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Telephone-based MAGDA in postpartum women with a prior history of gestational diabetes

A change in microsystem level

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CRE In Primary Health Care Microsystems

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Background and rationale

Currently about 1 million Australians were diagnosed with diabetes.[1] Most (85%) of those had type 2 diabetes (T2DM).[1] Local and international data suggest that about one-third to half of those with diabetes was undiagnosed.[2-4] More than half of the population in Australia is overweight and obese, which puts them at higher risk of T2DM. Diabetes is associated with a wide range of macrovascular and microvascular complications including blindness, amputations, renal disease, and cardiovascular diseases. Currently A$1507 million or 2.3% of the health budget was spent on diabetes.[5] It is projected that by 2033 T2DM will pose an economic burden of A$8 billion, with a 436% increase in projected expenditure compared to 2002-3.[6] This projected increase was driven by demographic factors, increase in obesity prevalence, extra services per case, and currently untreated diabetes.[6]

GDM is defined as any degree of glucose intolerance with onset or first diagnosis during pregnancy.[7] About 10-13% of all pregnancies in Australia are complicated by GDM.[8] Pregnancies with GDM are more likely to have adverse outcomes including macrosomia, perinatal mortality, preeclampsia and caesarean delivery.[9] Offsprings born to mothers with GDM are also at increased risk of obesity, abnormal glucose metabolism and cardiovascular diseases later in life.[10] About 30-84% of GDM patients re-develop the condition in subsequent pregnancies.[11]. One of the most significant long-term health impacts of GDM is the significantly increased risk of developing diabetes. The greatest increase in the incidence of type 2 diabetes following GDM occurs within the first five years, with up to 50% of women with prior GDM developing T2DM within this timeframe.[11]. As a young, at-risk group for T2DM, women with prior GDM represent a great opportunity for public health intervention in T2DM prevention.

In many cases T2DM is a preventable disease. Studies have consistently shown that dietary modification along with moderate physical activity reduces the incidence of diabetes in high-risk populations.[12, 13] Lifestyle intervention has also been shown to reduce the development of diabetes in women who had GDM (averaging 12 years from index pregnancy) by 50%.[14]

A well-timed lifestyle intervention program for women post-GDM that includes determination of individual risk of developing Type 2 Diabetes, setting priorities, problem solving and goal setting for lifestyle modification to reduce the likelihood of progression to T2DM, has the potential to positively change the longer term health of these women and their children.

HISTORY OF DIABETES PREVENTION IN AUSTRALIA

The Australian Government funded the Greater Green Triangle Diabetes Prevention Program (GGT DPP) to study the effectiveness and feasibility of identification of those at high risk, and a six-session group intervention in primary care. From waist circumference changes, it is estimated that the GGT DPP reduced the risk of developing diabetes by 40% and cardiovascular disease by 16%.[13] The results of this Project were used to inform the National Chronic Disease Strategy resulting in the recommendation of diabetes prevention to the Council of Australian Governments in 2007. Victoria has led the way with the Life! Program, group based intervention based on GGT DPP. The NHMRC-funded Melbourne Diabetes Prevention Study has demonstrated the effectiveness and cost-effectiveness of the Life! program.[15]

In 2012, the NHMRC-funded Mothers After Gestational Diabetes in Australia (MAGDA) Study evaluated a group-based intervention for post-GDM women, but found that there were barriers to attendance at the intervention such as childcare and travel. As it was delivered in a group setting, it was difficult to address individual needs such as tailoring for cultural differences.

Telephone-based interventions have been shown to be effective in producing and maintaining lifestyle changes.[16] The Australia's Get Healthy Information and Coaching Service® launched by the New South Wales government in 2009 provided telephone coaching services which

resulted in significant improvements in body weight, waist circumference, fruits and vegetable intake, and physical activity.[17] A more recent telephone-delivered lifestyle intervention targeting Australian primary care patients with Type 2 Diabetes also demonstrated effectiveness in weight loss and increase in physical activity.[18] This new delivery mode may suit postpartum mothers as it addresses some of the barriers to lifestyle intervention such as need for childcare and lack of time. [19] Delivering lifestyle intervention via telephone could also be more cost-effective.[20]

Study design

The TeleMAGDA pilot is a single-arm implementation trial with no randomization and no controls. Up to 35 participants will be recruited in Victoria and South Australia via the National Gestational Diabetes Register and through existing consented women in the MAGDA study control arm.

The objectives of this pilot are to determine:

- The feasibility of delivering a telephone-based lifestyle intervention for postpartum women with a history of gestational diabetes
- The participation/attrition rate of the intervention.
- The acceptability of telephone-based MAGDA among postpartum mothers

Methods

SELECTION AND RECRUITMENT

Recruitment

Participants will be recruited from the following sources:

- The MAGDA Study: Women from MAGDA NDSS NGDR mail-out who live too far away from MAGDA groups, MAGDA control participants who have completed their involvement, MAGDA participants who were ineligible for T1, MAGDA women in the intervention group but who have not been able to join any of the groups offered to them. All women approached will have already consented to future contact through the MAGDA study. Potential participants will be contacted by telephone by a research staff member.
- NDSS/NGDR mail out: A letter and a teleMAGDA information brochure (with contact details for the study) will be sent out to women registered with the National Gestational Diabetes Register and living in the Colac area.
- A supplementary form of recruitment will also be used. An invitation to participate webpage will be added to the MAGDA study website, which has been set up to support a national survey of women with GDM and their GPs. The invitation to participate will include a copy of the plain language statement on the page and participants will be able to express their interest in being contacted by research team for a thorough explanation through filling in their contact details onto the page's "contact us" section

Inclusion and exclusion criteria

Inclusion criteria:

- Diagnosed GDM in the last pregnancy (Fasting glucose ≥ 5.5mmol/L or 2-h glucose ≥ 8.0 mmol/L on a 75g OGTT) or a GCT ≥12.0mmol/L.
- Post natal OGTT does not show T2DM (Fasting glucose ≥ 7.0mmol/L or 2-h glucose ≥11.1mmol/L)
- Residing in Victoria or South Australia
- ≥3 months and less than/equal to 24 months post-partum

Exclusion criteria:

- Established diabetes (T1DM or T2DM)
- Cancer (not in remission)
- Severe mental illness in the last three months
- Substance abuse (illicit drugs) in the last three months
- Myocardial infarction in the last three months
- Difficulty with English
- Pregnant at any time during the study (from baseline to follow up data collection)
- Surgical or medical intervention to treat obesity

Screening procedures

If the woman is interested in the study, the teleMAGDA Recruiter will screen for eligibility. If eligible, the recruiter will review the teleMAGDA consent form with the participant; if still interested, the woman will be posted a Plain Language Statement and Consent Form along with a reply paid envelope and asked to complete and return the consent form.

The teleMAGDA recruiter will address the following:

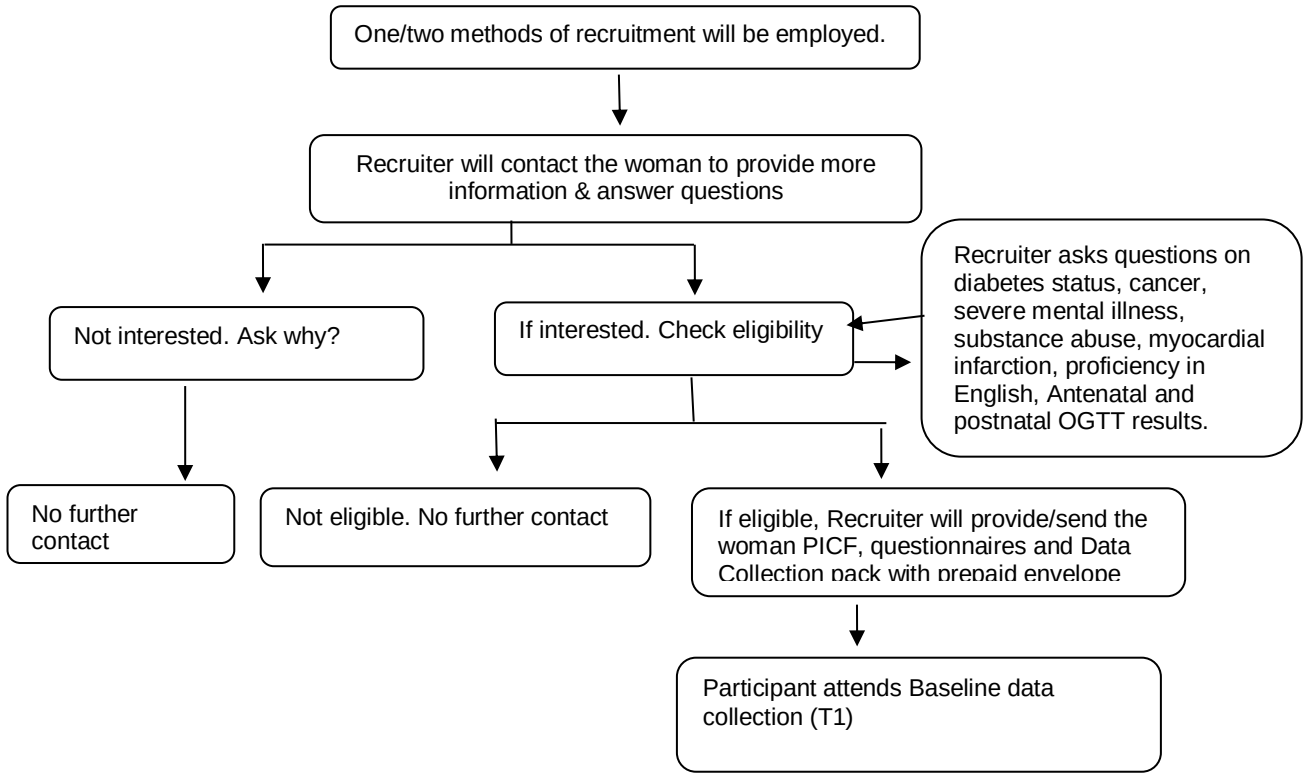
- Ask participant what motivated them to respond
- Find out their antenatal **and** postnatal OGTT results
- Describe the program—what it involves, tests, commitment
- Describe the research
- Obtain verbal consent (signed consent)
- Go through eligibility criteria
- Post them a PLSCF, instructions for baseline testing, clinical test form and questionnaires

If ineligible, no further contact will be made with the woman. If the consent form is not received within one week, the TeleMAGDA Recruiter will contact the woman.

Second Screening:

> If the woman does not have recent OGTT results (post-natal, within last 6-months), she will be asked to contact her GP and have one done in order to exclude T2DM and commence participation in the study.

Fig 1: Recruitment Flowchart



REPORTING

The TeleMAGDA trial will be reported according to the CONSORT (Consolidated Standards of Reporting Trials) 2010 Statement (see link).

http://www.consort-statement.org

STUDY INTERVENTION

Theoretical framework

The theoretical framework of this intervention is based on the Health Action Process Approach (HAPA) and self-regulation theory.[21,22] Several other theories, strategies and constructs are incorporated into the design of the intervention. These include the social learning theory, [23,24] empowerment-oriented counseling,[25-27] goal-setting approach, [28, 29] self-efficacy and self-evaluation.[22, 30]

The HAPA model was developed by Ralph Schwarzer. This information has been taken from: **http://www.hapa-model.de/.**

The Health Action Process Approach (HAPA) suggests that the adoption, initiation, and maintenance of health behaviours must be explicitly conceived as a process that consists of at

least a motivation phase and a volition phase. The latter might be further subdivided into a planning phase, action phase, and maintenance phase. It is claimed that perceived self-efficacy plays a crucial role at all stages along with other cognitions (Bandura, 1997). For example, risk perceptions serve predominantly to set the stage for a contemplation process early in the motivation phase but do not extend beyond. Similarly, outcome expectancies are chiefly important in the motivation phase when individuals balance the pros and cons of certain consequences of behaviours, but she lose her predictive power after a personal decision has been made. However, if one does not believe in one's capability to perform a desired action, one will fail to adopt, initiate and maintain it.

The Motivation Phase

In the motivation phase, the individual forms an intention to either adopt a precaution measure or change risk behaviours in favour of other behaviours. Self-efficacy and outcome expectancies are seen as the major predictors of intentions. Most previous models treat these two as being unrelated predictors. However, there might be a temporal and causal order among her. Outcome expectancies can be seen as precursors of self-efficacy because people usually make assumptions about the possible consequences of behaviours before inquiring whether she can really take the action herself. If self-efficacy is specified as a mediator between outcome expectancies and intention, the direct influence of outcome expectancy on intention may dissipate. But the research findings on this issue are very inconsistent, rendering both cognitions primary candidates for motivating change. Under conditions where individuals have no experience with the behaviour she is contemplating, we assume that outcome expectancies may have a stronger direct influence than self-efficacy. Only after a sufficient level of experience is attained does self-efficacy become more influential in forming an intention.

The influential role of risk perception (or threat) in the motivation and volition process may have been overestimated in past research and interventions. Fear appeals are of limited value; rather, the message has to be framed in a way that allows individuals to draw on her coping resources and to exercise skills in order to control health threats. In persuasive communications, a focus should be made on self-percepts of personal coping capabilities to manage effective precaution strategies. This suggests a causal order where threat is specified as a distal antecedent that helps to stimulate outcome expectancies which further stimulate self-efficacy. A minimum level of threat or concern must exist before people start contemplating the benefits of possible actions and ruminate her competence to actually perform her. The direct path from threat to intention may become negligible if expectancies are already well established.

In establishing a rank order among the three direct paths that lead to intention, it is assumed that self-efficacy and outcome expectancies dominate, whereas threat (or risk perceptions) may fail to contribute any additional direct influence. As indirect factors, however, threat may be of considerable significance within the motivation phase. The particular context and one's personal experience play a role and may change the pattern of weights.

The Volition Phase

It is common knowledge that good intentions do not necessarily guarantee corresponding actions. Correlations between intentions and behaviours vary tremendously. While in the motivation phase it is described what people choose to do, in the subsequent action or volition phase it is described how hard she try and how long she persist. The right-hand part of Figure 1 consists of three levels: cognitive, behavioural, and situational. The focus is on cognitions that instigate and control the action, i.e., a volitional or self-regulative process which is subdivided into action plans and action control.

When a preference for a particular health behaviour has been shaped, the intention has to be transformed into detailed instructions of how to perform the desired action. If, for example, someone intends to lose weight, it has to be planned how to do it, i.e., what foods to buy, when

and how often to eat which amounts, when and where to exercise, and maybe even whether to give up smoking as well. Thus, a global intention can be specified by a set of subordinate intentions and action plans that contain proximal goals and algorithms of action sequences. The volition process is hardly influenced by outcome expectancies, but more strongly by self-efficacy, since the number and quality of action plans are dependent on one's perceived competence and experience. Self-efficacy beliefs influence the cognitive construction of specific action plans, for example, by visualizing scenarios that may guide goal attainment. These post-decisional pre-actional cognitions are necessary because otherwise the person would act impulsively in a trial-and-error fashion and would not know where to allocate the available resources.

Once an action has been initiated, it has to be controlled by cognitions in order to be maintained. The action has to be protected from being interrupted and abandoned prematurely due to incompatible competing intentions which may become dominant while a behaviour is being performed. Meta-cognitive activity is needed to complete the primary action and to suppress distracting secondary action tendencies. Daily physical exercise, for example, requires self-regulatory processes in order to secure effort and persistence and to keep other motivational tendencies at a distance (such as the desire to eat, socialize, or sleep) until these tendencies can prevail for a limited time period.

When an action is being performed, self-efficacy determines the amount of effort invested and the perseverance. People with self-doubts are more inclined to anticipate failure scenarios, worry about possible performance deficiencies, and abort her attempts prematurely. People with an optimistic sense of self-efficacy, however, visualize success scenarios that guide the action and let her persevere in face of obstacles. When running into unforeseen difficulties she quickly recover.

Performing an intended health behaviour is an action, just as is refraining from a risk behaviour. The suppression of health-detrimental actions requires effort and persistence as well, and therefore is also guided by a volitional process that includes action plans and action control. If one intends to quit smoking or drinking, one has to plan how to do it. For example, it is important to avoid high-risk situations where the pressures to relapse are overwhelming. Attaining proximal subgoals helps increase the difficulty level of situations until one can resist under all possible circumstances. If someone is craving a cigarette or a drink, action control helps him or her to survive the critical situation. For example, individuals can make favourable social comparisons, refer to her self-concept, or simply pull herself together. The more these meta-cognitive skills and internal coping dialogues are developed and the better she is matched to specific risk situations, the easier the urges can be controlled. Self-efficacy helps to re-establish the perseverant efforts needed for the accomplishment of self-imposed goals.

Finally, situational barriers as well as opportunities have to be considered. If situational cues are overwhelming, meta-cognitive skills fail to protect the individual and the temptation cannot be resisted. Actions are not only a function of intentions and cognitive control, but are also influenced by the perceived and the actual environment. A social network, for example, that ignores the coping process of a quitter by smoking in his presence, creates a difficult stress situation which taxes the quitter's volitional strength. If, on the other hand, a spouse decides to quit too, then a social support situation is created that enables the quitter to remain abstinent in spite of lower levels of volitional strength.

In sum, the action phase can be described along three levels: cognitive, behavioural, and situational. The cognitive level refers to self-regulatory processes that mediate between the intentions and the actions. This volitional process contains action plans and action control and is strongly influenced by perceived self-efficacy, but also by perceived situational barriers and support.

Materials

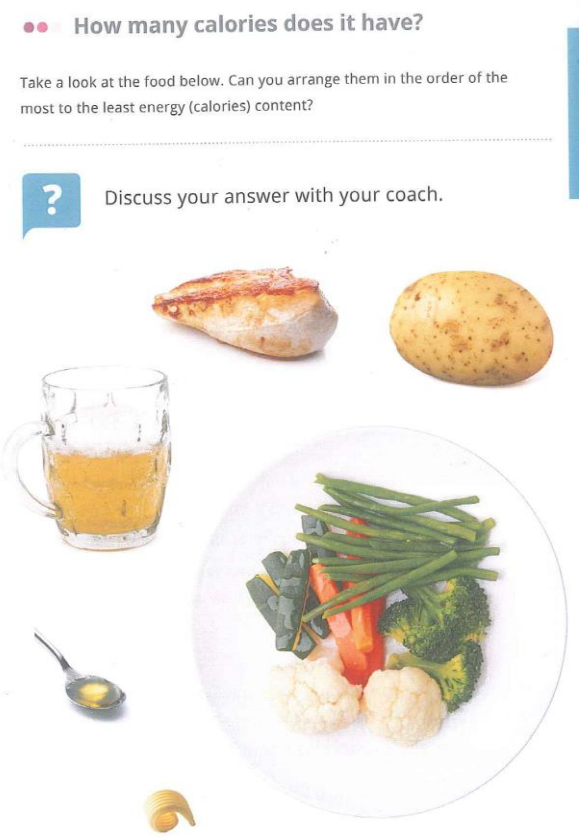
Participant Handbook

This is a self-help manual for the participants. It provides information on the study as well as introduces the intervention goals along with strategies to achieve them. This material helps to keep the telephone session short and manageable (20-30 mins), while still building the same range of skills in the participants as they would receive in a 2-hour in-person session. Each chapter consists of a series of short articles which are developed specifically to engage postpartum women. The articles describe the significance of the intervention goals to their health and provide the knowledge required to achieve that goal e.g. types of fat and fibre and their food sources, the science of energy balance, the concept of energy density, portion sizes, glycemic index, the amount of fibre, fat and energy in common food items, the amount of sleep a baby needs, sleep-training techniques, ways to relieve stress, identifying anxiety and depression etc.

Practical tips are included throughout the manual to address the physical, mental, emotional and social needs of postpartum women, e.g. having a high-fibre breakfast with protein to keep the energy up, making baby and toddler-friendly family meals, finding time to eat instead of multitasking, make and freeze baby-friendly meals, not to worry about competing baby's developmental milestones with other mums, making time to do something fun with partner etc.

Skills required for lifestyle modification are also included in the manual e.g. ingredients substitution, recipe modification, food label reading, choosing healthy take-away choices etc. These skills are reinforced through homework and activities at the end of each chapter (see example in Fig 3.

Fig 3. An example of homework in the TeleMAGDA Participant's Manual



The participant will read a chapter and complete the homework and activities at the end of the chapterin preparation for the upcoming session .

During the telephone session, the coach will refer to the Participant Handbook to address any knowledge gap and to go through the answers for the homework with the participants.

The content of the Participant Handbook is as follow:

- Ready, set go!
- How to use this manual
- First session: Why am I doing this?
- Chapter A: How do celebrities lose their baby weight
- Chapter B: Why Eskimos don't have heart attacks
- Chapter C: How Disney princesses keep their figure
- Chapter D: Why cows don't get diabetes
- Chapter E: A beautiful mind
- Last session: Planning for the long haul
- Tracking tools
- Additional facts

Coach Manual

This is a manual for the coaches. It provides an overview of the study and the intervention sessions. It describes the structure of calls and ways to facilitate goal-setting and problem-solving (see excerpt below). Suggested scripts for the telephone sessions are also included in the manual. Homework and other important points of discussion are included. The section on Session Guides provides an outline of each telephone session on a single page for the coach to refer to during the telephone session.

Below is an excerpt from the Facilitators Manual on goal setting:

> ## *FACILITATING A SMARTER GOAL-SETTING SESSION*
>
> ### *Review goal*
>
> *Use open questions to ask the participant what the goal she set at the last session and how well that has gone. Write down her previous goal on the participant casebook. Acknowledge ANY progress she made, and how difficult it can be to make these changes. Once she has described her success in her own words, ask her to summarize her success on a 5 point scale (5-achieved goal completely, 1-did not achieve at all, 3-achieved about half of the goal) and note this beside her goal. Using open questions, if she managed or nearly managed her goal, ask her what the biggest barrier she encountered was.*

The content of the Coach Manual is as follow:

- Acknowledgements
- About TeleMAGDA
- About this manual
- Program timeline
- Basic structure of calls (after the first session)
- Effective communication
- What is a SMARTER goal
- Facilitating a SMARTER goal-setting session
- Tracking tools
- Phone session 1
- Chapter A: Exercise
- Chapter B: Fat and saturated fat
- Chapter C: Weight management
- Chapter D: Fibre
- Chapter E: Sleep, stress and depression
- Last session: Rewards and Lapses
- Appendix
- Session guides

Participant Casebook

This is a data tracking instrument to be filled in by the coaches. It collects process data such as the attempts of calls, time and duration of calls. It also record personal information on the participants such as their perceived risks, previous goals, perceived barriers etc, which helps the coach to provide continuous ‘care’ to the participants. The content of the Participant Casebook is as follow:

- Appointment schedule
- Consents
- Personal information
- Outcome measurements (T1)
- Phone session 1
- Phone session 2
- Phone session 3
- Phone session 4
- Phone session 5
- Phone session 6
- Phone session 7

- Outcome measurements (T2)
- Notes

Delivery

The intervention will be administrated by trained health care professionals. All facilitators will be provided with a manual and a one-day training by an experienced researcher in telephone-based intervention. .

The training will include:

- Motivational interviewing skills
- Effective communication skills
- Goal setting and problem solving
- Role-play of the telephone sessions

After Baseline results and questionnaires have been received by the Research Assistant, the participant will be posted a participant handbook. Participants will be involved in the study for 3 months. The intervention group will be asked to complete a series of seven sessions. All the sessions will be carried out at two week intervals (apart from where public and other holidays interrupt the sequence of sessions). If participant availability is a problem the sessions will be conducted no more than 4 weeks apart. Each telephone session will run for approximately 30 minutes.

Intervention goals

There have been successful implementation trials for diabetes prevention in Finland[31] and Australia.[13] Evidence-based goals used in the GGT Life! Program, Melbourne Diabetes Prevention Study and Mothers After Gestational Diabetes in Australia (MAGDA) Study are used this study:

1. Reduce fat intake (no more than 30% of energy from fat)
2. Decrease saturated fat intake (no more than 10% of energy from saturated fat)
3. Increase fibre intake (at least 15g/1000Kcal per day)
4. Increase physical activity (at least 30 minutes of moderate exercise per day)
5. Reduce body weight (at least 5% of body weight reduction within 12 months)

Intervention topics

The first session is about establishing the participants' reasons to be in the program and addressing their risk perception. The last session is about maintaining the changes in the long term. Sessions 2 to 6 introduces the five intervention goals for diabetes prevention. The intervention goals can be delivered in any order, depending on the participant's choice.

Table 1: An example of TeleMAGDA session topics

Session	**Content**
Session 1	Establishing why she wants to be in the program Her risks of developing diabetes Introduction to the TeleMAGDA goals Setting a physical activity goal
Session 2	Fat and saturated fat Review and set physical activity and healthy eating goals
Session 3	Weight Management Review and set physical activity and healthy eating goals
Session 4	Fibre Review and set physical activity and healthy eating goals
Session 5	Exercise Review and set physical activity and healthy eating goals
Session 6	Sleep, stress and depression Review and set physical activity and healthy eating goals Set goals on sleep, stress and/or depression
Session 7	Lapses and relapses, rewards Long term goal setting

Adherence assessment

Participant completion of each telephone session will be recorded and a continuous analysis kept. Program completers defined as those women who completed 5 or more telephone sessions. Note what has been achieved from the 5 goals from changes over length of program in study questionnaire data.

STUDY PROCEDURES

Data collection

Table 2: Schedule for data collection

Assessment	**Screening 1 (Before recruited into the study)**	**Between Screening 1 and Baseline testing**	**Baseline (T1) postpartum (Screening 3)**	**After last phone coaching session (T2)**
Informed Consent		x		
Results of antenatal and postnatal OGTT		x		
Capillary Fasting Glucose			x	x
Anthropometric Measurements (height, weight, waist, hip)			x	x
BP			x	x
Demographics			x	
Health Status			x	x
Food Frequency Questionnaire			x	x
The Active Australian Questionnaire			x	x
Quality of Life (AQOL-8D)			x	x
Risk Perception			x	x
Psychological wellbeing (PHQ9)			x	x
Social Support (Multidimensional Scale of Perceived Social Support)			x	x
Exclusion Criteria	x		x	x

Baseline assessments (Time 1)

- Fasting Capillary Blood Glucose reading using Glucometer (Finger Prick)
- Anthropometric measurements
    - Height
    - Weight
    - Waist Circumference
    - Hip Circumference
- Blood Pressure
- Questionnaires
    - Demographics
    - Health Status
    - Food Frequency Questionnaire
    - Risk Perception Questionnaire
    - Quality of Life (AQOL-8D)
    - The Active Australian Questionnaire
    - Psychological Health (PHQ9)
    - Social Support (Multidimensional Scale of Perceived Social Support)

Completion/Final data collection (Time 2)

<u>After the final telephone session</u>

- Fasting Capillary Blood Glucose reading using Glucometer (Finger Prick)
- Anthropometric measurements
    - Height
    - Weight
    - Waist Circumference
    - Hip Circumference
- Blood Pressure
- Questionnaires
    - Demographics
    - Health Status
    - Food Frequency Questionnaire
    - Risk Perception Questionnaire
    - Quality of Life (AQOL-8D)
    - The Active Australian Questionnaire
    - Psychological Health (PHQ9)

- Social Support (Multidimensional Scale of Perceived Social Support)

Data collection will be conducted by the participant's GP. The participants recruited in the Colac area, via the mail out, will be required to attend their local pharmacy for data collection.

Participants will have options for questionnaire completion:

- Paper copy, with included reply paid post envelope
- Email web surveys link
- Via the MAGDA website

Feasibility and attendance data

A log of the following data will be recorded for each participant:

- Estimated number and % of the target population with GDM
- Estimated number of eligible participants based on inclusion/exclusion criteria
- List the reasons for and number of exclusions by the investigators or program.
- List the number of "lost or indeterminate cases" - e.g., wrong information, not able to be contacted, moved, no answer.
- Actual number exposed to recruitment
- Actual number who respond to recruitment
- List reasons for declining participation
- Actual number who are eligible
- List number and reasons for ineligibility
- Actual number who started
- List number and reasons pre-commencement attrition
- Compare demographics of those who participated and those who didn't
- Record how many ____ and when (what week of the intervention) _____ subjects dropped from the study.
- An exit survey will be conducted with all participants following their completion of the study, including those who withdraw
- Compare differences between those completing and those not completing the study on adverse events, illness status, sociodemographics, geography, baseline scores on dependent variables, and other key variables.

Cost

The following will be collected and used as a measure of cost of delivering the intervention:

- Intervention materials
- Equipment
- Personnel
- Time
- Space

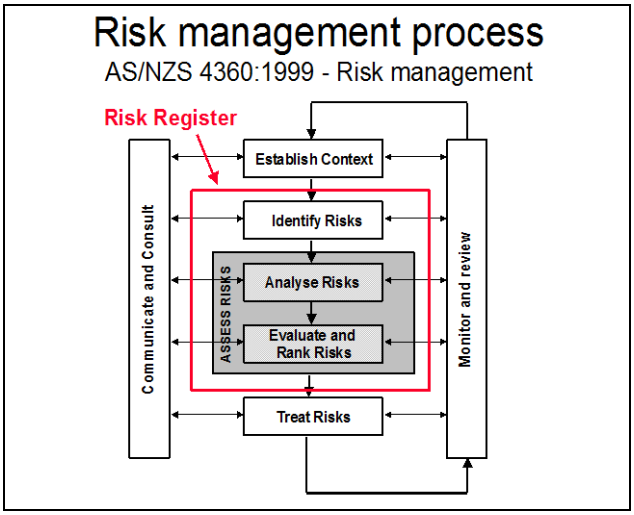
- Number of missed calls, completed calls, rescheduled calls, call duration, topics covered, goals reviewed, setting new goals.
- Type of method used for questionnaire completion
- Effectiveness of pharmacy in data collection

SAFETY ASSESSMENT

Risk management process

The process of risk management for TeleMAGDA will follow the path set out in the diagram below.

Fig 3: Risk management process



Source: Standards Australia International & Standards New Zealand (2001) Guidelines for Managing Risk in the Healthcare Sector: Australian/New Zealand Handbook. Sydney: Standards Australia International; p. 21, Figure 3.

Specification of Safety Parameters

If measurements are taken by pharmacist, a feedback letter will be sent to the participants GP.

Adverse events and serious adverse events

Adverse events

- Needle stick injury to participant or study staff, use of lancet

Serious adverse events

- Injury sustained by the mother and / or infant (or accompanying child(ren)) either while in transit to / from the Data Collection sessions or while participating in the Testing sessions.

Reporting procedures for adverse events

A primary role of the Project Management Group will be to monitor and review the adverse events through its monthly meetings. The Board will be kept informed on a quarterly basis of any adverse events. NHMRC and involved HRECs will be informed as required.

Follow-up for adverse events

Standard operating procedure for research personnel, Data Collectors (GPs or pharmacists) and Facilitators will outline steps to be taken in the event of either an adverse event or a serious adverse event. In the event that an adverse event does occur the risk management process, as outlined in Figure 2 above, will be followed immediately. The adverse event will be reported to the Project Board.

Safety Monitoring

The TeleMAGDA study will follow the NHMRC Australian Health Ethics Committee (AHEC) position statement: Monitoring and reporting of safety for clinical trials involving therapeutic products (2009).

Monitoring and reporting of safety for clinical trials involving therapeutic products guidelines can be viewed here:
http://www.nhmrc.gov.au/_files_nhmrc/file/health_ethics/hrecs/reference/090609_nhmrc_position_statement.pdf

James Dunbar (CIA) will oversee the whole project with support from all site-specific investigators in order to ensure that risk management processes are implemented.

Intervention discontinuation

If the woman develops cancer, severe mental illness, experiences a heart attack or stroke, becomes pregnant or commences another lifestyle intervention which impacts on primary outcome measures during the study period, the woman may be withdrawn from the study if she is unable to continue or it is inappropriate for her to continue her involvement. Each case will be evaluated by the Protocol Violation Committee.

DATA COLLECTION

Data collection forms

Online and paper based forms will be used to collect information. The clinical measurements will be recorded by the GP/pharmacist, with all other questionnaires containing self-report information. The only identifying information will be the participant ID which is located on the front of each form/questionnaire, with the exception of the patient demographic questionnaire SECTION A-1 which contains participants' contact details.

Data collection forms used by the GP (containing only ID codes) will be posted/faxed/emailed/MMS to Research Assistant at Deakin Burwood.

Participant will have the option of completing either the web based survey (either via email link or the MAGDA website) or paper copy. Any paper questionnaires will be posted back by participant in provided envelopes (with identifiable documentation sent in an Express post envelope and non-identifiable documentation sent in standard post). These data will be collected by the Research Team and transferred to locked cabinets at Burwood site (Melbourne).

Web-based surveys

The Health Surveys service run by the Faculty of Health, Deakin University, has the endorsement of the University Solicitor's office, the Faculty Research Ethics Group (HEAGH) and the University Human Research Ethics Group (DUHREC) for its use in high-risk research.

The process which governs this service requires a single point of contact, called the User (normally the CI, always a University Employee, in this case the DPP-PM) who has sole access to the data once exported to the share.

In all instances, the strongest recommendation is made that the User collect only data which is not identifiable within the survey instrument, and the issuing of ID codes is handled entirely within the research team, with the Health Surveys Contact never able to access this information as a safeguard for respondents' privacy and anonymity. This has been strictly adhered to in the case of the MAGDA study.

All data are stored on Deakin University eSolutions servers, which are ISO 9000 compliant for data security and access and quality control.

During the survey data collection period, only the person in charge of running the service is able to access the data, and is legally and ethically bound by the rules of the University and the Grant-issuing body, as defined in the aforementioned Health Surveys process map.

At the end of the data collection period, the Health Surveys contact exports all reports and data, as well as a full backup of all pilot and final survey instruments (with results) to the Specified Share, which is created early in the process, accessible only by the User, and is read-only to safeguard the data in its unmodified state. The User alone is then responsible for copying the data to a suitable Deakin University share for analysis and dissemination within the research team. Once the User has accepted custodianship of the data, all records of the survey instruments and respondent data are permanently removed from the Health Surveys server, and remain only in the Specified Share.

Data management

Data collected from women at baseline and as soon as possible after the last group session are sent back to office in Burwood via post, email, fax or MMS by the data collectors (GPs/pharmacists).

Questionnaires are either completed directly online via Deakin health surveys or posted back to office in Burwood by participant (with identifiable documentation sent in an Express post envelope and non-identifiable documentation sent in standard post). These questionnaires are checked for accuracy and completeness by the Research Assistant on to ensure there is no missing data, any missing fields will be clarified with participant over phone to confirm intentional omission.

QUALITY ASSURANCE

Data Collection

The Data Collection Forms will contain easy to read instructions about performing data collection alongside required measurements.

Training

Training will be provided for the facilitators. The training will include

- Practical facilitation skill development activities, including:
    - Engaging the mothers

    - Effective communication
    - Goal setting
    - Problem solving
- Rehearsal of telephone sessions
- Facilitators may be observed delivering sessions of the program by a trained observer in order to ensure fidelity of session delivery or sessions may be audio recorded for audit purposes using a uni-directional microphone. Recordings will be stored securely on USB memory sticks in the research office. Recordings may be coded using validated tools and the recordings would then be deleted as per the TeleMAGDA Facilitator's Quality Assurance Framework.

PROTOCOL DEVIATIONS

Any protocol deviations will be registered on the Protocol Exception Register and discussed at regular Protocol Exception Meetings with a clinical Chief Investigator, Associate Investigator and the TeleMAGDA Project Manager.

The TeleMAGDA Project Management group will meet regularly to monitor the progress of the overall intervention across all sites, with particular responsibility for risk management.

TIMELINE

30th June 2015

- Literature review completed
- Study protocol finalized
- Study materials (coaching and participant handbooks) designed and printed
- Ethics approvals received from each jurisdiction
- Participants recruited (n=35) and consented
- Baseline data collected from all participants
- Negotiations with national telephone health coaching providers underway for partnership in major study

31st December 2015

- All participant data collected, cleaned and analyzed
- Preliminary publication of findings submitted
- Policy brief presented to Victorian Department of Health and SA Health
- Knowledge translation symposium hosted to highlight lessons learned from MAGDA and teleMAGDA studies
- Draft NHMRC application submitted for peer review

Results

Findings from the pilot will be available by the end of 2015. Main outcomes are:

- Acceptability
- Feasibility
- Participation rate
- Barriers to participation (reasons for non-participation)
- Attrition rate

Discussion

Results from the pilot study will be available by the end of 2015.

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