Progress Report-ABC Prediabetes Clinical Trial

(November'22 - January '23)

PROJECT DETAILS	
Project Title	**Effect of almond supplementation on gut health and glycemic control in adults with prediabetes in rural settings of Karnataka, India: impact assessment in a cluster parallel randomized trial**
Project Organisation	**Ramaiah International Centre for Public Health Innovations** Bangalore, Karnataka India
Principal Investigator	**Dr Ruchi Vaidya** Assistant Professor, Ramaiah International Centre for Public Health Innovations, Bangalore, Karnataka, India
Project Mentors	**Dr Nayanjeet Chaudhury** Director, Ramaiah International Centre for Public Health Innovations, Bangalore, Karnataka, India **Dr Pramila Kalra** Professor and Head, Dept. Of Endocrinology Ramaiah Medical College, Bangalore, Karnataka, India
Grant and Sponsor Organisation	**Young Investigator Grant,** **Almond Board of California, USA**
Project Duration	**August 2022 – July 2024**

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Public Health Innovations

california almonds
Almond Board of California

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Introduction

The Almond Board of California, USA (ABC) commissioned a Randomized Trial to study the ***"Effect of almond supplementation on gut health and glycemic control in adults with prediabetes in rural settings of Karnataka, India"***. Importantly, the study is expected to provide mechanistic insights about the prebiotic potential of almonds on gut health and its association with metabolic control by determining short-chain fatty acid levels, GLP 1 levels, HbA1c, inflammatory markers and gut microbial load. Given that Indians demonstrate a distinct Asian Indian phenotype, with lower thresholds for cardio-metabolic risks and type 2 diabetes, studying possible dietary modifications that are culturally appropriate to the Indian context will help to understand effective lifestyle modification for the at-risk population to prevent or postpone the manifestation of type 2 diabetes and other chronic metabolic diseases.

The project duration is from March 2022 to May 2024. The study proposal is designed with a hypothesis that almond consumption may induce colonization of good bacteria in the gut which play a vital role in the management of blood glucose levels in prediabetes adults compared to the usual cereal pulse-based snacks consumption.

Study objectives

- **Primary Objectives**

1. To study the effect of almond consumption for 16 weeks on glycemic control (HbA1c) among rural Indian adults with prediabetes compared to the traditional cereal-pulse based snacks consumption.

2. To determine the effect of almond consumption on the colonization of beneficial gut microbiota and fecal SCFA levels among rural Indian adults with prediabetes.

- **Secondary Objectives**

1. To understand the association of gut bacterial activities and blood glucose levels in rural Indian adults with prediabetes.

2. To study the role of almond consumption on anthropometric measurements, lipid profile and inflammatory markers among rural Indian adults with prediabetes.

Project Team

Principal Investigator

Dr Ruchi Vaidya, Assistant Professor, Ramaiah International Centre for Public Health Innovations, Bangalore, Karnataka, India

Project Mentors and Co-Investigators

1. Dr Nayanjeet Chaudhury, Director, Ramaiah International Centre for Public Health Innovations, Bangalore, Karnataka, India
2. Dr Pramila Kalra, Professor and Head, Dept. Of Endocrinology, Ramaiah Medical College, Bangalore, Karnataka, India

Project Advisors

1. Dr. Sreekumaran Nair, Professor, and Head, Department of Biostatistics, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, Tamil Nadu, India
2. Dr. Nomita Chandhiok, Former Senior Deputy Director General/Scientist 'G' at the Indian Council of Medical Research (ICMR), New Delhi, India
3. Dr. Bellur Prabhakar, Professor, Dept. of Microbiology & Immunology and Associate Dean, College of Medicine, University of Illinois, Chicago, USA
4. Dr. Mini Sheth, Prof. and Head of Department, Department of Foods and Nutrition, The M. S. University of Baroda, Vadodara, Gujarat, India

Field Operation Team

1. Mr. Kothandan Kumar, Lead, Community Outreach
2. Sreedhara N., Research Fellow
3. Ravi Kumar, Research Fellow
4. Anusha Gatty, Research Fellow
5. Prakrithi Nayak, Research Fellow

Data Management Team

1. Dr. Santosh Kaza, Manager- Data and Analytics
2. Dr Pallavi Gupta, Sr. Data Analyst
3. Ms. Renuka Devi, Biostatistician

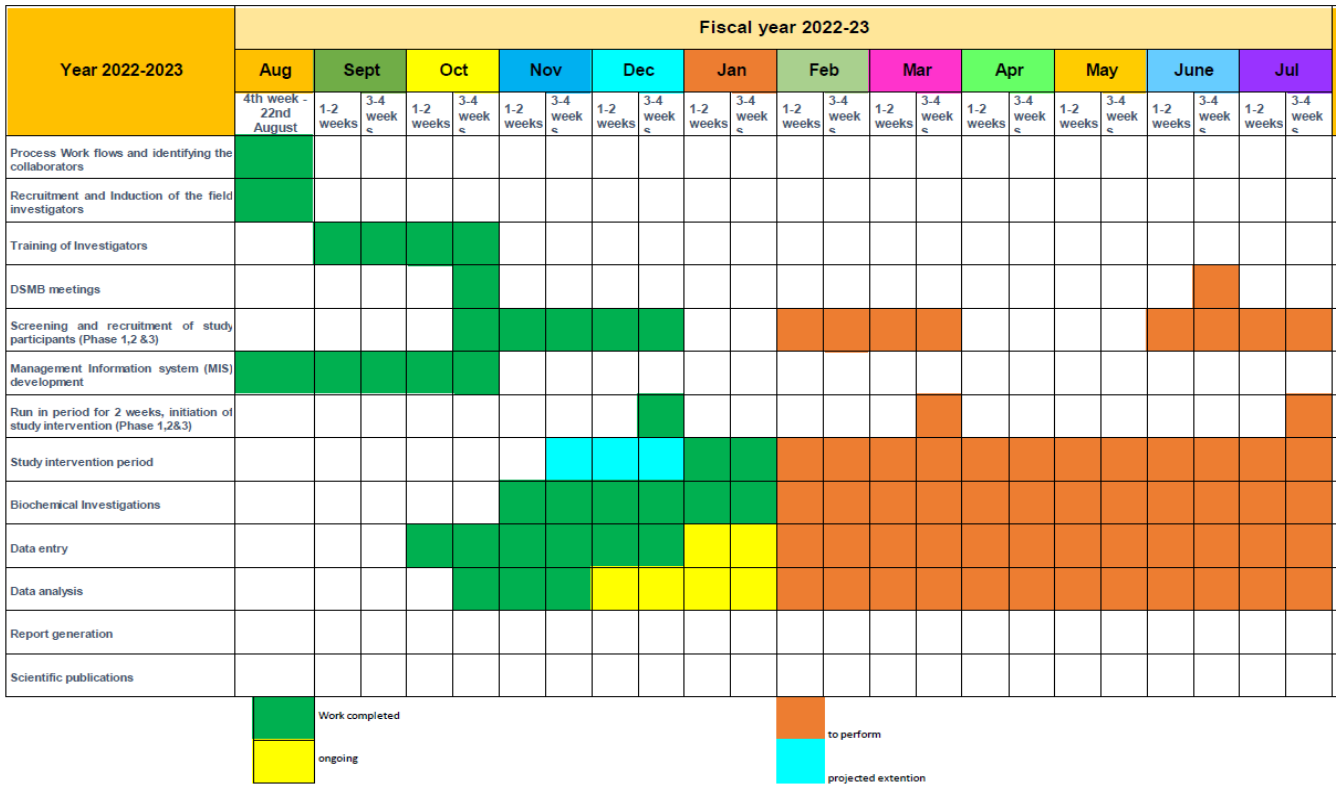
Lab Investigation Team

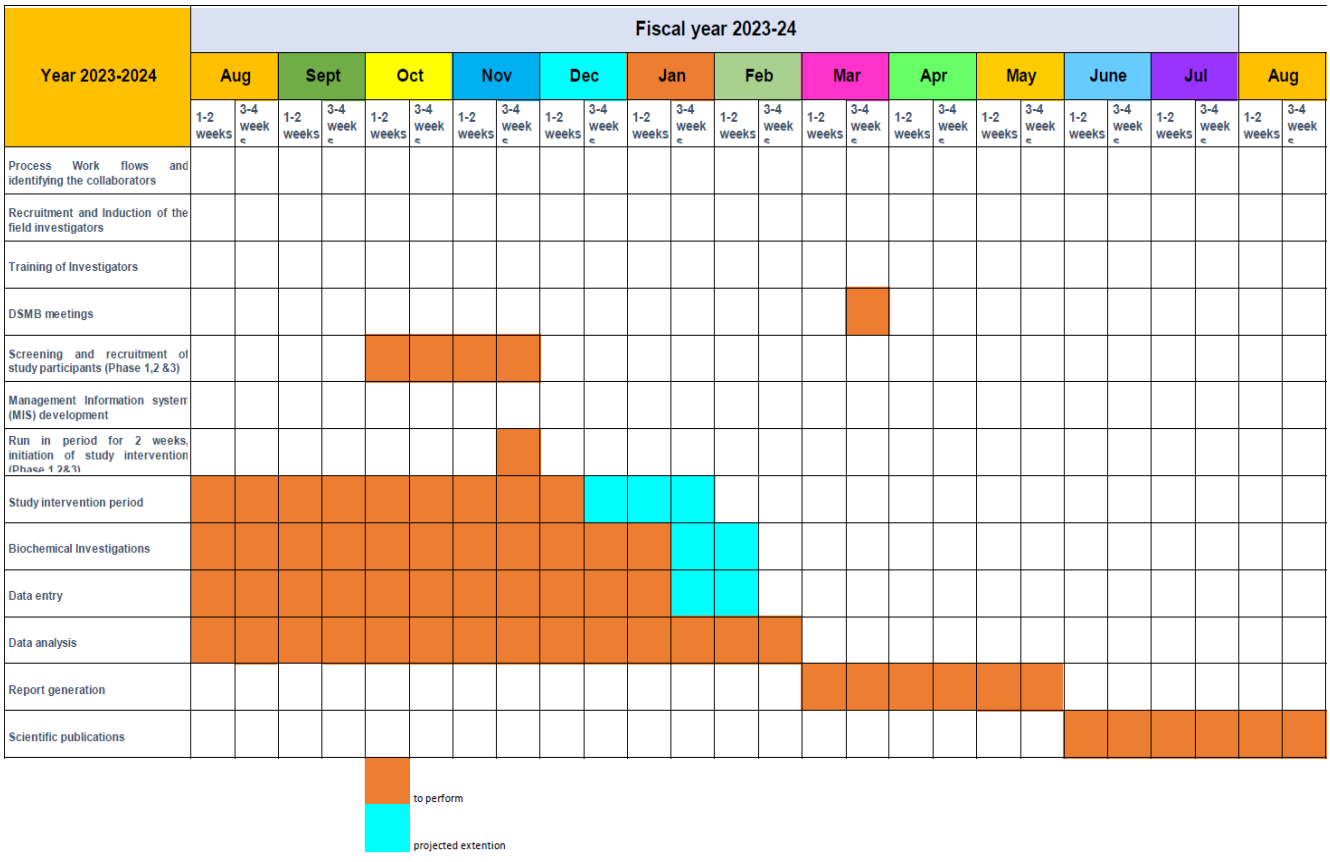
1. Mr. Prem Kumar, Lab Technician, Department of Pathology, Ramaiah Medical College

Administration and Management Team

1. Ms. Nisha Raghavan, Chief Quality Assurance Officer & Manager, Logistics and Administration
2. Ms. Shailee Shah, Manager, Learning and People Management
3. Sneha Sewa, Management Trainee cum Admin Assistant

Project Timelines



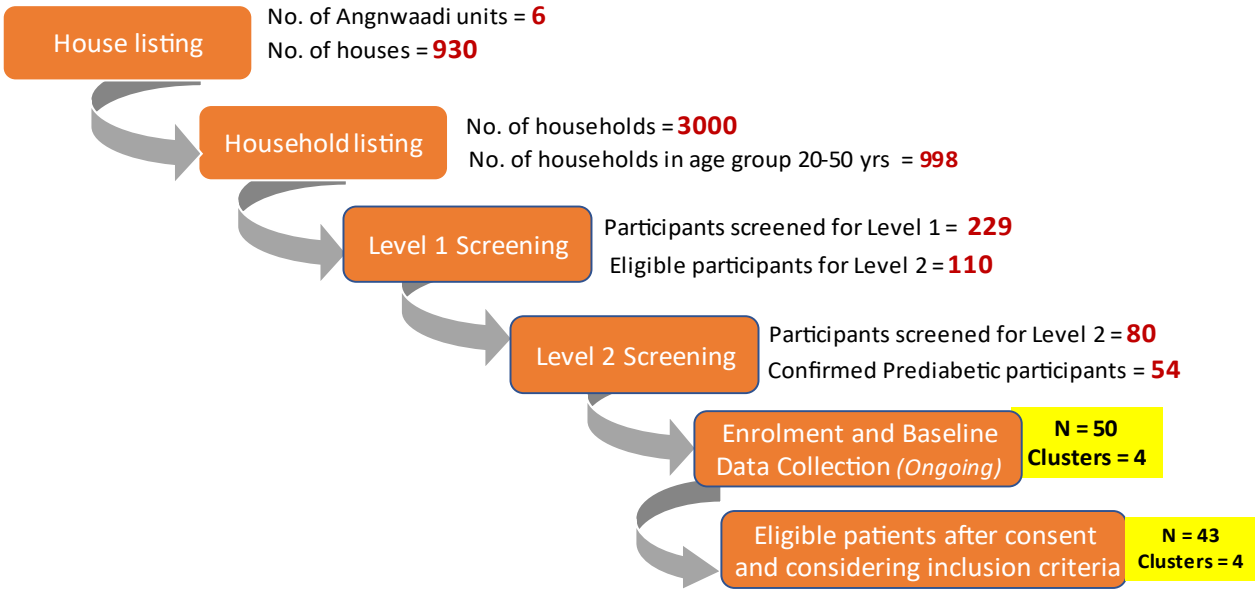


SECTION I: PROJECT IMPLEMENTATION ACTIVITIES

I. Screening of the study participants

The team conducted screening of the study participants in 3 villages (6 Anganwadi units). The research fellows meticulously performed house-listing and household listing in these villages to identify eligible participants for the study. Out of the 3000 households, 998 individuals were in the age between 20 and 50 years, who were the target population for the study. Of these eligible households, almost 229 participants provided their consent to undergo screening tests for prediabetes. The screening was based on prediabetes risk scores such as PRESS (Prediabetes Risk Score) and IDRS (Indian Diabetes Risk Score). Out of these 229 participants who underwent screening, only 110 participants had elevated fasting blood sugar (FBS) levels and were eligible for the study. The participants with high-risk scores were then subjected to further diagnostic tests (HbA1c and OGTT) to confirm the presence of prediabetes. The team performed level 2 screening on 80 participants who had provided informed consent. Out of these 80 participants, only 50 were confirmed to have pre-diabetes, as they showed HbA1c levels in the range of 5.7% to 6.4%.

Figure 1: SCREENING AND ENROLMENT OF PARTICIPANTS (BATCH 01)



II. Enrolment and baseline data collection

Out of the 50 eligible participants, 43 provided their consent to participate in the study and have their baseline data collected. The team collected comprehensive information about the participants' demographic profile, including anthropometric measurements, blood pressure, medical history, dietary pattern, and physical activity pattern. The information was collected using a questionnaire and measurements. Additionally, blood samples were collected from the participants to determine various health markers, such as liver function tests, inflammatory markers (hs CRP, IL 6), thyroid function tests, lipid profile, creatinine, and urea levels. Fecal samples were also collected to analyze the gut bacterial composition and short-chain fatty acid

levels. These tests provided a comprehensive understanding of the participants' health status at the start of the study and would help the team to assess the impact of the intervention.

III. Packaging, Storage and Distribution of Almonds and Control food

The almonds for first batch were procured from a local vendor of California almonds in India, repacked in single doses of 56g at the Institute following safety protocols, labelled and stored at 4°C in the refrigerator. The control food was procured from a local distributor, repacked in isocaloric amounts as the almonds and stored. Both control food and almonds were packed and distributed every 14 days following the FIFO (First-In-First-Out) method and proper protocols, with records kept for packaging, transportation, storage, and distribution (Figure . Empty sachets were collected before replacement of the lot in the study sites.

IV. Trial initiation

The participants were divided into four clusters based on their Anganwadi units and were randomly assigned to either the control or intervention groups. Before the initiation of the intervention, a two-week washout period was implemented to ensure accurate results. The intervention commenced on January 9th and was carried out under close supervision by the research fellows. Participants were invited to a communal area where they consumed the almonds and control food while engaging in various enjoyable activities such as socializing, singing, watching television, and movies. The consumption time was recorded and empty sachets were collected daily to monitor compliance. The intervention food was dispensed every 14 days from the main office to the study sites, with proper record maintenance to ensure the quality and safety of the food. To monitor the participants' dietary and physical activity patterns, the research fellows conducted dietary recalls and physical activity assessments every two weeks. Proper documentation was maintained by using both physical log books and a digital Management Information System (MIS) to record all data. The compliance log book was used to track adherence to the study protocol and to record any deviations from the study plan. This systematic approach ensured that the study was conducted efficiently and with proper documentation.

V. Compliance management

The almond and control foods were administered under close supervision by the research fellows. The team monitored the participants for any adverse events or discomfort after consuming the food. The intervention has been ongoing for a month and no adverse events have been reported thus far. Incentives are provided every 2 weeks for the participation in the study and encourage participants for the better compliance.

A supervision team, consisting of a Field Leader, Quality Assurance Manager, biostatistician, and the principal Investigator, visited the study sites every 14 days to oversee the intervention and ensure that it was being conducted properly. The frequent supervision visits were aimed at maintaining the quality and integrity of the study and ensuring that the participants were safe and comfortable throughout the intervention period.

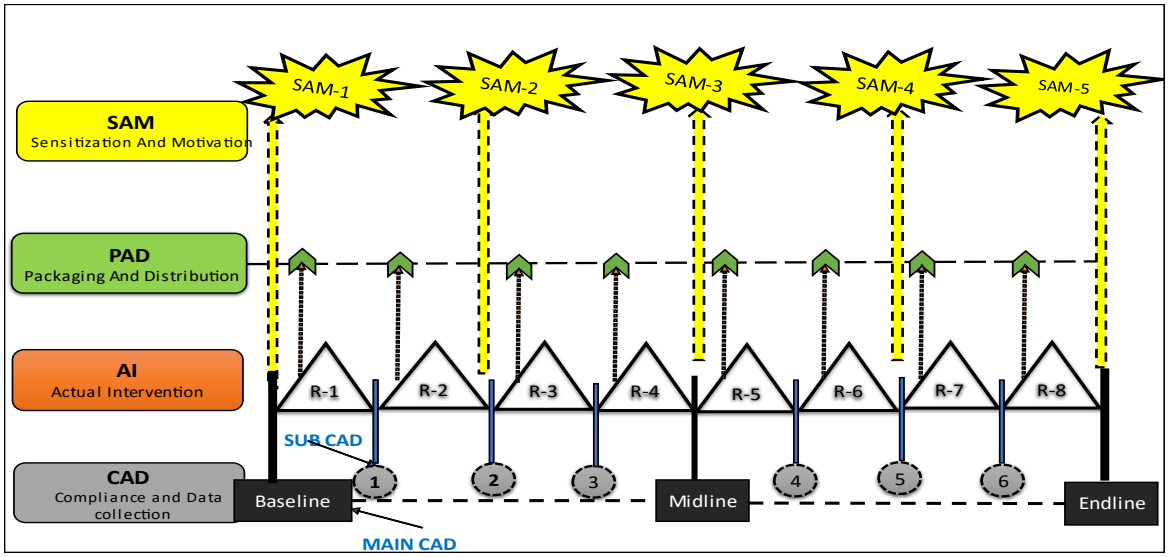


Figure 2: Trial Implementation plan

VI. Rapport building and community sensitization

The study team makes a concerted effort to engage and motivate the study communities through various initiatives. One such initiative is the monthly rapport-building and community motivation program. In January, a yoga session was arranged and organized in the 3 study villages, where a professional yoga expert was invited to lead the session. A large number of community members, including those with non-communicable diseases such as diabetes, heart disease, thyroid problems, and high blood pressure, participated in the program. The participants expressed their enjoyment of the session and requested additional similar activities in the future. These efforts help to foster a positive and supportive environment for the study and ensure the active participation of the study communities.

VII. Laboratory Investigations

The blood samples from the participants were collected in the field and analyzed in the Inhouse Teaching Laboratory of Ramaiah Institute on the same day within 3 hours of collection. The blood samples were collected in fluoride tubes for stability and separation of plasma and serum was performed in the field. Only 33 participants provided their fecal samples, which were brought to the main centre from the field in the dry ice and then immediately stored at -80°C. They were further transported to an outsourced laboratory for microbiome analysis. All 33 samples showed positive amplification for the V3 V4 gene and are being subjected for microflora identification.

Our Institute lacks the capability for SCFA analysis and will obtain the services from sophisticated instrumentation laboratory in Gujarat. The Principal Investigator collaborated and worked with chemist scientists in Gujarat to design a protocol for SCFA analysis. The protocol has been established and we are now working on its validation. After validation, we will analyze the baseline samples for SCFA content.

SECTION II- INTERNSHIPS, TRAINING AND WORKSHOPS

I. Internship for the masters in Public Health

An internship program was established in ABC clinical trial project to provide educational opportunities for students pursuing Masters in Public Health. Four interns joined the project in December and will be working for a four-month period. The interns will be stationed at various study sites to gain practical experience with field implementation, under the supervision of research fellows.

II. Training for the research fellows and interns

The refresher training for research fellows aimed to refresh their knowledge and skills on clinical trials and assessments. This was done before they began the screening and data collection process. The training covered informed consent procedures and the fellows were trained through role plays. The interns were also trained before starting their field activities. The training was organized by Subject Matter Experts at RICPHI and was part of a carefully planned training plan.

Training topic	Conducted by
Introduction to ABC project	Dr. Ruchi Vaidya
Basics of clinical trials	Dr. Nayanjeet Chaudhury
Assessment activities	Dr. Ruchi Vaidya and Dr Ananthram
Screening and Baseline tools	Dr. Santosh Kaza and Ms. Anjana George
Communication and Leadership	Ms. Shailee Shah
Obtaining Informed consent	Dr Ruchi Vaidya and Ms Nisha Raghavan
Orientation to the field implementation activities and geography	Mr. Kothandan Kumar

III. Problem solving workshop for the field team

In order to properly implement the project, it was necessary to address a variety of concerns and challenges at the earliest opportunity. In relation to this, Dr. Nayanjeet Chaudhury, Director of RICPHI, convened a session to conduct a problem-solving workshop on the RICPHI campus. All of the ABC Project's team members, including the Principal Investigator, Biostatistician, Research Fellows, Managers, and Lab Technician, were present. The goal of the meeting was to identify the underlying source of the issue, consider all possible solutions, and then either put the plan into action or test it in the community.

The workshop focused to address the different areas of challenges such as:

a. Challenges in the field- Community and the participants
b. Communication challenges between the field team and the head office
c. Challenges in the effective team work
d. Challenges in the logistics

e. Challenges with the knowledge and skills

As each team members pondered on the aforementioned difficulties in light of their own experiences, they identified a few persistent problems that were common to all of them. These problems included a lack of preparation for participant's availability and reporting, delays in the work process, and participant's reluctance to participate due to a lack of health awareness and trust. The field team came to the conclusion that they required training in order to address all of their issues, particularly with regard to problem-solving and fostering community trust. To further address the issue, it was determined that a community-wide sensitization programme would be run at regular intervals, and it is currently being carried out in the field while the intervention is ongoing.

IV. Data analysis workshop

The Data Analysis Workshop was held on December 5th and 6th, 2022, and was led by Dr. Sreekumaran Nair, Professor at JIPMER in Puducherry, India and a Scientific Advisor for the ABC Project. Key members of the ABC Project team attended the 2 day workshop, including the Principal Investigator, Biostatistician, Quality Assurance Officer, Data Manager, and Research Assistant. Dr. Nair covered important topics during the workshop, including the objectives of data analysis, orientation on cluster data analysis, importance of uniform data collection, crucial steps in study design, and design of the statistical analysis plan. He also discussed how to produce scientific papers from the available data.

SECTION III- SAC and DSMB Meetings

I. Scientific Advisory Meeting

The first Scientific Advisory Meeting was held on 14th December 2022 in a hybrid mode, with some team members physically present at the Ramaiah Medical College and others joining virtually, allowing for flexibility and inclusiveness. The Scientific Advisory Board consisted of four experts with different backgrounds, including Public Health Experts, Clinical Research Biostatistics and Nutrition research. These experts were able to provide valuable insights and recommendations based on their extensive knowledge and experience.

Scientific Advisory Board Members:

1. Dr. Sreekumaran Nair, Professor, and Head, Department of Biostatistics, Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER), Puducherry, Tamil Nadu, India
2. Dr. Nomita Chandhiok, Former Senior Deputy Director General/Scientist 'G' at the Indian Council of Medical Research (ICMR), New Delhi, India
3. Dr. Bellur Prabhakar, Professor, Dept. of Microbiology & Immunology and Associate Dean, College of Medicine, University of Illinois, Chicago, USA
4. Dr. Mini Sheth, Prof. and Head of Department, Department of Foods and Nutrition, The M. S. University of Baroda, Vadodara, Gujarat, India

During the meeting, the Principal Investigator presented the study design and updated everyone on the current status and challenges of the field. One of the main challenges discussed was the difficulties in collecting OGTT data, which led to all advisors agreeing to consider HbA1c levels as a more reliable diagnostic criteria. Working on field clinical trials can be challenging, as there are often a large number of dropouts expected. However, the advisors recognized that community-wide sensitization programs and effective rapport building can help improve compliance and study participation. These programs could involve educating the community about the importance of the study and the benefits of participating, as well as building strong relationships with participants to ensure their continued involvement. Overall, the first Scientific Advisory Meeting was a valuable opportunity for the project team to receive expert guidance and recommendations, and to collaborate and discuss important issues in the field.

II. Data Safety and Monitoring Board Meeting

The DSMB acts as a monitoring and advisory capacity to the Ramaiah International Centre for Public Health Innovations to monitor participant safety, data quality and progress of the ABC Trial program. The members of the DSMB were selected by the Advisory panel and are experts in biostatistics and Endocrinology.

Members of the DSMB

1. Dr Arvind Pandey (Chair of DSMB), National Chair – Biostatistics, ICMR, New Delhi, India
2. Dr Binu S, Assistant Professor, Department of Biostatistics, NIMHANS, Bangalore, Karnataka, India
3. Dr Rajeshwari S, Consultant Endocrinologist, Manipal Hospitals, Bangalore, Karnataka, India

The first meeting of the DSMB board was conducted in 27th December ’22. In the meeting, the DSMB Charter was developed and approved by all DSMB Members. The Principal Investigator updated the project implementation activities. The trial biostatistician presented statistical analysis plan to the DSMB. The members appreciated the project design and its current implementation plan and also provided their expert guidance for the data management for the study. The next DSMB is planned after the completion of 2/3rd of the intervention in the month of October.

SECTION IV- DATA MANAGEMENT

I. Statistical Analysis Plan

This trial plans to use multiple statistical analysis methods to ensure a comprehensive and unbiased evaluation of the results. The intention-to-treat and per-protocol analysis will help address any potential biases. The three stages of analysis - primary level (individual level), secondary level (cluster level), and bivariate analysis - will provide a comprehensive evaluation of the data. The regression analysis will help identify any confounding factors that could impact the results.

III. Summary of the Screening Data

The section highlights the screening data for the phase 1 of the study. Screening was conducted among 229 participants of which 54 participants got diagnosed with prediabetes and from those, only 43 participants participated in the study intervention.
The given data representation is for the 229 participants screened for the study.

a. Basic characteristics and medical history of the screened participants

Table 1 shows the basic characteristics and medical history details of the screened participants. Majority of the screened participants belong to 36 to 50 years of age (61%), females (73%) and married (90%). Almost 80% of them have done their schooling and 13% didn't go to school. Agriculture and fishery work is the major means of livelihood in these villages. Almost every participant was residing in their village for more than 6 months. Only one third of the participants had family history of diabetes. Twenty nine of the participants suffered from NCDs like diabetes, kidney disease, thyroid, skin disease and hypertension and had undertaken medical treatment for their conditions in last 6 months. These participants were not eligible for the study.

b. Lifestyle habits of the study participants

Most of the participants did not smoke or consume alcohol. However, 21% of them were addict to chewing tobacco in form of gutka, supari and other forms. Only 5 of them had allergy to nuts and were excluded from the baseline data collection. There were almost equal number of physically active and inactive participants in the screening. The lifestyle habits of the screened participants are shown in Table 2.

c. Anthropometry and bio-clinical parameters

More than half of the participants were overweight (55%) and centrally obese (Male-46%; Female-67%). The average systolic and diastolic blood pressure was 120.75 ± 16.46 (Mean ± SD) and 81.02 ± 10.58 respectively showing most of them with normal blood pressure levels. The average FBS levels of the screened participants were 106.91 ± 27.67.

Table 1: Distribution of Basic characteristics and Medical History of the screened Participants

Parameters	Village 1 (N=75)	Village 2 (N=154)	Total (N=229)
Basic characteristics	N(%)	N(%)	N(%)
Age Category			
20 to 35 years	35(46.7)	55(35.7)	90(39.3)
36 to 50 years	39(52)	99(64.3)	138(60.7)
Gender			
Male	21(28)	41(26.6)	62(26.6)
Female	53(70.7)	113(73.4)	166(73.4)
Marital Status			
Married	65(86.6)	143(92.8)	208(89.9)
Single	7(9.3)	6(3.9)	13(6.6)
Widow	3(4)	5(3.2)	8(3.5)
Level of Education			
Illiterate	12(16)	18(11.7)	30(13.1)
Graduate	9(12)	3(1.9)	12(5.2)
Schooling	54 (72)	131(85)	185(80.8)
Occupation			
Clerks	3(4)	8(5.2)	11(4.8)
Craft & Related trade workers	3(4)	21(13.6)	25(9.6)
Elementary Occupation	1(1.3)	6(3.9)	7(3.1)
Plant & Machine Operators	1(1.3)	3(1.9)	4(1.7)
Professionals (*Dr/CA/Lawyer/Engineer etc)*	1(1.3)	43(27.9)	44(25.3)
Skilled Agricultural & Fishery Workers	15(20)	34(22.1)	79(22.3)
Skilled Workers; Shop & Market Sales	17(22.7)	2(1.3)	19(2.2)
Unemployed	34(45.3)	37(24)	71(31)

Residence			
Less than 6 months	2(2.7)	2(1.3)	4(1.7)
More than 6 months	73(97.3)	152(98.7)	225(98.3)
Medication History			
Family History of Diabetes			
Both parents	0	4(2.6)	4(1.7)
Either parent	20(26.7)	31(20.1)	51(22.3)
No family history	55(73.3)	119(77.3)	174(76)
Any treatment undertaken			
Yes	14(18.7)	15(9.7)	29(12.7)
Heart disease	0	0	0
Liver disease	0	0	0
Thyroid disease	5(6.7)	5(3.2)	10(4.4)
Kidney disease	0	1(0.6)	1(0.4)
Skin disease	2(2.7)	3(1.9)	5(2.2)
Diabetes	3(4)	2(1.3)	5(2.2)
Hypertension	0	3(1.9)	3(1.3)
Cancer	0	0	0
Others	4(5.3)	1(0.8)	5(2.2)
Any medication undertaken			
Yes	10(13.3)	13(8.4)	23(10)
Heart disease	0	0	0
Liver disease	0	0	0
Thyroid disease	5(6.7)	5(3.2)	10(4.4)
Kidney disease	0	0	0
Skin disease	0	1(0.6)	1(0.4)
Diabetes	1(1.3)	2(1.3)	3(1.3)
Hypertension	1(1.3)	0	1(0.4)
Cancer	0	0	0
Others	3(4)	5(3.3)	8(3.5)

Table 2: Distribution of Lifestyle habits of the study Participants

Parameters	**Village 1 (N=75)**	**Village 2 (N=154)**	**Total (N=229)**
Life style habits			
Alcohol consumption			
Daily	0	2(1.3)	2(0.9)
occasionally	0	15(9.7)	15(6.6)
used to consume in the past	0	2(1.3)	2(0.9)
No	75(100)	134(87)	209(91.3)
Smoking			
Daily	0	7(4.5)	7(3.1)
occasionally	0	2(1.3)	2(0.9)
No	75(100)	145(94.2)	220(96.1)
Smokeless Tobacco consumption			
Daily	7(9.3)	17(11)	24(10.5)
Occasionally	2(2.7)	8(5.2)	10(4.4)
No	66(88)	129(83.8)	195(85.2)
Allergy to nuts			
Yes	1(1.3)	4(2.6)	5(2.2)
No	73(97.3)	148(96.1)	221(96.5)
Don't Know	1(1.3)	2(1.3)	3(1.3)
Physical activity			
Physically Active	30(40)	96(74)	126(55)
Physically inactive	45(60)	39(25.3)	102(44.5)

Table 3: Anthropometry and Bioclinical parameters of the screened participants

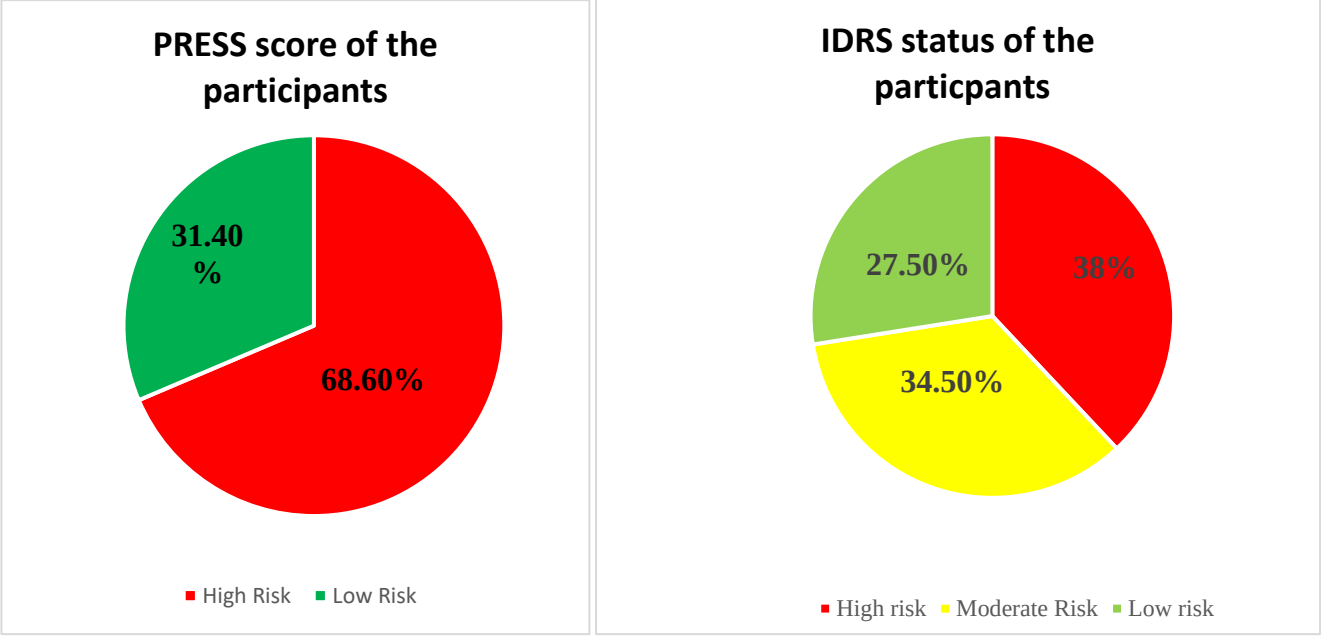
Parameters	Village 1 (N=75) Mean ± SD	Village 2 (N=154) Mean ± SD	Total (N=229) Mean ± SD
Anthropometric Measurements			
Height(cm)	156.37 ± 11.78	155(150,162)	155(150.5,162.75)
Weight (Kg)	61.97 ± 15.50	56(49.5, 56)	57(50,69.75)
BMI (kg/m^2) n(%)			
Underweight	9(12)	23(14.9)	32(13.9)
Normal	17(22.7)	51(33.1)	68(29.6)
Overweight	49(65.3)	77(50)	126(55)
Waist Circumference (cm)			
Male n(%) Normal	10(50)	22(55)	32(53.3)
Centrally obese	10(50)	18(45)	28(46)
Female n(%) Normal	15(27.8)	39(34.5)	54(32.3)
Centrally obese	39(72.2)	74(65.5)	113(67.7)
Neck Circumference (cm)	34.32 ± 3.65	33.08 ± 3.39	34(31,36)
Hip circumference(cm)	99.38 ± 16.30	95.20 ± 12.03	96(89,104)
Waist Height ratio	0.54 ± 0.12	0.55 ± 0.09	0.55(0.49,0.61)
Waist Hip Ratio			
Male n(%) Normal	9(69.2)	13(31.7)	22(40.7)
Centrally obese	4(30.8)	28(68.3)	32(59.3)
Female n(%) Normal	27(52.9)	43(27.9)	70(34.1)
Centrally obese	24(47.1)	111(72.1)	135(65.9)
Bio-clinical Parameters			
Systolic BP (mm/hg)	116.08 ± 15.51	123.04 ± 16.48	120.75 ± 16.46
Diastolic BP (mm/hg)	77.21 ± 9.92	82.88 ± 10.41	81.02 ± 10.58
Fasting Blood sugar (mg/dl)			
Median (Q1,Q3)	105.7 ± 25.29	107.47 ± 28.83	106.91 ± 27.67

PRESS STATUS n(%)			
High Risk	47(62.7)	110(71.4)	157(68.6)
Low Risk	28(37.3)	44(28.6)	72(31.4)
IDR STATUS n(%)			
High Risk	30(40)	57(37)	87(38)
Moderate risk	31(41.3)	48(31.2)	79(34.5)
Low Risk	14(18.7)	49(31.8)	63(27.5)
PRESS SCORE	46.93 ± 26.37	50.1 ± 21.87	49.13 ± 23.43
IDRS SCORE	52.4 ± 21.04	47.21 ± 22.62	48.91 ± 22.20

d. RISK SCORE- Prediabetes Risk Score and Indian Diabetes Risk Score

The Prediabetes Risk score and Indian Diabetes Risk score was used to identify the at risk population. Indian diabetes risk score is calculated using FBS, WC, Age, Family History and Physical Activity parameters. PRESS score is calculated using Age, Family History, Waist height ratio and Diastolic Blood pressure parameters. Almost 69% showed high risk of prediabetes based on the PRESS scores where as 38% and 35% showed high risk and moderate risk for diabetes respectively based on IDRS score.

Figure 3 : PRESS and IDRS score of the screened participants



SECTION V: CHALLENGES AND ACCOMPLISHMENTS

Few challenges were faced during the execution of the study so far. However, the project team was able to overcome them with cumulative effort and team support.

- The first order of 320kg of almonds from Tajir Private Limited, a local vendor in Mumbai, India, was procured as suggested by the ABC team. However, the initial batch was found to be infested with worms and insects, resulting in a delay of the intervention trial by one month. The entire batch was replaced and the quality check was performed on the new batch, which was received on December 20th, 2022. The packing of the almonds started on December 27th and the intervention of the first batch began on January 9th, 2023.

- The field team encountered numerous challenges when mobilizing the community for screening and baseline data collection. Out of the 229 participants who were screened for prediabetes risk, only 80 agreed to get their blood tested for HbA1c test. During the problem-solving workshop, it was identified that many people were scared to give their blood samples and shy to provide stool samples, and there was a lack of trust and poor health literacy in the community. It was difficult to get participants, especially for baseline data collection, as many of them would have tea or coffee before coming to get their blood checked even though they were told to fast. Men and family heads did not allow the female members of the family to come for blood sample collection. Most of them were very busy with their jobs and daily chores and had no time for the participation. Even though participants provided consent for the study, some of them backed out and did not come for blood collection. Therefore, three Anganwadi units in one village had to be merged into one cluster and screening had to be done in an Anganwadi in a new village to get the second cluster.

- The team worked on the solutions and we have introduced community-wide sensitization programs and effective rapport building in the community and already initiated in the new villages for the phase 2. This will help to improve compliance and study participation in the new villages for phase 2 intervention.

SECTION VI: MILESTONES FOR THE NEXT 3 MONTHS

Milestones and Timeline

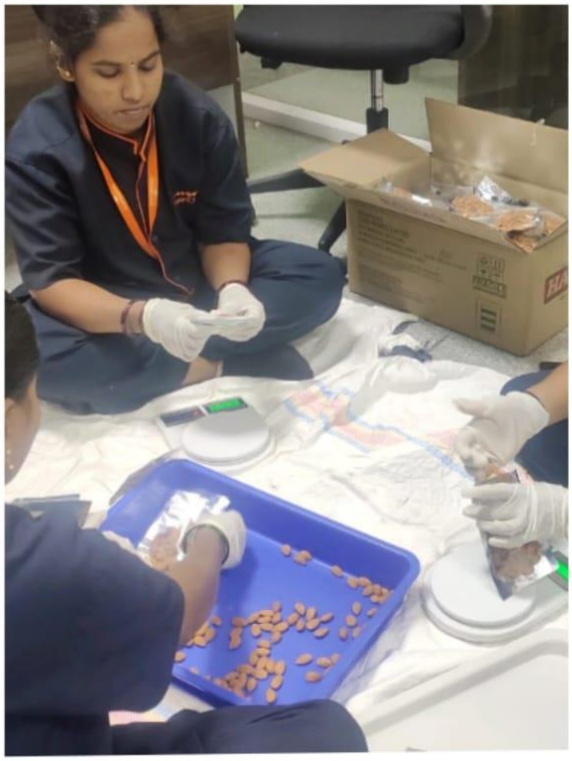
Project Milestones	February		March		April	
	1-2 wk	3-4 wk	1-2 wk	3-4 wk	1-2 wk	3-4 wk
Intervention of Phase 1						
Houselisting and Screening of Phase 2						
Intervention of the Phase 2						
Midline data collection for the Phase 1						
Baseline of Phase 2						
Data analysis of Phase 1 baseline and midline data						
Study protocol paper writing						

Photos Gallery

a. Screening of study participants

b. Baseline data collection

c. Packaging and distribution of Almonds



d. Trial initiation at study sites






e. Motivation and rapport building

f. Problem solving workshop

g. Data analysis Workshop

h. DSMB meeting