

APPENDIX C

INFORMATION SHEET FOR SUBJECT (INTERVENTION PHASE)

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Research title

Effects of polyphenols-rich tropical fruits on mental health protection – A clinical trial among middle-aged adults

Introduction

Poor mental health has been identified as one of the main health problems among middle aged adults (National Mental Health Registry 2003). Polyphenols, which are a major antioxidants source, have been proven to be beneficial towards the prevention of various diseases including cancer and diabetes and more recently in mental health. The aim of this research is to determine the effectiveness of polyphenols-rich tropical fruit juice towards the improvement of mental health status.

What would this involve?

Subjects aged 45 to 59 years who had given consent to this research will be divided into 2 groups; Group A and Group B. Group A will receive supplementation of polyphenols-rich juice for 3 months. This will then followed by another 3 months where subjects of Group A will not receive any intervention. Group B will start with no intervention. This is then followed by 3 months period of supplementation of polyphenols-rich juice for 3 months. Subjects will be interviewed about personal and social information, medical history, lifestyles factors, dietary history questionnaire and food frequency questionnaire (polyphenols). Besides that, mental health status will also be assessed with several questionnaire. Anthropometric measurements and blood pressure will also be conducted. During the intervention period, you will be given polyphenols-rich tropical juice 3 times a week for a period of 3 months. Blood test will be conducted at baseline and after 3 months of juice supplementation. Three weeks after the day of last juice supplementation, blood test will be conducted and again after 3 months. A total of 10 mL of blood will be drawn by a trained phlebotomist during each blood test. Urine test will be conducted every month during the juice supplementation period.

The benefits

Subjects will be able to know their health status, through the blood and urine analysis, mental, physical and dietary intake assessment. In addition, this study will improve our knowledge regarding the prevalence mental health among residents of DBKL flats. *The risks*

No risks known as the procedures involve are part of standard procedures. There are no drug involves in this study.

Confidentiality

The result of the data obtained will be reported in a collected manner with no reference to a specific individual. Hence, the data from each individual will remain confidential. As a subject, you are entitled to know your result only.

Do I have to take part?

The participation into this study is voluntary. If you prefer not to take part, you do not have to give any reason. You may also withdraw at any point in time during the study.

Payment and compensation

You do not have to pay for participating in this study. Similarly, no payment is available for you for participating in this study. In the event that this study results in the development of any marketable product(s), you will have no ownership interest in the product and no right to share in any profits from its commercialization whatsoever.

Any inquiry, please contact:

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APPENDIX E
CONSENT FORM FOR INTERVENTION PHASE

CONSENT FORM FOR SUBJECT (INTERVENTION PHASE)

Research Title

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I, _____ (name), IC no: _____, have read the information of this study and have also been given the explanation by the researcher about the purpose of this document. I understand the aims of the study including its risks and benefits. I ***agree/disagree** to participate in the study as stated above.

I ***would like to know/don't want to know** the result of this study (*delete where necessary)

Signature: _____

Date: _____

Witness

Name: _____

IC no: _____

Signature: _____

Date: _____

Researcher

Name: _____

IC no: _____

Signature: _____

Date: _____