Title: The Performance of Red Tinted Contact Lenses of Various Tones on Colour Deficient Subjects

Date: 1/12/2022

INFORMATION SHEET

Research Title:

Suitability of Red Tint Lens on Colour Deficient Subjects: A Pilot Study

Introduction:

You are invited to participate in a research study. Before participating in this study, it is important that you take time to read and understand the information in this Information Sheet.

Purpose of Study:

Colour vision deficiency is common disorder that happens when any type of cone photoreceptor (L-cone, M-cone or S-cone) is defective or missing, leading to limitation in colour discrimination. This condition makes life of colour deficient subject more challenging, especially in differentiating traffic light signals, identify ripeness of fruits, discriminating colour coding which is designed for safety purposes, limitation in career selection, etc. To date, there is no treatment to cure colour vision deficient problem. Many researchers use red filter to enhance colour perception. However, there is no guideline in fitting the suitable tone of red filter for different types of colour vision deficiency. They manage colour vision deficient subject by using "try and error" method without any effective fitting guide. Therefore, this study aims to identify the most suitable red tint contact lens for colour vision deficient subjects by determining the correlation between wavelength of red tint lens and the total error score (TES) value of colour vision deficient subjects from Farnsworth-Munsell 100 Hue test.

What will the study involve?

This study involves four red tint contact lens from different companies. The wavelength of the red tint lens will be measured using a spectrophotometer. Colour vision deficient subjects will go through Farnsworth-Munsell 100 Hue test to identify the type of colour vision deficiency and TES value. Next, the subjects will undergo Ishihara test with habitual vision. Then, the red tint lens will be worn on the non-dominant eye. An adaptation period of 15 minutes will be given. Ishihara test will be tested binocularly again. This procedure will be repeated by using the four red tint lenses. The amount of pass and fail plates will be recorded. After all the measurements have been taken, subjects will be discharged.

Risks and Benefits:

The colour vision deficient subjects could identify the most suitable red tint lens which helps in enhancing colour perception after participating in this study. Risk of each procedure will be unlikely as procedures that are chosen are minimally invasive and there will be no drug or topical drops involved in this study.

Do you have to take part?

Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet. Should you decide to participate, you can still withdraw from the study without penalty. However your data will be retained by us. The researcher may also remove you from the study for a variety of reasons. In this event, you will not be penalized or lose your rights as a patient.

Data & Confidentiality:

The data from this study will be made into a report which may be published. Access to the data is only by the research team and the REC UKM. The data will be reported in a collective manner with no reference to an individual. Hence your identity will be kept private and confidential.

Payment and compensation:

You do not have to pay nor will you be paid to participate in this study. There will be no compensation or travel allowance given as the participant of this study. However, during the 15 minutes time interval, light snacks will be provided by the research team.

Who can I ask about the study?

If you have any questions, you can direct them to the research team.

Research Team

Main Researcher: Associated Prof. Dr. Haliza Abdul Mutalib

Student Researcher: Ong Yi Lin (A162789)

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Appendix C. Informed Consent Form

INFORMED CONSENT FORM

Research Title: Suitability of Red Tint Contact Lens on Colour Vision Deficient Subject: A Pilot Study.

Researcher's Name: Ong Yi Lin

I, ……IC No : …….....

- have read the information in the Patient Information Sheet **including information regarding the risk in this study**
- have been given time to think about it and all of my questions have been answered to my satisfaction.
- understand that I may freely choose to withdraw from this study at anytime without reason and without repercussion
- understand that my anonymity will be ensured in the write-up.

I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.

……. ……..

(Signature) (Date)

…….	…….
Witness (if any)	Researcher
…….	…….
(Signature)	(Signature)
…….	…….
(IC Number)	(IC Number)
……..…	…….
(Date)	(Date)