08 October 2019

Informed Consent Form

Effect of endurance exercise on nrf2 mRNA expression gene and physical fitness (VO_{2max}) of Indonesian Hajj Health Officers

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[Informed Consent form for Indonesian Hajj Health Officers]

Name the group of individuals for whom this informed consent form is written.Because research for a single project is often carried out with a number of different groups of individuals - for example healthcare workers, patients, and parents of patients - it is important that you identify which group this particular consent is for.

This Informed Consent Form is for attendees, and we invite you to participate in our research under the title Effect of endurance exercise on Nrf2 mRNA expression gene and physical fitness (VO2max) of Indonesian Hajj Health Officers

You may provide the following information either as a running paragraph or under headings as shown below.

PART I: Information Sheet

Introduction
Briefly state who you are and explain that you are inviting them to participate in the research you are doing. Inform them that they may talk to anyone they feel comfortable talking with about the research and that they can take time to reflect on whether they want to participate or not. Assure the participant that if they do not understand some of the words or concepts, that you will take time to explain them as you go along and that they can ask questions now or later.

I am Ismail Ahmad a student of the Medical Studies Program at the University Hasanuddin Makassar Indonesia. We are conducting research on Indonesian Hajj Health Officers Physical Fitness. I will give participants information and invite them to be part of this research. Participants do not have to decide today whether Participants will participate or not in the study. Before participants decide, participants can talk with anyone who is comfortable with the research.

There may be some words participants don't understand. Please ask me to pause and I will take the time to explain. If participants have questions later, participants can ask me, study doctors or research staff

Purpose of the research
Explain in lay terms why you are doing the research. The language used should clarify rather than confuse. Use local and simplified terms for a disease, e.g. local name of disease instead of malaria, mosquito instead of anopheles, "mosquitoes help in spreading the disease" rather than "mosquitoes are the vectors". Avoid using terms like pathogenesis, indicators, determinants, equitable etc. There are guides on the internet to help you find substitutes for words which are overly scientific or are professional jargon.

Indonesian Hajj Health Officers have the responsibility and very important role in providing health services for Indonesian pilgrims during embarkation and debarkation. One of the main indicators of success is they have excellent physical fitness. This study aims to determine the effectiveness of an intervention program by comparing the results of (intervention) intervention groups, namely the effect of physical exercise interventions (endurance exercise) measured before and after the intervention.

Type of Research Intervention
Briefly state the type of intervention that will be undertaken. This will be expanded upon in the procedures section but it may be helpful and less confusing to the participant if they know from the very beginning whether, for example, the research involves a vaccine, an interview, a biopsy or a series of finger pricks.

This research is an intervention study, and I understand that the process of taking blood can occur with fear, pain due to being pricked by a needle, can faint or be infected. However, previous blood pressure tests, sterile collection techniques and performed by experts, are very unlikely to cause side effects.

Participant selection
State why this participant has been chosen for this research. People often wonder why they have been chosen to participate and may be fearful, confused or concerned.

We invite all Indonesian Hajj Health Officers candidates to participate in research on physical fitness (VO2max) which is an important part of providing Hajj health services in Saudi Arabia while they are on duty.

Voluntary Participation
Indicate clearly that they can choose to participate or not. State, what the alternative - in terms of the treatment offered by the clinic - will be, if they decide not to participate. State, only if it is applicable, that they will still receive all the services they usually do whether they choose to participate or not. This can be repeated and expanded upon later in the form as well, but it is important to state clearly at the beginning of the form that participation is voluntary so that the other information can be heard in this context.

I was involved in the RT-PCR examination and physical fitness test (VO2max) that was carried out before the intervention program, and was briefed on the examination protocol before being tested. The consent form was given to me first to be handled. I was informed about the intervention process and the purpose of the research, as well as the confidentiality of the data collected. And it was also stated that I would be allowed to withdraw from research at any time without pressure and coercion from any party.

- ***Examples of question to elucidate understanding:*** *If you decide not to take part in this research study, do you know what your options are? Do you know that you do not have to take part in this research study, if you do not wish to? Do you have any questions?*

Include the following section only if the protocol is for a clinical trial:

Information on the Trial Drug [Name of Drug]
1) give the phase of the trial and explain what that means. Explain to the participant why you are comparing or testing the drugs.
2) provide as much information as is appropriate and understandable about the drug such as its manufacturer or location of manufacture and the reason for its development.
3) explain the known experience with this drug
4) explain comprehensively all the known side-effects/toxicity of this drug, as well as the adverse effects of all the other medicines that are being used in the trial

The procedure we will do is take samples from prospective Indonesian Hajj Health Officers undergoing a series of anamneses and physical examinations by doctors, in the form of personal data, physical activities, general physical examinations including TB, BB, HR, RR, then performed the physical activity eligibility forms. . Next, a 1 ml blood sample is taken into a purple test tube containing EDTA to prevent lysis. The blood sample is taken to the HUM-RC Makassar Biomolecular Biology laboratory and stored in a frozen cupboard, after which an initial physical fitness measurement (VO2max) test is carried out using
the Multi Fitness Test (MFT) or Bleep Test → PRE TEST at the Health Training Center (Health Training Center) BBPK) Makassar, followed by running exercises intervention as far as 1600 meters 3 times a week duration of 20-30 each training session with a frequency of exercise 16 times 5 weeks according to a predetermined schedule, then conducted a physical fitness test (VO2max) using the same method when PRE TEST → POST TEST I, followed by 1 ml blood sampling at Sudiang Embarkation Hajj Makassar, then 1 week later physical fitness test (VO2max) → POST TEST II without blood sampling is taken again.

Procedures and Protocol
Describe or explain the exact procedures that will be followed on a step-by-step basis, the tests that will be done, and any drugs that will be given. Explain from the outset what some of the more unfamiliar procedures involve (placebo, randomization, biopsy, etc.) Indicate which procedure is routine and which is experimental or research.Participants should know what to expect and what is expected of them. Use active, rather than conditional, language. Write "we will ask you to…." instead of "we would like to ask you to….".

In this template, this section has been divided into two: firstly, an explanation of unfamiliar procedures and, secondly, a description of process.

A. Unfamiliar Procedures
This section should be included if there may be procedures which are not familiar to the participant.

If the protocol is for a clinical trial:
1) involving randomization or blinding, the participants should be told what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

Participants (n = 30), measured physical fitness level (VO2max) using the Multistage Fitness Test (MFT) Bleep Test (level and feedback) method before being given intervention (pre exercise), after that given a running intervention 1600 meters duration 20 -30 minutes each training session 3 times a week with a frequency of exercise16 times for 5 weeks, then physical fitness measurements (VO2max) → (post exercise 1), then intermittent 1 week duration of physical fitness measurements (VO2max) again without intervention and without blood sampling (post exercise 2).

Participants only joined in one group will be given intervention for 5 weeks in the form of running 1600 meters duration of 20-30 minutes for 3 times a week. It is important for the participants as well as for us to know which training methods are given. this information will be documented in our file, but we will not see these files until after the research is complete. this is the best way we have for testing without being influenced by what we think or expect might happen.

The doctor in charge of research will always look after participants very carefully during the study. If we are worried about what is done, we will find out how the level of physical fitness that participants get and make changes. If there is something the participant is worried about or is disturbing the Participant about the research, please talk to me or one of the other researchers.

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

In this study we did not use a placebo term, but we still explained to participants in the world of research that the term placebo is known as clinical trials or interventions given to participants that are not genuine but fake. For good research, it is important that participants do not know whether the participants have been properly measured according to the criteria or not. This is one of the best ways we have to find out what level of physical fitness we are actually testing.)

3) which may necessitate a rescue medicine, then provide information about the rescue medicine or treatment such as what it is and the criterion for its use. For example, in pain trials, if the test drug does not control pain, then intravenous morphine may be used as a rescue medicine.

No side effects might occur because the previous sample was very rigorously selected through analysis, physical examination and physical activity feasibility testing. If Participants find that Our interventions are very uncomfortable for participants, we can use other exercise options more comfortably according to the available exercise choices.

<u>If the protocol is for clinical research:</u>
Firstly, explain that there are standards/guidelines that will be followed for the treatment of their condition. Secondly, if as part of the research a biopsy will be taken, then explain whether it will be under local anesthesia, sedation or general anesthesia, and what sort of symptoms and side effects the participant should expect under each category.

The possibility of danger, risk, or side effects in this study is very small, because the selection of samples is done very closely starting with anamnesis and head-to-toe physical examination and continued with a physical activity feasibility test (PAR-Q). If the physical fitness test occurs when there is suffocation, the researcher has prepared 2 medical staff who
accompanied the subjects during the physical fitness test and also in this study we prepared 2 clinics namely the Makassar BBPK Health Clinic which was used during the physical fitness pre-test and the Clinic Musytasyfa Health Makassar Haji Sudiang Dormitory that was used at the time of physical fitness post test.

<u>For any clinical study (if relevant):</u>
If blood samples are to be taken explain how many times and how much in a language that the person understands. It may, for example, be inappropriate to tell a tribal villager that blood equal to a wine-glass full will be taken but it may be very appropriate to use pictures or other props to illustrate the procedure if it is unfamiliar.

If the samples are to be used only for this research, then explicitly mention here that the biological samples obtained during this research procedure will be used only for this research, and will be destroyed after ____ years, when the research is completed. If the tissues/blood samples or any other human biological material will be stored for a duration longer than the research purpose, or is likely to be used for a purpose other than mentioned in the research proposal, then provide information about this and obtain consent specifically for such storage and use in addition to consent for participation in the study - (see last section)

We will take a blood sample from the participant's arm using the Vacutainer Holder tube. Every time we will take a blood sample of 1 ml. In total, we will take about 3 ml of blood sample for 2 times. At the end of this study, in 1 year, all remaining blood samples will be destroyed.

B. Description of the Process

Describe to the participant what will happen on a step-by-step basis. It may be helpful to the participant if you use drawings or props to better illustrate the procedures. A small vial or container with a little water in it is one way of showing how much blood will be withdrawn.

During the study we carried out a series of research processes as follows:

Pre exercise

- *In the first stage: Conducting anamneses and physical examinations by doctors, in the form of personal data, physical activity, general physical examination including Height, Weight, Heart Rate, Respiratory Rate, Blood Pressure (BP)*
- *In the second stage: Completion of physical activity eligibility forms.*
- *In the third step: 1 ml blood sample is taken into a purple test tube containing EDTA to prevent lysis. The blood samples were taken to the Makassar HUM-RC Biomolecular Biology laboratory and stored in a frozen cupboard.*
- *In the fourth step: Measurement of the initial physical fitness test (VO2max) using the Multi Fitness Test (MFT) or Bleep Test → PRE TEST at the Makassar Health Training Center (BBPK)*

Endurance Exercise

- *In the first stage: Selecting an exercise schedule according to the provisions of the study*
- *In the second stage: Exercise choice I: Monday-Wednesday-Friday; Exercise choice II: Tuesday-Thursday-Saturday; Exercise choice III: Wednesday-Friday-Sunday*
- *In the third stage: Document endurance exercises in the form of a video exercise*

Post Exercise I

- *In the first stage: Initial physical fitness test (VO2max) measurement using the Multi Fitness Test (MFT) or Bleep Test → POST TEST I at the Haji Sudiang Makassar Dormitory In the second stage: Recovery 1 hour after the physical fitness test In the third stage: Taking 1 ml of blood sample inserted in a purple test tube containing EDTA to prevent lysis. The blood samples were taken to the Makassar HUM-RC Biomolecular Biology laboratory and stored in a frozen cupboard.*

Post Exercise II

Measurement of the initial physical fitness test (VO2max) using the Multi Fitness Test (MFT) or Bleep Test → POST TEST II at the Makassar Sports Hall

Duration

Include a statement about the time commitments of the research for the participant including both the duration of the research and follow-up, if relevant.

Study lasted for 5 weeks (1 month 7 days). During the research process we monitor closely, especially the training schedule, implementation and evaluation, directly and indirectly. Directly assisting participants to do endurance training activities, not directly monitoring via telephone or whatsapp.
There were no possible side effects because the previous sample was very rigorously selected through anamnesis, physical examination and physical feasibility testing before endurance training was carried out. If there are side effects of endurance training, participants are referred to the doctor in charge of the designated research. We collaborate with Makassar Sports Health Clinic to conduct medical treatment in the event of unexpected things during the study.

- ***Examples of question to elucidate understanding:*** *Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?*

Side Effects
Potential participants should be told if there are any known or anticipated side effects and what will happen in the event of a side effect or an unexpected event.

By participating in this study, it is possible that participants will face unpleasant conditions. For example, the risk of exercise fatigue. Participants will be accompanied to recover their physical fitness by providing supplementary medicines to increase endurance during exercise.

Risks
Explain and describe any possible or anticipated risks. Describe the level of care that will be available in the event that harm does occur, who will provide it, and who will pay for it. A risk can be thought of as being the possibility that harm may occur. Provide enough information about the risks that the participant can make an informed decision.

We gave participants an understanding that the samples from our research form were targeted, through the method of recording therapeutic responses (description and evaluation of methods and frequency of measurement), follow-up procedures, and if possible, the proposed measures to determine the level of compliance of participants who received interventions during research in progress.

If Participants participate in this study, Participants will get the following benefits: each participant will be recommended to pass the Hajj health competency training. If a participant's child becomes ill during the study period, we provide free medical services. If it is lacking benefits for Participants, Participant participation might help us find answers to research questions. There may not be benefits to the community at the research stage, but prospective Indonesian hajj health workers may be beneficial

- ***Examples of question to elucidate understanding:*** *Do you understand that, while the research study is on-going, no-one may know which medicine you re receiving? Do you know that the medicine that we are testing is a new medicine, and we do not know everything about it? Do you understand that you may have some unwanted side-effects from the medicines? Do you understand that these side-effects can happen whether or not you are in the research study? Etc. Do you have any other questions?*

Benefits

Mention only those activities that will be actual benefits and not those to which they are entitled regardless of participation. Benefits may be divided into benefits to the individual, benefits to the community in which the individual resides, and benefits to society as a whole as a result of finding an answer to the research question.

If Participants participate in this study, Participants will get the following benefits: each participant will be recommended to pass the Hajj health competency training. If a participant's child becomes ill during the study period, we provide free medical services. If it is lacking benefits for Participants, Participant participation might help us find answers to research questions. There may not be benefits to the community at the research stage, but prospective Indonesian hajj health workers may be beneficial

Reimbursements

State clearly what you will provide the participants with as a result of their participation. WHO does not encourage incentives. However, it recommends that reimbursements for expenses incurred as a result of participation in the research be provided. These may include, for example, travel costs and money for wages lost due to visits to health facilities. The amount should be determined within the host country context.

We provide compensation as research participants in the form of: IDR 150,000 transport fee / participant / training time; consumption of IDR 50,000 / participant / practice; lumpsum IDR 350,000 / participant / practice times and free medical expenses if sick

- ***Examples of question to elucidate understanding:*** *Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you know if the study will pay for your travel costs and time lost, and do you know how much you will be re-imbursed? Do you have any other questions?*

Confidentiality

Explain how the research team will maintain the confidentiality of data, especially with respect to the information about the participant which would otherwise be known only to the physician but would now be available to the entire research team. Note that because something out of the ordinary is being done through research, any individual taking part in the research is likely to be more easily identified by members of the community and is therefore more likely to be stigmatized.

With this study, something extraordinary is being done in the Hajj Nurse Health community. It is possible that if others at the Indonesian Hajj health nurse forum realize that Participants are participating, they can ask questions to Participants. We will not share their identities. participate in research. The information we have collected from this research project will be kept confidential. Information about Participants that will be collected during the research will be stored and no one except the researchers will be able to see it. Every information about Participants will have their own code number. Only the researchers will know what the Participant number is and we will lock that information up nicely. It will not be shared with or given to anyone except [names that will have access to information, such as the Faculty of Medicine, Hasanuddin University Makassar Indonesia, Ministry of Health, Hajj Republic of Indonesia].

- ***Example of question to elucidate understanding:*** *Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?*

Sharing the Results
Where it is relevant, your plan for sharing the information with the participants should be provided. If you have a plan and a timeline for the sharing of information, include the details. You should also inform the participant that the research findings will be shared more broadly, for example, through publications and conferences.

The knowledge we gained from doing this research will be shared with participants through the Indonesian Hajj Implementation Evaluation meeting. Confidential information will not be shared. There will be a small meeting in the Indonesian Hajj Nurse Health community and this will be announced after this meeting, we will publish the results so that interested people can learn from our research.

Right to Refuse or Withdraw
This is a reconfirmation that participation is voluntary and includes the right to withdraw. Tailor this section to ensure that it fits for the group for whom you are seeking consent. The example used here is for a patient at a clinic.

Participants do not have to take part in this study if participants do not want to do it and refuse to participate will not affect health services to Indonesian pilgrims. Participants will still have the opportunity to obtain the benefits participants should get at the Hajj health service center. Participants can stop participating in research whenever they want without losing the participant's right as a Indonesian Hajj Health Officers candidate. The implementation of the Indonesian pilgrimage will not be affected at all.

Alternatives to Participating
Include this section only if the study involves administration of investigational drugs or use of new therapeutic procedures. It is important to explain and describe the established standard treatment.

If the participant does not want to take part in this study, participants will still be provided with stersertar services available at the Indonesian Hajj Health Training Center.

Who to Contact
Provide the name and contact information of someone who is involved, informed and accessible (a local person who can actually be contacted. State also that the proposal has been approved and how.

If Participants have questions, Participants can ask now or later, even after the research has begun. If participants want to ask questions later, participants can contact one of the following: [Ismail Ahmad, Jl. Soppeng Raya Blok G / 72 BSP Makassar / 081354916037 / ismailskpns@gmail.com].

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find about more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the World Health Organization (WHO), which is funding/sponsoring/supporting the study.

- *Did the participants know that they did not have to take part in the study if they did not want to? Participants can say NO. Do participants know that they can ask me questions later, if they want to? Do participants know that I have provided contact details from*

people who can give participants more information about this study? Participants can ask me more about this part of the study. Participants have questions?

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

This section should be written in the first person and have a statement similar to the one in bold below. If the participant is illiterate but gives oral consent, a witness must sign. A researcher or the person going over the informed consent must sign each consent. The certificate of consent should avoid statements that have "I understand…." phrases. The understanding should perhaps be better tested through targeted questions during the reading of the information sheet (some examples of questions are given above), or through the questions being asked at the end of the reading of the information sheet, if the potential participant is reading the information sheet him/herself.

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 have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant Sri Wahyuni Mansur

Signature of Participant _____

Date, April 10, 2020
Day/month/year

If illiterate

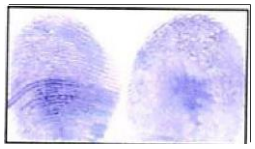
A literate witness must sign (if possible, this person should be selected by the participant and should have no connection to the research team). Participants who are illiterate should include their thumb-print as well.

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

Print name of witness Nurhafifah **AND** **Thumb print of participant**

Signature of witness _____

Date, October 08, 2019
Day/month/year



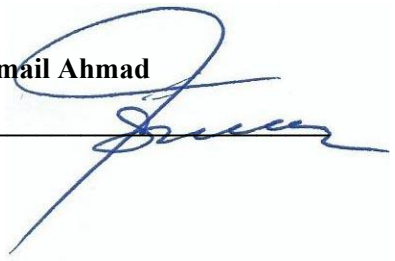
Statement by the researcher/person taking consent

1. I have accurately read out the information sheet to the potential participant, and to the best of my ability made sure that the participant understands that the following will be done:

2. I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability.
3. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent Ismail Ahmad

Signature of Researcher /person taking the consent 

Date, October 08, 2019
Day/month/year