancer cells were treated with the second generation cephalosporins, cefaclor, cefprozil, cefuroxime and ceftriaxone for 24-72 h. It was

observed that at 72h, compared to other drugs, cefuroxime was found to be potent against HeLa, SiHa and C33A with IC₅₀ of 408.9, 367.9 and 493.8 µg, respectively. Interestingly, at 800 µg/ml dose, in CasKi, cefuroxime reduced the viability to 28.3 % in 48 h compared to 52.6 % in 72 h. The third generation cephalosporins, cefixime and ceftiofur were not found to be as potent as first and second generation at 72h. Among the fourth generation cefepime and cefpirome. It was observed that compared to cefepime, at 800 µg/ml dose, at 72h, cefpirome reduced the viability of HeLa, SiHa, C33A and CaSki to 35.4 ± 8.3, 64.1 ± 8.0, 66.4 ± 4.8 and 81.7 ± 2.2 %, respectively. In HeLa, IC₅₀ of cefpirome was found to be 579.4 µg. Comparatively, at 800 µg/ml dose, cefepime reduced the viability of HeLa, SiHa, C33A and Ca Ski to 62.7±9.0, 40.2 ± 7.1, 85.6 ± 8.8 and 80.17 ± 1.5%, respectively, at 72h. IC₅₀ of cefepime in SiHa was found to be 647.2 µg. IC₅₀ of fifth generation cephalosporin, ceftazoline at 800 µg/ml dose, at 72h, for HeLa and SiHa was found to be at 752.6 and 614.3 µg. In Caski, the drug reduced the viability to 76.9 % in 48 h. Interestingly in C33A, ceftazoline reduced the viability to 39% in 48 h. From the above results, Cefazolin, Cefuroxime and Cefepime were taken for Insilco studies. Cefpirome, the fourth generation cephalosporin will also be studied further. Further, the differentially expressed genes (putative drug targets) of selected cephalosporins were identified from TTDB and Drug Bank. The targets were also extracted by using different databases like PubChem, BioGrid database, ChEMBL etc. The entire data was collected and analyzed in Microsoft Excel to identify putative protein targets of cephalosporins. Experimentally validated targets and Known binders of common targets were identified. The common targets mostly belong to solute carrier family group, JAK, TNF, ATP binding cassette subfamily C (ABCC) and G-protein-coupled receptors (GPCRs). The literature survey showed that cephalosporins have affinity towards the targets identified from different data bases. However, the effect of cephalosporin on these targets have been studied in terms of their safety, efficacy as an antibiotic, drug resistance and their safe clearance from body. The common targets of Cefazolin, Cefuroxime and Cefepime obtained from insilico fishing were found to have association with Wnt signaling pathway.

Conclusion:

If cephalosporin shows promising activity against cervical cancer, it can be tested in future in a clinical trial to establish its usage as an anticancer drug.

2. Title: Phytochemical standardization and evaluation of anti-cancer and immunomodulatory activity of Unani formulation, *Itrifal ghudadi*. **Project ID:** (CR/2020/2/E); **Funding:** AYUSH-EOI; **Duration:** Mar 2020-Mar 2023; **Sanctioned amount:** 43, 57,750/-; **Investigators:** PI: Dr BothiRaj, Poona college of Pharmacy **Co-PI:** Dr. Ruchika Kaul Ghanekar, IRSHA **Human Ethical Approval:** NA

Background:

In the previous year, the anticancer potential of Unani formulation Itrifal ghudadi was explored in cervical, breast and oral cancer cell lines. In addition to this, the mechanism of action of drug on the cell line was investigated.

Work done:

The mechanism of cell death in cervical cancer cell line SiHa was explored. Along with this, gene and protein expression studies of some common cancer targets such as MDM-2, P53, MMP-2, and VEGF were studied in response to the formulation Itrifal ghudadi.

Results:

Mitochondrial membrane depolarization was observed in the cells of SiHa suggesting apoptosis activation in cells

Levels of MMP-2 (metastatic marker) m-RNA was significantly reduced in response to drug
Tumor suppressor protein p53 was significantly increased in SiHa cells (performed using ELISA). Angiogenic factor VEGF remain unchanged at gene as well protein level in the cells (q-PCR and ELISA)

Oncoprotein MDM-2 did not show significant change in its protein level via Western blotting

Conclusion: IG must be explored at in vivo level for proving its anti-tumoral activity using tumor retardation studies.

3. Title: Role of Selected Phytochemicals in Regulation of Aberrant Lipid Metabolism in Prostate Cancer. **Project ID:** (CR/22/1/I); **Funding:** Nil; **Duration:** July 2022- June 2023; **Investigators:** PI- Dr. Ruchika Kaul-Ghanekar, **Co-PI-** Nil; **Ph.D. Students:** Minal G. Mahajan; **Human Ethical Approval:** NA

Background: Matairesinol (MR) was tested for its activity against androgen- independent prostate cancer cell line PC3. MR induced apoptosis and regulate de novo lipogenesis pathway in PC3 cells.

Work done: The effect of MR in regulating the expression of fatty acid oxidation genes was determined in PC3 cells.

Results:

In PC3 cells, at 100 μ M dose of MR, gene expression of CPT1 was decreased by 6.2 folds. At the same concentration, mRNA expression of SLC25A1 was down regulated by 2.6 folds.

Conclusion: MR has a potential to regulate fatty acid oxidation in prostate cancer cells.

5. **Title:** Exploring the therapeutic potential of Matairesinol for targeting metastasis in Prostate cancer. **Project ID:** (CR/19/2/I); **Funding:** NA, **Duration:** Feb2019- Feb 2024, **Sanctioned Amount:** NA, **Investigators:** **PI:** Dr. Aniket Mali, **PhD Student:** Ms. Rama Rajadnya, **Human Ethical Approval:** NA

Background:

Prostate cancer (PCa) is the most diagnosed carcinoma in men, mostly non-symptomatic un-till reaches the advanced stage. Statistically, Second most frequently observed cancer and the fifth leading cause of cancer-related death in men globally. Network pharmacology is a rapidly growing branch of research that is useful for applying biology in multi-directional pharmacology. It provides a computational approach for the generation of a large, complex linkage between the drug and disease. It would give the major hints underlying biological mechanisms and involved signaling pathways in drug-targeted disease treatment.

Work Done-

Previously, we found Matairesinol (MAT) as an effective target for the inhibition of various pro-inflammatory cytokines, chemokines, and some selected signaling molecules in PCa progression. In the present study, we have shown network pharmacology analysis of MAT to identify its potential therapeutic targets in aggressive metastatic PCa. The human genes associated with metastatic PCa and the targets of MAT were acquired from the online databases. The network pharmacology analysis showed that MAT could be a potential therapeutic candidate for targeting metastatic PCa as based on the KEGG enrichment analysis where the pathways such as Prostate

cancer, PI3K-Akt signaling pathway, Focal adhesion, MAPK signaling pathway, IL-17 signaling pathway, TNF signaling pathway, Estrogen signaling pathway were identified as major therapeutic targets which are already known in enhancing metastatic PCa progression. The STRING analysis exhibited EGFR, AKT1, ERBB2, IGF1 (PIK3-AKT signaling associated genes), MMP-2, -9, HIF1A (ECM remodeling components) and IL-2, TNF (pro-inflammatory markers) genes as prominent markers which play a significant role in the transition of PCa to metastatic PCa. Furthermore, molecular docking and in-vitro validation studies are required to be performed to validate the findings of Network Pharmacology analysis.

Conclusion:

Overall, the study highlights MAT's potential in targeting mPCa through multiple therapeutic targets and mPCa associated signaling pathways. These findings will be further validated by MD simulation and in vitro q-PCR study.

6. Title: Investigating the Therapeutic Potential of Plant Lignan for targeting Lipid Metabolism Reprogramming in Breast Cancer. **Project ID:** (CR/19/3/I); **Funding:** NA, **Duration:** Nov 2019 – Nov 2024, **Sanctioned Amount:** NA, **Investigators:** **PI:** Dr. Aniket Mali, **PhD Student:** Ms. Prajakta Devappa Patil, **Human Ethical Approval:** NA

Background:

Metabolic reprogramming is a recognized hallmark of breast cancer, with lipid metabolism playing a crucial role in cancer progression. This study investigated the potential of lignans, specifically Sesamin (SE), to target key lipid metabolism pathways in breast cancer. Using virtual screening of 88 lignans, molecular docking, molecular dynamics simulations, and binding free energy calculations, Sesamin emerged as the top candidate for impacting lipid metabolism. It showed significant downregulation of genes involved in cholesterol (HMGCR, SREBP-2) and fatty acid synthesis (FASN, SREBP-1) in MCF-7 and MDA-MB-231 breast cancer cell lines. Additionally, Sesamin increased the expression of LXR α , a gene linked to cholesterol efflux, and decreased the expression of LDLR and SCD1, involved in lipid uptake and desaturation, respectively. These changes correlated with a reduction in lipid droplet accumulation in both cell lines. Sesamin's ability to influence lipid metabolism in breast cancer provides a new perspective on its therapeutic potential, indicating its role in reprogramming cancer cell metabolism. This is

the first study to report Sesamin's impact on lipid metabolism in breast cancer, offering a promising new avenue for cancer treatment.

Work Done:

The effect of SE on the growth kinetics of MCF-7 cells was determined by the trypan blue dye exclusion method and the effect on genes involved in the lipid pathway was determined by qRT-PCR.

Results and Conclusion:

- Compared to control cells, treatment with SE at 100 μ M significantly reduced MCF-7 growth by 1.6, 3.0, and 3.5-folds at 24, 48, and 72 hours.
- Additionally, SE downregulated mRNA expression of key cholesterol and fatty acid synthesis genes: HMGCR, SREBP2, FASN, SREBP-1, and ACC1 in both MCF-7 and MDA-MB-231 cell lines.
- SE caused a 1.91 and 2.52-fold decrease in HMGCR expression, and a 2.12 and 3.20-fold decrease in SREBP2 expression for MCF-7 and MDA-MB-231, respectively.
- It also reduced FASN, SREBP-1, and ACC1 expression in both cell lines. Interestingly, SE increased LXR α mRNA expression, indicating enhanced cholesterol efflux. Concurrently, SE reduced LDLR and SCD1 expression in both cell lines, suggesting reduced lipid uptake and lipid desaturation.
- These results demonstrate that SE can influence lipid metabolism pathways, suggesting a therapeutic potential in breast cancer treatment

7. Title: Evaluation of anti-cancer potential of selected phytochemicals against breast cancer stem cells (BCSCs), **Project ID:** (CR/18/4/I); **NA,** **Funding:** NA, **Duration:** Oct 2018 – Oct 2023, **Sanctioned Amount:** NA, **Investigators:** NA, **PI-** Dr. Aniket V. Mali, **Ph.D. Students:** Ms Akanksha Mahajan, **Human Ethical Approval:** NA

Background: Breast cancer still remains the major cause of cancer related deaths in women, despite of numerous advancements in treatment approaches. Even after removal of tumor from primary cancer site, in some patients tumor relapses aggressively at distant sites in the body. Treatment failure in cancer is governed by a smaller subset of tumor seed cells called as Cancer Stem Cells (CSCs) which have capability to generate entire tumor mass. Breast cancer stem cells

are the root cause of tumor relapse, migration and drug resistance. Not more than a few synthetic drugs are available to target BCSCs, but they pose a drawback of inducing resistance in the BCSCs. Natural or herbal medicines have proven themselves better with their more effective, targeted action with less or no side effects. The plant *Xanthium strumarium* has gained recognition through various forms of traditional medicine. Also, recently studies have shown various medicinal properties of the plant such as anodyne, antibacterial, antifungal, antimalarial, antirheumatic, antispasmodic, antitussive, cytotoxic, hypoglycaemic, etc. but there is less data on the anticancer studies of this plant. The study proposes to evaluate the anticancer activity of the aqueous seed extract and to evaluate its phytochemical composition. We further propose to screen down the most active phytochemical against breast cancer stem cells and cancer stem cell regulating pathways. The molecular mechanism of action of selected phytochemical would be evaluated.

Work done:

The previous report outlined the completion of the first objective concerning the establishment of the mammosphere model and the examination of GR's effect on MDA-MB-231 cell viability. However, subsequent investigation into the molecular mechanisms of GR yielded inconsistent and non-dose-dependent results. GR displayed limited efficacy on MDA-MB-231 cells and mammospheres, with potential cell cycle arrest observed at lower doses. Notably, GR is a synthetic drug used clinically for chemotherapy side effects, suggesting its presence in XSAq may be due to impurity or contamination, rendering it unsuitable for the proposed study's objectives. Consequently, a new topic and title were proposed following a guide change and discussion with the scientific committee.

Further we started work under the objective 1, which involved identifying potential therapeutic targets of Enterolactone (EL) for targeting Triple Negative Breast Cancer-Cancer Stem Cells (TNBC-CSCs). Therapeutic targets for TNBC and CSCs were sourced from various drug target prediction and curated databases. A total number of 53 gene targets were identified, which correspond with TNBC-CSCs and are responsive to EL. KEGG and GO enrichment analysis highlighted molecular mechanisms and biological processes associated with TNBC-CSCs, supporting EL's potential efficacy. Molecular docking further revealed EL's strong interaction with key targets like ESR1, AKT1, EGFR, etc., indicating therapeutic promise. Network

pharmacology analysis reinforced EL's ability to target multiple pathways crucial in TNBC-CSCs. These findings lay the groundwork for subsequent in vitro mechanistic studies.

8. Title: Evaluating the macrophage polarization mediated anti-cancer effect of matairesinol on triple-negative breast cancer. **Project ID:** CR/17/1/P), **Funding:** NA, **Duration:** Sep 2017- Sep 2024, **Sanctioned Amount:** NA, **Investigators:** PI- Dr. Ruchika Kaul-Ghanekar, **Ph.D. Students:** Amol Rajendra Chaudhary, **Human Ethical Approval:** NA

Background:

Matairesinol (MAT), a dietary lignan, shows promise against various cancers by reducing cell viability, inhibiting angiogenesis, and inducing apoptosis. Recent studies indicate its potential in restoring chemosensitivity and suppressing cancer progression. MAT also exhibits anti-inflammatory and immunomodulatory effects, including repressing the M2 marker Arginase-1. Our previous work demonstrated MAT's ability to repolarize M2 macrophages towards an anti-tumoral M1 phenotype. Yet, its impact on macrophage-induced cell death in triple-negative breast cancer (TNBC) remains unexplored. Here, we investigated MAT-treated macrophages' effect on viability and apoptosis induction in the TNBC cell line MDA-MB-231.

Work done: In TNBC cells, MAT-modified M0, M2a, and M2d conditioned medium (CM) significantly reduced viability, indicating macrophage repolarization by MAT. MAT-treated M1 CM had no impact on TNBC viability. MAT did not affect M0 and M1 macrophages' mitochondrial membrane potential (MMP), suggesting specificity in inducing apoptosis in TNBC cells. MAT-treated M2a and M2d CM induced apoptosis in TNBC cells, similar to FCCP, a known apoptosis inducer. These findings underscore MAT's potential in modulating macrophage polarization, particularly in repolarizing M2 macrophages towards an anti-tumoral phenotype, without affecting M1 macrophages.

Results and conclusion: MAT induces reduction viability of MDA-MB-231 by inducing apoptosis.

Name of the Programme : Obesity-Diabetes

1.Title :Effect of Yoga intervention on skeletal muscle linked glucose homeostasis in pre-diabetic individuals. (Project ID: OBDB/19/1/E), Funding:DST (SATYAM). Duration:March 2019- September 2022 Sanctioned Amount:Rs.46, 74,200/- Investigator: PI: Dr. Supriya Bhalerao Co-Investigators 1*:Dr. Jayshree Kharache (Tenure 16.03.2019- 31.08.2019) Dr. Pranita Ashok (Tenure 01.09.2019- 28.02.2022) Dr. Anuradha Joshi (Tenure: 01.03.2022 to 14.09.2022) Co-Investigator 2^s:Mrs. Anita Patil; Project Staff :Dr. Ravina Randive (SRF), Dr. Suresh Khadke (JRF) Ethics Approval:IEC/2019/05 (04.03.2019) IEC/2019/35 (06.07.2019 amended) IEC/2019/05 CTRI registration :

Background:

Currently, prevalence of diabetes is rising in India. India ranks second in case of pre-diabetes, increasingly recognized as an important asymptomatic metabolic state. The role of Yoga has been well documented in pre-diabetes, though its mechanism of action has not been explored so far. In the present study, pre-diabetic individuals are randomly allocated to follow either Yoga or exercise for a period of 4 months. The effect of these interventions is being assessed on functional capacity of skeletal muscles as they form the major site for glucose uptake and their strengthening may enhance proper glucose disposal. It is expected that the project will enable to bridge the gap in existing knowledge about Yoga and its effect on skeletal muscle linked glucose homeostasis.

Objectives.

1. To evaluate the effect of Yoga interventions on muscle mass, strength, endurance and flexibility which are direct or indirect indicators of fat deposition in skeletal muscles.
2. To study the association between changes in muscle quality/ functionality and glycemic control.

Work done

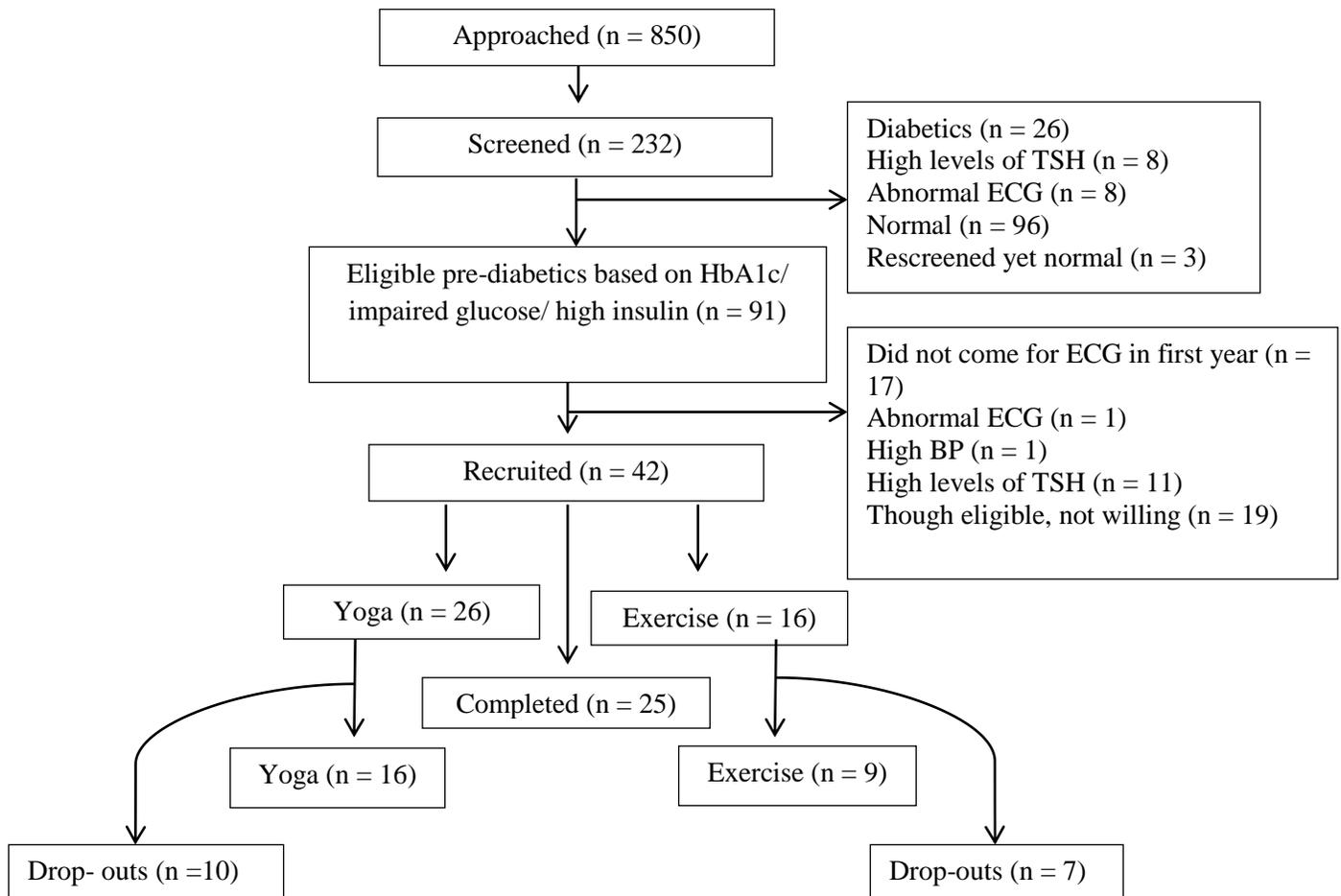
The study was initiated after obtaining Institutional Ethics Committee permission (IEC/2019/05) and CTRI registration (CTRI/2019/05/019149). A community-based screening was carried out for identification of pre-diabetic individuals as per the eligibility criteria. The identified

individuals were randomized into two intervention groups; Yoga or Exercise and recruited. The interventions were administered for a duration of 120 days; 1 month of training followed by 3 months of actual practice.

To ensure the quality of collected data, an independent study monitor was called at regular study intervals for reviewing all the study related documents.

Results:

Figure 1: Consort flow diagram

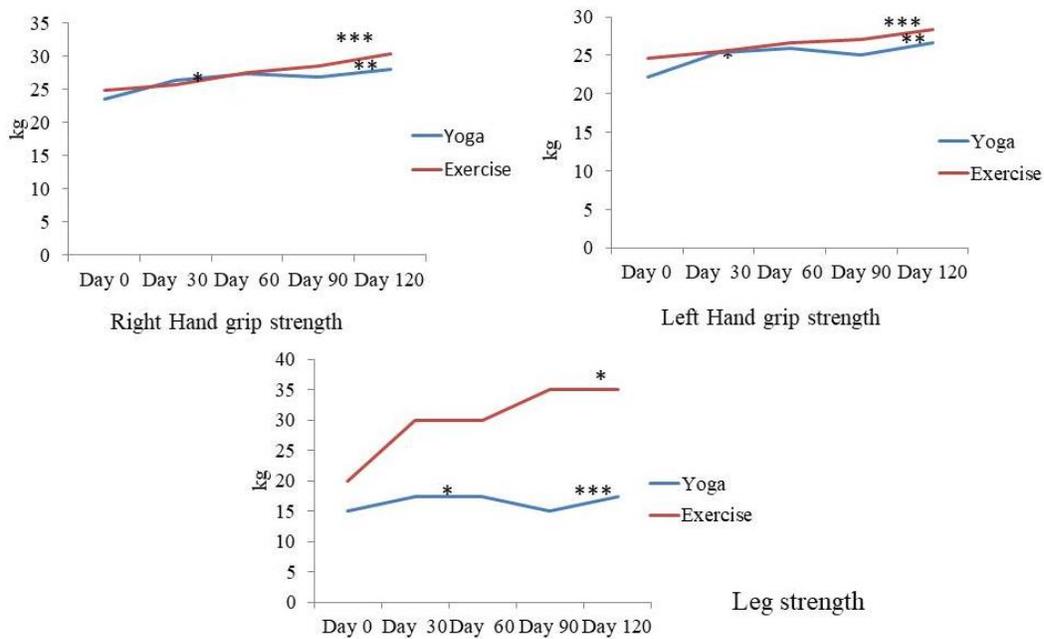


Muscle functions

There was significant improvement on day 120 in almost all the muscle function parameters in both Yoga and Exercise groups in comparison to day 0. There was no significant difference

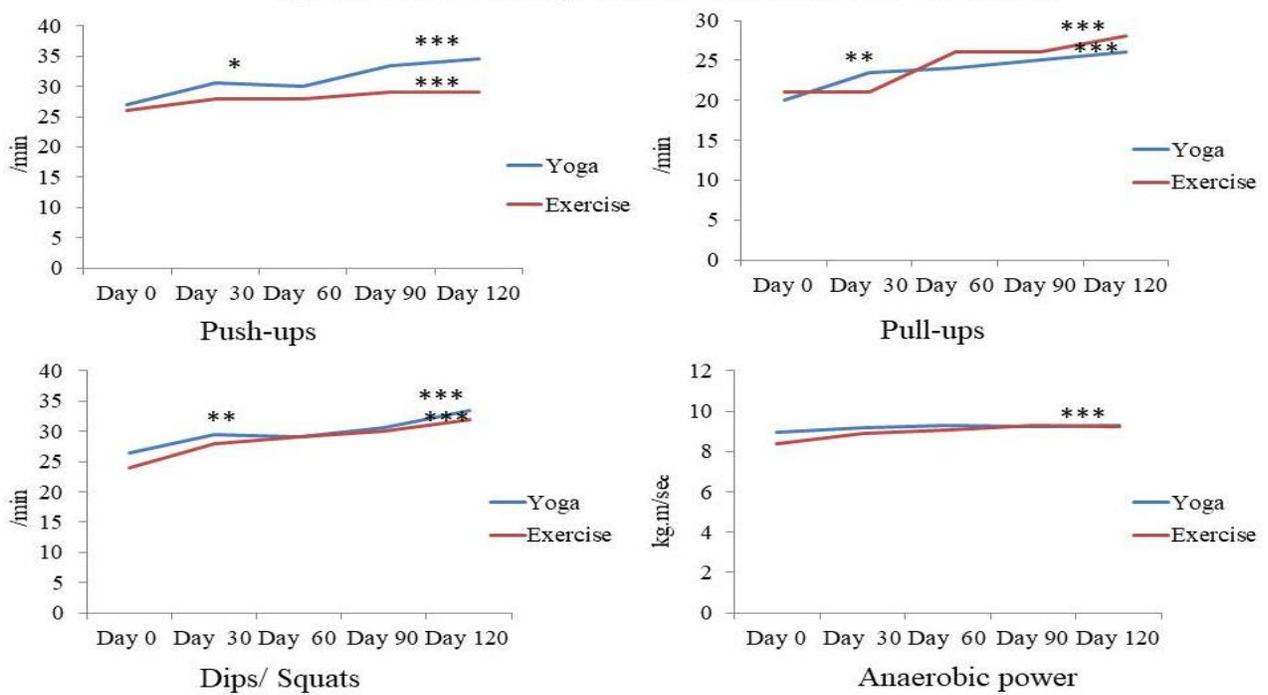
between them when compared against each other. Interestingly, the Yoga group showed a significant improvement on day 30 (post training period) compared to day 0 in all parameters. The exercise group showed a significant ($p < 0.05$) improvement on day 30 only in case of $VO_2\text{max}$. (Figures 2- 4)

Figure 2: Effect of Yoga intervention on muscle strength



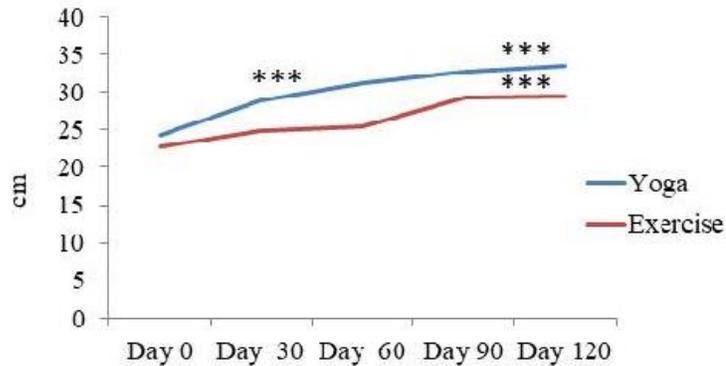
* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$ compared to day 0 using Repeated measures ANOVA followed by Tukey's test/ paired t test/ Friedman's test with post-test/ Wilcoxon matched pairs test

Figure 3: Effect of Yoga intervention on muscle endurance



*p < 0.05, **p < 0.01, ***p < 0.001 compared to day 0 using Friedman's test with post-test/ Wilcoxon matched pairs test/ Repeated measures ANOVA followed by Tukey's test/ paired t test

Figure 4: Effect of Yoga intervention on muscle flexibility



***p < 0.001 compared to day 0 using Repeated measures ANOVA followed by Tukey's test/ paired t test

Biochemical investigations

There were no significant differences between either of the glucose or lipid metabolism parameters in both the groups after the study.

The other major observations from our study include –

- Reduction in anthropometric parameters by both Yoga and exercise, though non-significant; Median weight loss was more in Yoga group
- Body composition parameters remained almost constant
- There was a greater decrease for systolic pressure in Yoga group compared to exercise group among vitals

Conclusions:

The Yoga intervention administered for a duration of 4 months caused a significant improvement in all the muscle function parameters viz. strength, flexibility, aerobic capacity comparable to the Exercise. Yoga group caused a significant improvement in muscle function even during first 30 days of the training.

Our results indicate that Yoga can offer benefits similar to exercise on muscle quality and thereby muscle linked glucose homeostasis when administered in pre- diabetic individuals. In addition, Yoga has advantage of being affordable and home based modality.

2.Title : Evaluation of Phonophoresis Therapy with Myostaal Gel in Participants suffering from Acute Musculoskeletal Conditions: A Randomised, Controlled Clinical Study (Project ID: OBDB/22/2/E),Funding:Solumiks Herbaceuticals Pvt. Ltd.Duration:August 2022- May 2023 Sanctioned Amount:Rs. 480520/-.Investigators:

PI- :Dr. Poonam Gupte Co-Investigator 1:Dr. Supriya Bhalerao Co-Investigator 2^{*}:Dr. G.R.Joshi Co-Investigator 3[§]: Dr. Neeraj Athavale. Project Staff:Dr. Revati Bhat Ethics Approval:BVDUMC/IEC/205 (23/08/2022). CTRI registration : CTRI/2022/09/045330

Background:

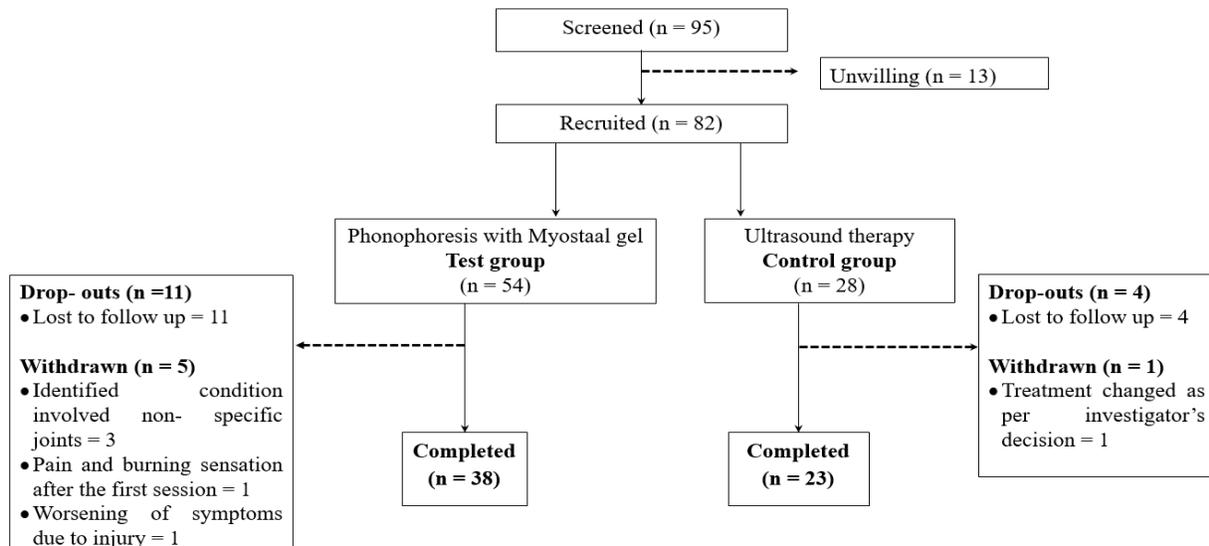
Musculoskeletal conditions have been ranked fifth among all diseases in disability-adjusted life-years (DALYs) and first in years lost due to disability globally. They significantly limit mobility and dexterity, thereby leading to early work retirement, hampered well-being and decreased participation in social life. Ultrasound Therapy is a commonly used modality in physiotherapy that provides deep heating to soft tissues like muscles, tendons, ligaments etc., involved in these conditions. Phonophoresis is a superior technique in which therapeutic ultrasound is administered along with anti-inflammatory or analgesic pharmacological agents. Myostaal Gel, a rational proprietary topical Ayurveda preparation marketed by Solumiks Herbaceuticals Ltd. is available in the Indian market for over 2 decades and used in the management of Knee Osteoarthritis and other musculoskeletal disorders. It was thus thought interesting to explore effect of Phonophoresis Therapy with Myostaal Gel in participants suffering from painful acute musculoskeletal conditions.

Objectives:

1. To determine the effect of phonophoresis therapy with Myostaal gel on pain
2. To determine the effect of phonophoresis therapy with Myostaal gel on activity limitation and functional outcomes
3. To study the effect of phonophoresis therapy with Myostaal gel on pressure pain threshold
4. To evaluate the effect of phonophoresis therapy with Myostaal gel on the need for rescue analgesics and further sessions

Results:

Figure 1: Consort flow diagram



Pain

There was a significant decrease in the pain in both Test Group ($p < 0.0001$) and the Control Group ($p < 0.0001$) on Day 14 and Day 21 as compared to the baseline visit. On Day 21, there was a further gradual decrease in pain in Test Group, compared to Day 14, though non-significant, despite stopping the treatment on Day 14, which was absent in Control group.

Functional outcomes

A significant increase in the functional outcomes and better performance of activity on Day 14 and Day 21, was seen in both the groups compared to baseline visit. Even after 1 week of discontinuation of therapy on Day 21, there was a gradual increase in activity performance in Test Group, compared to Day 14, which was not observed in the Control Group.

PPT

Both groups showed an increase in the PPT on Day 14 as compared to the baseline visit. Also, on Day 21, there was an increase in the pain threshold levels as compared to Day 14. The increase observed on Day 14 and 21 was better in the Control Group, but with no significant difference between the two groups.

Need for rescue analgesics and additional sessions

Two participants, one each from both groups, reported the need for a rescue analgesic during the entire course of therapy. The participant from Test Group took one dose of Tablet Chondroitin sulphate (40 mg) for 3 days between day 15 and day 21; while another participant from Control Group applied combination of cinnamon and clove oil once a day on two days between Day 1 and Day 7 of the therapy course. None of the participants from any group documented the need for further sessions after completion of the therapy.

Conclusion

Phonophoresis Therapy with Myostaal Gel can act as a better topical application in similar painful musculoskeletal conditions. This effect can be explored further in a larger sample size in individual chronic musculoskeletal conditions like osteoarthritis.

3.Title : Effect of different varieties of Fenugreek on gastric enzymes and hormones in healthy volunteers: An open – label randomized clinical study. **Duration:** April 2023- July 2023 .
Project ID : ObDb/23/2/E. **Funding:** DBT-Boost to University Interdisciplinary Life Science Departments for Education and Research (DBT-Builder) Sanctioned Amount : Collaborative project
Investigators: PI-*: Dr. Rakhee Dangi; Co-Investigator 1 : Dr. Supriya Bhalerao
Co-Investigator 2^s:Dr. Asmita Wele **Ethics Approval :** BVDUCOA/EC/3052 (A)/2022-23 (10/03/2023). **CTRI registration :** CTRI/2023/07/054751

Background:

Fenugreek or Methi, finds its use in many Indian recipes and is beneficial for health as per traditional Ayurvedic and Chinese medicines. Its actions include antidiabetic, hypocholesterolemic, antioxidant, digestive stimulant action, and hepatoprotective effect. The human gut is an incredibly complex ecosystem consisting of diverse bacterial species forming the microbiota. It influences overall glucose homeostasis and insulin resistance in major metabolic organs such as liver, muscle and fat. It was thereby thought interesting to evaluate the effect of two different species of fenugreek; *Trigonella foenum-graecum*, *Trigonella corniculata* (Kasuri Methi) and their combination on gut specific enzymes and hormones to gauge their mechanistic action on insulin sensitivity.

Objectives:

1. To determine the individual and combined effect of *Trigonella foenum-graecum*, *Trigonella corniculata* on appetite patterns and bowel movements.
2. To evaluate the individual and combined effect of *Trigonella foenum-graecum*, *Trigonella corniculata* on weight.
3. To assess the individual and combined effect of *Trigonella foenum-graecum*, *Trigonella corniculata* on glucose homeostasis.
4. To assess the individual and combined effect of *Trigonella foenum-graecum*, *Trigonella corniculata* on gastric enzymes and hormones.

Work done:

A total of 31 healthy individuals were recruited in the study. Of these, 9 individuals in *Trigonella foenum-graecum* group and 11 each individuals in *Trigonella corniculata* and the combination group, were recruited. Out of the 25 completed participants, 9 were from *Trigonella foenum-graecum* group, while 8 each were from *Trigonella corniculata* and the combination group. As, no significant differences were observed in any of the assessment parameters in this study, it was decided to modify the protocol and reconduct the study in the next phase.

4.Title : **Investigating the effect of Triphala extract on Leptin induced inflammation in RAW 264.7 cell line Project ID: ObDb/22/2/I** Funding: Generated funds. Duration: November 2022- May 2023 Sanctioned Amount : Investigators: PI:- Dr. Supriya Bhalerao Co-Investigator 1 : Mrs. Asavari Joshi Co-Investigator 2* : Dr. Alpana Moghe ;Project Student : Dr. Varsha KP

Background:

Adipose dysfunction is a major pathophysiological event seen in obesity. The adipose dysfunction leads to secretion of pro-inflammatory adipokines like Leptin. These adipokines, especially Leptin lead to further atherosclerotic events and can result into cardiovascular diseases. Triphala is known to have anti-inflammatory activity. The present project was planned to evaluate whether Triphala exerts anti-inflammatory activity even against Leptin induced inflammation. For this, we used RAW 264.7 cell line, which is a mouse macrophage cell line.

Objectives:

To evaluate the anti-inflammatory effect of Triphala extract in Leptin-induced inflammation in the RAW 264.7 cell line.

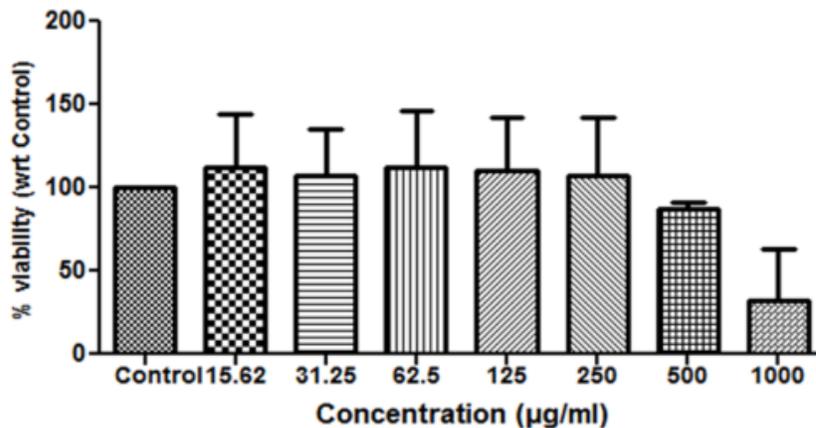
Work done:

Initially, the effect of different concentrations of Triphala extract was studied on viability of the RAW 264.7 cell line. Further, the effect of different concentrations of Leptin was studied on the cells. Subsequently, release of Nitric oxide (NO), an inflammatory marker, after pre-treatment of cells with different concentrations of Leptin was estimated by Griess method. Finally, effect of co-treatment of Triphala extract with Leptin on NO release was elucidated.

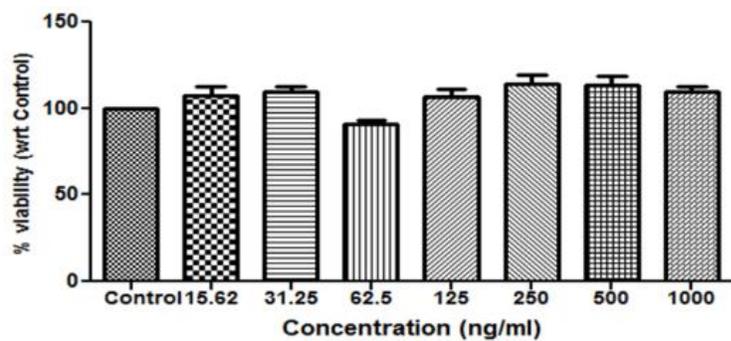
Results:

Both Triphala extract and Leptin did not affect the cell viability till 500 µg/ml and 1000 ng/ml concentration respectively. (Figure 1)

Figure 1: Effect of Triphala (A) and Leptin (B) on cell viability



(A)



(B)

Leptin treatment increased release of NO as compared to control cells, though not significant statistically, while co-treatment with Triphala reduced these levels.(Figure 2 & 3)

Figure 2: Estimation of NO released on insult of Leptin to cells

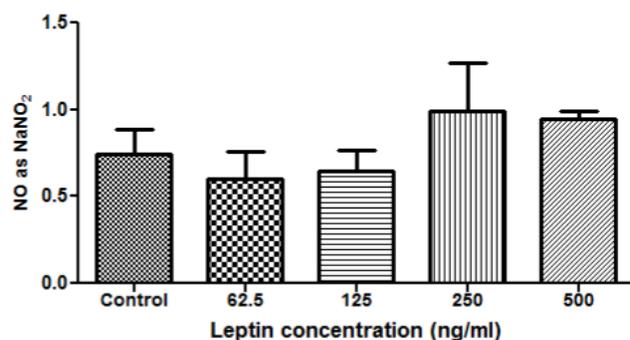
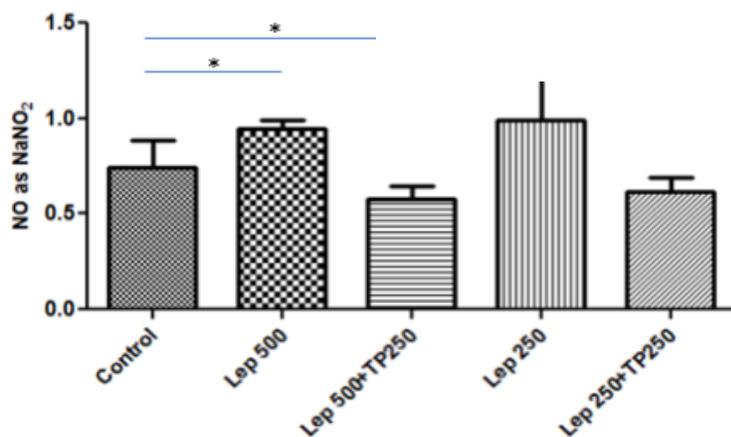


Figure 3: Effect of Triphala treatment on NO release after Leptin insult



Conclusion:

Though Triphala showed decrease in NO release that was seen after Leptin insult, further studies are required with more sensitive inflammatory markers.

Name of the Programme: Herbal Medicine

1. **Title:** Chemometric analysis and development of methodology for quality standardization of *Vidanga*. **(Project ID:** HM/22/1/I) **Funding:** CSIR HRDG **Duration:** 01-01-2022 to 31-12-2022 **Sanctioned Amount:** Rs. 5,20,800 **Investigators:** NA **PI Co PI-** NA **Ph.D. Students:** Manoj Khavate **Human Ethical Approval:** NA

Background: Vidanga, also known as *Embelia ribes*, is a high-value (Rs. 8000/ kg) sold medicinal medication with an annual demand of more than 100 Metric tonnes. However, Vidanga collection has recently dropped, and as a result, a crude medicine from another species, *Embelia tsjeriam-cottam* Roxb, has been marketed as Vidanga. *E. tsjeriam-cottam* is also much easier to collect than *E. ribes* because it is a large shrub that produces more fruits and is widespread all over India, whereas *E. ribes* has a limited distribution. Embelin, a prominent secondary metabolite found in both *E. ribes* and *E. tsjeriam-cottam*, is a common phytochemical. Because of its phytochemical similarities to *E. ribes*, *Embelia tsjeriam-cottam* has the potential to be reused as Vidanga. As a result, it was critical to develop analytical methods with high sensitivity and accuracy for detecting adulteration.

Work done: The present investigation was aimed to elucidate the effectiveness of *E. tsjeriam-cottam* and *E. ribes* on attenuation of inflammation in rat models. The untargeted metabolomics study was under taken for analyzing the alteration in metabolites caused due to dosage of *E. tsjeriam-cottam* and *E. ribes*. UV-visible spectroscopy and partial least squares discriminant analysis (PLS-DA) for determining the difference between *E. ribes* and *E. tsjeriam-cottam* was assessed in this study. Before utilising Ethyl acetate to extract phytochemicals, authentic samples were obtained and processed. A UV-visible spectrometer was used to collect spectral data in the 190-1100 nm region. The Vidanga was be classified using a PLS-DA classification model based on their UV visible spectra. The findings show that UV-visible spectroscopy combined with PLS-DA can be used to discriminate between adulterations and detect *E. tsjeriam-cottam* in a sensitive and accurate manner.

Results: The feasibility of employing UV-visible spectroscopy and PLS-DA method for discrimination between *E. ribes* and *E. tsjeriam-cottam* was confirmed.

Conclusion: This promising result may open the way for a potential application of UV-visible spectroscopy for the authentication of herbal drugs in the near future.

2. **Title:** Development of a novel synbiotic using *Dioscorea* as a prebiotic against Ulcerative Colitis . **(Project ID:** HM/21/2/I) **Funding:** UGC **Duration:** 01-11-2021 to 13-08-2024 **Sanctioned Amount:** Rs. 5, 20, 800 **Investigators:** NA **PICo PI-** NA **Ph.D. Students:** Apurva Jadhav **Human Ethical Approval:** NA

Background: Synbiotics have been found to reduce levels of inflammation, improve digestion, and improve the balance of bacteria in the gut, all of which can help reduce the symptoms of ulcerative colitis. Prebiotics are naturally occurring complex carbohydrates found in plants and the *Dioscorea* spp. Plants of Maharashtra will be an excellent source of prebiotics. The secondary screening will be conducted for anti-inflammatory properties, and consent will be obtained from the Maharashtra State Biodiversity Board. The plant parts will be assessed for their prebiotic potentials and combined with probiotics to create synbiotic formulations. The best and most effective formulations will be evaluated for their anti-inflammatory potential in vivo.

Work done: The present investigation is aimed to purify and assess the prebiotic potential of *Dioscorea* collected from Maharashtra; hence different species of *Dioscorea* plant have been collected, extraction of prebiotics is done, and further optimization of the dosage for probiotics, prebiotics and synbiotics in an in-vivo *Drosophila melanogaster* model is going on.

Results: Among different species of *Dioscorea* collected from Maharashtra, we have prioritized selected species based on their prebiotic potential and in vivo studies in the *Drosophila* model.

Conclusion: The *Dioscorea* plant has good prebiotic potential, and now work is underway for its synbiotic potential.

3. **Title:**Anti-inflammatory and immunomodulatory activity of synbiotic formulation against intestinal inflammation (**Project ID:** HM/21/3/I) **Funding:** BVDU **Duration:** 2021-2022 **Sanctioned Amount:** Rs. 1,00,000 **Investigators:** Dr. Suresh Jagtap **PICo PI-** NA **Ph.D. Students:** Mayur Aswani **Human Ethical Approval:** NA

Background:

The gut immune system is influenced by many factors, including dietary components and commensal bacteria. Nutrients that affect gut immunity and strategies that restore it by affecting the microbial composition are being developed as new therapeutic approaches to treat several inflammatory diseases. Owing to urbanized diet, lifestyle and overuse of antibiotics have led to condition known as dysbiosis ultimately affecting gut immunity and thereby provoking inflammatory response. These food supplements termed as functional foods have been demonstrated to alter, modify and reinstate the pre-existing intestinal flora. They also facilitate smooth functions such as eliminate pathogens, improve immunity, maintain luminal pH, etc. In this project we have evaluated the efficacy of selected synbiotics to modulate the immunity.

Results:

Prioritized synbiotic formulation has shown significant effect on immunomodulation with respect to parameters viz. body weight, organ weight, hematology, liver enzymes such as SGPT, SGOT, total serum protein and directly using both arm of immunity i.e., humoral and cell mediated immunity.

Centre for Innovation in Nutrition Health Disease (CINHD)

1. **Title:** ICAR -AICRP- Linseed Value Addition Centre **Project ID:** INHD/15 (15-18)/1/E **Funding:** ICAR, New Delhi **Duration:** April 2015 onwards **Scientist in-charge:** Dr. Anand A. Zanwar
Amount received: Total 132.19 Lakh (2015-23), 17.32 Lakh (2022-23)

Background:

Broad objective is linseed value addition. Following objectives for 2022-23 were planned and approved during Annual Linseed Group meeting of Linseed organized by College of Agriculture, Dr. Panjabrao Deshmukh Krishi Vidyapeeth, Nagpur, during September 1-2, 2022.

Objectives:

- A. Blending of linseed oil with edible oil
- B. Development of linseed derived omega-3 health supplements
- C. Development of omega-3 wheat bread
- D. Nutritional evaluation of released linseed varieties in India

Work done:

A. Blending of linseed oil with edible oil:

- To carry out frying stability study of blended oil with selected antioxidants:

Following fresh blends of edible oils with linseed oil were prepared

- Base oil: Palm olein (PO), Coconut oil (CO), Rice bran oil (RBO)
- Blended oils: Palm Olein+ linseed oil (PO:LO-80:20), coconut oil + linseed oil (CO:LO-80:20), rice bran oil + linseed oil (RBO:LO-80:20)
- Following antioxidants were studied with blended oils during frying stability study:
 - Black pepper oil (used in coconut and palm olein oil and its blend)
 - AP+ Tri E (used in rice bran oil and its blend)

The heating and frying was done under controlled condition using lab scale electrical fryer filled with 3 liters of respective oil/blend. The temperature of the oil in the fryer was monitored by a glass thermo meter. The heating and frying was carried out in intermittent mode. Five batches of frying (each 3 min) were conducted in a day keeping gap of 5 minutes in each cycle, which was referred as heating/frying cycles for a day. For each frying experiment, 50-60 grams of French fries were taken for each batch and fries were fried at $180\text{C}^{\circ}\pm 5^{\circ}\text{C}$ temperature. This experiment

was continued for total 6 days (5 cycles/day for 6 days, total 30 cycles for each group). Thereafter oil was extracted from these fries and subjected for stability assessment using various parameters such as fatty acid profile and trans-fat content. Here in this heating trial, antioxidant namely black pepper was found to be effective in palm olein blend, in rice-bran blend itself without antioxidant was effective, however in case of coconut oil blend there was significant reduction in omega-3 content was noted and black pepper was showed effective antioxidant in thermal stability study. In case of trans-fat analysis, all the tested blends recorded very limited trans-fat content and were within acceptable levels of trans-fat content (i.e.<0.1%).

B. Development of linseed derived omega-3 health supplements

In this study, oil-in water type linseed oil emulsion, linseed oil + vitamin emulsion and linseed oil + protein emulsion was prepared in 1 kg each using colloidal mill (scale up operation) and these formulations were studied for its nutritional evaluation followed by stability assessment of emulsion formulation for the period of 1 year.

Table: Nutritional evaluation of the formulation:

Parameter	Units	Fat Emulsion Plain	Fat Emulsion Vit.	Fat emulsion Protein
Moisture	g/100g	14.14	13.14	12.75
Carbohydrate	g/100g	30.08	31.43	33.2
Protein	g/100g	0.1	0.25	3.4
Total Fat	g/100g	55.68	55.18	50.31
Total Ash	g/100g	<0.1	<0.1	0.34
Energy	kcal/100g	621.84	623.34	599.19
SFA	%	12.03±0.86	13.24±0.15	12.38±0.28
MUFA	%	19.33±0.04	19.39±0.43	18.50±0.29
LA	%	68.65±0.89	67.38±0.58	69.13±0.57

Table: Oxidative stability assessment of emulsified formulations

	Peroxide Value				
	Initial	3rd month	6th month	9th month	12th month
Linseed Emulsion	2.20±0.10	2.33±0.12	2.87±0.06	4.46±0.25	9.77±0.15
Linseed Emulsion +Vitamin	2.33±0.06	2.60±0.10	2.9±0.00	3.06±0.37	3.43±0.21
Linseed Emulsion +Protein	2.23±0.20	2.90±0.00	3.06±0.15	3.5±0.3	9.67±0.21
	Free fatty acid %				
Linseed Emulsion	0.083±0.001	0.081±0.00	0.119±0.01	0.16±0.00	0.18±0.01
Linseed Emulsion +Vitamin	0.087±0.002	0.079±0.00	0.122±0.00	0.15±0.00	0.17±0.01
Linseed Emulsion +Protein	0.085±0.002	0.078±0.001	0.118±0.00	0.12±0.00	0.13±0.00
	p-anisidine value				
Linseed Emulsion	2.44±0.38	2.95±0.62	3.39±0.34	3.80±.79	4.44±0.32
Linseed Emulsion +Vitamin	2.59±0.39	3.11±0.73	4.05±0.43	4.73±0.47	6.80±0.28
Linseed Emulsion +Protein	2.28±0.04	3.16±0.43	4.21±0.37	5.83±1.13	8.17±0.79

Table 2.10: Fatty acid analysis of emulsified formulations (stability study)

		Linseed Emulsion	Linseed Emulsion +Vitamin	Linseed Emulsion +Protein
SFA	Initial	12.03±0.86	13.24±0.15	12.38±0.28
	6th month	13.27±0.28	14.74±2.19	13.21±1.08
	9th month	11.36±0.76	11.16±0.61	11.15±0.21
	12th month	12.47±0.07	12.51±0.31	12.70±0.58

MUFA	Initial	19.33±0.04	19.39±0.43	18.50±0.29
	6th month	19.58±0.12	18.51±0.19	19.42±0.11
	9th month	20.46±0.51	21.05±0.68	20.14±0.37
	12th month	20.13±0.14	19.92±0.52	19.98±0.60
PUFA	Initial	68.65±0.89	67.38±0.58	69.13±0.57
	6th month	67.15±0.16	66.75±2.01	67.38±1.19
	9th month	68.18±0.25	67.79±1.29	68.72±0.17
	12th month	67.40±0.22	67.58±0.82	67.32±1.19

There was gradual increase in the peroxide value in all tested groups and ‘Linseed Emulsion +Vitamin group’ was comparatively more stable at the end of 12 months. The % of free fatty acid were also almost equivalent in all the three formulations at the end of 12 months. Although there was gradual increase in p-anisidine value. The final values of oxidative stability assessment were within acceptable limit in all the formulations upto nine months. At the end 12 months there were non-significant alterations in the fatty acid profile of the emulsion including total PUFA content, indicating stability of emulsion for the period of 12 months.

C. Development of omega-3 wheat bread

In this experiment, we developed omega-3 fortified bread (wheat based) using fully automatic bread maker using standard operative procedure provided by manufacture and its complete characterization was carried out using various parameters such as proximate analysis, fatty acid analysis, texture and colour analysis. Finally, stability assessment of wheat bread was carried out based on the fatty acid profile. For fortification of omega-3 fatty acid, linseed based premix 5% and 10% was selected.

Table: Nutritional analysis, fatty acid composition, colour and texture analysis of wheat bread

Parameter	Units	Control	5% Premix	10% Premix
Proximate Analysis				
Moisture	g/100g	36.97	42.37	37.81
Protein	g/100g	7.26	6.91	7.82
Fat	g/100g	3.72	3.38	3.84
Carbohydrate	g/100g	50.71	45.89	49.02
Ash	g/100g	1.34	1.45	1.51
Dietary fibre	g/100g	13.78	7.35	8.54
Energy	Kcal/100g	265.36	241.62	261.92
Fatty Acid Profile				
SFA	%	21.84±0.30	21.03±0.52	20.61±0.01
MUFA	%	22.13±0.10	21.11±0.83	19.68±0.51
PUFA	%	56.03±0.20	57.87±1.35	59.71±0.49
LA	%	53.31±0.24	51.19±1.43	49.84±0.35
ALA	%	2.72±0.04	6.68±0.08	9.88±0.15
O6/O3 ratio		19.60±0.39	7.67±0.30	5.05±0.04
Universal Texture Analysis				
Hardness	N	91.44±12.80	98.17±35.82	91.98±34.19
Cohesiveness		0.34±0.03	0.36±0.02	0.27±0.15
Springiness	mm	6.02±0.67	5.95±0.35	4.35±2.31

Springiness Index		0.75±0.05	0.79±0.05	0.58±0.31
Gumminess	N	3.12±0.30	3.68±1.50	3.21±1.03
Chewiness	Nm	18.68±1.75	21.53±7.47	17.16±6.47
Adhesive Force	N	0.16±0.11	0.11±0.02	0.10±0.04
Colour Analysis				
L*		4.59±0.26	17.64±0.72	18.12±0.45
a*		22.75±0.48	18.07±0.74	18.65±0.46
b*		23.21±0.49	77.47±0.59	76.40±0.60
DE*ab		69.36±1.16	61.15±1.59	61.26±1.28

Table: Stability assessment of wheat bread

	SFA		MUFA		O-6		O-3		O6/O3	
	Initial	After 7 days	Initial	After 7 days	Initial	After 7 days	Initial	After 7 days	Initial	After 7 days
Wheat Bread Control	21.84±0.30	23.00±0.80	22.13±0.10	20.87±0.65	53.31±0.24	53.45±0.07	2.72±0.04	2.69±0.22	19.60±0.39	19.91±1.66
Wheat Bread 5% Premix	21.03±0.52	24.63±1.43	21.11±0.83	20.77±0.07	51.19±1.43	48.84±0.98	6.68±0.08	5.78±0.55	7.67±0.30	8.48±0.61

Wheat	20.61±	20.51±	19.68±	20.28±	49.84±	49.70±	9.88±0	9.52±0.	5.05±0.	5.22±0.
Bread	0.01	0.02	0.51	0.15	0.35	0.11	.15	06	04	02
10% Premix										

Conclusion: In this experiment linseed based flour premix was developed for incorporation of omega-3 fatty acid in bread and omega-3 enriched wheat bread has been successfully attempted and stability study showed non-significant alterations in omega-3 fatty acid content at the end of 7 days was noted.

D. Nutritional evaluation of released linseed varieties in India

In this study, five released linseed varieties namely Gaurav, Shikha, Subhra, Priyam and Sweta were considered for overall nutritional evaluation purpose.

Among the tested varieties, the protein content was ranging between 17.27-25.7%. The highest protein content was recorded in Gaurav variety and lowest in Priyam variety. The fat content was varied between 37.13 % (Subhra) - 43.57 % (Priyam). However in case of dietary fibre there was wide variation ranging between 11.24 % to 36.00 %. The lowest was in Subhra variety and highest in case of Gaurav linseed varieties. There was not much variation in energy value (more than 550 Kcal/100g) and ash content (more than 3%) between the tested varieties. In case of essential mineral, these varieties were tested for calcium, iron, potassium and zinc etc. Calcium ranged between 230.75 mg/kg (Sweta) to 269.67 mg/kg (Priyam). Iron was ranging between 4.93 mg/kg (Gaurav) to 58.82 mg/kg (Shikha). Potassium ranged between 499.24 mg/kg (Shikha) to 639.73 mg/kg (Gaurav) and zinc ranged between 5 mg/kg (Subhra) to 23.96 mg/kg (Priyam). The saturated fatty acid ranged between 11.79±0.18% (Subhra) to 13.45±0.12% (Sweta). The mono-saturated fatty acid levels ranged between 22.61±0.52% (Priyam) to 27.66±0.09% (Subhra). Linoleic acid (omega-6 fatty acid) levels ranged between 10.44±0.07% (Sweta) to 15.65±0.08% (Gaurav). α -linolenic acid (omega-3 fatty acid) was ranging between 45.88±0.07% (Subhra) to 53.19±0.87% (Priyam). So far we have tested 16 released varieties from last three years.

2. **Title:** Extraction of bioactive lignan and development of value added products from flaxseed. **Project ID:** INHD/19/2/E **Funding:** SERB and Industry (RWNLF, Pune) **Sanctioned amount:** 51.30 Lakh **PI:** Dr. Anand Zanwar **Co-investigator:** M. L. Panse **Collaborator:** Real World Nutritional Laboratory Foundation, Pune
- Duration:** 27th November 2019 to 26th Nov 2022 **Ethics Committee approval:** BVDUMC/3020/2019/001/009

Background:

Last year Lignan extraction using pilot plant model, its characterisation, and toxicity study (in vivo acute oral toxicity study and in vitro toxicity study) was completed along with two products was developed namely, development of fortified cookies and development of flaxseed omega-3 flour pre-mix.

Work done:

- Sub-acute toxicity study:

Wistar rats of either sex were divided randomly into four groups (n = 10; five males and five females per group). Lignan concentrate was dissolved in distilled water for oral administration daily for 28 days in three dose level as per body weight (low-100, 200 and 400 mg/kg). The control rats (group IV) received only vehicle (distilled water). Additional animals, 5 for each sex, were kept in control and the high dose group (400 mg/kg) for the recovery study. Toxic manifestations and mortality were monitored daily for 28 days and physical examinations i.e. signs of morbidity were conducted every week during the study period by visual observations. At the end of the 28 days of administration, all of the rats were anesthetized, and blood samples were collected via retro orbital puncture into both non-heparinized and EDTA-containing tubes for biochemical and hematological analyses, respectively. The vital organs were excised (liver, heart, intestine, stomach, pancreas, spleen, kidneys, brain, lung, and sex organs-testes/ovaries), and then fixed in 10 % formalin for histopathological study by H and E staining.

- **Development of formulation containing curcumin and flaxseed oil (omega-3 fatty acid)**

In this study, oil in water type emulsion containing flaxseed oil (as source of omega-3 fatty acid) along with curcumin powder (curcumin concentrations 25, 50 and 75 mg/100 g) were developed. These formulations were studied for initial oxidative stability assessment, fatty acid profile, zeta

potential, particle size analysis and PDI etc. This year these formulations were subjected for stability assessment.

Results:

- **Sub-acute toxicity study**

There was no mortality in any of the experimental (lignan concentrate 100 mg/kg, 200 mg/kg, 400 mg/kg and 400 mg/kg satellite group) and control group (vehicle distilled water) throughout the dosing period of 28 days and the post-dosing recovery period (satellite group). There was no gross visible clinical sign of toxicity during study period. Gradual increase in body weight was observed in both control and experimental groups. Hematological investigations such as WBC, LYMPH, MON, GRAN, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV, PDW and PCT conducted at the end of 28 days and the end of recovery period, recorded significant changes in the values of different parameters studied when compared with that of respective vehicle controls. However, these alterations in the values were within normal biological and laboratory limits or these alterations were not dose-dependent both in male and female rats. Further in blood biochemical parameters such as glucose, cholesterol, triglyceride, HDL-C, LDL-C, VLDL-C, urea, creatinine, uric acid, protein, albumin, globulin, T. bilirubin, D. bilirubin, I. bilirubin, AST, ALT, LDH, Alk.PO4, calcium, and phosphorus etc. were recorded. Overall there was marginal alterations/significant alterations were noted, however these. However, the increase or decrease in the values of blood chemistry parameters were within normal biological and laboratory limits or the effect was not dose-dependent. In case of histopathological investigations, no gross pathological lesions in control, experimental and recovery groups was observed. The photomicrographs of the liver, heart, intestine, stomach, testis/ovary, pancreas, spleen, kidney, lung and brain of the control and experimental groups as well as of satellite group, showed with normal morphological architecture in both male and female. The histopathological study of sub-acute toxicity study did not recorded any morphological abnormalities that could be attributed to the oral administration of lignan concentrate to the rats. In conclusion, histopathological, hematological and biochemical observations of experimental group were comparable to control group and no abnormal changes were detected which could be correlated to treatment of lignan concentrate.

- **Development of formulation containing curcumin and flaxseed oil**

Here oil in water emulsion type of formulation was developed using omega-3 fatty acid and with curcumin along with water soluble vitamin pre-mixes (Vit B1, B2, B3, B6, B12, folic acid, vit C and vit B5) and fat-soluble vitamin (Vit. A, D, E) and the formulation was subjected for initial characterization followed by stability study at 2-8 °C. The appearance was opaque, nature was homogenous, texture was smooth, dark yellow colored and no oil separation was observed in all the formulations at the end of study period. There was non-significant alteration in pH and density of all three formulations. The pH of the formulations was found ranging between 6.5-7 which is generally acceptable for food emulsions. The common signs of instabilities such as creaming, sedimentation, and gravitational separation were not observed visually at the end of the stability study. Further important parameters such as particle size, zeta potential and polydispersity index were also non-significantly altered. Although there was marginal alterations in oxidative stability parameters such as peroxide value, free fatty acid content and p-anisidine value and there were non-significant alterations in fatty acid profile. The emulsified formulation developed was found to be stable for the period of 6 months at tested condition.

3. **Title:** Polyunsaturated fatty acid enriched nano-formulation for diabetes: In vivo efficacy and bioavailability studies **Project ID:** CINHD/22/3/E **Funding:** Chellaram Diabetic Research Centre **Sanctioned amount:** 27.38 Lakh **PI:** Dr. Anand Zanwar **Ph.D. Student:** Ms. Prajakta Sadashiv Gaikwad (Provisional registration date: 21-07-2022) **Duration:** 08-06-2022 to 07-06-2025

Background:

In view of the higher omega 6: omega 3 ratio has created a necessity to include omega 3 content in the therapeutics for better human health. In the present study two omega-3 enriched oils flax oil (FO) and krill oil (KO) are considered for the development of two different formulations. However poor solubility and lower stability, addition of omega 3 content in the desired products in expected amount is difficult. To overcome these issues in the construction of formulation, the better fitted approach is to make nano-emulsions. Nano-emulsions are kinetically stable colloidal dispersion that has a lower particle size. Having superior advantage of better bioavailability, and reduced particle size, the present study focuses on the use of nano-emulsions as a relevant choice for the advanced mode of oral drug delivery system and to understand its effect on streptozotocin induced type 2 diabetes rodent model along with its bioavailability studies.

Work done:

Development of nano-formulations:

In the present study two omega-3 enriched oils FO and KO are considered for the development of two different formulations. Based on the literature review done, selection of the ingredients and emulsifiers to prepare the o/w nano-emulsions was done followed by its procurement. Various number of trials were taken for the development of different batches using flax oil and krill oil. The optimized batches were passed through high pressure homogenizer (HPH) for optimization of the size and maintaining the homogeneity of the formulations and subjected for characterization using following parameters:

- Dynamic light scattering (DLS) measurements - Particle size, poly dispersity index and zeta potential
- Proximate analysis - for the quantitative determination of proximate composition of the emulsions, nutritional analysis of the different parameters was done.
- Bio-actives analysis - individual analysis of the active ingredients added in the nano-emulsions has been studied. Fatty acid profile using gas chromatography, α -lipoic acid analysis using LC-MS/MS and lignan analysis using LC-MS/MS
- Physio-chemical characterization (density, pH, color, Viscosity)- to study the basic characteristics of the formed emulsions, parameters like density, pH color and viscosity have been assessed.
- Oxidative stability studies: This study was done only for batches of flax oil emulsion analysis for determination of peroxide value and % free fatty acid value.

Results:

Based on the results obtained in trial batches, 3 batches of flax oil (20-30%) along with flax-lignan, α -lipoic acid were screened down. In case of krill oil, we have screened down to three emulsified formulations wherein KO ranging between 2.5-10% along with α -lipoic acid.

The particle size of few batches of flax oil krill oil fell under the nano-range. The remaining batches were passed through HPH to attain the desired size. Homogeneity of the sample was also maintained. All the batches were analyzed for its nutritional content which included parameters like ash content, moisture content, fat content and many more as per FSSAI, India/ AOAC standard methods. The bioactive content of SDG and alpha lipoic acid was estimated using LC-MS method and results obtained were comparable. The GC analysis was performed using

Agilent GC 8890 equipped with flame ionization detector using a fused silica capillary column (Supelco-SP-2330). Column dimensions were 30 m (length) × 0.32 mm (internal diameter) × 0.2 µm (film thickness). The fatty acid (omega 3) content incorporated in the formulations was estimated using GC-MS. The GC analysis was performed using Agilent GC 8890 equipped with flame ionization detector using a fused silica capillary column (Supelco-SP-2330). Column dimensions were 30 m (length) × 0.32 mm (internal diameter) × 0.2 µm (film thickness). Gradual increase in the Omega-3 content was observed in the respective batches in accordance to the percentage of oil used and Omega-6 to Omega-3 ratio was less than 1:1. Physico-chemical characteristics like pH, density, color and viscosity showed comparable results across the batches.

Conclusion

In this tenure nano-emulsion batches were successfully prepared using both the low and high energy emulsification method. A major challenge to develop an oil in water nano-emulsions is its low solubility, low bioavailability. The developed formulations in this study are easily soluble in water to give a homogenous mixture. Further the particle size and zeta potential studies confirmed the emulsions to fall under the nano range. Additionally, the initial characterization studies confirmed oxidative stability and the added bioactive content in the batches.

- 4. Title:** Evaluating effects of linseed oil blends on omega-6 to omega-3 ratio of various tissues in an animal model. **Project ID:** CINHD/21/1/I **Funding:** Institutional (Intra-mural) **Duration:** 2021-2022. **Sanctioned Amount:** 1,00,000/- **Co-investigator-** Dr. Anand A. Zanwar

Background

Animals were procured after receiving approval from Institutional Animal Ethics Committee. The study was initiated after acclimatization.

Work done:

1. FA profile of the RBCs at the basal level (before initiating treatment) was determined
2. Animals were treated with oil or blend based on the assigned group for three months
3. Hemograms after the treatment were determined
4. Various biochemical parameters were determined at the end of the study

5. FA profiling of key organs was determined at the end of the study

Results

1. Basal fatty acid profiling for rat RBCs

Table 1 FA profile of rat RBCs at beginning of study

	1	2	3	4	5	6
Lauric acid	0.59	0.66	0.89	0.56	0.89	0.52
PA	20.94	23.54	18.94	21.32	22.73	24.53
SA	12.29	11.03	10.97	11.40	10.89	12.55
OA	2.44	2.22	4.60	2.13	2.23	2.18
LA	6.32	6.05	4.39	5.83	6.02	7.33
AA	18.87	20.09	14.97	18.73	17.76	21.89
DPA6	4.00	3.47	2.28	2.84	2.55	3.00
DPA3	0.00	0.96	0.61	0.56	0.81	0.69
DHA	1.36	1.36	0.80	1.04	0.85	1.21
ω-6: ω-3	21.46	12.76	15.35	17.13	15.86	16.96

Before initiating the treatment, blood was collected from the rats, RBCs were harvested and processed for fatty acid profiling. Here, FA profile of seven rats is presented. Data is presented as % FA from total extracted lipids from the RBCs

Blood was collected from randomly selected animals through retro-orbital vein and immediately processed for RBC separation and FA profiling. From the Table 1 it is clear that RBCs were devoid of ALA but they had DPA3 and DHA omega-3 FA acids.

2. Effect of the blends on hemogram

Table 2 Hematological parameters determined in whole blood

Parameter	Control	PO	P20	CO	C20
WBC X 10³ / μL	14.21 \pm 2.55	10.96 \pm 1.71	14.99 \pm 4.65	11.39 \pm 2.10	13.66 \pm 3.12
Lymphocyte X 10³ / μL	8.18 \pm 1.51	7.24 \pm 1.36	9.04 \pm 2.57	6.56 \pm 1.65	8.44 \pm 1.90
Monocyte X 10³ / μL	0.45 \pm 0.12	0.29 \pm 0.07	0.46 \pm 0.23	0.39 \pm 0.09	0.40 \pm 0.15
Granulocyte X 10³ / μL	5.59 \pm 1.41	3.43 \pm 0.72	5.49 \pm 1.97	4.44 \pm 0.69	4.81 \pm 1.14
Lymph%	57.71 \pm 5.80	65.91 \pm 5.51	60.50 \pm 4.15	57.16 \pm 5.77	61.70 \pm 2.38
Mon %	3.14 \pm 0.45	2.79 \pm 0.43	3.06 \pm 0.40	3.33 \pm 0.27	3.06 \pm 0.39
Gran %	39.15 \pm 5.49	31.30 \pm 5.17	36.44 \pm 4.04	39.51 \pm 5.78	35.24 \pm 2.13
RBC X 10⁶ / μL	9.59 \pm 0.15	9.20 \pm 0.40	9.46 \pm 0.26	9.32 \pm 0.27	9.33 \pm 0.50
HGB g/dL	14.73 \pm 0.28	14.90 \pm 0.54	15.33 \pm 0.32	15.04 \pm 0.51	14.96 \pm 0.55
HCT %	45.15 \pm 0.64	45.54 \pm 1.54	47.09 \pm 0.99	45.23 \pm 1.69	45.60 \pm 1.74
MCV fL	47.14 \pm 0.98	49.59 \pm 0.99	49.85 \pm 2.13	48.59 \pm 1.06	48.97 \pm 2.03
MCH pg	15.31 \pm 0.35	16.14 \pm 0.42	16.18 \pm 0.63	16.10 \pm 0.52	15.97 \pm 0.60

Protein g/dL	32.50 ± 0.35	32.66 ± 0.25	32.50 ± 0.29	33.21 ± 0.61	32.76 ± 0.35
RDW %	11.46 ± 0.36	12.36 ± 0.62	12.09 ± 0.72	11.51 ± 0.77	11.46 ± 0.71
PLT X 10³ / μL	1111.50 ± 166	1179.86 ± 189	1099.00 ± 287	1093.29 ± 215	1047.00 ± 188
MPV fL	5.89 ± 0.38	5.33 ± 0.35	5.83 ± 0.55	5.33 ± 0.24	5.90 ± 0.40
PDW	16.04 ± 0.24	15.74 ± 0.22	16.01 ± 0.19	15.84 ± 0.23	15.96 ± 0.13

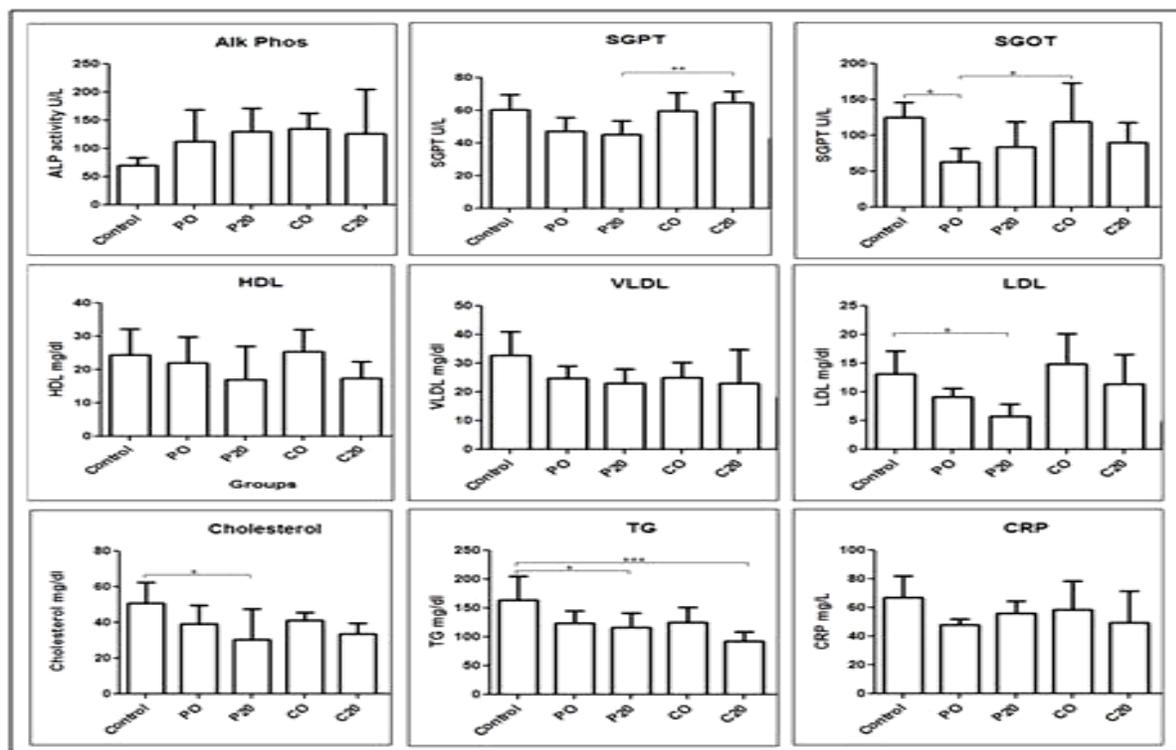
Hematological parameters were determined in whole blood at the end of study period (i.e. 90 days). Immediately after blood collection, hematological parameters were evaluated for the animals from all the treatment groups and Control. Data is presented as Mean ± SD (n = 6). Two way ANOVA and Bonferroni posttests were applied to determine statistically significant differences. PO: Palm olein treated group, P20: Palm olein + 20 % flaxseed oil treated group, CO: Coconut oil treated group, C20: Coconut oil + 20 % flaxseed oil treated group, WBC: White blood cells count, RBC: Red blood cells count, HGB: Hemoglobin, HCT: Hematocrit, MCV: Mean corpuscular volume, MCH: Mean corpuscular hemoglobin, RDW: Red Cell Distribution Width, PLT: Platelet count, MPV: Mean platelet volume, and PDW: Platelet distribution width

Various hematological parameters determined in the whole blood are presented in the Table 2 parameters evaluated were total WBCs, absolute lymphocytes, monocytes, granulocytes counts and their percentages, RBC and platelets absolute counts, hemoglobin, hematocrit, mean corpuscular volume, mean corpuscular hemoglobin, red cell distribution width, mean platelet volume, platelet distribution width and protein content. There were no differences in the studied parameters when compared with Control. Similarly, these parameters were not different for blend treated and individual oil treated groups.

3. Effect of the blends on various biochemical parameters and liver function test

As shown in the Figure 1, blend treatments particularly P20 resulted in lower LDL, cholesterol and TG which were statistically significant ($p \leq 0.05$). Additionally, C20 lowered TG level most significantly when compared with Control ($p \leq 0.001$). In case of SGOT, PO treatment resulted in significantly lower level when compared to Control ($p \leq 0.05$). Rest all the parameters were similar to Control for all the treatment groups. Within the groups; PO: P20 and CO: C20 were not significantly different for all the parameters. Still the trend of lower levels of HDL, LDL, Cholesterol and TG was observed for blend treated groups than the pure individual oil treated groups. CRP levels for treatment groups remained similar to Control group.

Figure 1 Effect of PO or CO blend on clinical parameters



Biochemical parameters were determined from the serum collected at the end of the study (i.e. Day 90). Data is presented as Mean \pm SD ($n = 6$). Statistical significant differences were determined by applying One way ANOVA and Tukey's multiple comparison test. *, $p \leq 0.05$, **, $p \leq 0.01$ and ***, $p \leq 0.001$. PO: Palm olein treated group, P20: Palm olein + 20 % flaxseed oil treated group, CO: Coconut oil treated group, C20: Coconut oil + 20 % flaxseed oil treated group. Alk Phos: Alkaline phosphatase, SGPT: Serum Glutamic Pyruvic Transaminase SGOT: Glutamic-oxaloacetic

transaminase, HDL: High density lipoprotein, VLDL: Very low density lipoprotein, LDL: Low density lipoprotein, TG: Triglyceride, and CRP: C-reactive protein

4. FA profiling of the key organs after oil/ blend treatment for three months

Table 3 Total PUFA, LA: ALA and ω 6: ω 3 for the harvested tissues

Fatty acid	Control	PO	P20	CO	C20
RBCs					
Σ PUFA	29.51 \pm 1.10	34.66 \pm 2.21**	32.14 \pm 2.55	28.27 \pm 4.29	34.29 \pm 1.23** Ω
LA: ALA	-	-	-	-	41.04 \pm 0.3
ω6: ω3	13.48 \pm 1.41	12.19 \pm 1.97	4.88 \pm 0.39*** μ	12.98 \pm 1.40	3.95 \pm 0.58*** Ω
Liver					
Σ PUFA	46.15 \pm 1.67	41.31 \pm 1.63**	43.57 \pm 1.82	45.58 \pm 0.49	43.78 \pm 2.19
LA: ALA	52.36 \pm 7.02	65.40 \pm 14.73	17.39 \pm 3.51** μ	73.81 \pm 22.39	11.70 \pm 3.40** Ω
ω6: ω3	8.43 \pm 0.66	9.22 \pm 1.11	4.74 \pm 0.85*** μ	8.42 \pm 1.00	3.71 \pm 0.63*** Ω
Heart					
Σ PUFA	47.88 \pm 1.34	43.99 \pm 3.45	45.94 \pm 2.70	46.50 \pm 2.16	47.67 \pm 2.79
LA: ALA	148.93 \pm 43.06	176.15 \pm 78.14	58.51 \pm 5.79* μ	169.44 \pm 40.62	50.30 \pm 15.06* Ω
ω6: ω3	6.44 \pm 0.22	7.04 \pm 0.90	3.41 \pm 0.48***	6.01 \pm 0.42	3.27 \pm 0.16*** Ω

			μ		
Brain					
Σ PUFA	15.67 \pm 3.33	18.26 \pm 2.87	18.78 \pm 3.65	19.00 \pm 0.91	18.14 \pm 2.29
LA: ALA	1.17 \pm 0.17	1.55 \pm 0.68	1.91 \pm 0.88	1.80 \pm 0.68	1.29 \pm 0.41
ω6: ω3	1.11 \pm 0.20	0.98 \pm 0.03	0.92 \pm 0.11	0.85 \pm 0.07	0.85 \pm 0.09
Adipose tissue					
Σ PUFA	33.20 \pm 1.36	23.64 \pm 1.19 ^{***}	26.81 \pm 1.11 ^{***μ}	24.48 \pm 1.54 ^{***}	26.76 \pm 1.33 ^{***}
LA: ALA	24.73 \pm 2.07	29.12 \pm 1.24 [*]	6.63 \pm 0.46 ^{***μ}	24.66 \pm 1.69	4.81 \pm 1.01 ^{***Ω}
ω6: ω3	25.16 \pm 2.02	29.64 \pm 1.28 [*]	6.74 \pm 0.48 ^{***μ}	25.09 \pm 1.73	4.86 \pm 0.99 ^{***Ω}

Animals were treated with oil or blend as per designated groups for three months. At the end of the study, tissues were harvested and fatty acid composition was determined for the mentioned tissues (n = 4). One way ANOVA and Tukeys's multiple comparison test was carried out to determine statistically significant differences. *, **, ***; $p \leq 0.05$ vs Control, μ ; $p \leq 0.05$ vs PO and Ω ; $p \leq 0.05$ vs CO. PO: Palm olein treated group, P20: Palm olein + 20 % flaxseed oil treated group, CO: Coconut oil treated group, C20: Coconut oil + 20 % flaxseed oil treated group. ω 6: Total ω 6 fatty acids, ω 3: Total ω 3 fatty acids, Σ SFA: Total saturated fatty acids and Σ PUFA: Total poly-unsaturated fatty acids

In FA profiling of the key organs after three month's treatment, all the FA present in the oil/ blend were identified. But, here, summary of the data is presented. From the table, it is clear that both the blends were able to lower ω 6: ω 3 ratio in all the organs studied except brain

Conclusion

From the data, it is clear that blends have no adverse effect on studied hematological parameters and liver function test. Blends particularly P20 had positive effect on serum lipid profile and except brain, blends were able to lowered omega-6 to 3 ratio

5. **Title:** Developing high oleic safflower genotypes through functional genomics **Funding:** Institutional

Project ID: CINHD/21/2/I **PI:** Dr. P. B. Ghorpade **Technical Assistant:** Mr. Yogesh S. Badhe
Duration: 2021 onwards

Background:

High oleic safflower genotype was developed with ICAR-NASF funding during (2015-18). From 2015 onwards the high oleic lines being tested in the field over the last 7 years for its agronomic characteristics, oil content and oleic content. We are now reporting the result of M-8 generation (2022-23)

Work done:

15 high oleic genotypes from M7 (2021-22) were grown in 2022-23 season for high oleic acid content. At the end of the season seeds were harvested and analyzed for high oleic acid content by gas chromatography. The fatty acid content of different genotypes is presented in table 1. Out of the 15 genotypes NASF-12 (NGP-08) which had highest oleic acid content (82.09%) was selected to be grown in field during 2023-24 season (M-9 generation) for commercial production. The genotype NASF-12 (NGP-08) had not only high oleic acid content but also had higher oil content 34.9%.

Table: The fatty acid content of different safflower genotypes

			Fatty acid (%)			
Sr. No	Genotypes	Code	Palmitic	Stearic	Oleic	LA
1	NASF-6	NGP-04	5.28	2.14	79.25	13.32
2	NASF-6	NGP-07	5.09	1.92	79.56	13.42
3	NASF-7	NGP-04	5.02	1.93	79.05	14
4	NASF-8	NGP-01	4.89	2.25	79.46	13.4
5	NASF-11	NASF-11	5.28	2.00	80.35	12.07

6	NASF 12	NGP-03	5.22	1.56	79.06	14.16
7	NASF 12	NGP-04	5.80	1.39	79.10	13.70
8	NASF 12	NGP-05	5.91	1.58	80.09	12.42
9	NASF 12	NGP-08	5.25	1.43	82.09	11.24
10	NASF 12	NGP-09	5.24	1.53	81.45	11.78
11	NASF 29-8	NGP-02	5.12	2.42	78.76	13.71
12	NASF 29-8	NGP-06	5.44	2.33	78.35	13.88
13	NASF 29-9	NGP-04	4.91	2.07	79.20	13.82
14	NASF 29-9	NGP-05	5.39	2.51	78.41	13.70
15	NASF 29-9	NGP-06	5.39	2.14	78.57	13.90

Conclusion:

From 2018-2023 for 5 years to establish the stability of the genotype with respect to high oleic, oil content and productivity now, finally the genotype NASF-12 (NGP-08) which is producing 82.09% of oleic acid will be multiplied during 2023-24 season for taking up commercial production.

6. Title: Developing omega-3 edible oil blends and evaluating their effects and safety in pre-clinical studies

Project ID: CINHD/18/4/I/P **Funding:** Departmental. **Duration:** Registered in 2018 **Sanctioned Amount:** NA; **Guide:** Dr. Anand A. Zanwar; Co-Guide: Prof. M. V. Hegde **Name of Ph.D. student:** Mrs. Asavari Joshi

Background

During 2021-2022, effect PO and CO blends on HepG2 cells was studied. As adipose tissue represents principal organ for lipid storage, effect of these blends on adipocyte cell line was determined.

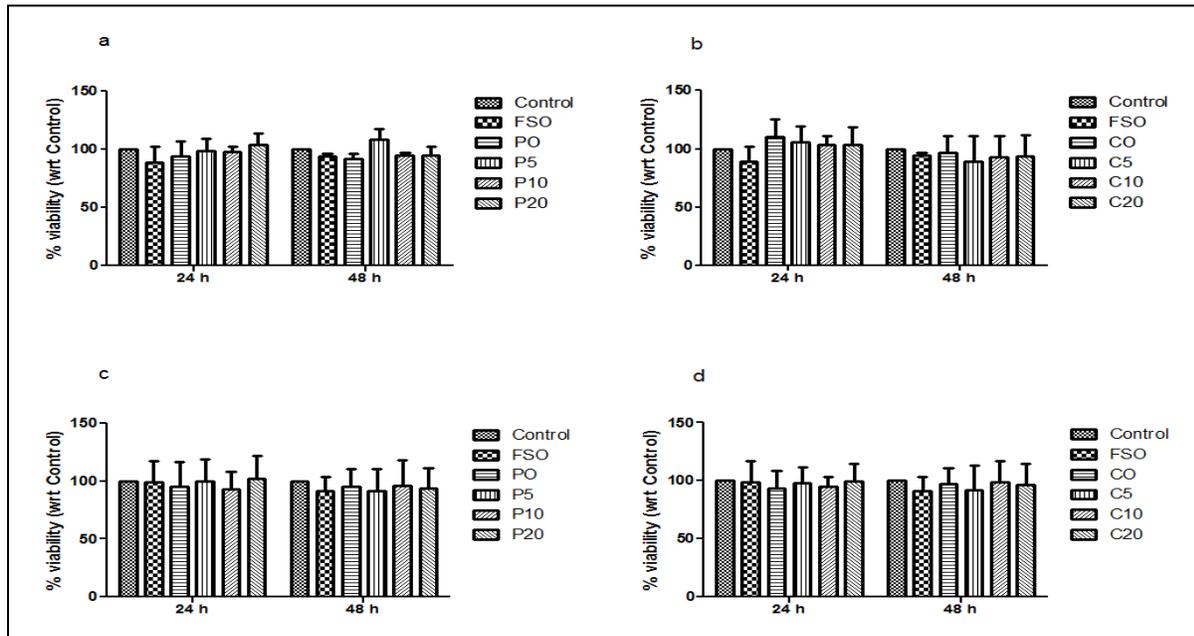
Work done

1. Effect of PO and CO blends on 3T3-L1 cell viability was determined
2. Effect of PO and CO blends on FA profile of 3T3-L1 was determined

Results

1. Effect of PO and CO blends on 3T3-L1 cell viability was determined

Figure 1. Effect of PO and CO blends on 3T3-L1 cell viability



Undifferentiated (a and b) and differentiated (c and d) 3T3-L1 cells were treated with oils or blends for 24 and 48 hour. At the end of each incubation period, MTT assay was performed to determine cell viability. Data is presented as Mean \pm SD (n = 3). FSO: flaxseed oil alone, PO: Palm olein alone, P5: Palm olein blend containing 5 % flaxseed oil, P10: Palm olein blend containing 10 % flaxseed oil, P20: Palm olein blend containing 20 % flaxseed oil, CO: Coconut oil alone, C5: Coconut oil blend containing 5 % flaxseed oil, C10: Coconut oil blend containing 10 % flaxseed oil, C20: Coconut oil blend containing 20 % flaxseed oil

Figure 1a and 1b represents effect of PO or CO blends at 125 $\mu\text{g}/\text{mL}$ on undifferentiated 3T3-L1 cell viability while Figure 1c and 1d represents effect of individual oils/ blends at 125 $\mu\text{g}/\text{mL}$ on differentiated 3T3-L1 cell viability. As shown in the Figure 1, all the individual oils/ blends at 125 $\mu\text{g}/\text{mL}$ had not affected cell viability upto 48 hours in undifferentiated and differentiated 3T3-L1 cells.

2. Effect of PO and CO blends on FA profile of 3T3-L1

Table 1 Fatty acid composition of undifferentiated 3T3-L1 cells treated with PO or CO blends

Table 1a Fatty acid composition of undifferentiated 3T3-L1 cells treated with PO blends

FA	Control	FSO	PO	P5	P10	P20
Palmitic acid (PA)	11.04 ± 0.65	7.62 ± 0.91 [#]	9.8 ± 1.63 ^{\$}	9.19 ± 0.76	8.95 ± 0.92 ^{&}	9.29 ± 0.69
Stearic acid (SA)	12.99 ± 0.59	6.79 ± 0.76 [#]	6.55 ± 0.86 [#]	5.53 ± 1.03 [#]	5.95 ± 1.05 [#]	5.98 ± 0.54 [#]
Oleic acid (OA)	9.83 ± 0.95	4.35 ± 0.69 [#]	4.44 ± 0.6 [#]	7.16 ± 0.48 [©] β%	5.94 ± 0.52 [#]	3.84 ± 0.45 [#]
Linolenic acid (LA)	0.53 ± 0.13	1.16 ± 0.1	0.58 ± 0.11	0.68 ± 0.18	0.7 ± 0.06	0.75 ± 0.1
Alpha linolenic acid (ALA)	0.00 ± 0.00	1.53 ± 0.17	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Arachidonic acid (AA)	3.83 ± 0.39	1.92 ± 0.54	1.93 ± 0.24	1.9 ± 0.43	1.22 ± 0.30 [©]	1.87 ± 0.35
Docosahexanoic acid (DHA)	1.12 ± 0.25	1.09 ± 0.15	0.48 ± 0.13	0.48 ± 0.08	0.27 ± 0.07	0.53 ± 0.08
ω6: ω3	3.60 ± 0.29	1.18 ± 0.23 [©]	5.46 ± 1.71 ^K	5.55 ± 2.25 ^K	7.2 ± 1.00 [#] ^K	4.97 ± 0.32 ^K

FA	Control	FSO	CO	C5	C10	C20
Palmitic acid (PA)	11.04 ± 0.65	7.62 ± 0.91 [#]	10.26 ± 0.50 ^κ	10.13 ± 0.46 ^κ	10.60 ± 0.85 ^κ	10.61 ± 0.98 ^κ
Stearic acid (SA)	12.99 ± 0.59	6.79 ± 0.76 [#]	12.24 ± 0.54 ^κ	10.98 ± 0.88 [Ⓞ] ^κ	10.75 ± 0.28 [Ⓞ] ^κ	11.98 ± 0.88 ^κ
Oleic acid (OA)	9.83 ± 0.95	4.35 ± 0.69 [#]	10.44 ± 1.08 ^κ	10.17 ± 1.03 ^κ	9.71 ± 0.98 ^κ	8.44 ± 1.12 ^{κ%}
Linolenic acid (LA)	0.53 ± 0.13	1.16 ± 0.1	0.64 ± 0.16	0.68 ± 0.16	0.52 ± 0.19	0.41 ± 0.13
Alpha linolenic acid (ALA)	0.00	1.53 ± 0.17	0.13 ± 0.06	0.55 ± 0.17	0.68 ± 0.18	1.5 ± 0.13
Arachidonic acid (AA)	3.83 ± 0.39	1.92 ± 0.54 ^{&}	3.04 ± 0.19	4.07 ± 0.33 ^β	3.81 ± 0.28 [§]	3.60 ± 0.34 [§]
Docosahexanoic acid (DHA)	1.12 ± 0.25	1.09 ± 0.15	0.74 ± 0.20	0.69 ± 0.12	0.90 ± 0.14	0.98 ± 0.17
ω6: ω3	3.60 ± 0.29	1.18 ± 0.23 [#]	4.08 ± 1.20 ^κ	3.04 ± 0.70 [§]	2.28 ± 0.55 [*]	1.25 ± 0.02 ^{Ⓞ Σ}

Table 1b Fatty acid composition of undifferentiated 3T3-L1 cells treated with CO blends

Undifferentiated 3T3-L1 cells were treated with the FSO, PO, CO and their blends for 48 hour at 125 µg/ mL. Total lipids were extracted and FAME were prepared for FA analysis by GC-FID. Data is represented as Mean ± SD of % FA of the total extracted lipids (n=2). FSO: flaxseed oil alone, PO: Palm olein alone, P5: Palm olein blend containing 5 % flaxseed oil, P10: Palm olein blend containing 10 % flaxseed oil, P20: Palm olein blend containing 20 % flaxseed oil, CO: Coconut oil alone, C5:

Coconut oil blend containing 5 % flaxseed oil, C10: Coconut oil blend containing 10 % flaxseed oil, C20: Coconut oil blend containing 20 % flaxseed oil. Two-way ANOVA and Bonferroni posttests were applied to determine statistical significance. #; $p \leq 0.001$ vs Control, ©; $p \leq 0.01$ vs Control, &; $p \leq 0.05$ vs Control, K; $p \leq 0.001$ vs FSO, β; $p \leq 0.01$ vs FSO, \$; $p \leq 0.05$ vs FSO, *; $p \leq 0.05$ vs PO/ CO, %; $p \leq 0.01$ vs PO/ CO and Σ; $p \leq 0.001$ vs PO/ CO

Table 2 Fatty acid composition of differentiated 3T3-L1 cells treated with PO or CO blends

FA	Control	FSO	PO	P5	P10	P20
Palmitic acid (PA)	9.05 ± 0.22	8.52 ± 0.74	10.41 ± 0.84	8.83 ± 0.33	10.18 ± 1.45	9.80 ± 1.00
Stearic acid (SA)	8.27 ± 1.04	9.12 ± 1.22	9.19 ± 0.83	9.75 ± 0.49	10.29 ± 0.30	10.43 ± 1.10 ^{&}
Oleic acid (OA)	9.81 ± 0.98	5.92 ± 0.83 [#]	8.89 ± 0.45 ^K	6.98 ± 1.06 [©]	6.42 ± 1.42 ^{#%}	6.12 ± 1.44 ^{#*}
Linolenic acid (LA)	0.36 ± 0.08	1.17 ± 0.27	0.53 ± 0.11	0.62 ± 0.11	0.52 ± 0.13	0.61 ± 0.13
Alpha linolenic acid (ALA)	0.00 ± 0.00	0.53 ± 0.18	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00	0.00 ± 0.00
Arachidonic acid (AA)	1.93 ± 0.15	2.57 ± 0.24	3.69 ± 0.73	3.62 ± 0.40	3.56 ± 0.65	2.52 ± 0.59
Eicosapentanoic acid (EPA)	0.00 ± 0.00	2.46 ± 0.47 [©]	0.20 ± 0.11 ^{\$}	0.21 ± 0.15 ^{\$}	0.38 ± 0.13 ^{\$}	0.80 ± 0.16
Docosahexanoic acid (DHA)	1.44 ± 0.48	1.56 ± 0.41	0.78 ± 0.20	0.87 ± 0.21	0.90 ± 0.08	0.97 ± 0.18
ω6: ω3	1.65 ± 0.39	0.83 ± 0.04	4.63 ± 2.10 ^{#K}	4.23 ± 1.68 ^{©K}	3.26 ± 0.94 ^{\$}	1.77 ± 0.43 [%]

Table 2a Fatty acid composition of differentiated 3T3-L1 cells treated with PO blends

Table 2b Fatty acid composition of differentiated 3T3-L1 cells treated with CO blends

FA	Control	FSO	CO	C5	C10	C20
Palmitic acid (PA)	9.05 ± 0.22	8.52 ± 0.74	9.26 ± 0.37	9.70 ± 0.42	10.55 ± 0.49 ^β	11.40 ± 0.85 ^{#κ%}
Stearic acid (SA)	8.27 ± 1.04	9.12 ± 1.22	8.40 ± 1.13	8.53 ± 0.95	9.49 ± 0.86	10.38 ± 0.35 ^{©%}
Oleic acid (OA)	9.81 ± 0.98	5.92 ± 0.83 [#]	10.52 ± 0.97 ^κ	10.70 ± 1.00 ^κ	11.25 ± 1.21 ^κ	11.35 ± 1.20 ^κ
Linolenic acid (LA)	0.36 ± 0.08	1.17 ± 0.27	0.40 ± 0.11	0.60 ± 0.21	0.87 ± 0.19	1.10 ± 0.31
Alpha linolenic acid (ALA)	0.00 ± 0.00	0.53 ± 0.18	0.00 ± 0.00	0.00 ± 0.00	0.06 ± 0.01	0.11 ± 0.02
Arachidonic acid (AA)	1.93 ± 0.15	2.57 ± 0.24	1.42 ± 0.20	2.09 ± 0.30	2.11 ± 0.27	1.78 ± 0.40
Eicosapentanoic acid (EPA)	0.00 ± 0.00	2.46 ± 0.47 [#]	0.14 ± 0.05 ^κ	0.54 ± 0.19 ^β	0.66 ± 0.22 ^{&}	1.23 ± 0.25
Docosahexanoic acid (DHA)	1.44 ± 0.48	1.56 ± 0.41	1.16 ± 0.37	0.86 ± 0.20	1.04 ± 0.31	0.87 ± 0.15
ω6: ω3	1.65 ± 0.39	0.83 ± 0.04	1.44 ± 0.23	2.02 ± 0.62	1.77 ± 0.48	1.33 ± 0.22

Differentiated 3T3-L1 cells were treated with the FSO, PO, CO and their blends for 48 hour at 125 μg/ mL. Total lipids were extracted and FAME were prepared for FA analysis by GC-FID. Data is

represented as Mean \pm SD of % FA of the total extracted lipids (n = 2). FSO: flaxseed oil alone, PO: Palm olein alone, P5: Palm olein blend containing 5 % flaxseed oil, P10: Palm olein blend containing 10 % flaxseed oil, P20: Palm olein blend containing 20 % flaxseed oil, CO: Coconut oil alone, C5: Coconut oil blend containing 5 % flaxseed oil, C10: Coconut oil blend containing 10 % flaxseed oil, C20: Coconut oil blend containing 20 % flaxseed oil. Two-way ANOVA and Bonferroni posttests were applied to determine statistical significance. #; $p \leq 0.001$ vs Control, ©; $p \leq 0.01$ vs Control, &; $p \leq 0.05$ vs Control, , K; $p \leq 0.001$ vs FSO, β; $p \leq 0.01$ vs FSO, \$; $p \leq 0.05$ vs FSO, %; $p \leq 0.01$ vs PO/ CO and *; $p \leq 0.05$ vs PO/ CO

FSO treatment had significantly altered FA composition of the undifferentiated cells. As seen in Table 1, after FSO treatment, % of SFA (PA and SA) was significantly lowered ($p \leq 0.001$). In FSO treated cells, ALA was accreted in the cells at non-significant level which resulted in lowering of $\omega 6$: $\omega 3$ ratio significantly when compared with Control ($p \leq 0.01$). Similar to FSO, PO treatment (Table 1a) also lowered PA, SA and OA but raised $\omega 6$: $\omega 3$ ratio non-significantly when compared with Control. Similar trend was followed by P5, P10 and P20. In all the treatments, LA, AA and DHA levels remained relatively unaltered and there was no accretion of ALA in the cells.

In case of CO blends (Table 1b), as the percentage of FSO in the blends increased, ALA levels in the undifferentiated cells increased. Incorporation of the ALA in adipose tissue resulted in the significant lowering of $\omega 6$: $\omega 3$ ratio as compared to CO treated cells ($p < 0.05$). In these cells, long chain metabolites like EPA, DPA3 and DPA6 were not detected. Similar to PO blend treated 3T3-L1 cells, compared to Control, LA, AA and DHA levels remained unaltered.

Similar to undifferentiated 3T3-L1 cells, differentiated adipocytes were treated with PO or CO blends for 48 hour at 125 $\mu\text{g}/\text{mL}$. Total lipids were extracted from the cells and FA composition was analyzed by GC-FID. As seen from the Table 2a, it is clear that Control cells were devoid of the $\omega 3$ FA except DHA. But treatment with FSO resulted in accretion of ALA which was further metabolized in the EPA and DHA ($p < 0.05$). Interestingly, FSO treated undifferentiated cells had higher % ALA than the FSO treated differentiated cells but differentiated cells had highest EPA and DHA levels. This resulted in lowest $\omega 6$: $\omega 3$ level in FSO treated cells while in PO treated cells though ALA was not detected, small amount of EPA was detected. PO treated cells had highest $\omega 6$: $\omega 3$ ratio ($p < 0.001$). In case of blends, ALA was

not detected but there was rise in the EPA and DHA content dose dependently which resulted in the lowering of $\omega 6: \omega 3$ ratio accordingly. It is important to note that even if PO was rich in SFA and MUFA, there was lowering of these FA in the PO and its blend treated cells.

Similar to PO treated differentiated cells, in CO treated differentiated cells (Table 2b), ALA was absent but EPA was present. In case of CO blend treatment, as the % FSO in the blend increase, % ALA also increased which was further reflected in the rise of EPA dose dependently. But levels of DHA and $\omega 6: \omega 3$ ratio remained almost constant. Again, even though CO was rich in LAU and MA, no significant difference in the Control and CO treated cells was observed (data not shown).

Conclusion

At non-toxic concentrations of the oils/ blends, effect of the blends on FA compositions was different for undifferentiated and differentiated 3T3-L1 cells. In undifferentiated cells only CO blends were able to significantly lower the $\omega 6: \omega 3$ ratio, in differentiated cells PO blends were able significantly lower the $\omega 6: \omega 3$ ratio.

7. **Title:** Development of premix for fortification of omega-3 fatty acids and protein in cereal based functional food **Project ID:** CINHD/21/5/I **Funding:** Institutional **Registration date:** 29th Dec 2021 **Ph.D. Students:** Ms. Gauri Ligade **Guide:** Dr. Anand Zanwar

Work done:

1. Detailed review of literature was carried out
2. Aims and objectives was outlined
3. Objective-wise plan of work

Rationale of the study:

As regular food is deficient in essential nutrient it has now become imperative to consume functional food (Topolska et al., 2021). Cereal products constitute major part of our food and hence modifying cereal products to functional food with omega-3 and protein is desirable. The current fortification trend in cereal based functional foods is mainly focused on fiber and micronutrients only and they are deficient in omega-3 and low in protein content (Garg et al., 2021).

Objectives:

- To prepare flour pre-mix fortified with omega-3 fatty acid and protein

- To develop cereal based functional foods using pre-mix
- To assess the stability of pre-mix and final product

Methodology: (Objective-wise)

- To prepare flour pre-mix fortified with omega-3 fatty acid and protein

Here the selection of ingredients to fortify omega-3 and protein for developing flour pre-mix will be carried out. For the fortification of Omega-3 fatty acid, flaxseed powder in the form of whole seed, cake, de-hull powder form will be used. For fortification of protein, flours or powders such as soy flour, chick-pea flour, rice protein, pea protein, protein Hydrolysate etc. will be tried. Among these, individual and combination of the flours will be tested and best one will be selected to fortify to develop flour pre-mix. Once flour pre-mix is ready, then it will be characterized using following parameters:

Nutritional assessment: Fatty acid profile and proximate analysis (carbohydrate, fat, protein, fibre, moisture and ash content)

Functional assessment: Bulk density, Water solubility index and Water absorption capacity

- To develop cereal based functional foods using pre-mix

Here to optimize best level of Pre-mix for enhancing the nutritional quality of wheat and rice based cereal functional foods will be optimized. Various concentrations of the flour premix in the cereal product will be formulated and further compared with control samples.

The prepared food product will be tested as per standard AOAC methods for carbohydrate, fat, protein, fibre, moisture and ash content followed by fatty acid profile and cooking and functional properties of the dough/ batter of different flour formulations will be determined. Then sensory performance of the product will be evaluated using various sensory attributes such as appearance, tearing strength, pliability, aroma, eating quality and overall quality of the developed product.

- To assess the stability of pre-mix and final product

Storage stability studies of the flour premix will be conducted at room temperature and accelerated stability study using stability chamber at 40°C and 65 Rh.

For the stability of the final product only storage stability at room temperature will be conducted.

Parameters for stability study:

Oxidative stability - peroxide value (A.O.A.C 17th edn.2000, official method 965.33), acid value (AOAC Official Method 993.20) and free fatty acids (AOAC Official Method 993.20) followed by fatty acid profile using GC-FID and functional analysis.

Result:

Detail literature review was done as mentioned above and same was approved by Research Advisory Committee (RAC)

Name of the Program: Communicable Diseases

1. Title: Establishment of National Centre for Immunogenicity Testing (NCIT) to evaluate vaccines in clinical trials (**Project ID:** CD/19/1/E). **Funding:** DBT-BIRAC (Under National Biopharma Mission) **Duration:** March 2019 – March 2023 **Sanctioned Amount:** Rs. 16 crores **Investigators:** PI - Dr A C Mishra; **Co-Investigators** – Dr. Vidya Arankalle, Dr. Shubham Shrivastava, Dr. Harshad Patil, Dr. Ruta Kulkarni, Dr. Rashmi Virkar, Dr. Archana Kulkarni-Munje, Dr. Suhas Mhaske, Dr. Sudha Ramkumar **Ph.D. Students:** None **Human Ethical Approval:** IEC/2019/33

Background:

At the Department of Communicable Diseases (renamed as Translational Virology), cell-based, Plaque Reduction Neutralization Tests (PRNT) were developed for dengue and chikungunya viruses and validated as per ISO 17025-2005 guidelines. The laboratory was accredited for these assays and ELISAs for dengue seromarkers. In view of the requirement of a specialized laboratory for the assessment of these and upcoming vaccines and antivirals, the Department of Biotechnology, Government of India under BIRAC-National Biopharma Mission (Rs 12.5crores) and Bharati Vidyapeeth Deemed to be University provided Rs 3.5crore) provided funding. The duration of the project is for 4 years (2019-23). Notably, a State-of-the-art facility with one BSL-3 and 8 BSL-2 laboratories was established in a record time of one year. The available tests were reaccredited in the new facility by NABL under ISO 17025-2017 standards and GCLP compliance. With the emergence of the SARS-CoV-2 virus and several variants causing a long-lasting pandemic, the focus was shifted to COVID-19 as a national priority. The laboratory performed excellent work with utmost care and speed.

Objectives of the project:

1. Initiation of services of accredited assays in the existing facility & establishment of a new State-of-the-art GCLP facility.
2. Standardization, accreditation, reaccreditation, and providing services for dengue assays.

- Standardization, accreditation, reaccreditation, and providing services for chikungunya assays.

The most significant development has been the certification of NIBAC’s BSL-3 facility by the Department of Biotechnology in May 2022. Ours is the first certified BSL-3 laboratory in the country.

1.1 Services provided to the industries:

During the current year, we provided invaluable services to many vaccine manufacturers as well as for anti-viral testing against SARS-CoV-2 and some of its variants. Services were also extended to startups and academia.

Immunogenicity testing:

Table 1 displays services provided for immunogenicity testing. These projects were managed by Drs Shubham Shrivastava, Ruta Kulkarni, and Rashmi Virkar.

Total tests performed: 10178.

Table 1: Immunogenicity testing services provided by NIBEC during 2021-2022

Sr. No.	Project Title (Project ID)	Client	Name of test
1.	A Phase 1, double blind, randomized, placebo-controlled study to evaluate the safety and immunogenicity of Dengusiil in healthy adults (Dengusiil)	Serum Institute of India, Pvt. Ltd.	Dengue PRNT
2.	A prospective, randomized, adaptive, phase I/II clinical study to evaluate the safety and immunogenicity of	Zydus Cadila Healthcare Ltd.	SARS-CoV-2 PRNT

	Novel Corona Virus - 2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects. (CoV-ZC-2013)		
3.	Testing of animal sera samples and human clinical sera samples for SARS-CoV-2 virus neutralization potential using a microneutralization and / or plaque reduction neutralization test (PRNT) assay established and validated at IRSHA as advised by Zydus (CoV-ZC-2005)	Zydus Healthcare Ltd.	Cadila PRNT
4.	To study virus neutralization assay (PRNT) in human sera samples (CoV-ZC-2017)	Zydus Healthcare Ltd.	Cadila PRNT
5.	Virus neutralization assay (SARS-CoV-2 PRNT) for dog serum samples (CoV-ZC-2101)	Zydus Healthcare Ltd.	Cadila PRNT
6.	A prospective, randomized, phase I/II clinical study to evaluate the safety and immunogenicity of 3mg dose of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects (CoV-ZC-2112)	Zydus Healthcare Ltd.	Cadila PRNT
7.	A phase III, randomized, multi-centre, double blind, placebo controlled, study to evaluate efficacy, safety and immunogenicity of Novel	Zydus Healthcare Ltd.	Cadila PRNT

	Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited (CoV-ZC-2113)		
8.	A prospective, open-label, single arm, multicenter, phase III clinical study to evaluate the immunogenicity and safety of 3mg (2 dose) regimen of Novel Corona Virus -2019-nCov vaccine candidate of M/s Cadila Healthcare Limited by intradermal route in healthy subjects (CoV-ZC-2114)	Zydus Cadila Healthcare Ltd.	SARS-CoV-2 PRNT
9.	Development of monoclonal antibody against SARS-CoV-2 (CoV-SI-2021)	Serum Institute of India, Pvt. Ltd.	SARS-CoV-2 PRNT
10.	Randomized, Phase I/II, Placebo-controlled, Dose-Ranging, study to evaluate the Safety, Tolerability and Immunogenicity of the candidate HGCO19 (COVID-19 vaccine) in healthy adult (CoV-GN-2104)	Gennova Biopharmaceuticals Ltd	SARS-CoV-2 PRNT
11.	Development of human monoclonal antibodies against SARS-CoV-2 using convalescent patient blood (CoV-BK-2020)	Bioklone Biotech Pvt Ltd	SARS-CoV-2 PRNT
12.	A Phase II/III Adaptive Seamless Design, Randomized, Controlled Trial to Evaluate Safety and Immunogenicity of 2-dose regimen of BBV87 Chikungunya Vaccine in Healthy Subjects Aged 12 to 65 years in Panama, Colombia and Thailand (IVI-CHIK)	International Vaccine Institute, South Korea	CHIKV IgG ELISA, CHIKV PRNT

13.	A Phase II, Single blind, Randomized, Parallel group, Dose ranging, Single Dose Study of Dengue Monoclonal antibody (Dengue mAb) in Adults with Dengue Fever (SII-DEN-Mab)	Serum Institute of India, Pvt. Ltd.	Dengue ELISA, NSET, PCR and PRNT
14.	A Seamless Phase II/III, Observer-blind, Multi-Centre, Randomized Clinical Trial to Evaluate Immunogenicity and Safety of BBV87, an Inactivated Chikungunya Virus Vaccine in Healthy Subjects 12-65 Years of Age (BBIL-CHIK)	Bharat Biotech	CHIKV IgG ELISA, CHIKV PRNT
15.	A Prospective double-blind randomised Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Single Booster dose of Biological E's CORBEVAX vaccine when Administered to COVID-19-Negative Adult Volunteers Previously vaccinated with 2-doses of either Covishield or Covaxin (BioE-CoV)	Biological E Ltd	SARS-CoV-2 PRNT
16.	A randomized, double-blinded, placebo-controlled, parallel-group, multi-centre, adaptive, seamless bridging study followed by a phase II/III study to assess the safety and immunogenicity of Anti-COVID-19 AKS-452 vaccine for SARS-Cov-2 infection in Indian healthy subjects (Akston-CoV)	Akston Biosciences	SARS-CoV-2 PRNT
17.	Establish serial sero-surveillance to monitor the trend of SARS-CoV-2, Dengue and Chikungunya infection transmission in the	BIRAC-NBM	DENV PRNT, CHIKV PRNT, SARS-CoV-2

	general population, India (DRIVEN 2020)		PRNT
18.	Active virosome vaccine for prevention of COVID-19 sponsored by BIRAC (CoV-SG-2110)	Seagull Biosolutions Pvt Ltd	SARS-CoV-2 PRNT
19.	Serum evaluation against SARS-CoV-2 strains (Reliance-CoV-PreC)	Reliance Life Sciences	SARS-CoV-2 PRNT and CBA
20.	Pre-vaccination screening of subjects for CHIKV IgG for Bharat Biotech CHIKV vaccine trial (BVDU-CHIK)	Bharati Vidyapeeth Medical College	CHIKV IgG ELISA
21.	SARS-CoV-2 virus neutralization of equine Anti-COVID antibody fragments (Vinsbio)	Vins Bioproducts	SARS-CoV-2 MNT

Anti-viral testing: The details of the anti-viral services offered this year are provided in Table 2. For antiviral testing Dr. Rashmi Virkar and Dr. Sudha Ramkumar were responsible.

Table 2: Antiviral testing services carried out during 2021-22

Sr. No.	Title of the Project	Client/Customer's Name
1	Determination of antiviral assessment of Wipro Enterprises Limited Products against SARS-CoV2 Virus	Wipro Enterprises Pvt Ltd
2	Determination of antiviral assessment of Wipro Enterprises Limited Products against SARS-CoV2 Virus	
3	Determination of antiviral assessment of Wipro Maxkleen floor cleaner against SARS-CoV2 Virus	

4	Determination of antiviral assessment of Santoor Handy Gel Handwash against SARS-CoV2 Virus	
5	Invitro assessment of alpha monalaurin against SARS-CoV-2	Clintrek Research Pvt Ltd
6	Evaluation of Recoverz Capsules against SARS-CoV-2 Wild Strain	Zum Helen Diagnostics and Therapeutics Pvt Limited
7	Evaluation of Recoverz Capsules against SARS-CoV-2 Delta variant	
8	Antiviral efficacy of LIVINGUARD Technology against COVID 19	Livingurad Technologies Pvt Limited
9	Antiviral efficacy of LIVINGUARD Hand Sanitizer against COVID 19	
10	Ivermectin for treatment of COVID 19	ICT (Institute of Chemical Technology)
11	Antiviral Activity of Colloidal Silver Hand Sanitizer against SARS-CoV2 Virus	Nanz Med Pharma Pvt Ltd
12	Anti SARS-COV-2 (Covid-19) Activity of Cov-Cur Nano-Curcumin	Oncocur India Pvt Ltd
13	In-Vitro Virucidal activity of Povidone Iodine 2% w/v Gargle (Cofsils Experdine Gargle & Cipladine gargle) against SARS-CoV-2	Cipla Health Limited
14	In-Vitro Virucidal activity of Povidone Iodine 0.5% w/v Naselin Anti-viral Nasal Spray against SARS-CoV-2	Cipla Health Limited
15	Effect of Lactoferrin Mouthwash Solution on SARS Cov-2 virus	La Renon and Frimline Pvt Limited

16	Effect of Lactoferrin Mouthwash Solution on SARS Cov 2 variants	
17	In Vitro study of Covifight against respiratory virus	Meril Life Science Pvt Limited
18	Virucidal activity assessment of products against SARS-CoV-2 Virus	Sundar Dezire Pvt Limited
19	Virucidal activity assessment of products against SARS-CoV-2 Virus	
20	CPE Score based SARS-CoV-2 antiviral studies against ARNA Samples in three modes	Arna Immuno ingredients Pvt Ltd
21	ISO 18184 Test Work ORDER 1	Anabio Technologies Private Limited
22	Antiviral activity of disinfectant liquid	
23	ISO 18184 Test for Nanofiber	
24	ISO18184 and ISO21702	
25	Thermoplastic polyurethane SARS-CoV-2 test Is0 21702	
26	Anti-Viral Testing of NCEs	Sai Life Science Pvt Limited
27	Anti-Viral Testing of NCEs	
28	Anti-Viral Testing of NCEs	
29	Deactivation efficiency of SCoV-35 on AiRTH Coated filter.	Airth Research Private Limited
30	Antiviral Study of Ber and Pc dyes	ICT MUMBAI

Additionally, the following tests were standardized and validated as part of extended objectives or readiness and were proved significant to the industries.

2 Title: Isolation/characterization of SARS-CoV-2 Omicron variants and standardization/validation of cell-based neutralization assays (**Project ID:** CD/21/1/I) **Funding:** DBT-BIRAC (as part of NIBEC Project CD/19/3/E) **Duration:** July 2021 – June 2022 **Sanctioned Amount:** NA **PI:** Dr. Rashmi Virkar, **Co-PI/ Co-Investigators:** Dr. Vidya A. Arankalle, Dr. A.C. Mishra. **Ph.D. Students:** NA **Human Ethical Approval:** IEC/2020/25

Fifty-two Nasopharyngeal swab samples (NPS) collected during different times within the third wave were used for virus isolation in VERO cells. We could isolate SARS-COV-2 from 13 samples. The variant type was determined by full genome/spike region sequencing. These included: BA.1 (n=5), BA.2 (n=6), and BA.5 (n=2) variants.

For the development of PRNT for BA.1 Omicron variant, CD/22/0005 virus was propagated in Vero cells and used to develop plaque assay and PRNT. The optimized assay was validated employing ICH (Q2) guidelines.

3 Title: Evaluation of neutralizing antibody response against wild-type SARS-CoV-2 and Delta, Kappa, Omicron BA.1 variants among Covishield and Covaxin recipients (**Project ID:** CD/21/2/I) **Funding:** DBT-BIRAC (as part of NIBEC Project CD/19/3/E and CD/21/1/E) **Sanctioned Amount:** NA **Duration:** July 2021– June 2022. **PI:** Dr. Vidya A. Arankalle, **Co-PI/ Co-Investigators:** Dr. Rashmi Virkar, D. A C Mishra **Ph.D. Students:** NA **Human Ethical Approval:** BVDUMC/IEC/71, BVDUMC/IEC/185A

Background: COVISHIELD and COVAXIN are the two vaccines used in India. Several variants emerged during the pandemic, some being immune escape mutants. To understand the neutralization potential of the vaccine-induced antibodies, it is essential to perform neutralization tests against the emerging variants.

Work done: The standardized and validated PRNT50 assays for the detection and quantitation of neutralizing antibodies against the wild type (D614G), delta, kappa variants, and BA.1, the subvariant of Omicron were used to compare the response against Covishield and Covaxin. Samples collected 1-month post-complete immunization with two vaccine doses were tested.

Among Covishield recipients (n=33), a significant reduction in neutralizing antibody titers was noted against Delta (p=0.0020), Kappa (p=0.0002), and BA.1 (p<0.0001) variants when compared to the wild type. (Figure 6A). A similar trend was noted among Covaxin recipients (p=0.0034, <0.0001 (n=33) and 0.0020 (n=22) respectively (6B). When the variant-wise response was compared among the recipients of the two vaccines, Nab titers among Covishield recipients were higher against the wild-type virus, and kappa and Omicron variants.

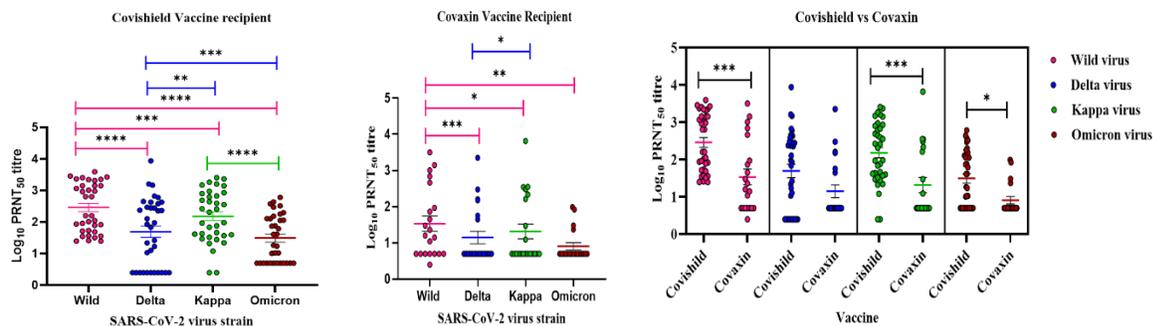


Figure 1:

4 Title: Validation of CMI assays for dengue & chikungunya (**Project ID:** CD/21/4/I)
Funding: DBT-BIRAC (as part of NIBEC Project CD/19/3/E) **Sanctioned Amount:** NA
Duration: July 2021– June 2022 **PI:** Dr Archana Kulkarni-Munje, **Co-PI/ Co-Investigators:** Dr. Vidya A. Arankalle, Dr. A C Mishra **Ph.D. Students:** NA **Human Ethical Approval:** BVDUMC/IEC/71, BVDUMC/IEC/185A

Background: Given the importance of cell-based assays in vaccine immunogenicity, developing such assays for dengue and chikungunya was considered important.

Dengue:

Assay for enumeration of virus-specific T cells (CD4/CD8 T cells), memory T cells, cytotoxic T cells, and Th1 cytokine (IFN- γ , IL-2 & TNF- α) secreting cells were developed using overlapping NS3 and NS5 peptides consensus in all dengue 1-4 serotypes. This flow cytometry-based assay was validated according to H62 guidelines designed specifically for flow cytometry assays by CLSI (Clinical and Laboratory Standards Institute, Malvern, PA, US). Additionally, dengue-specific (NS3 & NS5) Th1/Th2/Th17 cytokine secretion (pg/ml) in PBMC culture supernatants was standardized using a commercially available cytometric bead array kit (CBA) kit. IFN- γ ELISPOT to evaluate dengue virus-specific T cell functionality was validated.

Chikungunya:

For the assessment of CMI, E1, E2 and nsp1 peptides were used for the stimulation of PBMCs. The assay included enumeration of virus-specific T cells (CD4/CD8 T cells), memory T cells, cytotoxic T cells and Th1 cytokine (IFN- γ , IL-2 & TNF- α) secreting cells. Validation of the assay according to the H62 guidelines for flow cytometry is in process. To evaluate Chikungunya virus-specific T cell functionality, IFN- γ ELISPOT was standardized.

For all the CMI assays, GCLP guidelines were followed for training & competency of technical staff, test-specific SOP release, and validation process.

5. Title: Capacity enhancement of National Immunogenicity and Biologics Evaluation Center for assessing the immunogenicity of SARS-CoV-2 vaccines (**Project ID:** CD/21/2/E) **Funding:** DBT-BIRAC (Under National Biopharma Mission) **Duration:** February 2021 – January 2022 **Sanctioned Amount:** Rs. 13.41 crore **Investigators - PI:** Dr. A C Mishra, **Co-Investigators** – Dr. Vidya Arankalle, Dr. Shubham Shrivastava, Dr. Harshad Patil, Dr. Ruta Kulkarni, Dr. Rashmi Virkar, Dr. Archana Kulkarni-Munje, Dr. Suhas Mhaske, Dr. Sudha Ramkumar **Ph.D. Students:** NA **Human Ethical Approval:** IEC/2020/25

Background:

Unprecedented collaborative efforts have been made globally to reduce the duration of the development of effective vaccines for COVID-19. Several vaccines employing different

platforms have been developed and evaluated in clinical trials. More and more industries are coming forward for the development of such vaccines. Considering the need for large-scale testing during clinical trials, the NIBEC was supported by BIRAC-DBT by providing additional funds for enhancing the capabilities of testing samples in clinical trials with expected accuracy and in a short time.

Objectives:

1. Facility Augmentation and Upgradation of technology for existing key tests
2. Pseudo virus technology transfer and standardization of surrogate neutralization assay
3. Development of tests for CMI responses to natural COVID-19 infections and the vaccines
4. Manpower training, ILC activities and develop and share standardized reagents and protocols for testing.

Work done:

- 1.1.All the instruments requested under the project were received and the procedures were standardized for the automated machines.

Title: Production of Lentivirus-based pseudovirus and development of pseudo-virus-based neutralization assay. (Project ID: CD/21/ 5/I) Duration: July 2021– June 2022

PI: Dr Rajashree Patil. Co-investigators: Dr V A Arankalle, Dr A C Mishra

Background: Lentivirus-based pseudoviruses are generated by removing the envelope protein gene and pathogenic genes of HIV-1 retrovirus. This results in lacking autonomous replication capacity and being able to infect host cells for just one cycle. Pseudoviruses provide high safety, robust operability, and suitability for efficient rapid throughput detection. The safety profile of pseudoviruses allows studying the neutralization assay without needing specialized BSL-3 or BSL-4 labs.

Work performed in the lab using the lentiviral system:

The Lentiviral vector system was established to develop SARS-CoV-2 pseudovirus and reporter stable cell lines.

- For this work, 2nd and 3rd generation lentivirus production systems were developed. These systems provide more safety because the components necessary for virus production are split across multiple plasmids (3 plasmids for the 2nd-generation system and 4 plasmids for the 3rd-generation system).
- Further, we have generated genome-integrating as well as non-genome-integrating lentivirus systems.

7.Title: Production of Lentivirus-based pseudovirus and development of pseudo-virus-based neutralization assay (**Project ID:** CD/21/6/I) **Funding:** DBT-BIRAC (as part of NIBEC Project CD/21/3/E) **Duration:** February 2021 – January 2022 **Sanctioned Amount:** Rs. 13.41 crore **Investigators - PI:** Dr. Rajashree Patil, **Co-Investigators** – Dr. Vidya Arankalle, Dr. A C Mishra **Ph.D. Students:** NA **Human Ethical Approval:** IEC/2020/25

Background: Lentivirus-based pseudovirus is generated by removing the envelope protein gene and pathogenic genes of HIV-1 retrovirus. This results in lacking autonomous replication capacity and being able to infect host cells for just one cycle. Pseudovirus provides high safety, robust operability, and suitability for efficient rapid throughput detection. The safety profile of pseudovirus allows for studying the neutralization assay without needing specialized BSL-3 or BSL-4 labs.

Work done:

The Lentiviral vector system was established to develop SARS-CoV-2 pseudovirus and reporter stable cell lines. For this work, 2nd and 3rd-generation lentivirus production systems were developed. These systems provide more safety because the components necessary for virus production are split across multiple plasmids (3 plasmids for the 2nd-generation system and 4

plasmids for the 3rd-generation system). Further, we have generated genome-integrating as well as non-genome-integrating lentivirus systems.

Second-generation pseudovirus production - An initial attempt at pseudovirus production was made using a second-generation lentiviral system. GFP reporter-based SARS-CoV-2 spike pseudo-typed virus particles were successfully generated and transduced into permissive HEK-ACE2 cells (Figure 2A). Quantitation of GFP-positive cells was performed using CTL-Fluorospot (Figure 2B). This pseudovirus showed neutralization results with SARS-CoV-2 specific monoclonal antibody, however, with clinical samples variable neutralization activity was observed. Hence, the GFP reporter-based SARS-CoV-2 spike pseudo-typed virus was not used for further neutralization assay development.

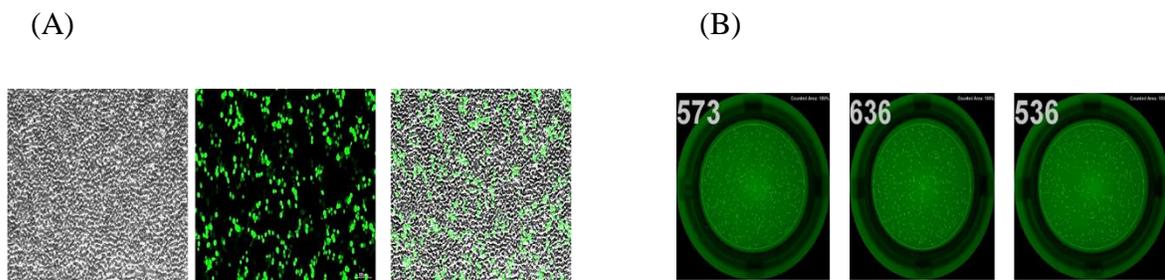


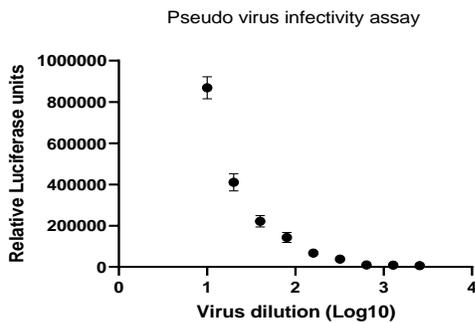
Figure 2: A) Microscopic image indicating green fluorescence due to transduction of GFP-based SARS-CoV-2 spike pseudo-typed virus particles in HEK ACE2 cells (10X magnification). B) Quantification of GFP-based SARS-CoV-2 spike pseudo-typed virus-infected cells using CTL-Fluorospot instrument (Cellular Technology Ltd).

Development of neutralization assay using third-generation luciferase-based pseudovirus:

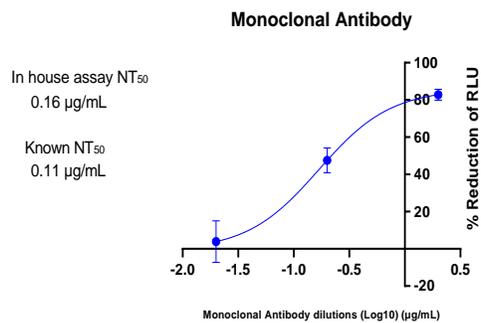
Next, we implemented the third-generation lentiviral system to produce Luciferase reporter-based SARS-CoV-2 spike pseudo-typed virus particles. Virus infectivity assays were performed on HEK ACE2 cells to determine the virus titer. 1.8×10^7 RLU/mL pseudo virus titer was obtained (Figure 3A). Next, to check the functionality of pseudovirus SARS-CoV-2 Spike

(D614G-IMG06) specific monoclonal antibody was used. Neutralization assay with SARS-CoV-2 specific monoclonal antibody showed 0.16 $\mu\text{g/mL}$ NT₅₀ (Mab known NT₅₀= 0.11 $\mu\text{g/mL}$) (Figure 3B). Further, input virus optimization was carried out using a neutralization assay with the available SARS-CoV-2 antibody positive reference material. Three virus dilutions were tested 1:100, 1:500, 1:1000 (Figure 3C). Using 1:500 virus dilution, 15 clinical samples showed a significant correlation with PRNT₅₀ ($r=0.8155$, $p<0.0001$) (Figure 3D). Other conditions such as the stability of diluted virus and the use of attached or freshly trypsinized cells for neutralization test were also tested. To increase the contact between the virus and cells, freshly trypsinized cells were added to the mixture of virus and serum instead of attached cells and neutralization titer was compared. Both the methods showed comparable NT₅₀ (Figure 3E). To study the stability of diluted virus, a neutralization assay was performed with freshly diluted virus and stored diluted virus (Figure 3F). It was observed that only one freeze-thaw cycle is acceptable for neutralization assay with stored diluted virus.

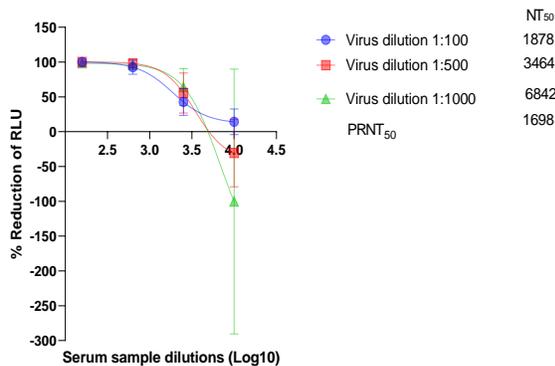
A)



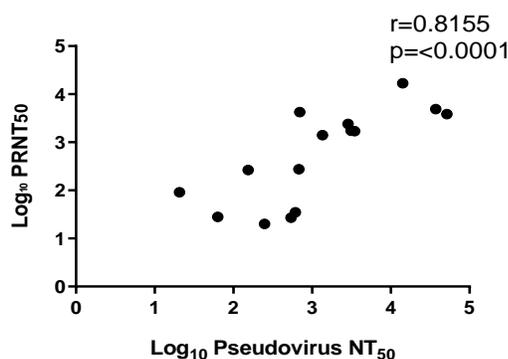
B)



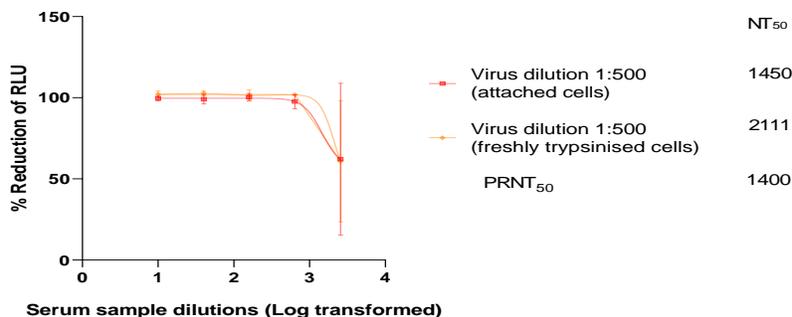
C)



D)



E)



F)

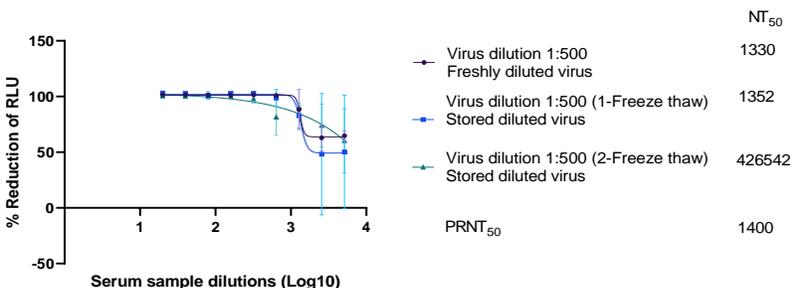


Figure 3: A) Luciferase-based reporter pseudo virus titration. HEK ACE2 cells (2×10^4) were seeded in 96 well plates. Pseudo virus was diluted 10-fold and subsequently two-fold serial dilutions were performed (eight replicates were performed). Titer was expressed as relative luciferase units per ml (RLU/ml) and B) Functional assay for confirmation of pseudovirus. Neutralization assay was performed with SARS-CoV-2 (IMG06) specific monoclonal antibody using 1:500 diluted virus. C) Input virus optimization was carried out employing neutralization assay with internal SARS-CoV-2 antibody positive reference material. Three virus dilutions were tested 1:100 (blue line), 1:500 (red line), 1:1000 (green line). D) Titers obtained by pseudovirus neutralization were individually compared with neutralizing antibody titers by PRNT₅₀. Spearman's correlation test was used to assess the correlation between pseudovirus neutralization and PRNT₅₀ E) attached and freshly trypsinized cells F) using stored diluted virus.

The pseudovirus NT₅₀ values were calculated with non-linear regression [log (inhibitor) vs. response (four parameters)].

Conclusion: We have optimized the conditions for second-generation, Integrase free-second generation, and third-generation lentiviral-based pseudovirus production. Under this activity following parameters were standardized:

1. Optimum vector ratio of lentiviral transfer (**T**) (pLV-eGFP/ pHAGE-CMV-Luc2-IRES-ZsGreen-W), envelope (**E**) vector (T: P: E) determined for SARS-CoV-2 Spike pseudo-typed virus generation.
2. Optimization performed for media composition, vector transfection conditions, pseudovirus harvest time, virus concentration method, and storage conditions for virus stability.
3. Optimization of lentivirus transduction steps using VSV-G pseudo-typed virus.
4. Optimization of infectivity and neutralization assay conditions.
5. Quantitative output method selection for high throughput pseudovirus neutralization assay-Flurospot- Cellular Technology Limited (CTL) was the most efficient, accurate, and cost-effective for GFP reporter pseudovirus-based neutralization. For the Luciferase reporter pseudovirus, the microplate reader was a more convenient method.
6. Pseudovirus-based neutralization assays were standardized with standard monoclonal antibody.

8.Title: T cell immune response to Spike & Nucleocapsid proteins of SARS CoV-2 (**Project ID:** CD/21/5/I) **Funding:** DBT-BIRAC (as part of NIBEC Project CD/21/3/E) **Duration:** February 2021 – January 2022 **Sanctioned Amount:** Rs. 13.41 crore **Investigators - PI:** Dr. Archana Kulkarni-Munje, **Co-Investigators** – Dr. Vidya Arankalle, Dr. A C Mishra **Ph.D. Students:** NA **Human Ethical Approval:** IEC/2020/25

Background:

Previously, it has been shown that antibody levels wane with time in SARS-CoV-1 infection, while cellular immunity can last 6 to 11 years. Similarly, a recent study of antibody levels revealed that 40% of asymptomatic and 13% of symptomatic patients infected by SARS-CoV-2

became negative for immunoglobulin G eight weeks post-recovery. A recent study in recovered COVID-19 patients revealed that even in the absence of antibodies to SARS-CoV-2, a robust T-cell immune response was measured, indicating the importance of T-cell immunity in response to COVID-19. All current SARS-CoV-2 vaccines include the Spike protein and a robust T-cell immunity against Nucleocapsid-derived peptides can be detected in convalescent COVID-19 patients. Besides this, inactivated virus vaccines such as Covaxin are used in India. Therefore, identifying T-cell epitope-derived peptides within these two viral proteins will provide effective tools for measuring T-cell responses in COVID-19 patients with different degrees of disease severity and evaluating the immunogenicity of vaccine candidates in clinical trials. The T cell responses can be analysed by two assays namely, flow cytometry-based intracellular cytokine assay and ELISPOT technique-based for the quantification of T cells secreting IFN- γ .

Assay-1

Evaluation of cell-mediated immune response (CMI) to Spike & Nucleocapsid proteins of SARS CoV-2- by Intracellular cytokine secretion (ICS) assay using flow cytometry approach (CoV-CMI -ICS)

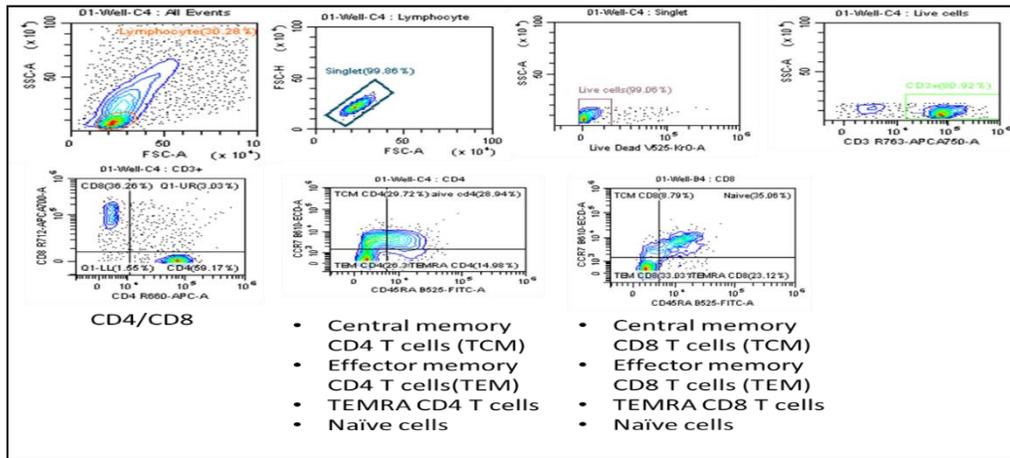
Methodology

The PBMCs of vaccine recipient are exposed to Spike & Nucleocapsid peptide pool for about 48 hrs in a humidified CO₂ incubator in a sterile condition in the presence of golgi inhibitors along with CD107a antibody and then the cells are harvested and subjected to immunostaining by live dead stain and fluorochrome-labeled antibodies against surface markers (CD3, CD4, CD8, CD137, CCR7, CD45RA) and intracellular proteins (IFN- γ , IL-2, TNF- α , GranzymeB). After immunostaining the cells are acquired on a flow cytometer (CytoFLEX LX) and the desired cellular population is identified and enumerated as follows:

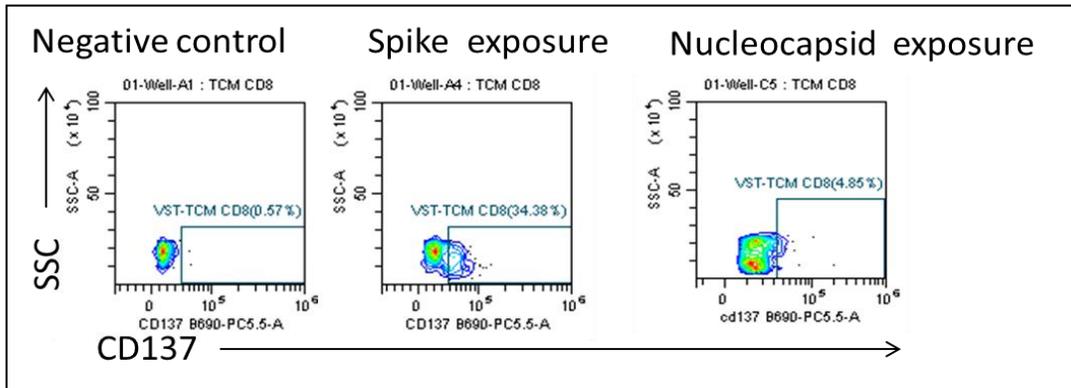
- Antigen specific CD4 and CD8 T cells based on CD137 expression.
- Antigen specific memory CD4 and CD8 T cells based on absence of CD45RA expression.
- Antigen specific central memory and effector memory CD4 and CD8 T cells (CCR7 expression).

- Antigen specific TEMRA (effector memory T cells re-expresses CD45RA) based on CD45RA & CCR7 expression.
- Monofunctional, bifunctional, and polyfunctional antigen-specific T cells (based on either separate or combinational expression of IFN- γ , TNF- α & IL-2)
- Antigen-specific cytotoxic T cell response (Coexpression of CD107a, Granzyme B, and IFN- γ)

(A)



(B)



(C)

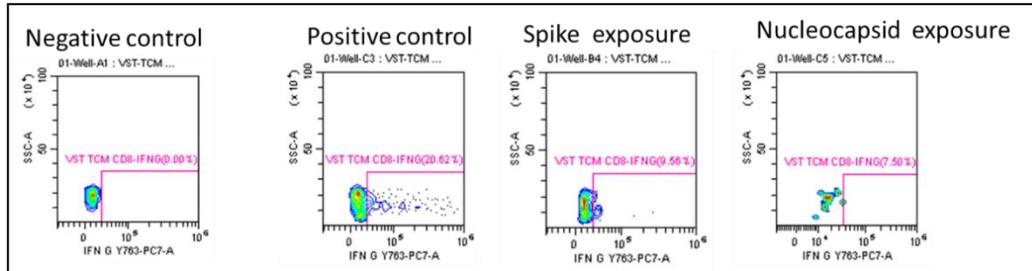


Figure 4: A Flow cytometry gating strategy to identify memory T cell subsets. (A) Gating strategy used to identify memory T cells. During acquisition, the lymphocytes were live-gated using the side and forward scatter dot plot display. Singlets were segregated based on the area and height of the Forward scatter. The live lymphocyte population was further discriminated against based on the live dead stain. CD3 positive population of live cell population was used to identify CD4 and CD8 T cells. Based on the expression of CCR7 and CD45RA, the expression of CD4 and CD8 T cells were categorized as Central memory, Effector memory, and TEMRA population. (B) Gating strategy used to identify antigen-specific T cells. CD137 expression was used to identify antigen-specific memory T cell subsets. The functionality of these subsets was assessed in terms of cytokine production (e.g. IFN- γ) was analyzed. Three controls were used in the assay namely, FMC (Fluorescence minus cytokine antibodies and CD137 antibody), negative control, and positive control. While giving final readouts for percentages of antigen-specific cell or cytokine-producing cells, the negative control values are subtracted from the readouts obtained in spike or Nucleocapsid peptide pool exposed cells.

Assay 2: Evaluation of cell-mediated immune response (CMI) to Spike & Nucleocapsid proteins of SARS CoV-2 by ELISPOT assay to assess Interferon- γ production by T cells after the antigenic stimulus. (SARS Cov-2- Spike & Nucleocapsid peptides) (CoV-CMI-ELISPOT)

Methodology

ELISpot assays employ the sandwich enzyme-linked immunosorbent assay (ELISA) technique. Either a monoclonal or polyclonal antibody specific to the chosen analyte is pre-coated onto a

PVDF (polyvinylidene difluoride)-backed microplate. We used the commercially available kit for ELISPOT assay which comprised precoated plates. Peptide-based antigenic stimulated cells are pipetted into the wells and the microplate is placed into a humidified 37°C CO₂ incubator for a specified time. During this incubation period, the immobilized antibody, near the secreting cells, binds to the secreted analyte. After washing away any cells and unbound substances, a biotinylated antibody specific to the chosen analyte is added to the wells. Following a wash to remove any unbound biotinylated antibody, alkaline phosphatase-conjugated to streptavidin is added. The unbound enzyme is subsequently removed by washing and a substrate solution (BCIP/NBT) is added. A blue-black colored precipitate forms and appears as spots at the sites of cytokine localization, with each spot representing an individual analyte-secreting cell. The spots can be counted with an automated ELISpot reader system, CTL S6 macroanalyser. Most studies have demonstrated strong T cellular immunity against Spike and Nucleocapsid hence, peptide pool array covering whole spike and Nucleocapsid are used for PBMC stimulation.

Both the assays were validated according to H62 guidelines designed specifically for flow cytometry assays by CLSI. Besides, these were used in research on the immunogenicity of COVID-19 vaccines.

8 Title: To study neutralizing antibody levels in COVISHIELD vaccinee and COVID-19 patients using MSD ACE2 neutralization assay (**Project ID:** CD/21/6/I) **Funding:** DBT-BIRAC (as part of NIBEC Project CD/21/3/E) **Duration:** February 2021 – January 2022 **Sanctioned Amount:** Rs. 13.41 crore **Investigators - PI:** Dr. Vidya Arankalle, **Co-Investigators –** Dr.Rajashree Patil, Dr. A C Mishra **Ph.D. Students:** NA **Human Ethical Approval:** IEC/2020/25

Background:

Assessing the neutralization potential of vaccine recipients and COVID-19 patients against emerging viral variants is essential. Developing variant-based PRNTs for all the emerging SARS-CoV-2 variants is a difficult task. With the availability of an MSD platform that can simultaneously detect and quantitate antibodies against multiple SARS-CoV-2 variants, we explored the use of the V-PLEX SARS-CoV-2 Panel 15 (ACE2) Kit available at the time of conducting this study. This is a multiplex assay for measuring the antibodies that block the

binding of ACE2 to Spike antigens from variants of SARS-CoV-2 including the wild type-Wuhan, Alpha, Beta, and Delta variants and other variants present in the kit.

Results:

We first assessed the performance of the MSD assay. None of the thirty-eight IgG-anti-SARS-CoV-2 negative pre-vaccination plasma samples scored reactive against all the 10 variants when a cutoff value of ≥ 1.5 fold was used in the MSD assay. Next, we compared the MSD assay with a live virus neutralization assay (PRNT₅₀) that uses the Wuhan-Hu-1 strain (B.1, D614G-Wild-type). For this, seven serum and forty plasma samples (n=47) from the first wave of COVID-19 patients were used. ACE2 competition by the MSD assay and antibody titers from PRNT50 assay showed excellent correlation when all the variants used in the MSD assay were considered ($r=0.76-0.83$, $p < 0.0001$, Fig 1a). Despite differences in the biological properties of the variants, the cross-reactivity of antibodies against multiple variants might explain why the PRNT exhibited a high correlation with other variants besides Wuhan. In India, the first COVID-19 wave was dominated by the Wuhan-Hu-1 strain (B.1), while the second wave was initially caused by the B.1.617.1/ Kappa lineage variant and, later by the B.1.617.2/ Delta lineage variant. We first compared anti-variant-antibody seropositivity among the three patient groups (figure 1b). Percent seropositivity against different variants was comparable among Wuhan (63-89%) and Delta (68-79%) variant-infected patients. However, most of the Kappa-infected patients (56-72%) were antibody-negative. Though the number of patients was small, when the samples were collected within one week of the onset of symptoms, antibody response in Kappa patients seemed to be delayed. To understand variant-specific quantitative differences in all patient groups, ACE2-competition was compared. In accordance with the highest antibody negativity in the Kappa patients, the median ACE2 competition was lowest in this patient group across all the variants (figure 1c).

Figure 1d provides variant pairs with significant differences in the patient groups [Wuhan-Delta (n=8), Wuhan-Kappa (n=0), Delta-Kappa (n=27)]. Given the lack of antibodies among majority of Kappa patients, we considered only antibody-positive samples (figure 1e). This analysis revealed that whenever antibodies were present at the time of blood collection, both Kappa and Delta patients exhibited high and comparable neutralizing antibody levels against different variants. We would like to point out here that the Kappa variant has E484Q mutation. The 484

position in the RBD region is crucial for the interaction of neutralizing antibodies, mutation at this position resulted in a reduction in neutralizing antibody titer. In addition, E484Q mutation hinders electrostatic bonds at E484 and K31 in the Spike RBD region affecting interaction with ACE2. Delta variants carry L452R, T478K (RBD region) mutations that affect binding at ACE2 by enhancing the stabilization of the ACE2-RBD complex. These mutations have been shown to alter viral interaction with ACE2 and might have affected antibody response in these patient groups. In the absence of follow-up samples, a subsequent comparison was not possible.

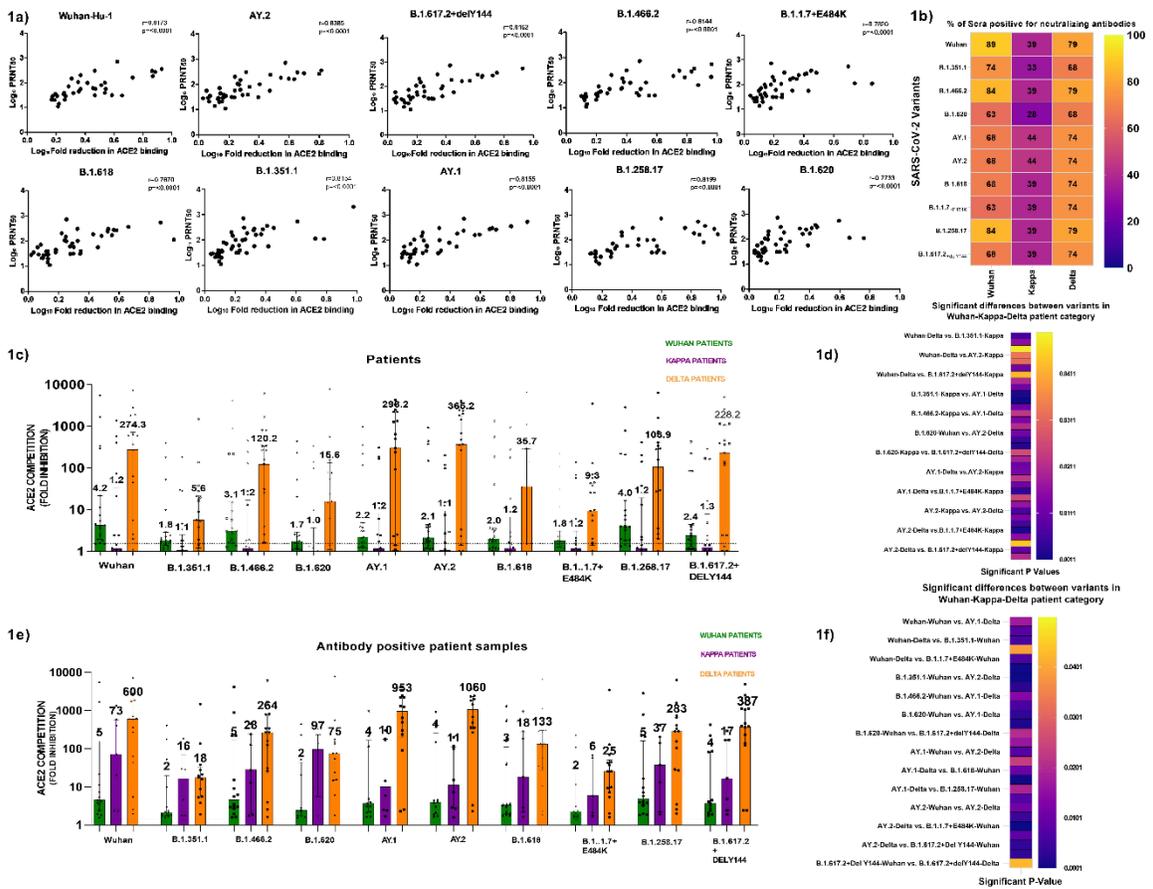


Figure 5: (A) For assessing the performance of MSD in relation to PRNT50 employing the Wuhan-Hu-1 strain, 47 samples from COVID-19 patients infected during the first wave were tested by both methods. ACE2 competition by all the ten variants present in the MSD-15 panel was individually compared with neutralizing antibody titers by PRNT50. The correlation between ACE2 competition and PRNT50 for every variant was analyzed by Spearman's

correlation. Spearman's $\rho = r$ value varied from 0.76 to 0.83 while the p -value was <0.0001 for all the variants. (B) MSD ACE2 assay was performed on plasma samples of COVID-19 patients naturally infected with Wuhan virus ($n=19$), B.1.617.1/ Kappa lineage variant ($n=18$), and B.1.617.2 strain/ Delta lineage variant ($n=19$). Individual variant-wise percent positivity in the patient groups is depicted. (C) For the comparisons of anti-variant antibody levels in the three patient groups, ACE2 competition values were compared across the ten variants in all three patient groups. One-way ANOVA corrected for multiple comparisons by Tukey's test was performed. This analysis included all the patients irrespective of antibody positivity. (D) The heat map depicts variant pairs showing significant differences (one-way ANOVA) in the patient groups. The significant p values are indicated using color code. (E) For this analysis, samples positive for anti-variant antibodies were considered for assessing the cross-reactivity of the generated antibodies. For the comparisons of anti-variant antibody levels in the three patient groups, ACE2 competition values were compared across the ten variants in all three patient groups. One-way ANOVA corrected for multiple comparisons by Tukey's test was used. (F) The heat map for antibody-positive patients depicts variant pairs with significant differences (one-way ANOVA) in the patient groups. Significant p values are marked using color code ACE competition values are presented as Median \pm IQR. The dotted line indicates the cutoff value (≥ 1.5) for ACE2 competition (fold inhibition). P values <0.05 were considered significant.

Neutralization potential against the major VOCs is reduced in COVISHIELD vaccine recipients -

Low anti-variant neutralizing antibody response in the pre-negatives: At 1-month post-vaccination (Figure 6A), antibody positivity for the Wuhan strain was 88.4% in MSD which was comparable ($p=1$) to 95% (114/120) in PRNT50 when the same vaccinees were tested earlier. Surprisingly, almost 40% of the vaccinees lacked antibodies against AY.2, B.1.1.7+E484K, B.1.351.1, B.1.620 ($p=0.002-0.006$). Even when optimum antibody response is expected, a large proportion of the pre-negative vaccinees were at risk of infection from these variants. For the other variants, positivity was comparable with Wuhan.

At 6 months, antibody positivity decreased for all the variants (Figure 6B). When compared with the Wuhan strain (68.8%), a lower proportion of antibody positives (15.6- 37.5%, $p= 0.02- <0.001$) were detected for eight variants; the difference with B.1.258.17 (43.8%) was not significant ($p=0.07$). Thus, by 6 months post-immunization, most of the pre-negatives lacked anti-variant neutralizing antibodies and could be susceptible to infections with a variety of variants. At 6 months, a significant decline in Nab levels was recorded for an additional four variants. Except for Wuhan (Median±IQR, 1.6; 1.4-2.1), median ACE2-competition against all the other variants was below the cutoff value of 1.5 (Figure 6E). Taken together, Nab response to the variants known to have immune evasion-associated mutations was inferior even at 1 month and declined sharply for all the variants by 6 months.

Higher and more durable anti-variant Nab response in the pre-positives: At 1-month post-immunization, all the 32 vaccinees with hybrid immunity were Nab positive for all the variants examined (Figure 6B). As the vaccine was administered post-1st wave, the highest ACE2 competition was observed against the Wuhan strain (Figure 6D). High fold reduction in ACE-2 binding (5.6-20.9fold, $p=0.039- <0.0001$) was recorded for B.1.351.1, B.1.620, B.1.618, and B.1.1.7+E484K variants with characteristic mutations in the S protein (Figure 6D). Notably, except B.1.618 these variants are classified by the WHO as VOCs. At the 6-month follow-up, a small proportion (3.5-10.7%, Figure 6B) of the pre-positive vaccinees circulating lower Nab levels at 1 month, turned out antibody negative against the same four variants. Nab levels continued to be lower for these variants while comparable levels were recorded against the remaining variants (Figure 6F). Overall, irrespective of the prior antibody positivity, Nab levels were consistently lower for the VOCs included in the MSD panel.

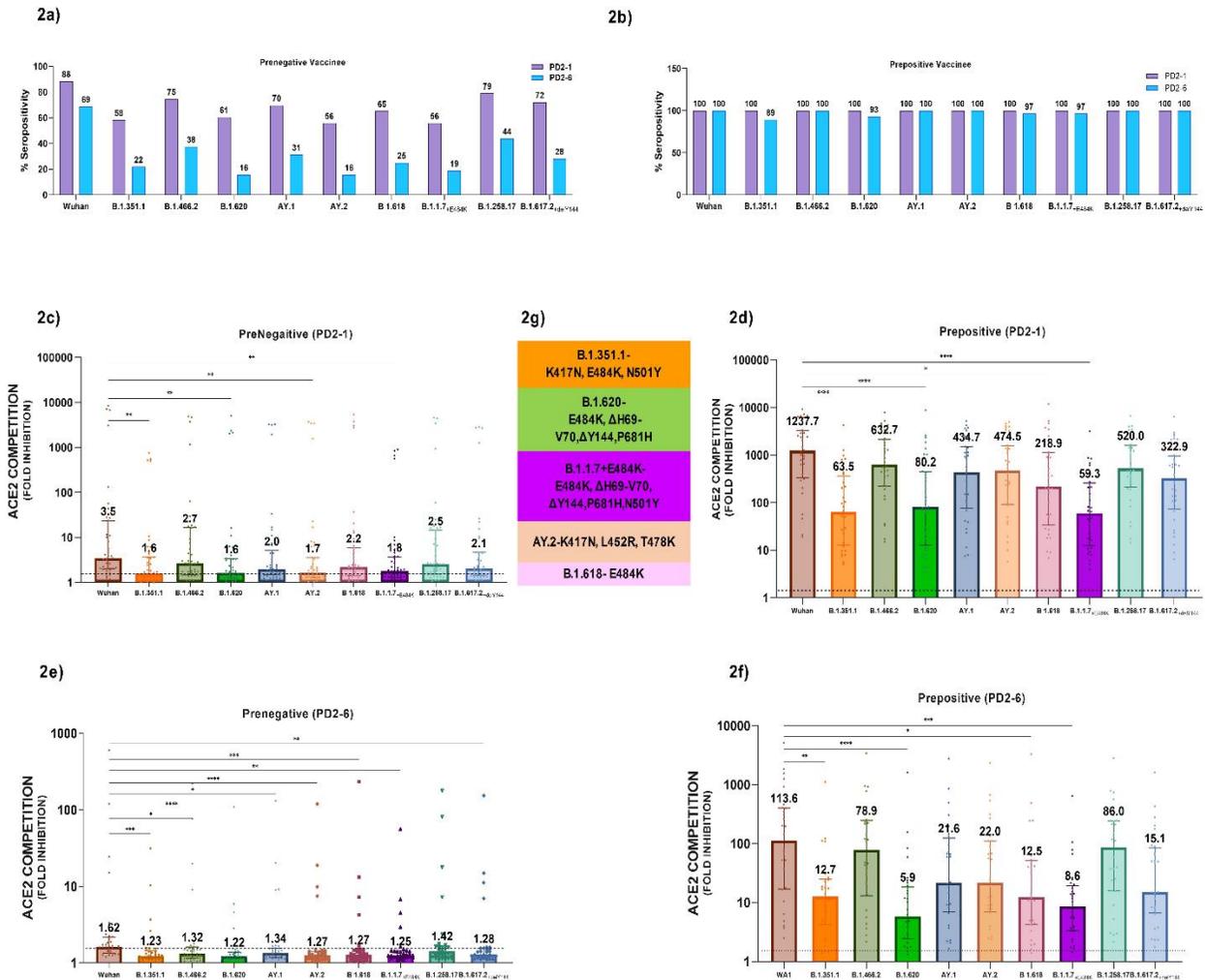


Figure 6: Plasma samples from COVISHIELD vaccine recipients either negative (prenegative) or positive (prepositive) for IgG-anti-SARS-CoV-2 antibodies were tested for anti-variant antibodies in the MSD-15 assay at 1 (PD2-1) and 6 months (PD2-6) after complete vaccination with two doses. The cutoff value for the assay was > 1.5 . (A, B) provide variant-specific percent antibody positivity among prenegatives and prepositives respectively at both the time points. The value above each bar represents % seropositivity. ACE2 competition (fold inhibition) values were compared between all the variants at PD2-1 and PD2-6 among prenegatives (C, E) and prepositives (D, F). Inter-variant comparisons were made for the vaccinee groups at both the timepoints using the Kruskal–Wallis test (post-hoc test–Dunn’s test). The dotted line indicates

*the cutoff value (≥ 1.5). The value above each bar represents the median ACE2 competition value; variation measures the interquartile range (25%–75%), $n = 43$ PD2-1 prenegative vaccinee, $n = 32$ PD2-6 prenegative vaccinee, $n = 32$ PD2-1 prepositive vaccinee, $n = 28$ PD2-6 prepositive vaccinee. Stars expressing p values are: **** $p < 0.0001$, *** $p < 0.001$, ** $p < 0.01$, and * $p < 0.05$. (G) denotes mutations identified in the respective variants with confirmed immune evasion by experimental studies.*

9 Title: Development of potent adjuvanted respiratory syncytial virus vaccine for mucosal delivery (**Project ID:** CD/19/3/E) **Funding:** Wellcome-DBT India Alliance **Duration:** January 2019 - December 2023

Sanctioned Amount: 1.69 crore **Investigators - PI:** Dr. Harshad Padmanabh Patil, **Co-Investigator:** Dr. Vidya Arankalle **Ph.D. Student:** Mr. Ahmedali Mandviwala **Animal Ethical Approval:** BVDUMC/1881/2018/002/010 (renewed number BVDUMC/570/2021/001/008)

Background: The study plans to evaluate the immunogenicity of the RSV-virus-like-particles (RSV-VLP) vaccine with chimeric adjuvants recognized by two PRR ligands following sublingual or pulmonary delivery in mice. During the previous year, the RSV virus A2 strain obtained from American Type Culture Collection (ATCC) was propagated, three structural proteins of RSV viz M, G, and F were expressed using baculovirus expression systems and RSV-VLPs were developed.

Objectives:

1. Production of candidate RSV vaccines, consisting of VLPs plus different combinations of adjuvants
2. Determination of the immunological and protective properties of these vaccine candidates in mice
3. Evaluation of the effects of these vaccine candidates on human PBMC or PBMC-derived cells

Work done:

Work on objective 2 was executed in the year.

Humoral immune responses after immunization - In vivo studies were conducted to determine the immunogenicity of the VLPs. The immune response elicited by BPL-RSV and FI-RSV were the comparators. Of significance, the mice immunized with RSV-VLPs (5 or 10 μ g) generated significantly higher VLP-specific IgG titers than the mice that received BPL- or formalin-inactivated RSV (Figure 7A). Similarly, IgG responses against RSV fusion (RSV-F, Figure 7B) and matrix (RSV-M, Figure 7D) proteins were higher in the VLP-immunized mice. Surprisingly, the response against glycoprotein, RSV-G, was not enhanced for the VLP (p value 0.07 to 0.88) (Figure 7C). B cell ELISpot using splenocytes from immunized mice was conducted to determine the numbers of antigen-specific ASCs. The VLPs induced a comparable number of ASCs as the inactivated RSV antigens (Figure 7E). Determination of neutralizing antibody titers highlighted that the mice immunized with either 5 or 10 μ g VLPs generated significantly higher levels of neutralizing antibodies than those with either inactivated RSV antigens (Figure 7F).

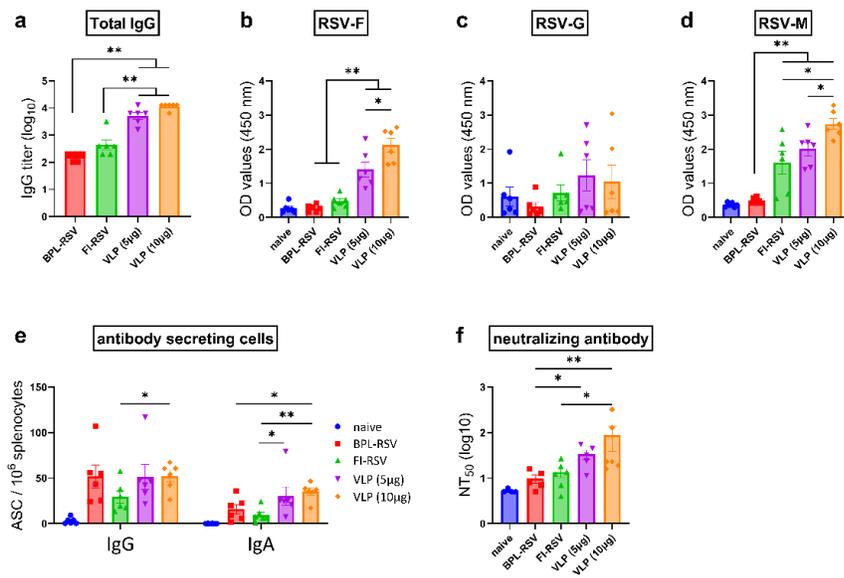


Figure 7. Figure 1. Humoral response after immunization with RSV-VLPs. Mice ($n=6$ per group) were immunized twice on days 1 and 21 with $5\mu\text{g}$ BPL-RSV, FI-RSV or 5 or $10\mu\text{g}$ RSV-VLP. Control mice remained unimmunized. Blood was collected 21 days after the first dose and 7 days after the second dose (day 28) upon sacrifice. Antibody responses after immunization were determined by measuring (a) the total IgG titre against RSV and ELISA reactivity of the collected sera against (b) RSV-F, (c) RSV-G, and (d) RSV-M proteins. (e) ASCs producing RSV-specific IgG or IgA from splenocytes were measured by ELISpot. HEp-2 cells were used to determine (f) neutralizing antibody levels in sera. Statistical analysis was accomplished by using the non-parametric Kruskal-Wallis test : *, $p < 0.05$; **, $p < 0.01$. Bar represents mean \pm SEM.

In vivo studies were conducted to determine the immunogenicity of the VLPs. The immune response elicited by BPL-RSV and FI-RSV were the comparators. Of significance, the mice immunized with RSV-VLPs (5 or $10\mu\text{g}$) generated significantly higher VLP-specific IgG titers than the mice that received BPL- or formalin-inactivated RSV (Fig. 1a). Similarly, IgG responses against RSV fusion (RSV-F, Fig. 1b) and matrix (RSV-M, Fig. 1d) proteins were higher in the VLP-immunized mice. Surprisingly, the responses against glycoprotein, RSV-G, were not enhanced for the VLP (p value 0.07 to 0.88) (Fig. 1c). B cell ELISpot using splenocytes from immunized mice was conducted to determine the numbers of antigen-specific ASCs. The VLPs induced similar numbers of ASCs as the inactivated RSV antigens (Fig. 1e). Determination of neutralizing antibody titers highlighted that the mice immunized with either 5 or $10\mu\text{g}$ VLPs generated significantly higher levels of neutralizing antibodies than in mice immunized with either of the inactivated RSV antigens (Fig. 1f).

IFN- γ and IL-4 response after immunization:

To characterize the immune response generated after immunization, we quantified Th1 cytokine (IFN- γ) and Th2 cytokine (IL-4) generated from in-vitro stimulated or non-stimulated splenocytes. Immunization with VLPs induced the highest numbers of IFN- γ SFCs upon stimulation compared to inactivated RSV virus or mock immunizations. The number of IL-4 SFCs was similar in all immunized groups after stimulation. Similar observations were noticed for secreted IFN- γ and IL-4 in supernatants of the restimulated and non-stimulated splenocytes

(p values 0.11 to 0.90) (Fig 2d-e). No difference in the IFN- γ and IL-4 levels was observed in sera of naïve and immunized mice.

Protection from live RSV after challenge in immunized mice:

To investigate the possibility of enhanced respiratory disease (ERD), we examined lung pathology in the immunized mice, upon RSV challenge (Fig. 3a-e). The lungs of mice infected with the live virus had mild congested vascular tissue in the lung parenchyma, mild alveolar pathological changes with alveolitis with mononuclear inflammatory cellular infiltration in the alveolar parenchyma (Fig. 3b). Minimal pathology was seen in mice that received BPL-RSV (Fig. 3c). However, mice immunized with FI-RSV showed signs of enhanced inflammation such as alveolitis and infiltrates in both the peribronchial and perivascular areas (Fig. 3d). In contrast, the lungs of the mice that received RSV-VLP (Fig. 3e) showed no signs of lung pathology and were very similar to the lungs of naïve mice (Fig. 3a). Overall, mice immunized with FI-RSV showed ERD while immunization of mice with VLPs prevented lung inflammation after RSV challenge (Fig. 3f). No weight loss was observed in the RSV challenged mice.

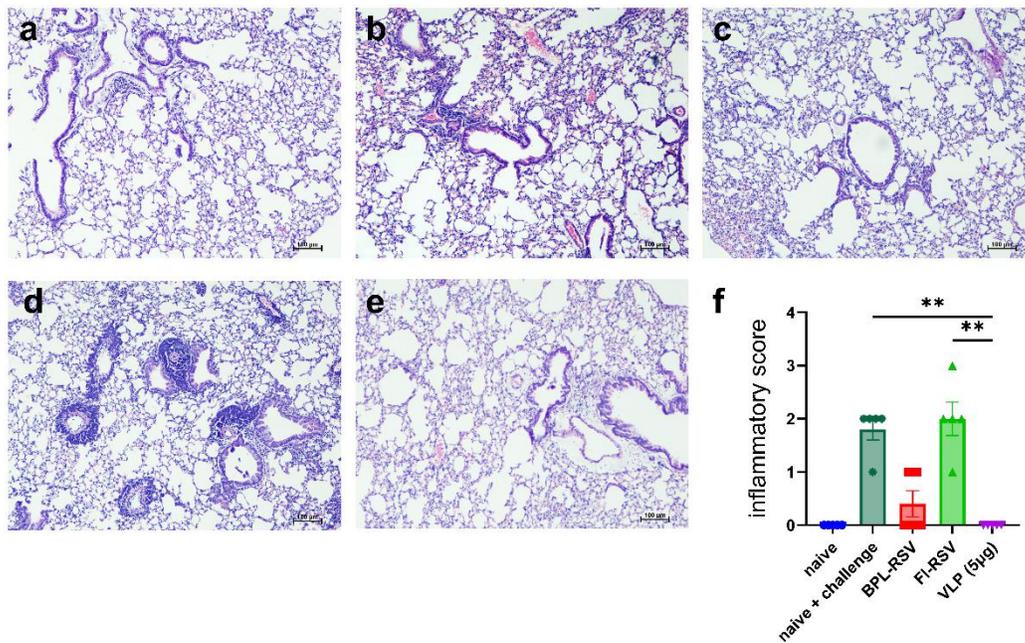


Figure 8. Lung pathology in mice challenged with live RSV after immunization. Mice ($n=5$ per group) were immunized twice and subsequently challenged with live RSV 7 days after the second dose. The lungs were harvested 4 days post-challenge, fixed, sectioned, and stained with H&E to evaluate RSV-mediated enhanced respiratory disease. Representative images of lungs from (a) naive, (b) non-immunized and challenged, (c) BPL-RSV-, (d) FI-RSV- and (e) RSV-VLP-immunized and challenged mice. (f) The lung pathology score was calculated after analysing the lung sections from each mouse. Statistical analysis was accomplished by using the non-parametric Kruskal-Wallis test: *, $p < 0.05$; **, $p < 0.01$. Bar represents mean \pm SEM.

Conclusion: Mice immunized with VLPs developed high levels of serum IgG and neutralizing antibodies compared with mice immunized with inactivated virus. The VLP vaccine also induced higher levels of IFN- γ and IL-4-producing cells. VLP immunization abolished lung pathology in the mice after the RSV challenge. Overall, our results indicate that RSV-VLPs consisting of prefusogenic F, glycoprotein, and matrix proteins are a potential vaccine candidate against RSV.

Other Information**Budget****Extramural Grants (newly sanctioned and ongoing) Total Projects:**

S.No	Name of the Scheme/Project/Endowments/Chairs	Name of the Funding agency	Year of Award	Funds provided (INR in lakhs)	Duration of the project	Funds Received in April 2022-March 2023
1	Capacity enhancement of National Immunogenicity and Biologics Evaluation Center for assessing the immunogenicity of SARS-CoV-2 vaccines	DBT-BIRAC	2021	134.15	Feb 2021- Feb 2023	Nil
2	Establishment of National Centre for Immunogenicity Testing, NCIT to evaluate vaccines in clinical trials	DBT-BIRAC	2019	160.00	2019-2023	Nil
3	Development of potent adjuvanted respiratory syncytial virus vaccine for mucosal delivery	Wellcome-DBT Indian Alliance	2019	168.93	2019-2023	15.78

4	Repurposing of cephalosporins in cervical cancer treatment.	EMR-ICMR	8 Sep 2021	31.15	2021-2024	12.29
5	Phytochemical standardization and evaluation of anti-cancer and immunomodulatory activity of Unani formulation, Itrifal Gudadi.	Expression of Interest Scheme, CCRUM	11 March 2020	43.57	2020-2023	11.45
6	Continued Medical Education Program (CME) on Effective Science Communication for Ayush teachers	Rashtriya Ayurveda Vidyapeeth (RAV), Ministry of Ayush		9.00		9.00
7	Evaluation of Phonophoresis Therapy with Myostaal Gel in participants suffering from Acute Musculoskeletal Conditions: A Randomised, Controlled Clinical Study	Solumiks Herbaceuticals Pvt. Ltd.		4.80		3.31

8	Effect of Lipitaezar tablets, a proprietary formulation in patients suffering from Non-alcoholic fatty liver disease (NAFLD): an open label, randomized, controlled clinical study	Amardeep Pharma Pvt. Ltd.		5.41		
9	ICAR -AICRP- Linseed Value Addition Centre	ICAR	2015	17.77	2015 onwards	17.32
10	Extraction of bioactive lignan and development of value added products from flaxseed	SERB-IRRD	2019	27.85	2022	4.40
11	Polyunsaturated fatty acid enriched nano-formulation for diabetes: In vivo efficacy and bioavailability studies	Chellaram Diabetes Research Centre	2022	27.38	2025	4.33
12	Investigating Mechanisms Leading to Preeclampsia	Indian Council of Medical Research, Centre for Advanced	2017	757.95	2017-2022	25.58

		Research				
13	Exploring the effect of prenatal omega-3 fatty acid supplementation on cognitive performance in the offspring born to dams with gestational diabetes mellitus	Dr. Nisha Kemse ICMR DHR	2021	46.6	2021- 2023	15.16

Intramural funding:

Sr. No	Name of the Project	Funding Agency	Sanctioned (INR)	Received (INR)	Expenditure (INR)
1	Investigating effect of Triphala in patients suffering from Non-alcoholic fatty liver disease (NAFLD): a proof of concept clinical study	Bharati Vidyapeeth Deemed University	1,00,000/-	-	-
2	In vivo efficacy studies of novel phytoformulations of selected phytoactives in model of high fat diet induced fatty liver	Bharati Vidyapeeth Deemed University	1,00,000/-	-	-

Student Fellowships

S.No	Funding Agency	Title of the project	Total grant sanctioned (In Lakhs)	Amount Received (INR) In Lakhs
1	Akanksha Mahajan	Evaluation of anticancer potential of selected phytochemicals against breast cancer stem cells	24.56	4.91
2	Rama Rajadnya	Evaluating the effect of selected bioactive on cytokine and chemokine regulation in prostate cancer	23.06	4.81
3	Prajakta Patil	Evaluating the effect of lignans in regulation of lipid and cholesterol metabolism in Breast Cancer	23.06	4.81
4	Samradni Pingale	Phytochemical standardization and evaluation of anti-cancer and immunomodulatory	43.57	11.45

		activity of Unani formulation, Itrifal Gudadi.		
5	Rushabh Waghmode	Repurposing of cephalosporins in cervical cancer treatment.	31.15	12.29
6	CSIR HRDG	Chemometric analysis and development of methodology for quality standardization of Vidanga	5.20	5.20
7	UGC	Development of a novel synbiotic using <i>Dioscorea</i> as a prebiotic against Ulcerative Colitis	5.20	5.20

Publications (Total No: 11)

1. Ashwini Kamble¹, Shilpa Naik², Manju Talathi³, Deepali Jadhav², Samradni Pingale¹, Ruchika Kaul-Ghanekar⁴ Cervicovaginal microbiota isolated from healthy women exhibit probiotic properties and antimicrobial activity against pathogens isolated from cervical cancer patients Arch Microbiol .2022 Jul 16;204(8):491. doi: 10.1007/s00203-022-03103-5.
2. Gupte, Poonam Ashish; Giramkar, Shital Ashok; Bhalerao, Supriya Sudhakar Influence of Socio-Economic Status on Lifestyle Preferences Contributing to Childhood Obesity Medical Journal of Dr. D.Y. Patil Vidyapeeth 15(4):p 565-571, Jul–Aug 2022. | DOI: 10.4103/mjdrdypu.mjdrdypu_485_20
3. Supriya Bhalerao a, Jayshree Kharche b 1, Shubhangi Harke c Effect of yoga intervention on skeletal muscle linked glucose homeostasis in pre-diabetic individuals: Study protocol for a randomized controlled trial☆ Advances in Integrative Medicine Volume 9, Issue 4, December 2022, Pages 230-234
4. Kamini Dangat 1, Sanjay Gupte 2, Girija Wagh 3, Sanjay Lalwani 4, Karuna Randhir 1, Shweta Madiwale 1, Hemlata Pisal 1, Vrushali Kadam 1, Shridevi Gundu 1, Nomita Chandhiok 5, Bharati Kulkarni 5, Sadhana Joshi 1, Caroline Fall 6, Harshpal Singh Sachdev 7 Gestational weight gain in the REVAMP pregnancy cohort in Western India: Comparison with international and national references Front Med (Lausanne). 2022 Oct 5;9:1022990. doi: 10.3389/fmed.2022.1022990. eCollection 2022.
5. Kinjal Dave 1, Lovejeet Kaur 2, Deepali Sundrani 1, Preeti Sharma 1, Swati Bayyana 2, Savita Mehendale 3, Karuna Randhir 1, Giriraj R Chandak 2, Sadhana Joshi 4 Association of placental fatty acid desaturase 2 (FADS2) methylation with maternal fatty acid levels in women with preeclampsia Prostaglandins Leukot Essent Fatty Acids . 2022 Sep;184:102472. doi: 10.1016/j.plefa.2022.102472. Epub 2022 Jul 6.
6. Juhi Nema 1, Nikita Joshi 1, Deepali Sundrani 1, Sadhana Joshi 2 Influence of maternal one carbon metabolites on placental programming and long term health Placenta. 2022 Jul;125:20-28.
7. Vidya Arankalle¹, Archana Kulkarni-Munje¹, Ruta Kulkarni¹, Sonali Palkar², Rahul Patil¹, Jitendra Oswal², Sanjay Lalwani^{2,3}, Akhilesh Chandra Mishra¹ Immunogenicity

- of two COVID-19 vaccines used in India: An observational cohort study in health care workers from a tertiary care hospital *Front Immunol.* 2022 Sep 23;13:928501. doi: 10.3389/fimmu.2022.928501. eCollection 2022.
8. Harshad P Patil¹, Mrunal Gosavi¹, Ruta Kulkarni¹, Akhilesh C Mishra¹, Vidya A Arankalle¹ Immunoglobulin G Subclass Response After Chikungunya Virus Infection *Viral Immunol.* 2022 Jul;35(6):437-442. doi: 10.1089/vim.2022.0055. Epub 2022 Jul 15.
 9. Mrunal Gosavi¹, Harshad P Patil² Evaluation of monophosphoryl lipid A as an adjuvanted for inactivated chikungunya virus Vaccine. 2022 Aug 12;40(34):5060-5068. doi: 0.1016/j.vaccine.2022.07.018. Epub 2022 Jul 21.
 10. Nisar Akib¹, Aswani Mayur², Kamyab Sara¹, Moghe Alpana¹ and Harsulkar Abhay^{2,3*} Isolation of prebiotics from wild vegetables: In vitro characterization by antioxidant assays and human adenocarcinoma cell line (HT-29) *Research Journal of Biotechnology* Vol. 17 (12) December (2022) *Res. J. Biotech.*
 11. Aabha Thite^{1 2}, Megha Agrawal², Daya Pavitrakar¹, Sarah Cherian², Rekha Damle¹ Delineation of an epitope recognized by a chikungunya virus anti-capsid monoclonal antibody on the protease domain using an immuno-informatics approach *J Biomol Struct Dyn.* 2022 Aug;40(12):5623-5633. doi: 10.1080/07391102.2021.1872416. Epub 2021 Jan 22.
 12. Joshi, A. A., Hegde, M. V., & Zanwar, A. A. April-June 2023. Modulation of essential fatty acid levels in coconut oil with flaxseed oil. *Grasas y Aceites*, 74(2), e503-e503. 10.3989/gya.1018212
 13. Nema J, Wadhvani N, Randhir K, Dangat K, Pisal H, Kadam V, Mehendale S, Wagh G, Kulkarni B, Sachdev HS, Fall C, Gupte S, Joshi S. Association of maternal vitamin D status with the risk of preeclampsia. *Food Funct.* 2023 May 22;14(10):4859-4865. doi: 10.1039/d3fo00007a.PMID: 37129568

Book chapters (Total No:)**Patents:**

Patent Title	Name of Innovators	Patent Application No.	Filing date	Current status
Coatings and methods for infection-resistant medical devices	The Trustees Of Columbia University In The City Of New York and Bharati Vidyapeeth Deemed University Pune	410915	5/10/2017	Published
IP purchase for a formulation consisting of Cyperus rotundus, Plumbago zeylanica, Embelia ribes	Dr. Supriya Bhalerao	NA	NA	NA
A method for the extraction of lignan	Bharati Vidyapeeth (Deemed to be University)	NA	6/8/2021	Published
A Herbal Composition (FC) For The Treatment Of Cancer	1) Dr. Ruchika Kaul Ghanekar 2) Amit SubhashChoudhary 3) Soumya Jayant Koppikar	2039/MUM/2010	16/07/20210	Granted
A method for the extraction of	Zanwar AA, Hegde MV	202121025529	08/06/2021	Complete specification

lignan				filled
A composition for providing an antimicrobial coating	Modak SM. Ghosh AK, DE Silva CC. Hegde MV, Zanwar AA, Dongre SH, Kadam SS	201827046613	10/12/2018	Granted on: 03/11/2022 Patent no. 410915

Awards and Honors:

Faculty				
Sr. No	Academic Year	Name of the Faculty Member	Name of Award / Honor	Details of Award / Honor
1	2022	Dr. Supriya Bhalerao	Convener of the 9 th World Ayurveda Congress, 2022 & Arogya Expo	Extensive planning, designing and execution of the conference
2	2022-23	Prof. M. V. Hegde	“Fellow of Maharashtra Academy of Science”	By Maharashtra Academy of Science
Students				
1	July2022- June 2023	Ms. Prajakta Devappa Patil	Third prize in poster presentation	Awarded third prize in poster presentation at the International Symposium on Recent Advances in Drug Discovery and Development
2	2022-23	Mr. Ahmedali Mandviwala	Global Conference on Novel RSV preventive & therapeutics intervention, Lisbon Portugal – Feb 2023	Travel Award for the poster presentation titled “NOVEL PREFUSOGENIC-F, G AND M PROTEIN-BASED VIRUS-LIKE PARTICLE AS VACCINE

				CANDIDATE FOR RESPIRATORY SYNCYTIAL VIRUS”
3	2022-23	Ms. Sayali Vedpathak	International conference on “Emerging and Re-emerging viral infections impacting Human, Animals, Plants, Fish and Environment” – Virocon 2022	Best (2nd) oral presentation award for the research work titled “Platelet secreted exosomes promote loss of vascular integrity during Dengue infection”
4	2022-23	Mr. Ahmedali Mandviwala	International conference on “Emerging and Re-emerging viral infections impacting Human, Animals, Plants, Fish and Environment” – Virocon 2022	Best (2nd) poster presentation award for the research work titled “Prefusogenic-F based VLP as vaccine candidate for respiratory syncytial virus”
5	2022-23	Ms. Prajakta Rane	International conference on “Emerging and Re-emerging viral infections impacting Human, Animals, Plants, Fish and Environment” – Virocon 2022	Best (2nd) poster presentation award for the research work titled “Antibody subclass response to SARS-Cov2 in severe and non-severe covid-19 patients”
6	2022-23	Mr. Shubham Kadlag	International conference on “Emerging and Re-emerging viral infections impacting	Best (2nd) poster presentation award for the research work titled “Antibody response to

			Human, Animals, Plants, Fish and Environment” – Virocon 2022	covid-19 vaccines used in India: An observational cohort study among healthcare workers”.
7	2022-23	Nikita Joshi	Altered expression of nutrient transporters in syncytiotrophoblast membranes in preeclampsia placenta	NSI Prize for Best Oral presentation in the Free Communication session (Experimental Nutrition) " Held on 22-23 December 2022, at ICMR-NIN, Hyderabad, Telangana.
8	2022-23	Shweta Madiwale	Longitudinal assessment of maternal plasma folate, vitamin B12 and homocysteine levels in women with gestational diabetes	NSI Prize for Best Poster presentation in the Free Communication session (Clinical Nutrition) Held on 22-23 December 2022, at ICMR-NIN, Hyderabad, Telangana.
9	2022-23	Nisha Kemse	Maternal Omega-3 Fatty Acid Supplementation Attenuates Memory Deficits in Offspring Born to Gestational Diabetes Mellitus Mothers: Animal Studies	NSI Prize for Best Poster presentation in the Free Communication session (Experimental Nutrition) " Held on 22-23 December 2022, at ICMR-NIN, Hyderabad, Telangana.
10	2022-23	Juhi Nema	'Association of Maternal Vitamin D Status and Risk of Preeclampsia'	Young Scientist's Senior Award (Community Nutrition) category at 54th Annual International Conference of Nutrition

				Society of India (NSI), at National Institute of Nutrition, Hyderabad, Telangana on 22nd-23rd December 2022.
11	2022-23	Nisha Kemse	Effect of Prenatal Omega-3 Fatty Acid Supplementation on Brain Neurotrophins in Offspring Born to Dams With Gestational Diabetes Mellitus (GDM)	2nd Prize for Oral Presentation at 22 nd Annual MRC-SNEHA International Workshop on Developmental Origins of Health and Disease (DOHaD) held at Interactive Research School for Health Affairs (IRSHA), BVDU, Pune, 4-5 th Feb, 2023

Papers presented in International Conferences/Seminars/Workshops: Nil

Papers Presented at National Conferences/Seminars/Workshops:

9th World Ayurveda Congress, 2022 & Arogya Expo, organized between 8-11 December at Panjim, Goa

- Paper presentation on the topic entitled, ‘Effect of Yoga intervention on glucose homeostasis in pre-diabetic individuals’, by Dr. Poonam Gupte, SRA, BVDU-IRSHA
- Paper presentation on the topic entitled, ‘Effect of Triphala on Palmitic acid induced lipotoxicity in neuronal cells’ by Shital Giramkar, TA, BVDU-IRSHA
- Asavari A. Joshi and Anand A. Zanwar. Evaluation of effects of flaxseed oil blends on omega-6 to omega-3 ratio of various tissues in an animal model at International Conference on “Recent advances in Translational Research and molecular medicines” organized by Shivajirao Kadam Institute of Pharmaceutical Education and Research, Indore during 24 – 25, February 2023 (virtual mode)

- Asavari A. Joshi, Anand A. Zanwar. Characterization and Stability Studies for Flaxseed oil and Groundnut oil Blend at 5th International Conference of Food and Nutrition during November 16-17, 2022 at Malaysia
- Pramod D. Farde, Mahabaleshwar V. Hegde, Anand A. Zanwar. Blending of linseed oil with edible oil to improve nutritional quality of edible oil blends at International Conference on Vegetable Oils 2023 (ICVO 2023), Jointly Organized by ICAR-ISOR and ICAR-IIOR Hyderabad during January 17-21, 2023
- Pramod D. Farde, Mahabaleshwar V. Hegde, Anand A. Zanwar. Development of value added omega-3 enriched energy bar at 54th Annual Conference of the Nutrition Society of India held at ICMR-NIN, Hyderabad during 22-23 Dec. 2022

Collaborations:

International Collaborations: One

Sr. No	Name of the Collaborator	Period of Collaboration	Objectives	Status
1.	Drugs for Neglected Diseases Initiative (DNDi), Geneva, Switzerland	August 2022 to July 2023	Technology transfer on dengue PRNT from IRSHA, India to IPD, Senegal	Ongoing
2.				
3.				

National Collaborations:

Sr. No	Name of the Collaborator	Period	Objectives	Status
1	Dr. Girish Tillu, CCIH, University of Pune	2016 till date	Scientific and technical inputs for developing project proposals, Network pharmacology of Ayurvedic formulations	Ongoing
2	Dr. D. C. Mathangi, Professor of Integrative Medicine, Shriramchandra Institute of Higher Education and Research, Porur, Chennai	Feb 2020- till date	Scientific and technical inputs for developing project proposals	Ongoing
3	Dr. Lalita Savardekar, Senior grade Deputy Director, National Institute for Research in Reproductive and Child Health, ICMR, Mumbai	Feb 2020- till date	Scientific and technical inputs for developing project proposals	Ongoing
	Dr. Bothiraja – PCP college, BVDU	3years		ongoing
	Dr. Manali Joshi- Pune University	3years		ongoing
	Dr.Gazalla Mulla- Department of Physiology,Z.V. MUnani medical collge and hospital azam campus Pune-	3years		On going
	TOXIINDIA	05 Years	Ph.D. Students enrolled and sharing facilities	Ongoing
	Dr. A L Kakrani, DY Patil	Mar	Collaboration on ongoing Dengue	Ongoing

	Medical College & Hospital	2021- Feb 2024	research	
	BVDU-RGITBT	2022- 2024	Research collaboration for assessment of antiviral activity of microbial compounds against SARS-CoV-2	Ongoing

Conference/ workshops/ Seminar attended

Type of the Event	Sr. No	Name of the Faculty	Date	Name of the Event	Organized By	Level (International / National / State / Institute)
Conference	1	Ms. Prajakta Devappa Patil	03/03 .2023	International Symposium on Recent Advances in Drug Discovery and Development	Poona College of Pharmacy	International
Conference	2	Amrita Ulhe	03/03 /2023	International Symposium on Recent advances in Drug discovery and Development	Poona College Of Pharmacy, Bharati Vidyapeeth(Deemed to University), Pune	International
Conference	3	Minal G.	03/03	International symposium on	Poona college of Pharmacy,	International

e		Mahajan	/2023	Recent Advances in Drug Discovery and Development 2023	BVDU	
Conferenc e	4	Amol Choudhary	03/03 /2023	International symposium on Recent Advances in Drug Discovery and Development 2023	Poona college of Pharmacy, BVDU	International
Conferenc e	5	Rama Rajadnya	03/03 /2023	International symposium on Recent Advances in Drug Discovery and Development 2023	Poona college of Pharmacy, BVDU	International
Workshop		Dr. Anand Zanwar and Dr. Prakash Ghorpade	Septe mber 1-2, 2022	Annual Linseed Group meeting of Linseed	ICAR, New Delhi and College of Agriculture, Dr. Panjabrao Deshmukh Krishi	National

					Vidyapeeth, Nagpur	
--	--	--	--	--	-----------------------	--

MOU's and Linkages:

Sr. No	Name of the Partner	Objectives	Status
1	Vaidya Sane Ayurved Laboratories Limited (Madhavbaug)	Collaborative Research	Ongoing
2	M/s Amardeep Pharmas LLP	Collaborative Research	Ongoing
3	Dr. Khadilkar, Hirabai Cowasji Jehangir Medical Research Institute, Pune	Research and developmental projects in the domain of public health to be undertaken in India	Ongoing
4	Shree Dhootpapeshwar Ltd., Mumbai	Provision of funding for conduct of projects in collaboration	Ongoing
5	Dr. Gaurang Baxi, D.Y.Patil College of Physiotherapy, Pimpri, Pune	Research Consultancy and collaboration	Ongoing
6	TOXIINDIA	Ph.D. Students enrolled and sharing facilities	Ongoing
	Drugs for Neglected Diseases Initiative (DNDi)	Technology transfer on dengue PRNT from IRSHA, India to IPD, Senegal	Ongoing
	Genova Biopharmaceuticals	Immunogenicity testing by SARS CoV-2 PRNT for COVID vaccine clinical trial	Ongoing
	IVI Korea	Immunogenicity testing by SARS CoV-2 PRNT for COVID vaccine clinical trial	Ongoing
	Abiogenesis Clinpharm Pvt Ltd	Immunogenicity testing for IIL-Dengue vaccine clinical trial	Ongoing
	Syngene International Ltd	SARS-CoV-2 PRNT	Ongoing
	Kashiv Biosciences	SARS-CoV-2 PRNT	Ongoing

	BVDU-RGITBT	Research collaboration for development of antiviral drugs/products	Ongoing
	DY Patil Medical College & Hospital	Collaboration on ongoing Dengue research	Ongoing

Ph. D Degree Awarded: 3

Sr. No	Name of the Student	Name of the Guide	Topic	Month and Year of Award
1	Ms. Mrunal Gosavi	Dr. Harshad Patil	Development of adjuvanted chikungunya vaccine for systemic delivery.	Nov. 2022
2	Ms. Juhi Nema	Dr. Sadhana Joshi	Maternal Vitamin D and its Association with Angiogenesis in Preeclampsia	Feb. 2023
3	Mr. Kartikey Jagtap	Dr. Suresh Jagtap	Studies in vidanga - Traditionally used plants with respect to their Pharmacology Activities-	Apr-23

Invited Talks by Faculty

Sr. No	Academic Year	Date	Name of the faculty	Topic
1	2022-23	09/01/2023	Dr. Supriya Bhalerao	Ethics guidelines for ASU drugs organized by Amrita Vishwa Vidyapeeth, Kerala
2		16/02/2023	Dr. Supriya Bhalerao	National Seminar on Ayurveda wisdom- A solution for lifestyle disorders organized by Directorate of Ayush, Maharashtra in collaboration with Arogya Bharati
3		1-2/04/2023	Dr. Supriya Bhalerao	Synapse 2023- International Conference on Mind Body Medicine- Integrated approach to Food and Nutrition- Case-based panel discussion
4		17/04/2023	Dr. Supriya Bhalerao	Introduction to Committees and councils IEC, IRB & IRC organized by College of Ayurveda, BVDU
		27/04/2023	Dr. Supriya Bhalerao	Research particulars and Protocol planning organized by Bharati Vidyapeeth Dental College
	2022-23	28 th March 2023	Dr. Anand Zanwar	Linseed Value Addition Technology at State level “Krishak Sangoshti” at College of Agriculture, IGKV, Raipur
		29 th Nov 2022	Dr. Harshad Patil	Biosafety & Biosecurity
		November 11-13, 2022	Dr. Sadhana Joshi	Maternal nutrition and Developmental Origins of Health and Disease: Indian Scenario 3rd International Conference on Maternal Newborn and Child Health in Belagavi
		23rd April 2023	Dr. Sadhana Joshi	“Health & Nutrition of women Keynote Speaker” for the webinar titled "Women's Health & Career

				Opportunities in Nutrition & Dietetics organized to commemorate World Health Day 2023 (NSI Mumbai Chapter for 23rd April 2023)
--	--	--	--	--

Other Activities

Sr. No	Type of the Event	Theme	Date	Level (International / National / State / Institute)
1	Continued Medical Education Program (CME) for Ayush PG teachers from all over India	Effective Science Communication	7-8/10/ 2022	National

Invited Lectures

Sr. No	Name of the Guest	Topic	Date
1	Dr. Ajit Kolatkar Director, I-Agni initiative Founder of Gastrolab	Obesity- A disorder of deranged gut-brain interaction	06/09/2022
2	Dr. Nilangi Sardeshpande, Independent Researcher	Gender Equity	08/03/2023

Events Organized at IRSHA

- **National Ayurveda Day:** The theme ‘Ayurveda for Holistic Health’, was declared by the Ministry of Ayush, New Delhi. On 21/10/2022, the Ayurveda day was celebrated beginning with Dhanwantari poojan followed by Prakriti estimation of Irsha staff and students
- **World Diabetes Day – Nil**
- On the Occasion of “World IP Day”, our department organized a one-day program. The theme was “Women and IP – Accelerating Innovation and Creativity” on 27th April 2023.

- **International Yoga Day:** The theme of Yoga Day was 'Yoga For Vasudhaiva Kutumbakam' i.e. Yoga for the welfare of all in the form of 'One World-One Family'. Demonstrations of Yogic postures and Chair Yoga based on the health theme 'Yoga break in your workspace' were shown by Dr. Kirti Bhati, Associate Professor, Dept. of Swasthavritta & Yoga, College of Ayurveda, Bharati Vidyapeeth University on 21st June, 2023.

Effective Science Communication, CME for Ayush PG teachers, funded by RAV, Ministry of Ayush held on 7-8th October, 2022



National Ayurveda day celebration, 21st October, 2022

Theme- Ayurveda for Holistic Health



International Yoga Day- Demonstrations of Yogic postures and Chair Yoga based on the health theme ‘Yoga break in your workspace’



Extension activities:

- Partial dissertation work in CINHD lab
 - Ms. Soumaya Sheikh - student of M. Sc. Biotechnology from Fergusson College, Pune under guidance of Prof. M. V. Hegde
 - Ms. Swati Kumari – student of M. Sc. Biotechnology from Fergusson College, Pune under guidance of Prof. M. V. Hegde
 - Ms. Shreya Asore – student of M. Sc. Biotechnology from Fergusson College, Pune under guidance of Prof. M. V. Hegde
 - Ms. Siddhi Khochare – student of M. Pharma. from BVDU’s Poona college of Pharmacy under co-guidance of Dr. Anand Zanwar
 - Ms. Kareena Khan – student of M. Sc. in Food Science & Technology from M. S. Ramaiah University of Applied Sciences, Bengaluru under guidance of Dr. Anand Zanwar

- Ms. Dhanashri Kulloli – student of M. Sc. in Food Science & Technology from M. S. Ramaiah University of Applied Sciences, Bengaluru under guidance of Dr. Anand Zanwar

Any other activities: Nil

Any other information or relevant photographs about the program which may be included in the report

Any other activities:

Any other information or relevant photographs about the program which may be included in the report

Staff Information

Staff Category	Number
Scientific staff	19
Technical Staff	14
Ph.D. students	
Administrative	10
Project Staff	62
Total	

A) Name of the Teaching/ Scientific Staff:

Sr. No.	Name of the Staff	Designation
1	Dr. Akhileshchandra Mishra	Director
2	Dr. Vidya Avinash Arankalle	Senior Scientist
3	Dr. Sadhana Ramchandra Joshi	Professor
4	Dr. Suresh Dnyandeo Jagtap	Associate Professor
5	Dr. Supriya Bhalerao	Associate Professor
6	Dr. Shubham Shrivastav	Associate Professor
7	Dr. Harshad Padmanabh Patil	Associate Professor
8	Dr. Anvita Kale	Assistant Professor

9	Dr. Ruta Kulkarni	Assistant Professor
10	Dr. Deepali Sundrani	Assistant Professor
11	Dr. Rashmi Govind Virkar	Assistant Professor
12	Dr. Archana Prasad Munje	Assistant Professor
13	Dr. Sudha Ramkumar	Assistant Professor

B) Name of the Technical Staff:

Sr. No.	Name of the Staff	Designation	Sign
1	Dr. Prerna Raina	Senior Research Assistant	
2	Dr. Poonam Ashish Gupte	Senior Research Assistant	
3	Dr. Kamini Dhanesh Dangat	Research Assistant	
4	Mrs. Hemlata Mahadeo Pisal	Research Assistant	
5	Dr. Anuradha Rajendra Mulik	Research Assistant	
6	Mr. Kartikey Tanaji Jagtap	Research Assistant	
7	Ms. Karuna N. Randhir	Technical Assistant	
8	Ms. Vrushali Kadam	Technical Assistant	
9	Mrs. Kavita Kadam	Technical Assistant	
10	Ms. Shital Ashok Giramkar	Technical Assistant	

C) Name of the Administrative Staff:

Sr. No.	Name of the Staff	Designation	Sign
1	Mr. Vijaychand Pandurang Gavade	Sub Accountant	
2	Mr. Shivaji Dhondiram More	Electrician	
3	Mr. Ananda Dinkar Jadhav	Junior Clerk	
4	Mr. Nitin Shankar Mote	Junior Clerk	
5	Mr. Dilip Kaka More	Trainee Clerk	
6	Mrs. Anjali Rajendra Gajare	Junior Clerk	
7	Ms. Supriya Anandrao Patil	Laboratory Assistant	
8	Mr. Ankush Rambhau Chandere	Driver	
9	Mr. Tushar Ashok Shinde	Peon	
10	Mr. Vijay Atmaram Dhanwade	Peon	

D) Bharati Hospital Staff:

Sr. No.	Name of the Staff	Designation	Sign
1	Mrs. Dipali Patole	Clerk	

E) Name of the Project Staff & Fellowship Staff:

Sr. No.	Name of the Staff	Designation	Sign
1	Ms. Akanksha Mahajan	JRF	
2	Ms. Samradni Pingale	JRF-EMR AYUSH UNANI Fellow	
3	Mr. AhmedAli Mandviwala	Technician Wellcome	

		DBT	
4	Ms. Himanshi Yadav	Project Technician(III)	
5	Dr. Nisha Kemse	Women Scientist	
6	Mr. Tushar Sarjerao Dalavi	Project Technician	
7	Mr. Rushabh Waghmode	RA-ICMR	
8	Mr. Manoj M. Khavte	JRF-CSIR	
9	Ms. Prajakta D. Patil	JRF-DST Inspire	
10	Ms. Sayali Vedpathak	JRF-UGC	
11	Ms. Apurva Jadhav	SRF-UGC	
12	Ms. Aishwarya Rajan Kharkhanis	JRF-DBT Bio-care	
13	Ms. Shweta Madiwale	Project Associate II DBT	
14	Ms. Brishty Roy	Project Assistant	
15	Ms. Nikita Joshi	SRF	
16	Ms. Rama A. Rajadnya	JRF	
17	Dr. Revati D. Bhat	Clinical Study Co- Ordinator	
18	Ms. Aditi Godhamgaonkar	Project Associate II DBT	

F) CAR Project Staff:

Sr. No.	Name of the Staff	Designation	Sign
1	Dr. Shridevi Gundu	Scientist B	
2	Ms. Prachi Joshi	Social Worker	
3	Ms. Madhura Sarada	Psychologist	
4	Ms. Anupam Poddar	Social Worker	
5	Ms. Preeti Sharma	Lab Assistant	
6	Ms. Anandi Shivram	Lab Assistant	
7	Ms. Sunaina Chhetri	Lab Assistant	
8	Ms. Nupur Kulkarni	Lab Assistant	
9	Ms. Divya Gaikwad	Data Entry Operator	
10	Mr. Ganesh Ashok Kumbhar	Data Entry Operator	
11	Mr. Aniket Shelar	Field Attendant	

G) NCIA Project Staff:

Sr. No.	Name of the Staff	Designation	Sign
1	Mrs. Rajashree Patil	Scientist 'B'	
2	Ms. Deepali Mali	Scientist 'B'	
3	Mr. Muneesh Kumar Barman	Scientist 'B'	
4	Ms. Anamika Solaskar	Technical Assistant	
5	Mr. ShambhuRaje Sunil Pisal	Technical Assistant	

6	Ms. Swati Dnyaneshwar Bargal	Qualitative Assurance Executive	
7	Mr. Tushar Lala Bhosale	Technical Officer	
8	Mr. Rahul Lalaso Patil	Health Educator	
9	Ms. Prajakta Sanjay Rane	Research Assistant	
10	Mr. Urmi Majumdar	Research Assistant	
11	Ms. Shweta Chelluboina	Research Assistant	
12	Ms. Amita Kasana	Research Assistant	
13	Mr. Rahul Harishchandra Kadu	Maintenance Engineer	
14	Ms. Aabha Thite	Project Assistant	
15	Mr. Shubham Kadlag	Junior Research Assistant	
16	Ms. Kajal Phadtare	Junior Research Assistant	
17	Ms. Sawani Karandikar	Junior Research Assistant	
18	Ms. Rajkanya Toge	Junior Research Assistant	
19	Ms. Jayshri Bhagat	Junior Research Assistant	
20	Ms. Tejashree Shendage	Junior Research Assistant	
21	Ms. Anuradha Patil	Junior Research Assistant	
22	Ms. Abhilasha Kadu	Junior Research Assistant	
23	Mr. Omkar Kalje	Junior Research Assistant	
24	Mr. Sourabh Pandharmise	Junior Research Assistant	
25	Ms. Shweta Pradip Kulkarni	Junior Research Assistant	

26	Mr. Manoj Mohan Kadam	Junior Research Assistant	
27	Ms. Komal Pandurang Jadhav	Junior Research Assistant	
28	Ms. Meghana Walke	Lab Assistant	
29	Mr. Darshan Pravin Kshirsagar	Technician	
30	Mrs. Kiran Sameer Shende	Technician	
31	Mrs. Prajakta Rishikesh Jaswante	Office Assistant	
32	Mr. Amol Kondibhau Ohol	Multitasking Staff	
33	Mr. Mahesh Vitthal Humbe	Multitasking Staff	

G) Name of the Centre for Innovation in Nutrition Health Disease (CINHD) Staff:

Sr. No.	Name of the Staff	Designation	Sign
<u>A) Name of the Teaching Staff</u>			
1	Dr. M. V. Hegade	Director CINHD	
2	Dr. P.B. Ghorpade	Emeritus Scientist	
3	Dr. Anand Zanwar	Scientist	
4	Ms. Asavari Joshi	Scientist	
5	Mr. Aniket Mali	Scientist	
6	Mr. Rajesh Shyamsundar Kirad	Manager Research & Development	

B) Name of the Non-Teaching Staff

1	Mr. Yogesh Badhe	Project Assistant	
2	Mr. Pramod Farde	Technical Assistant	
3	Ms. Gouri Shinde	Project Assistant	
4	Ms. Prajka Gaikwad	Junior Research Assistant	

H) Name of the PhD Student & Fellowship Staff:

S.No	Year of enrollment	Name of the Student	Student enrollment number (PRN)	Date of enrollment	Gender	Program admitted to	Year and Month of Completion
1	2015-16	Ms. Minal Mahajan	1502015	01/09/2015	Female	Ph.D.	Ongoing
2	2015-16	Ms. Shital Giramkar	1502012	01/09/2015	Female	Ph.D.	Ongoing
3	2016-17	Mr. Amol Chaudhary	1716020162	26/05/2017	Male	Ph.D.	Ongoing
4	2017-18	Ms. Mrunal Gosavi	1716020164	02/09/2017	Female	Ph.D.	Nov. 2022
5	2017-18	Ms. Juhi Nema	1716020166	02/09/2017	Female	Ph.D.	Feb. 2023
6	2017-18	Mr. Kartikey Jagtap	1716020157	02/09/2017	Male	Ph.D.	Apr-23
7	2017-18	Mrs. Asavari A. Joshi	1716020163	02/09/2017	Female	Ph.D.	Ongoing
8	2017-18	Ms. Anjali Jadhav	1716020167	02/09/2017	Female	Ph.D.	Ongoing
9	2017-18	Ms. Kinjal Dave	1716020172	02/09/2017	Female	Ph.D.	Ongoing
10	2017-18	Ms. Amrita Ulhe	1716020159	02/09/2017	Female	Ph.D.	Ongoing
11	2017-18	Ms. Apoorva Parimoo	1716020161	02/09/2017	Female	Ph.D.	Ongoing
12	2017-18	Ms. Nidhi Sharma	1716020171	02/09/2017	Female	Ph.D.	Ongoing
13	2017-18	Mr. Manoj khavate	1716020158	13/02/2018	Male	Ph.D.	Ongoing
14	2018-19	Ms. Akansha Mahajan	1916020004	16/10/2018	Female	Ph.D.	Ongoing
15	2018-19	Ms. Rama Rajadnya	1916020002	16/10/2018	Female	Ph.D.	Ongoing
16	2018-19	Mr. Mayur Aswani	1916020003	16/10/2018	Male	Ph.D.	Apr-23
17	2018-19	Ms. Prajakta Biradar	1916020005	17/01/2019	Female	Ph.D.	Ongoing
18	2019-20	Ms. Aditi Godhamgaonkar	1916020163	29/11/2019	Female	Ph.D.	Ongoing
19	2019-20	Ms. Anu C	1916020161	29/11/2019	Female	Ph.D.	Ongoing
20	2019-20	Mr. Suraj Bhongale	1916020165	29/11/2019	Male	Ph.D.	Ongoing
21	2019-20	Ms. Sayali Vedpathak	1916020167	29/11/2019	Female	Ph.D.	Ongoing
22	2019-20	Ms. Shweta Chelluboina	1916020166	29/11/2019	Female	Ph.D.	Ongoing
23	2020-21	Mr. Mandiwala Ahmedali	2116020159	16/03/2021	Male	Ph.D.	Ongoing
24	2020-21	Mr. Shrikant Thopte	2116020164	17/03/2021	Male	Ph.D.	Ongoing
25	2020-21	Mr. Prashant Dange	2116020165	17/03/2021	Male	Ph.D.	Ongoing
26	2020-21	Ms. Madiwale Shweta	2116020167	17/03/2021	Female	Ph.D.	Ongoing
27	2020-21	Ms. Gauri Vasant Ligade	2116020168	17/03/2021	Female	Ph.D.	Ongoing

28	2020-21	Mr. Mahesh Ekbote	2116020172	17/03/2021	Male	Ph.D.	Ongoing
29	2021-22	Ms. Apurva Jadhav	2116020173	30/11/2021	Female	Ph.D.	Ongoing
30	2022-23	Ms. Prajakta Gaikwad	2216020167	21/07/2022	Female	Ph.D.	Ongoing
31	2022-23	Ms. Vallari Nisargand	2216020168	18/08/2022	Female	Ph.D.	Ongoing

Institutional Committees

SCIENTIFIC REVIEW COMMITTEE

Name and Designation	Role
Dr. Akhilesh Chandra Mishra Director IRSHA.	Chairperson
Dr. Sadhana Joshi Professor & Head, Department of Nutritional Medicine, IRSHA.	Member
Dr. Vidya Arankelle Senior Scientist, Head, Department of Infectious Diseases, IRSHA.	Member
Prof. Mahabaleshwar Hegde Scientific Advisor, Centre for Innovation in Nutrition Health Disease, IRSHA.	Member
Dr. Supriya Bhalerao Associate Professor, Department Obesity, IRSHA.	Member Secretary

INSTITUTIONAL BIOSAFETY COMMITTEE (IBSC)

Approved by DBT, India

Name and Designation	Role
Dr. Akhilesh Chandra Mishra Director IRSHA.	Chairman
Dr. Debashis Mitra, Scientist G, NCCS, Pune.	DBT nominee
Dr. Harshad Patil Associate Professor, Department of Communicable Disease, IRSHA.	Member Secretary
Dr. Kunal Lahiri, Head of the Department, Department of Microbiology, Bharati Vidyapeeth Medical College and Hospital, Pune.	Outside Expert
Dr. Supriya Bhalerao Associate Professor, IRSHA, Bharati Vidyapeeth University, Pune.	Biosafety Officer
Dr. Vidya Arankelle Senior Scientist, IRSHA, Bharati Vidyapeeth University, Pune.	Internal Experts
Dr. Preeti Chavan, Assistant Professor, IRSHA, Bharati Vidyapeeth University, Pune.	
Dr. Ruchika Kaul-Ghanekar Associate Professor, IRSHA, Bharati Vidyapeeth University, Pune.	

PURCHASE REVIEW COMMITTEE

Name and Designation	Role
Dr. Akhilesh Chandra Mishra Director IRSHA.	Chairperson
Dr. Sadhana Joshi Professor & Head, Department of Nutritional Medicine, IRSHA.	Member
Mr. Vijaychand Gavade Sub-Accountant, IRSHA.	Member
Dr. Harshad Patil Associate Professor, Department of Communicable Disease, IRSHA.	Member Secretary