PARTICIPANT SUMMARY

The efficacy of adjunctive Garcinia mangostana linn (mangosteen) pericarp for bipolar depression: A 24-week double-blind, randomised, placebo controlled trial.

It is important that you read the Participant Information and Consent form, in full, prior to consenting to take part in this study. You may wish to discuss the study with your family, friends and treating clinicians. Participation in the study is purely voluntary and you may withdraw from the study at any point in time. You may also choose to agree to participate in the study, but not have bloods taken.

AIMS

The study aims to investigate if Mangosteen Pericarp 1000mg a day may help to reduce some symptoms of bipolar depression and improve general quality of life.

TIMELINE

There will be an initial interview to explain the study in detail and determine if you are eligible to participate. Once enrolled, there will be clinic visits at The Melbourne Clinic in Richmond every 4 weeks. At each clinic interview, the Research Assistant will go through your mood and general health over the past 4 weeks, collect your old bottle of medication and give you your next month's supply. You will have a maximum of 9 visits across 28 weeks. If you have agreed to bloods, these will be taken at your baseline visit (Day one of study medication) and week 24 visit (last day of study medication).

TRAVEL REIMBURSEMENT

You will receive re-imbursement of travel expenses up to $20 at each visit completed, once enrolled in the study.

STUDY MEDICATION

The study medication is a dietary fruit-based supplement - mangosteen pericarp. This is produced from an extract of the outer rind of the mangosteen fruit. There is equal (50%) chance that you will receive the mangosteen pericarp or placebo (dummy pills). During the study you will take two capsules once a day of either 500mg mangosteen pericarp or placebo. The study is double-blind which means that neither you nor the research team will know what group you were randomly assigned to until after the study is finished. After the study is completed, you will be notified of which group you were in and a brief summary of group results of the study.

USUAL TREATMENT

The study will be on top of your usual treatment. You may remain on any medication you are currently taking. Once you are enrolled, if your treating physician has recommended a change in the dose you are taking or a switch to another medication, this is allowed. Please let the Research Assistant know of all additions and changes to your medications.

The Melbourne Clinic

IMPACT
CENTRE FOR INNOVATION IN MENTAL AND PHYSICAL HEALTH AND CLINICAL TREATMENT

DEAKIN UNIVERSITY

THE UNIVERSITY OF MELBOURNE

Barwon Health