PARTICIPANT INFORMATION SHEET (PIS)

Survey - Baseline (Quantitative Component)

Study Title: Effectiveness of ECHO-India Tele-Mentoring Program on the Management of Cardio-Metabolic Syndrome by Primary Care Physicians in India, 2024-26

Principal Investigator's (PI) Name: Dr. Rajmohan Panda, Senior Advisor (Research), GRID

PI Contact address: GRID, 2nd Floor, Workspaces, H-54, Sector 63, NOIDA

IEC approval number and date: 10096/IRB/23-24 and 29/03/2024

Why are you doing this study?

This study titled: "Effectiveness of ECHO-India Tele-Mentoring Program on the Management of Cardio-Metabolic Syndrome by Primary Care Physicians in India, 2024-26", is being conducted by GRID for ECHO, India. This study aims to evaluate the effectiveness of tele-mentoring programs, considering various dimensions such as knowledge enhancement of Primary Care Physicians (Work package 1), patient satisfaction (Work package 2), cost-benefit analysis (Work package 3), and system-level changes (Work package 4).

This Participation Information Sheet focuses on Work Package 1 which will evaluate the effectiveness of the training intervention on the PCPs' knowledge and performance for management of Cardio-metabolic Syndrome. This comprehensive evaluation will provide valuable insights into the effectiveness of the ECHO training program in enhancing CMS management in Indian primary healthcare.

Who is doing this study?

The study is being conducted by GRID for ECHO (Extension for Community Healthcare Outcomes), India.

Who will be included and excluded in the study?

Primary Care Physicians (PCPs) enrolled in the ECHO training program for the management of Cardio-metabolic Syndrome in six states i.e., West Bengal, Tamil Nadu, Maharashtra, Karnataka, Gujarat and Arunachal Pradesh from April 2024 to October 2026 are being requested to participate in this survey.

PCPs that do not consent to participate in this or in the follow-up survey or do not fill out this survey after initial consent will be excluded.

Why am I being asked to take part in this study?

You are being requested to participate in this study because you have been enrolled for participation in the ECHO-India training program for PCPs for the management of CMS. We are interested in knowing your experience and perceptions about this program. We request you to consider participating in this study, as we feel that you will be able to provide us with information that will help in understanding and improving the training program.

Do I have to take part in this study?

Your participation in this study is voluntary at all times. It is your choice whether to participate or not and you are not bound to take part in this study if you do not wish to do so. Your choice to participate in this study will not affect you professionally or personally, in any way.

We want to assure you that the information that you provide will be kept confidential. Your name or other information that could identify you will not appear in study records or reports. You are free to withdraw from this study at any time, should you change your mind.

What information will be collected from me and how? OR What will happen to me if I take part in this study?

If you decide to take part in this study, you will be requested to fill out an electronic questionnaire on your mobile device or computer. The time taken to fill the questionnaire per participant will be about 20-30 minutes including going through the Participant Information Sheet (PIS) and consent form. The information sought from you purely pertains to your knowledge, experience, and perception of the training program. Irrespective of what you answer, there will be no any consequences of the same. Also, your response will have no implications on your job. You will be given the opportunity to ask questions and clarify any doubts before agreeing to participate.

What are the possible disadvantages/ risks of taking part?

For this study, the participants are requested to fill out questionnaires independently and on their own. This implicates 'minimal risk' to the participant. Probability of harm or discomfort anticipated due to participation in this study is not greater than that ordinarily encountered in routine daily life activities of an average healthy individual or general population. However, to minimize risk, we have put several safeguards in place. This study has been reviewed and approved by competent ethics committee. Your participation is voluntary and you have the option to avoid answering specific questions or decline participation in the interview at all points of time. You can fill out the form as per your convenience and comfort. We assure that the information shared by you will be kept confidential.

How will I benefit from this study? OR What are the possible benefits of taking part?

Your participation in this study will not have any direct benefits for you. The information provided by you will help researchers to evaluate the effectiveness of the training program. Your feedback will enhance researchers' understanding of Primary Care Physicians, potentially leading to improvements in future training programs.

How will the privacy and confidentiality of my information be maintained?

We will ensure your privacy is maintained during and after the conduct of the study. We will not collect any data that could identify you. Your identity will be masked using a unique identity number. All the information that you share with us will be coded. We will not share the information you provide with anyone other than the study team. The information will be collected privately in a secure manner and at your convenience. The information provided by you hence will not be attributed to you by name. Your identity will not be disclosed in any of the study findings and reports. All data collected for this study will be stored under password and/or lock and only the research team and their authorized representatives will have access to the data. The data will be used only for achieving the objectives of this study.

What is the system for data safety and storage?

The key researchers in this study are trained, certified and experienced. They understand their ethical responsibilities as public health researchers and will upheld high standards of conduct. The data collection instruments have been designed in a way that no personal identifiers will be collected from the participants. We will ensure that all personal identifiers except for the Participant UID are removed, and data then managed and analyzed under the UID code. Paper copies of data collection forms will similarly be identified only by UID and will be stored securely in password protected electronic lockers. The UID will also code the electronic consent form and electronic data collection forms, to protect confidentiality. All soft (electronic) forms will be stored and archived on password protected cloud-server based folder to ensure privacy and confidentiality, during and after the study. Raw unprocessed data will not be shared onwards. Data will be accessed only by the study team for data quality check and analysis. The data collected from participants will be maintained for five years after study completion.

Will I get any compensation or reimbursement for participating? (In terms of time lost from work)

No, you will not be provided any compensation or reimbursement or any other type of direct or indirect monetary benefit for your participation in this study.

Will I get any injury compensation if any is caused due to my participation in this study?

There is no active intervention in the project. There is no injury compensation provision for participants in this study. We do not anticipate that you will incur any injury due to your participation in this study.

Can I leave the study? What will happen to the information collected from me?

You do not have to take part in this study if you do not wish to do so. You may stop participating in this study at any time later on that you wish even if you consent to participate now. In case you decide to withdraw your participation from the study and wish that all information collected from you be discarded and not used for the study, please inform the investigator on the details provided below.

Will I be informed about the results of this study?

You will not be individually contacted to communicate the study findings. The study findings, without any personal identifiers, will be shared 1) on GRID's website 2) blogs and tweets 3) by the investigator team through professional and academic events and networks. You can access these, if interested.

Will I be given a copy of this PIS?

Yes, you have been provided with this PIS and the informed consent form. You are free to discuss these with anyone you wish to consult. Should you consent to participate in this study, you will be requested to indicate so on the consent form. You will receive a copy of the filled in consent form as well.

Who can I contact for additional information?

For questions about the study at any point in time, please contact the following:
Co-PI, Dr. Archisman Mohapatra,
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2nd Floor, Workspaces, H-54, Sector 63, NOIDA, Uttar Pradesh, PIN - 201301
Mobile No. +918527624924
Email: archisman.m@thegridcouncil.org

For any queries related to study ethics, you may also contact:
Member Secretary,
Institutional Ethics Committee
Sigma Consulting Private Limited,
Phone: 011- 41063450
Email: irb.sigma@sigma-india.in

INFORMED CONSENT FORM (ICF)

Quantitative Survey with the Primary Care Physicians – Baseline

Study Title: Effectiveness of ECHO-India Tele-Mentoring Program on the Management of Cardio-Metabolic Syndrome by Primary Care Physicians in India, 2024-26

Purpose of the study: To evaluate the effectiveness of the training of PCPs for management of Cardio-metabolic Syndrome.

Principal Investigator's (PI) Name: Dr. Rajmohan Panda, Senior Advisor (Research), GRID

IEC approval number and date: 10096/IRB/23-24 and 29/03/2024

"I have read the following information, or it has been read to me. The purpose of this study has been explained to me in my language. I have had the opportunity to ask questions about it and any questions I have asked have been answered to my satisfaction. I have received a copy of the participant information sheet and consent form".

I confirm that (select the boxes by ticking):

- I have been informed by the investigators about the process including nature, objective and, known likely risks and benefits related to this study, and I have understood them
- I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without it affecting me in any way.
- I also understand that if I have any concerns regarding this research, I can contact the Co-PI or the IEC member secretary.
- I understand that any information I provide will be kept confidential and no identifiable personal data will be published.
- I understand that I may be quoted in the study without any personal identifier.
- I understand that there is a chance that my information may be shared with other researchers in the future. I understand that this information will not include my name or any personal identification.
- I understand that as part of this study, I will be contacted for filling this survey once again after I have received the ECHO-India CMS training for PCPs and that I have the option of consenting / not consenting to participate in that survey at that point of time.
- By providing consent, I hereby give my informed consent to take part in this study as outlined in the information sheet and in this consent form