

EXPLANATORY STATEMENT: To be provided to all participants.

Project: Randomized control trial for effectiveness of acupressure to improve sleep among haemodialysis patients having CKD associated pruritus

Chief Investigator's name: Inayat Ur Rehman (PhD scholar)

Department: School of Pharmacy, Monash University Malaysia

Phone: +60 173485414, Email: inayat.rehman@monash.edu

You are invited to take part in this study. Please read this Explanatory Statement carefully before deciding whether or not to participate in this research. If you would like further information regarding any aspect of this project, you are encouraged to contact the researcher via the phone numbers or email addresses, which are provided below.

What does the research involve?

The research involves acupressure on acupoints in foot twice a week to improve sleep quality and then completing a short questionnaire regarding "effectiveness of acupressure to improve sleep among haemodialysis patients having CKD associated pruritus"

The aim of the study:

The aim of the study is effectiveness of acupressure to improve sleep among haemodialysis patients having CKD associated pruritus.

What the participants will be asked to do, and how much time it will take:

The research involves acupressure on acupoints in foot twice a week to improve sleep quality and then completing Pittsburgh sleep quality index (PSQI) questionnaire and Functional assessment of non-life threatening conditions (FANLTC) questionnaire. The questionnaire will take approximately 10-15 minutes to complete and upon completion can be return to researcher. No names are required on the questionnaires and your answers will remain anonymous.

Why were you chosen for this research?

You were chosen for this research because you are suffering from CKD associated pruritus with sleep disturbance. Your feedback on this survey is important for us to gain an insight on pruritus effect acupressure on sleep quality.

Consenting to participate in the project and withdrawing from the research

Participation in this research is entirely voluntary. You are in no way obligated to participate. Additionally, as the survey is anonymous, they will have no knowledge with regard to who participated and who did not.

Explain what the consent process involves

Your consent is implied by your choosing to participate in the research – completion of the questionnaire implies your consent to participate.

Possible benefits and risks to participants

Patients suffering from CKD associated pruritus have impaired quality of sleep and have negative impact on quality of life. This interventional trail is the first of its kind to focus on improvement of sleep quality and reduction in PSQI score by acupressure on foot acupoints among patients suffering from CKD associated pruritus

and are on haemodialysis. Acupressure is applied at specific meridians or acupoints in Traditional Chinese Medicine to improve sleep quality. Unlike pharmacological and other interventions acupressure is a non-invasive therapy, which is likely to be associated with a low risk of side effect profile.

There are no risks to participants. Dissemination of the findings will be in the form of numbers and percentages and individual contributions will not be identifiable.

<u>Describe</u> any potential level of inconvenience and/or discomfort to the participant.

There is no potential discomfort to patients as acupressure is well tolerated and non-invasive therapy with any side effects.

Confidentiality

The questionnaires will be entirely confidential. No names are required on the questionnaires. It is only the researchers who will manage, analyse, and disseminate the data collected as part of the research. The data from the research will only ever be reported/published in an aggregate form - no individuals will be identifiable.

Storage of data

Data collected will be stored in accordance with Monash University regulations – digital data will be stored in password-protected files, and hard copy data will be stored in locked cabinets, within locked rooms. Only the researchers will have access to the data.

Results

Should participants wish to access the research findings, they are encouraged to contact the researchers – details are provided.

Chief Investigator: Inayat Ur Rehman Tel: +60173485414. Email: inayat.rehman@monash.edu

Complaints

Should you have any concerns or complaints about the conduct of the project, you are welcome to contact the

Executive Officer, Monash University Human Research Ethics (MUHREC):

Senior Administrative Executive, Ethics Compliance and Research Engagement

Ms. Jocelyn Fam Suet Fong

Email:jocelyn.fam@monash.edu

Phone:+603 5514 5664 (Direct Line)

Thank you,

Inayat Ur Rehman