Appendix A

STUDY ON THE PREVALENCE OF OSTEOPOROSIS AND IMPACT ON INTERVENTION PROGRAM IN ADULTS (>35 YEARS OF AGE) OF DRDO BANGALORE

INFORMATION TO PARTICIPANTS AND CONSENT FORM

NAME OF THE FUNDING AGENCY: The Directorate of ER&IPR, Defense Research and Development Organization (DRDO), New Delhi

INVESTIGATOR: A. Sundaravalli (Principal Investigator, Senior Scale Lecturer, Mount Carmel College, Bangalore), Amrita A. Prabhu (IIR)

Name of Participant: 

Title: A single-center, randomized, open-label trial to determine the efficacy and safety of the intervention (Education, diet and yoga) in patients with osteopenia / osteoporosis.

You are invited to take part in this research study. The information in this document is meant to help you decide whether or not to take part. Please feel free to ask if you have any queries or concerns. You are being asked to participate in this study being conducted by Mount Carmel College (Autonomous), 58 Palace Road, Bangalore because you satisfy our eligibility criteria which are:

- Diagnosis of osteopenia / osteoporosis
- Age between 45 to 65 years
- No contra-indication to the use of the agents to be used in the study, which means absence of any disease or condition likely to get worsened by the intervention under the study

What is the purpose of research?

Osteoporosis is a degenerative bone disease in which bones become less dense, porous and more fragile and thus at greater risk for fracture, even with a small amount of trauma. This disease often affects bones in the arms, legs, hip, spine, and wrist. Osteoporosis is given less importance even though more than 300 million are affected in India. It occurs in both sexes, but women are four times more likely to develop osteoporosis than men. For women, particularly during/after menopause, the loss of bone mineral density is rapid for 5-10 years. Further, severity of this disease increases with age. Osteopenia is a precursor of osteoporosis that occurs due to low bone mass, it is not a disease but is a condition in which the bone density, or bone thickness, is lower than the average bone density of young healthy adults of the same gender. Both osteopenia and osteoporosis have to be given serious consideration and precaution to protect the bones from further degeneration. The intervention is focused mainly on post menopausal women as they are more vulnerable to this condition.

If not treated, the condition is known to lead to immobility and poor quality of life. The present treatment for this disease includes medications like calcium and vitamin D3 supplements, and exercise.

We want to test the efficacy of intervention in this disease. This intervention has been found to possess good benefits in earlier (animal/human) studies.

Participant’s initials: 

152
The proposed benefit(s) of the intervention over the existing treatment include(s)

- It is purely indigenous
- There are no chemicals included
- Small amounts of Calcium citrate and Vitamin D2 are added as additives

In the present study, we plan to see the efficacy of diet or yoga alone or diet and yoga together in treating / preventing the onset of osteoporosis. Information obtained from this study would be beneficial to other patients with the same disease. We have obtained permission from the Institutional Ethics Committee for conducting this study.

The study design

140 women subjects are planned to be recruited for the study. All women in the study will be divided into 4 groups. All the study participants will receive education (one group will be considered as a control), one group will receive diet alone and the other group will receive yoga alone. The last group will receive both diet and yoga for the period of 9 months or 270 days.

The treatment group you will be assigned to will be determined purely by chance, which, in scientific language, is called ‘randomization’. Randomization improves the scientific quality of research. This study will be open-label. This means that it will be known to you as well as your investigator whether you are receiving diet or yoga both as a part of the intervention.

Study Procedures

The study involves the subjects being tested with Dual Energy X-ray Absorptiometry (DEXA) for Bone Mineral Density. Subjects who are found to be positive with osteopenia or osteoporosis by this test will be considered eligible for the intervention programme. The study aims at evaluation of intervention for which we will be monitoring your bone density (using DEXA) and blood parameters. Once you are enrolled in the study, you will be required to follow the instructions diet, maintaining and food intake and activity diary and not taking any calcium supplements.

The participants will be given

- A diet supplement (for subjects who receive diet as intervention), which you will need to take once or twice a day for the entire period of intervention.
- A yoga module (for subjects who will receive yoga as intervention), which you will need to perform one hour per day for the entire period of intervention.
- Subjects who have to get both (diet and yoga) are expected to follow the same instructions as above.

If you notice any physical or mental change, contact the persons listed at the end of the document.

Possible risks to you

- The effective radiation dose from the DEXA procedure is about 0.01 mSv, which is about the same as the average person receives from background radiation in one day.
- No complications are expected with the DEXA procedure.
- Blood collection involves prick with a needle and syringe.

Participant’s initials: [Redacted]
Possible benefits to you
You are not expected to get any benefit from being on this research study, other than the treatment benefit and free investigations/tests.

The intervention programme (Education, Diet Supplement and Yoga) is believed to help in preventing further deterioration of the bone, if not the improvement in the Bone Mineral Density.

The outcome of the study hopes to educate the general population about osteoporosis and the importance of proper nutrition, exercise and healthy lifestyle during bone forming years to prevent/delay the same at later age.

Possible benefits to other people
The results of the research may provide benefits to the society in terms of advancement of medical knowledge and/or therapeutic benefit to future patients.

The Directorate of ER&IPR, Defense Research and Development Organization (DRDO), New Delhi will also benefit from the results of study.

The alternatives you have
If you do not wish to participate, you have the alternative of getting the standard treatment for your condition.

Cost to the participant
You will not be required to pay for the intervention or lab tests. You will not be paid to participate in this research study.

Who is paying for this research?
The Directorate of ER&IPR, Defense Research and Development Organization (DRDO) New Delhi are funding the study and are paying for the research.

What should you do in case of injury or a medical problem during this research study?
Your safety is the prime concern of the research. If you are injured or have a medical problem as a result of being in this study, you should contact one of the people listed at the end of the consent form. You will be provided the required care/treatment. The participants will not be covered by any insurance cover.

You have the right to confidentiality regarding the privacy of your medical information (personal details, results of physical examinations, investigations, and your medical history). By signing this document, you will be allowing the research team investigators, other study personnel, sponsors; institutional ethics committee and any person or agency required by law view your data, if required. The results of clinical tests and therapy performed as part of this research may be included in your medical record. The information from this study, if published in scientific journals or presented at scientific meetings, will not reveal your identity.

Participant’s initials: [Signature]
How will your decision to not participate in the study affect you?

Your decision not to participate in this research study will not affect your medical care or your relationship with the investigator or the institution.

Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary and you have the right to withdraw from this study at any time during the course of the study without giving any reasons. However, it is advisable that you talk to the research team prior to withdrawing. You may be advised about how best to stop the intervention. Though advisable that you give the investigators the reason for withdrawing, it is not mandatory.

Can the investigator take you off the study?

You may be taken off the study without your consent if you do not follow instructions of the investigators or the research team or if the investigator thinks that further participation may cause you harm.

Right to new information

If the research team gets any new information during this research study that may affect your decision to continue participating in the study, or may raise some doubts, you will be told about that information.

Contact persons

For further information / questions, you can contact us at the following address:

Principal Investigator: Ms. A. Sundaravalli Ph: 9343207060
Dept. of Home Science
Mount Carmel College (Autonomous)
Fax: 22286386

Co-Investigator: Ms. Amrita A. Prabhu Ph: 9886668825

Participant’s initials: _[Signature]_
PATIENT CONSENT FORM

A Study on the Prevalence of osteoporosis and the impact of intervention programme in adults (>35 years) of DRDO, Bangalore

Name of the participant: R. Jaka

Name of the Principal Investigator: A. Sundaravalli

Name of the Institution: Mount Carmel College (Autonomous), 58 Palace Road, Bangalore - 52

Name and address of the funding agency: The Directorate of ER&IPR, Defense Research and Development Organization (DRDO), New Delhi

Documentation of the informed consent

I, R. Jaka, have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in “A Study on the Prevalence of osteoporosis and the impact of intervention programme in adults (>35 years) of DRDO, Bangalore”

- I have read and understood this consent form and the information provided to me.
- I have had the consent document explained to me.
- I have been explained about the nature of the study.
- My rights and responsibilities have been explained to me by the investigator.
- I have been advised about the risks/benefits associated with my participation in the study.
- I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
- I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in the hospital.
- I am also aware that the investigators may terminate my participation in the study at any time, for any reason, without my consent.
- I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Government agencies, and ethics committee. I understand that they may inspect my original records.
- My identity will be kept confidential if my data are publicly presented.
- I have had my questions answered to my satisfaction.
- I have decided to be in the research study.
- I am aware, that if I have any questions during this study, I should contact at one of the addresses listed above. By signing this consent from, I attest that the information given in this document has been clearly explained to me and apparently understood by me.
- I will be given a copy of this consent document.

Participant’s initials: Jk
Name and signature of participant (or legal representative if participant is incompetent):

R. Male

(Name) R. Male

(Signature)

Date: 11/02/10 Time: 1645

Name and signature of the Investigator or his/her representative obtaining consent:

A. Sundaravalli

(Name) A. Sundaravalli

(Signature)

Date: 11/03/10 Time: 2:30pm

Investigator Certificate

I certify that all the elements including the nature, purpose and possible risks of the above study as described in this consent document have been fully explained to the subject. In my judgment, the participant possesses the legal capacity to give informed consent to participate in this research and is voluntarily and knowingly giving informed consent to participate;

Signature of the Investigator: A. Sundaravalli Dated: 11/03/10

Name of the Investigator: A. Sundaravalli

Participant’s initials: [Signature]