1. Study Introduction

The Medically Tailored Meals (MTM) study conducted by The George Institute for Global Health (TGI) is looking to recruit participants with type 2 diabetes (T2D) who has persistently high blood sugar levels and experience difficulties accessing and/or preparing nutritious meals.

The study will evaluate if the program improves blood sugar levels, blood pressure and body weight, and if the program can help people eat healthier. This information will help researchers and doctors understand the potential impact of the MTM program, and how it could be implemented and expanded in Australia.

2. How does the study work and what is involved?

Once eligible patients are identified (see flowchart on page 3), they will be randomised to either:

- Control group: participants will receive three (3) $75 vouchers (total of $225) that they can spend on grocery purchases over 6 months, without instructions on what they should purchase
- Intervention group: participants will receive 20 healthy pre-prepared meals and approximately 300 grams of nuts per fortnight delivered to their homes free of charge for six months. Participants will also receive three consultations with a dietitian.

Participants will be advised to continue their usual medications and self-blood glucose monitoring practices. Any changes to medication requirements will be at the discretion of their treating clinician.

Table 1. List of participant activities at each timepoint in the study.

Participant Activity	Week 0	Week 2	Week 4	Week 8	Week 13	Week 26
Screening questionnaire	X					
Baseline call	X					
Dietary recall call	X				X	X
Dietitian calls*		X	X	X		
Pathology assessment**	X				X	X
Home blood pressure measurements**	X				X	X
Week 13 mid-study assessment call					X	
Week 26 end of study assessment call						X
End of Study Interview***						X

* For participants randomised to the intervention group only
** Pathology request forms (for participant's nearest pathology testing centre) and blood pressure machines will be sent to participants by the TGI study team free of charge
*** For 20-30 select participants only

3. Who will pay for the cost of this study?

All costs related to this study, including the healthy meals, dietary consultations, food vouchers, blood tests, weighing scales, and blood pressure monitors will be covered by TGI study team.

4. What happens to the data collected?

All participants will need to provide informed consent to the researchers for collecting and using their information for the study. The information collected will be stored in secure databases. Identifiable information will be stored separately from the main study data using a restricted access Microsoft SharePoint file. This information will be stored and backed up on secure servers at TGI Sydney office. TGI will store personal information, survey responses, and measurements collected for the study for a minimum of 15 years after the publication of the research results.

5. Voluntary participation and withdrawal

Participation in this study is voluntary and participants can withdraw at any time. Any decision made on the participation in the study will not affect the medical treatment provided to the participant or the relationship between the medical staff and the participant.

6. How does the research team support the GP practices during the MTM study?

The GP practices will support the study by screening their medical records to identify potentially eligible patients (see flowchart on next page). The GPs would then speak to the identified patients and describe the study to them briefly. For patients who indicate that they are interested in taking part, GPs are expected to:

1. Add the patient's name and contact information to a list and send to the study team via the MTM study email (mtm@georgeinstitute.org.au), and
2. Pass the study team's email address to the patients in case they wish to contact the study team directly with any queries about the study.

After these initial steps, no further involvement from the GP practice will be required for the study. The study team will be responsible for all remiaining trial activites including:

- Obtaining informed consent
- Ordering and ensuring meals are delivered to patients in the intervention groups
- Analysing and sharing trial findings with the GP practices

MTM Study: Guide for Clinicians