Cardiovascular Disease Risk Reduction: A comprehensive package for the reduction of risk in Sindh, Pakistan

NCT Number: NCT06726057

Document date: 10 October 2023

Informed Consent

	Project Information
Project Title: **Cardiovascular Disease Risk Reduction: A comprehensive package for the reduction of risk in Sindh, Pakistan**	Version & Date:
ERC Project No:	Sponsor: NIHR
Principal Investigator: Dr Zainab Samad	Organization: Aga Khan University
Location: Karachi	Phone: 02134864660
Other Investigators: Dr Imran Naeem, Dr Sajid Soofi, Dr Romaina Iqbal, Dr Aysha Almas, Dr Saira Bukhari, Dr Zainab Siddiq, Dr Asim Shaikh, Dr Saad Zafar, Dr Sawera Hanif	Organization: Aga Khan University
Location: Karachi	Phone: 02134864887

I am Dr/Mr/Ms _____ from the Department of Medicine, Aga Khan University and doing research on "**Cardiovascular Disease Risk Reduction: A comprehensive package for the reduction of risk in Sindh, Pakistan**."

Hypertension is a major public health concern globally. It is a significant risk for cardiovascular disease (CVD) and premature deaths. In Pakistan, the prevalence of hypertension, including those on medication, has been found to be approximately 37%. However, there are high rates of undertreatment and underdiagnosis of hypertension in Pakistan. Addressing the prevention and control of CVD requires a multi-faceted approach that targets diverse populations across different settings. In some populations we have interventions that have been proven to be effective but have not been implemented for example in rural communities the COBRA-BPS trial has shown the effectiveness of a multi-component intervention in reducing blood pressure. However, the findings of this work have not translated to change in practice on the ground suggesting the need for implementation research to examine the best ways to implement this intervention in the real world. Hence, we aim to assess the impact of this evidence-based intervention when implemented at scale in rural communities.

1. PURPOSE OF THIS RESEARCH STUDY

You are being asked to participate in a research study designed to improve your blood pressure control. Intervention for this comprises of:

- Health education sessions
- Blood pressure measurements and referral to qualified medical practitioners for managing blood pressure as per need

2. PROCEDURES

As part of this study, you will undergo:

- Blood pressure measurements on regular intervals by lady health workers (10 min).
- Attending home health education sessions conducted by lady health workers (30 min).
- You may be referred to a nearby health facility/qualified medical practitioners for management of high blood pressure.
- Baseline survey at the start of the study having questions about your medical history, risk factors for cardiovascular disease and high blood pressure & bodily measurements including weight, height and waste circumference (30-45 min)
- Follow-up surveys every 6 months for a period of 2-3 years. The survey questions will comprise of medical history, risk factors for cardiovascular disease and high blood pressure & bodily measurements including weight, height and waste circumference (15-20 min)
- Blood and urine samples for testing at baseline survey and during endline survey

3. POSSIBLE RISKS OR DISCOMFORT

There are no risks involved as a result of your participation in this study except for your time. Since you'll be followed-up for a period of 2-3 years, any new information developed during the study that may affect your willingness to continue participation will be communicated to you. You may feel a little discomfort at the site of needle prick for drawing blood sample.

4. POSSIBLE BENEFITS

- You'll be able to know about your risk of high blood pressure and cardiovascular disease. You'll be referred to a qualified medical practitioner for management of your high blood pressure. Also results of your blood & urine tests will be shared with you that'll help you know about your health.

5. FINANCIAL CONSIDERATIONS

- There is no financial compensation for your participation in this research.
- In case you are referred to the nearest basic health unit/health facility, the cost of travel will be borne by you. However, the chosen health facility will be the nearest to your home and due to being a government health facility, treatment of high blood pressure at basic health unit will be free.

8. CONFIDENTIALITY

- Your identity in this study will be treated as confidential. The results of the study may be published for scientific purposes but will not give your name or include any identifiable references to you. The data will be anonymized by assigning codes and personal identifiers will be removed. However, any records or data obtained as a result of your participation in this study may be inspected by the sponsor or by AKU ERC members.

9. RIGHT TO REFUSE OR WITHDRAW

You are free to choose whether or not to participate in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate. You will be provided with any significant new findings developed during the course of this study that may relate to or influence your willingness to continue participation.

Please notify Dr Imran Naeem, at 02134864887 of your decision so that your participation can be orderly terminated.

In addition, your participation in the study may be terminated by the investigator without your consent in case the sponsor of the study decides to terminate the study without prior notice due to reasons such as loss of funding.

10. AVAILABLE SOURCES OF INFORMATION

- Any further questions you have about this study will be answered by the Principal Investigator:
  Name: Dr Zainab Samad
  Phone Number: 02134864660
- Any questions you may have about your rights as a research subject will be answered by:
  Name: Dr Imran Naeem
  Phone Number: 02134864887
- In case of a research-related emergency, call: Day
  Emergency Number:
  Night Emergency Number:

11. AUTHORIZATION

I have read and understand this consent form, and I volunteer to participate in this research study. I understand that I will receive a copy of this form. I voluntarily choose to participate, but I understand that my consent does not take away any legal rights in the case of negligence or other legal fault of anyone who is involved in this study.

Name of participant (Printed or Typed):
Date:

Signature of participant:
Date:

Signature of Principal Investigator:
Date:

Name and Signature of person obtaining consent:
Date:

For Participants unable to read

Witness:
I have witnessed the accurate reading of the consent form to the potential participants, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Witness Name: _____ Participant's Thumb Print: _____
Signature: _____
Date:_____