Date of informed consent: 28.07.2023
Study Title: Mild cognitive impairment among community-dwelling adults: Prevalence, associated factors, and feasibility of a multidomain intervention package for preventing cognitive decline

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What is this sheet?

This is an information sheet related to the above said study. It is given to each potential candidate of this study. This sheet contains details of this study's purpose, how it is done, benefits, possible risks or/and discomforts to the participant and precautions to be taken when involved in this study.

You have been given this sheet, because you qualify for screening for memory problems according to the criteria of the study. In case you are diagnosed to have mild memory problems, you may be invited to participate in a one month intervention program which includes diet modification, physical and brain exercises, social activities and management of your chronic diseases. This study will help us to understand difficulties faced by you while participating in this program. Hence, kindly take time to read this sheet carefully. You are encouraged to clarify any doubts. After reading this, you can make your own decision whether or not to take part in this study. You can discuss about this with anyone you feel comfortable.

I would like to invite you to take part in this research study because a) you are eligible to be screened for memory problems b) you are found to have mild memory problems.
If you are willing to take part, please sign at the end of this document. If not willing, no need to sign anywhere. You can take time to decide.

INTRODUCTION

Cognitive impairment is a condition in which an individual has difficulty remembering, learning new things, concentrating, or making decisions that affect their everyday life. It could range from mild to severe. People with cognitive impairment may find it difficult to carry out their daily activities and thus will have to depend on others as the condition progresses. This study will help to find the burden of cognitive impairment among people between 50-65 years in the community. We will include 481 eligible participants in the study for screening. We can enhance cognitive ability by modification in nutrition, physical activity, management of morbidities, improving social activities and brain training. Hence a module will be developed including the above mentioned interventions and it will be implemented for a period of one month to understand what the barriers and facilitators for adherence towards it are.

If you are selected for participation in this research it will include

1) Answering questionnaires on cognitive ability, depression, activities of daily living and quality of life. The screening session will be completed in approximately an hour.
2) From those who are identified to have mild cognitive impairment, 20 participants will be included in the pilot study where we will subject you to different kinds of lifestyle related modifications like diet, physical and brain exercises, social activities and proper management of your morbidities like diabetes and hypertension for a period of one month.
3) The nutritional intervention will include one individual and one group session each. The physical activities will include one group activity and 4 individual activities a week. There will be twice weekly session for brain exercises. Individual sessions (30-45 minutes) at your convenient location (mostly home) and group sessions (45-60 minutes) at Anganwadi (government centre) in your area will be conducted.
4) At the end of one month of the activities, an assessment session will be conducted where we will ask you detailed questions regarding the problems that you faced while

doing the different activities. This audio-recorded session will approximately take an hour and will be conducted at a place convenient to you (mostly at your home).
5) We will ask you to record your daily food intake, physical activity on a checklist given to you.

Tools used in the study and interventions planned

- Malayalam version of Addenbrookes Cognitive Examination will assess the cognitive ability
- Everyday ability scale for India to assess the functional ability
- Geriatric depression scale to assess depression
- SF -36 Quality of life scale (RAND questionnaire)

The interventions include lifestyle modifications like nutritional advice, physical activity brain exercises social activities and proper management of your morbidities like diabetes and hypertension

Confidentiality

Any information we obtain about you will be handled in a confidential and private manner consistent with other hospital medical records. We will take the following steps to ensure confidentiality.

- All information about you will be coded with a study number and kept in locked files. In a separate, secure location we will keep a coded list that matches your name to the number given to you. We will not share this coded list with anyone apart from the research staff. When we send your information to other scientists, we will label it with only your study number.
- Your results will be shared only with your family and nobody else.
- Your identity will not be revealed in any description or publication of this study. You, hence, consent to publication for scientific purposes. Your information will be kept separate from your medical records. Your research records, just like hospital records, may be subpoenaed by court order or may be inspected by government regulatory authorities.

Note that all research records must be maintained for at least 7 years following final reporting or publication of a project.

Benefits:
There are no benefits anticipated at present. However, you will get to know if you have any memory problems. Your memory (cognition) may improve and you may feel better. It will also help us to understand the problems that you faced while following the activities described earlier.

Risks:

There are no foreseeable complications involved in participation. Physical activity will be planned according to your needs and you may get some discomfort/ muscle aches during the initial days of the exercise.

Our doctor may be involved as an investigator in this research study. Before agreeing to participate, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not obligated to be a part of any research study offered by your doctor.

Costs and payments:

You will not be charged for any testing etc during the study. If you agree to take part in this research study, you will be paid for the travel costs related to participation. Participants will be compensated for their travel to group activities at a rate of 100 rupees per session. A study subject will participate in 8 group activities during a period of one month (pilot test among 20 individuals with mild cognitive impairments) and thus eligible for a compensation of Rs 800.

Right to participate or withdraw from participation:

It is possible that you may be removed from the research study by the researchers if you get any medical issues that prevents you from following the multidomain intervention package. You can withdraw anytime from the study, this will not affect your treatment etc. if needed.

All research records will be maintained for at least 7 years following final reporting or publication of a project.

New Findings
Significant new findings developed during the course of the research which may relate to your willingness to continue participation will be provided to you

Clinically relevant research results will be disclosed to subjects, and thus you can take further medical care.

The final research product will be disseminated through conferences, publications and academic purposes.

Compensation for injury:
In case of injury resulting from research, appropriate treatment will be available immediately, free of charge at BCMCH, or nearby Government tertiary care hospital. You will not receive any additional compensation from BCMCH Hospital as a result of the injury. At this time, there is no plan for any additional financial compensation.

You can contact the study investigator if you have any questions about the study, concerns or complaints. Co-Investigator, Dr. Saritha Susan Vargese at 0469 3503100 ext 2313 or email: sarithasusan@bcmch.edu.in

Voluntary consent:

I certify that I have been explained the nature and purpose of the study. The above information has been explained to me and all my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any part of this research study during this study. Any future questions, concerns or complaints will be answered by a qualified individual or by the investigator(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns or complaints be addressed by a listed investigator. By signing this form, I consent to participate in this research study. A copy of this consent form will be given to me.

_____ _____

Printed Name of Participant Date [add time if copy will be in medical record]

_____

Signature of Participant

_____

Participant Name (Print)

The above-named individual is unable to provide direct consent for study participation because he/she may have cognitive disability. Therefore, by signing this form, I give my consent for his/her participation in this research study.

_____ _____

Representative's Name (Print) Representative's Relationship to Participant

_____ _____
Representative's Signature Date [add time if copy will be in medical record]

_____ _____
Witness Signature Date [add time if copy will be in medical record]

Investigator certification

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions, concerns or complaints as they arise. I have asked the subject to explain the process of the study to make sure that he/ she understood it clearly. I further certify that no research component of this protocol was started until after this consent form was signed.

_____ _____
_____
Printed Name of Person Obtaining Consent Role in Research Study

_____ _____
_____
Signature of Person Obtaining Consent Date