

Date: February 29, 2020

NCT number: Not Available

Official Project Title

Investigating the Role of Yoga in Alleviating Chromosomal Translocations in Security Guards of Chandigarh Police Who Are Responsible for the Safety of VIPs

Participants Information Sheet

PROTOCOL NO:

Name of Participant:

Age: Sex:

Official Project Title: Investigating the Role of Yoga in Alleviating Chromosomal Translocations in Security Guards of Chandigarh Police Who Are Responsible for the Safety of VIPs

You are invited to take part in this research study. The information in this document is meant to help you decide whether 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 in PGIMER because you satisfy our eligibility criteria, which are:

- i. You are scoring more than 15 points on Cohen's scale that means you are stressed.

Purpose of research:

Investigating the effect of yoga on chronic life-threatening diseases

The study design/ Procedure:

The prime objective of this study is to understand if yoga can help in reducing diseases associated with stress in recruited healthy security guards upto 60 years of age working in Chandigarh Police. For this study, you will have to comply with yoga protocol where a trained yoga instructor will teach and help you in doing yogic exercises for 3 months. 10 ml blood will

be withdrawn from volunteers at the beginning and after 3 months. This blood will be subjected to isolation of different components of blood like serum, plasma and lymphocytes. Further, these samples will be analysed for levels of cortisol through biochemical test to correlate with the level of stress. PCR will be performed on genomic DNA to check for levels of joining between DNA (chromosomal translocations). Sociodemographic data will also be obtained from recruited individuals and psychosomatic tests to analyze the level of stress will be performed.

Possible benefits to you

It will instill a good habit of regular regulated breathing which has been widely believed to be a good tool for wellness.

Responsibility of the participant

You would be responsible for the compliance of study protocol under the guidance of trained yoga teacher recruited by the PI. You are required to inform any of us if you face any problem, to comply with the study. You are also required to not instill any major changes in your lifestyle.

Compensation

No compensation will be given.

Possible benefits to other people

The results of the research may provide benefits to the society in terms of advancement of medical knowledge and policies to improve the overall well-being of security guards recruited across the country.

Who is paying for this research?

DST-Chandigarh

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.

Confidentiality of the information obtained from you

The identity of the participant/subject shall be kept confidential and will be coded.

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. You will not lose any benefits to which you are entitled.

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.

Cost to the participant

The study will be cost free to the participant.

Contact person

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

Principal & Co-investigators:

Dr. Sheetal Sharma Assistant Professor Department of Experimental Medicine and Biotechnology, PGIMER, Chandigarh	Dr. NK Manjunath Director Anveshana SVYASA, Bengaluru	Dr. Akshay Anand Professor Neuroscience Lab Department of Neurology PGIMER, Chandigarh
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Participant's initials

Mobile No

Date

S. No.

Informed Consent Form (ICF)

Understandable Language:

English

Hindi

I, the undersigned,

Resident of

Mobile no.:

Accept to take part in the study with **Official Project Title: Investigating the Role of Yoga in Alleviating Chromosomal Translocations in Security Guards of Chandigarh Police Who Are Responsible for the Safety of VIPs.**

Khushboo Arya c/o Dr. N K Manjunath Director, Anveshana from Swami Vivekananda Yoga Anushandhan Samsthan University (SVYASA)/ **Dr. Sheetal Sharma**, Additional Professor, Department of Experimental Medicine and Biotechnology from PGIMER, Chandigarh/ **Dr. Akshay Anand**, Professor Neuroscience Research Lab from PGIMER, Chandigarh has fully informed me about the nature, objective and duration of the study. I have been given the opportunity to ask questions about all aspects of the study. The prime objective of this study is to understand if yoga can help in reducing diseases associated with stress in recruited healthy security guards up to 60 years of age working in Chandigarh Police. For this study, they have also given me a copy of the study participation information document.

After consultations, I agree to co-operate with all the members of this team. If I notice any ambiguity, I will immediately inform them.

I am donating here 10.0 ml blood for the study and I have noted that if I wish, I may discontinue my participation at any time, and I agree to absolve the investigators from any

legal claims/harm resulting from this procedure. I also give authority to use this sample for further research purposes. This will not affect the quality of subsequent care. I have been informed about the detail of risk involved with the procedure of blood sampling as well as its management.

Possible symptoms after blood sampling

- Excessive bleeding
- Hematoma (blood accumulating under the skin) Infection
- Loss of consciousness

Management

Apply cotton soaked in spirit or antiseptic liquid at site injection to stop bleeding immediately. Do not leave the needle prick area exposed; cover it immediately with a gauge or band-aid strip. However, if the procedure is properly performed the chances of complications are rare.

I don't need to be contacted for the above study or any other study in collaboration with PI for further use of samples including for quality assurance or as reference in other testing procedures. I agree to be contacted at my telephone number and in case of death following members can be contacted to obtain further details or provide information.

I allow the investigators to collect socio-demographic, dietary, economic and lifestyle information for research purposes. I agree to computerization of the data related to the present study, I have noted that I can exercise my right to access and correct data related to me.

My identity will not be disclosed at any time and the data related to me will be handled with utmost confidence. I agree that my samples could be used for any experiments or study conducted in future. I agree that such data can be inspected directly by health authority representatives and by study staff members authorized by the physician in charge of the study. I agree that I will keep away from placing limits on use of the findings of this study.

Record of agreement to a photographic record (still or video)

I agree that the photographic images and other pictures related to the procedure

.....
(a) Can be stored as part of a confidential medical record and used as an aid to diagnosis.

Yes No NA

(b) May be shown to appropriate health professionals to aid medical teaching and research.

Yes No NA

(c) May be published in a journal, textbook or website:

Yes No NA

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked to have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Signature/ Thumb impression of the participant

Signature of Principal Investigator

Date:

Date:

Date: _____

Signature of Witness: _____

Mobile No.: _____