Australian National University

GREATER GREEN TRIANGLE
University Department of Rural Health

TeleMAGDA, a telephone-based lifestyle-modification program for postpartum women with a prior history of gestational diabetes

A change in microsystem level

Lim S, Eakin L

CRE In Primary Health Care Microsystems
BUILDING QUALITY, GOVERNANCE, PERFORMANCE & SUSTAINABILITY
APHCRI CENTRE OF RESEARCH EXCELLENCE

Flinders UNIVERSITY

DEAKIN UNIVERSITY

ACKNOWLEDGEMENTS

This research is a project of the Australian Primary Health Care Research Institute, which is supported by a grant from the Australian Government Department of Health. The information and opinions contained in it do not necessarily reflect the views or policy of the Australian Primary Health Care Research Institute or the Australian Government Department of Health.

CITATION

Lim S, Skinner T, Eakin L. TeleMAGDA, a telephone-based lifestyle-modification program for postpartum women with a prior history of gestational diabetes: A change in microsystem level. APHCRI Centre of Research Excellence in Primary Health Care Microsystems, The University of Queensland, 2014.

APHCRI Centre of Research Excellence in Primary Health Care Microsystems

Discipline of General Practice

The University of Queensland

Level 8 Health Sciences Building, Building 16/910

Herston, QLD 4029 Australia

T 61 7 3365 5545

F 61 7 3346 5178

www.aphcricremicrosystems.org.au

TABLE OF CONTENTS

List of Abbreviations

AQoL-8D	Australian Quality of Life questionnaire, version 8D
BMI	Body Mass Index (kg/m^2)
CONSORT	Consolidated Standards of Reporting Trials
CTF	Clinical Test Forms
GCT	Glucose Challenge Test
GDM	Gestational Diabetes Mellitus
GGT DPP	Greater Green Triangle Diabetes Prevention Program
GGT UDRH	Greater Green Triangle University Department of Rural Health
GP	General Practitioner
HAPA	Health Action Process Approach
MAGDA	Mothers After Gestational Diabetes in Australia
MMS	Multimedia Messaging Service
MSPSS	Multidimensional Scale of Perceived Social Support
NHMRC	National Health and Medical Research Council
NDSS	National Diabetes Services Scheme
NGDR	National Gestational Diabetes Register
OGTT	Oral Glucose Tolerance Test
PICF	Project Information and Consent Form
PHQ9	Patient Health Questionnaire, nine-question
SPSS	Statistical Package for Social Sciences
T1DM	Type 1 Diabetes Mellitus
T2DM	Type 2 Diabetes Mellitus

Background and rationale

There are about a million Australians currently diagnosed with diabetes, most (85%) with type 2 diabetes (T2DM).[1] Local and international data suggest that about a third to a half of people with diabetes remain undiagnosed.[2-4] More than half of the population in Australia is overweight or 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 AU$1.5 billion 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 AU$8 billion, with a 436% increase in projected expenditure compared to 2002-3.[1] 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] Children 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 T2DM. 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]

Lifestyle interventions targeting postpartum women face the challenge of retention and engagement. In the postpartum period, the infant's needs pose a high demand on the mother's energy and time[15], which could affect the mother's ability to participate in a lifestyle program and to engage with the study requirements. Family commitments, such as being married or partnered and having children in the household, have been identified as predictors of attrition in lifestyle interventions[16,17]. For those successfully retained, poor engagement or attendance could still result in a non-significant outcome despite the number of sessions offered.[18] Differences in retention and engagement across the studies may have contributed to the wide range of effectiveness seen in lifestyle interventions in this group.[19-22]

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, using 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%.[23] 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, a group-based intervention based on the GGT DPP.

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 sessions for cultural differences.

Telephone-based interventions have been shown to be effective in producing and maintaining lifestyle changes.[24] 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, fruit and vegetable intake, and physical activity.[25] 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.[26]

TeleMAGDA, a telephone-delivered lifestyle intervention for diabetes, may suit postpartum mothers as it addresses some of their barriers to lifestyle intervention, such as need for childcare and lack of time.[27] Delivering lifestyle intervention via telephone could also be more cost effective than group-based interventions.[28]

Work on the TeleMAGDA project was funded through CRE Extension funding provided in 2015 by the Department of Health through the Australian Primary Health Care Research Institute.

STUDY DESIGN

The TeleMAGDA pilot is a single-arm implementation trial with no randomisation and no controls. Thirty three participants were 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 the pilot were 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.

TeleMAGDA was a pilot nested within the MAGDA study and was covered by the MAGDA study's ethics approval from the Human Research Ethics Committees of Flinders and Deakin Universities.

Methods

SELECTION AND RECRUITMENT

Recruitment

Participants were recruited from the following sources,

- **The MAGDA Study** – via phone contact or discussion at final MAGDA testing session
  - Women from MAGDA's NDSS (National Diabetes Services Scheme) NGDR (National Gestational Diabetes Register) mail-out who live to far away to attend MAGDA group sessions
  - MAGDA control participants who had completed their involvement in the MAGDA study
  - MAGDA participants who were unable to attend due to distance, and
  - MAGDA women in the intervention group who were not able to join any of the groups offered to them.
- **NDSS/NGDR mail out:** A letter and a TeleMAGDA information brochure (with contact details for the study) sent out to women registered with the National Gestational Diabetes Register and living in a regional / rural area of western Victoria.
- **MAGDA website:** An invitation to participate on the website where women could fill in their contact details to express their interest in being contacted by the research team for a detailed explanation.

Inclusion and exclusion criteria

Inclusion criteria

- Diagnosed GDM in the last pregnancy (fasting glucose ≥ 5.5 mmol/L or 2-hr fasting glucose ≥ 8.0 mmol/L on a 75g oral glucose tolerance test (OGTT)) or a glucose-challenge test (GCT) ≥12.0 mmol/L.
- Post-natal OGTT does not show T2DM (fasting glucose ≥ 7.0 mmol/L or 2-hr glucose ≥ 11.1 mmol/L)
- Residing in Victoria or South Australia
- Between three and 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

Recruitment procedures

Screening 1

Following expression of interest in the study, the TeleMAGDA recruiter screened for eligibility over the phone. If eligible, the recruiter reviewed the TeleMAGDA consent form with the participant and obtained verbal consent. The consent form was distributed to the women along with the questionnaires and CTF (Clinical Test Forms), in the format selected by participant (paper or online).

Data collected at this stage:

- Antenatal **and** postnatal OGTT results (patient or GP report)
- Verbal consent
- Written consent
- Eligibility (inclusion/exclusion criteria)

If the consent form, questionnaires and CTF were not received within one week, the TeleMAGDA recruiter contacted the woman to encourage return of the documents.

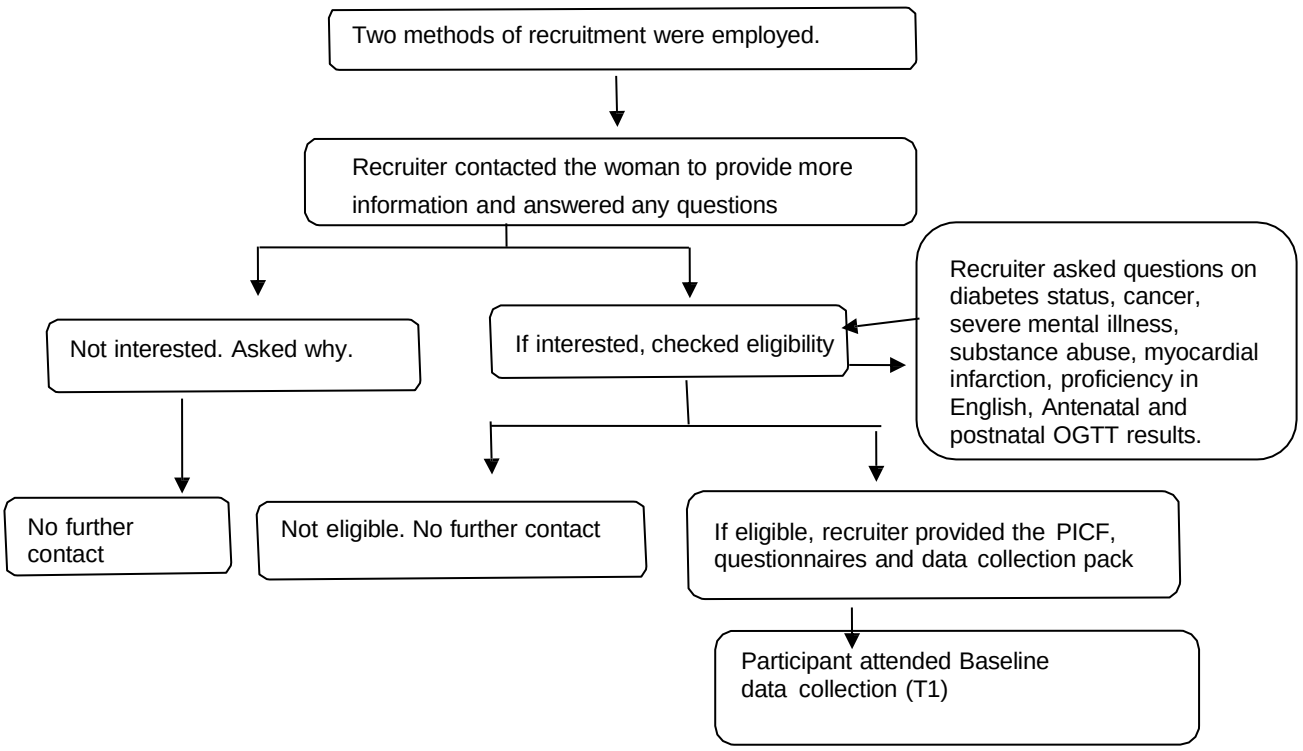

Figure 1: Recruitment Flowchart

REPORTING

The TeleMAGDA trial reported according to the CONSORT (Consolidated Standards of Reporting Trials) 2010 Statement (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.[29,30] Several other theories, strategies and constructs are incorporated into the design of the intervention. These include the social learning theory,[31,32] empowerment-oriented counseling,[33-35] goal-setting approach,[36,37] self-efficacy and self-evaluation.[21,29]

The HAPA model (figure 2) was developed by Ralph Schwarzer (http://www.hapa-model.de/.).

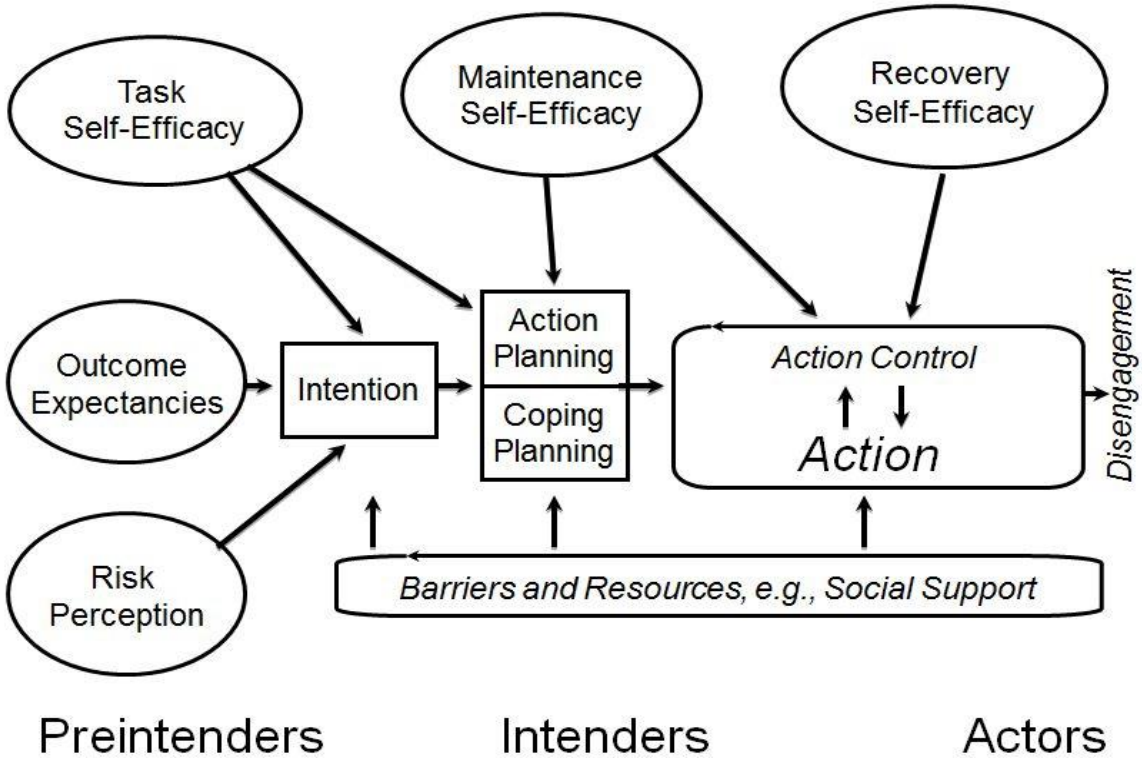

Figure 2: HAPA model

The Health Action Process Approach 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. 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 they 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 MAGDA Diabetes Prevention Program was a community-based group intervention. To ensure program fidelity, all coaches received one-day training on the content and style of the intervention as well as ongoing support. The theoretical framework for this intervention included HAPA and self-regulation theory. As consistent with population-based diabetes prevention programs [13,39] the five goals of MAGDA were weight control, reducing total energy intake, reducing fat intake to no more than 30% energy from fat, reducing saturated fat intake to no more than 10% energy from saturated fat, increasing fibre intake to at least 15g/1000 kCal, and increasing physical activity to at least 30 minutes/day of moderate intensity physical activity. The modification to adapt to a telephone delivery of the sessions in TeleMAGDA included decreasing the session duration from two hours to 30 minutes per session.

The TeleMAGDA intervention is an adaptation of the MAGDA intervention where the program structure and materials were adapted to be delivered by phone over seven sessions.[39] TeleMAGDA participants were given a handbook which covered each of the intervention goals, and homework and activities to be discussed during the telephone sessions. Apart from the first introductory session, participants could choose the order of topics to be covered in the sessions. Goal setting, barriers identification, problem solving and reflection on progress were an integral part of the program at every session. Women were also given self-monitoring diaries to track their progress.

Materials

Participant Handbook

The handbook was a self-help manual for the participants. It provided information on the study and introduced the intervention goals along with strategies to achieve them. This material helped 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 individual session. Each chapter consisted of a series of short articles which were developed specifically to engage postpartum women. The articles described 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.

Practical tips were 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 multi-tasking, make and freeze baby-friendly meals, not to worry about competing baby's developmental milestones with other mums, or making time to do something fun with partner.

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

The participant read a chapter and completed the homework and activities at the end of the chapter in preparation for the upcoming session.

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

Coach Manual

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

Participant Casebook

The casebook was a data tracking instrument to be filled in by the coaches. It collected process data, such as the attempts of calls, time and duration of calls. It also recorded personal information on the participants such as their perceived risks, previous goals, perceived barriers, which helped the coach to provide continuous care to the participants.

Delivery

The intervention was administrated by trained health care professionals. All facilitators were provided with a manual and a one-day training session by an experienced researcher in telephone-based intervention. The training included motivational interviewing skills, effective communication skills, goal setting and problem solving and role play of the telephone sessions.

After the baseline results and questionnaires were received by the research team, the participant was sent a participant handbook. Participants were asked to complete a series of seven sessions, all carried out at two week intervals, with a maximum of four weeks between sessions. Each telephone session was aimed to run for approximately 30 minutes.

Intervention goals

There have been successful implementation trials for diabetes prevention in Finland[38] and Australia.[13] Evidence-based goals used in the GGT UDRH *Life!* program, the Melbourne Diabetes Prevention Study, and the MAGDA study were used in TeleMAGDA:

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 within 12 months)

Intervention topics

The first session was about establishing the participants' reasons to be in the program and addressed their risk perception. The last session (session 7) was about maintaining the changes in the long term. Sessions 2 to 6 introduced the five intervention goals for diabetes prevention. These goals could be delivered in any order, depending on the participant's choice.

Table 1 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 was recorded and a continuous analysis kept. Program completers were defined as those women who completed five or more telephone sessions. Achievement of the five goals from changes over the length of program was measured in the study questionnaire data and the CTF.

STUDY PROCEDURES

Baseline Assessments (Time 1, T1)

- Fasting Capillary Blood Glucose reading using Glucometer (Finger Prick)
- Anthropometric measurements.
  - Height
  - Weight
  - Waist Circumference
  - Hip Circumference
- Blood Pressure (two measures one minute apart; if difference in systolic between both measures >10mmHg or diastolic >6mmHg, a third measure was taken)
- Questionnaires

Completion/Final data collection (Time 2)

After the final telephone session

- Fasting Capillary Blood Glucose reading using Glucometer (Finger Prick)
- Anthropometric measurements.
    - Weight
    - Waist Circumference
    - Hip Circumference
- Blood Pressure (two measures one minute apart, if difference in systolic between both measures >10mmHg or diastolic >6mmHg, a third measure was taken)
- Questionnaires

Data collection was conducted by the participant's GP. The participants recruited in the regional / rural area attended a local pharmacy for data collection. Participants had the option of completing the questionnaire by pen and paper, with included reply paid post envelope, email web surveys link or via the MAGDA website.

Data collection

Table 2. Schedule for Data Collection

Assessment	**Screening 1**	**Baseline (T1)**	**Follow up (T2)**
Exclusion Criteria	x	x	x
Informed Consent	x		
Results of antenatal and postnatal OGTT	x		
Capillary Fasting Glucose		x	x
Anthropometric Measurements		x	x
Blood Pressure		x	x
Demographics		x	
Health Status		x	x
Food Frequency Questionnaire		x	x
The Active Australian Questionnaire		x	x
Diet and Physical Activity self-regulation (based on the Treatment Self-Regulation 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

Feasibility and attendance data

An exit survey was conducted with all participants following their completion of the study, including those who withdrew before completion.

Attendance data were collected from the relevant casebooks.

Cost

To measure the total cost of delivering the intervention, the cost of intervention materials, personnel and time were recorded.

Health care usage of participants over the time they were involved in the program (minimum three months) was collected during the exit interview.

DATA COLLECTION

Data collection forms

Online and paper based forms were used to collect information.

The clinical measurements were recorded by the GP/pharmacist on the CTF, with questionnaires containing self-reported information. CTFs were returned to the research team via post, fax, email or MMS. Only the participant ID was recorded on all forms, with the exception of the patient demographic questionnaire SECTION A-1 which contains participants' contact details.

Web-based surveys

Health Surveys was used to develop the online questionnaire as it had been used for the Melbourne Diabetes Prevention Study and for MAGDA. The questionnaire was slightly modified from the MADGA questionnaire but retained all the same information for collection.

Only the study team had access to the data stored in the online survey. Data collected on the paper questionnaire were manually entered into Health Surveys.

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

Data management

Paper forms returned to the research assistant are stored in a locked cupboard in a locked room at Deakin University, Burwood. At the end of the data collection period, the online data were exported from Health Surveys and saved as a read-only file in the study team's share drive at Deakin University. Access is only available for the study team and is password protected.

QUALITY ASSURANCE

Data Collection

The Data Collection Forms contained easy-to-read instructions about performing data

collection alongside required measurements.

Intervention

Sessions were audio recorded for audit purposes using a uni-directional microphone. Recordings are stored securely on the research team's share drive at Deakin University.

Results

All statistical procedures were performed using SPSS Version 22. Baseline-carried-forward was used to treat missing data. Differences in characteristics, between engaged and non-engaged participants, between completers and non-completers, and the relationship between continuous outcomes and categorical demographic factors were assessed using independent sample *t*-tests. Weight change (kg) was assessed using paired *t*-tests. Levene's tests were used to assess the equality of variances between groups. If variances were significantly different between groups, *t*-tests assuming unequal variances (Satterthwaite equation) were used. Categorical variables between the groups were assessed using χ^2 tests. The relationship between continuous and continuous psycho-social variables were assessed using Pearson's correlation tests.

Qualitative data from the structured interviews were manually coded for common themes by the first author, which was reviewed by the co-author. The themes were presented as a frequency distribution. Quantitative results were presented as means with standard deviations. Statistical significance was accepted at $p < 0.05$.

Tables 3 to 9 and Figure 4 present the results of the pilot study.

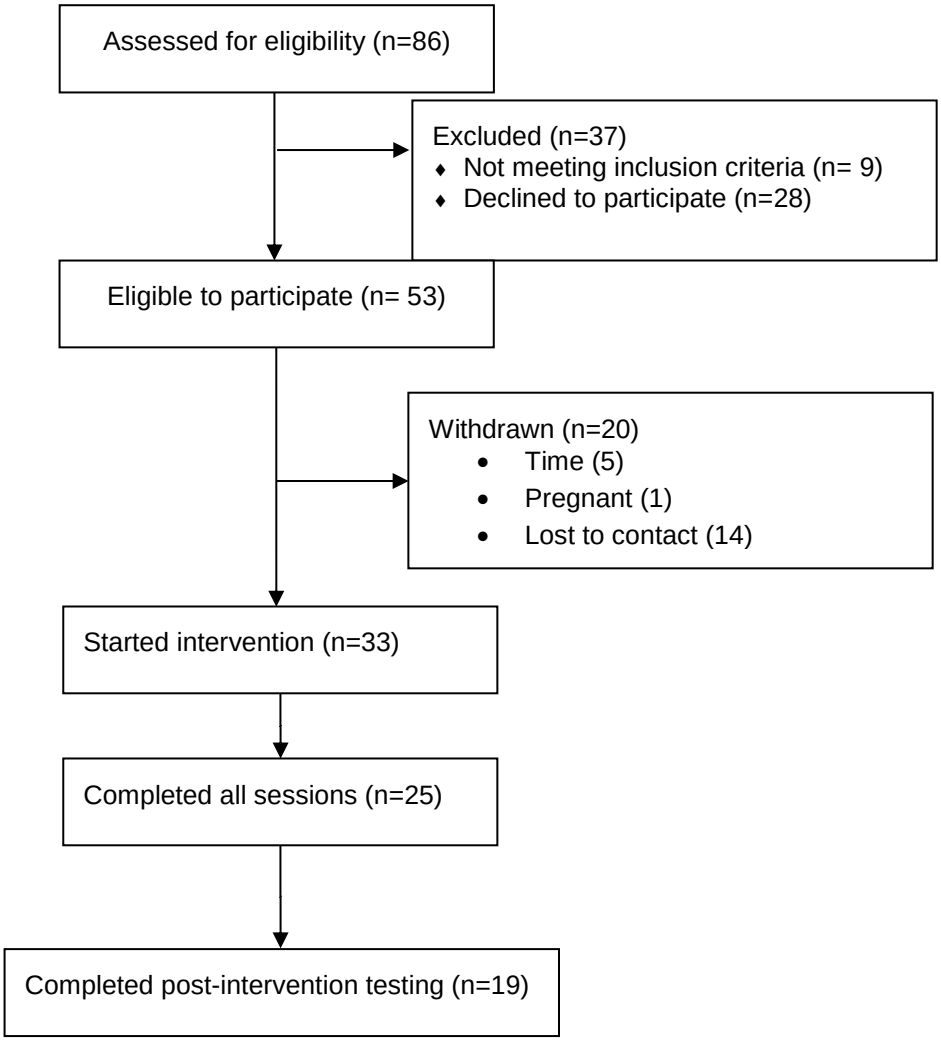

Figure 3: TeleMAGDA CONSORT Diagram

Table 3: Baseline characteristics of participants in TeleMAGDA

	Mean (SD)
Age	34.75 (4.80)
BMI	29.37 (5.96)
Fasting Blood Glucose (N=30)	4.95 (0.493)
	N (%)
Marital Status	
Married	24 (73)
Single	1 (3)
De-Facto	7 (21)
Not Recorded	1 (3)
Highest Level Of Education	
Secondary Education	2 (6)
Certificate Level	7 (21)
Diploma Level	3 (9)
Bachelor Degree	11 (33)
Masters Degree	7 (21)
Doctoral Degree	1 (3)
Not Recorded	2 (6)
Family Income Level	
Low	4 (12)
Medium	16 (49)
High	12 (36)
Country Of Birth	
Australia	18 (55)
Other	14 (42)
Not Recorded	1 (3)
Number Of Children	
1	11 (33)
2	14 (42)
3	4 (12)
4	3 (9)
Not Recorded	1 (3)

Table 4: Characteristics of postpartum women in diabetes prevention program by engagement level (completion of 7 sessions)

	Engaged (n=25)	**Non engaged (n=8)**	***p*-value**
	Mean (SD)	Mean (SD)	
Age, years	35.45 (4.21)	35.91 (6.95)	***p***=0.819
BMI, kg/m^2	27.96 (4.94)	34.41 (6.94)	***p***=0.009
Depression (PHQ9)	12.80 (3.53)	12.57 (3.41)	***p***=0.880
Quality of life (AQOL-8D)	0.77 (0.15)	0.82 (0.20)	***p***=0.543
Self-regulation (Relative autonomous score)	33.6 (16.9)	25.5 (18.3)	***p***=0.304
Social support (MSPSS)	5.98 (0.64)	5.95 (1.21)	***p***=0.944
Average session duration, minutes	26.8 (5.5)	33.8 (8.7)	***p***=0.014
Number of sessions received	7.0 (0.0)	3.1 (2.2)	***p***<0.001
Frequency of staff contact to organise each session	1.9 (0.8)	5.5 (2.9)	***p***=0.019
Time taken for staff to organise each session, minutes	3.4 (1.5)	9.0 (3.7)	***p***=0.007

Table 5: Characteristics of postpartum women in diabetes prevention program by retention (provided final measurement)

	Completers (n=19)	**Non completers (n=14)**	***p*-value**
	Mean (SD)	**Mean (SD)**	
Age, years	35.49 (4.45)	35.67 (5.61)	***p***=0.188
BMI, kg/m^2	27.21 (4.93)	32.15 (6.17)	***p***=0.017
Depression (PHQ9)	13.11 (3.84)	12.23 (2.86)	***p***=0.491
Quality of life (AQOL-8D)	0.74 (0.18)	0.84 (0.13)	***p***=0.085
Self-regulation (Relative autonomous score)	33.5 (15.8)	29.8 (19.6)	***p***=0.559
Social support (MSPSS)	5.81 (0.85)	6.24 (0.62)	***p***=0.152
Average session duration, minutes	28.03 (5.10)	28.87 (8.98)	***p***=0.763
Number of sessions received	6.9 (0.3)	4.9 (2.6)	***p***=0.003
Number of staff contact to organise each session	2.0 (0.9)	3.7 (2.9)	***p***=0.061
Time taken for staff to organise each session, minutes	3.75 (1.90)	6.00 (4.10)	***p***=0.085
Number of staff reminders to attend GP clinic	1.0 (1.3)	1.4 (1.3)	***p***=0.445

Baseline characteristics	**Mean**	**Standard deviation**
Age (n=32)	34.75	4.80
Fasting blood glucose (n=30)	4.95	0.49
Weight (n=33)	77.01	16.54
BMI (n=32)	29.37	5.96
Systolic blood pressure (n=33)	114.23	10.76
Diastolic blood pressure (n=33)	74.12	10.44
Waist (n=33)	91.18	13.79
Hip (n=33)	106.69	12.63
Waist to Hip Ratio (n=33)	0.85	0.06
Risk of developing Type 2 diabetes by 60 years of age (%) (n=28)	40.89	26.88
Modifiable component of Type 2 diabetes risk (%) (n=27)	26.59	21.51

Table 6: Session Times

	N	**Minimum**	**Maximum**	**Mean**	**Std. Deviation**
Time Contact per session (Session duration, min)	32	18.14	53.00	28.37	6.82
Time Admin per Session (Time taken to organise for each session, mins)	32	1.00	15.00	4.66	3.14
Total Time per session (Total staff time for session delivery per session), min	32	20.86	68.00	33.03	9.02
Admin Contact per Session (Contact frequency to organise each session, min	32	.86	9.33	2.42	1.74
Total Admin time (Time taken to organise sessions per participant, mins)	33	6.00	57.00	24.48	11.27
Total contact Time (Total session delivery time per participant, mins)	33	.00	243.00	166.39	59.65

	N	Minimum	Maximum	Mean	Std. Deviation
Time Admin plus Contact (Total staff time for session delivery per participant, mins)	33	6.00	277.00	190.88	64.13
Total Admin Contact (Number of contacts to organise sessions per participant, n)	33	4.00	28.00	12.79	5.85
Total No Sessions per participants (n)	33	.00	7.00	6.07	1.97
Valid N (listwise)	32				

Table 7: Intervention Topics/Chapters

Program contact time	**S1**	**Sleep**	**Weight**	**Fibre**	**Fats**	**Exercise**	**S7**	**Total**
No. of session	32	27	28	29	30	30	27	203
Total time (mins)	1349	696	721	811	780	591	543	5491
Average time per session (mins)	42.16	25.78	25.75	27.97	26.00	19.70	20.11	171.59
	Chapter covered							
Program Cost	S1	Sleep	Weight	Fibre	Fats	Exercise	S7	Total Cost
Total program cost	$1400.40	$722.72	$741.98	$842.01	$806.97	$604.42	$552.61	$5671.11
Staff time	$1222.14	$630.75	$646.70	$733.84	$703.90	$526.33	$480.86	$4945.52
Telephone	$178.26	$91.97	$95.28	$107.17	$103.07	$78.10	$71.75	$725.60
Average per participant								$177.22
Staff time								$154.55
Telephone								$22.67
Average per session	$43.76	$26.77	$26.50	$29.03	$26.90	$20.15	$20.47	

Table 8: Time/Cost Feasibility

Administration Contact Time	**No. Of Contact**	**Contact Time (Mins)**	
Total	416	809	
No. Of Participant	33	33	
Average per Participant	12.61	24.52	
Administration Cost	**Staff Time**	**Telephone Cost**	**Total Cost**
Total Cost	$ 741.84	$ 84.65	$ 826.49
No. Of Participants	33	33	33
Average per Participant	$ 22.48	$ 2.57	$ 25.05

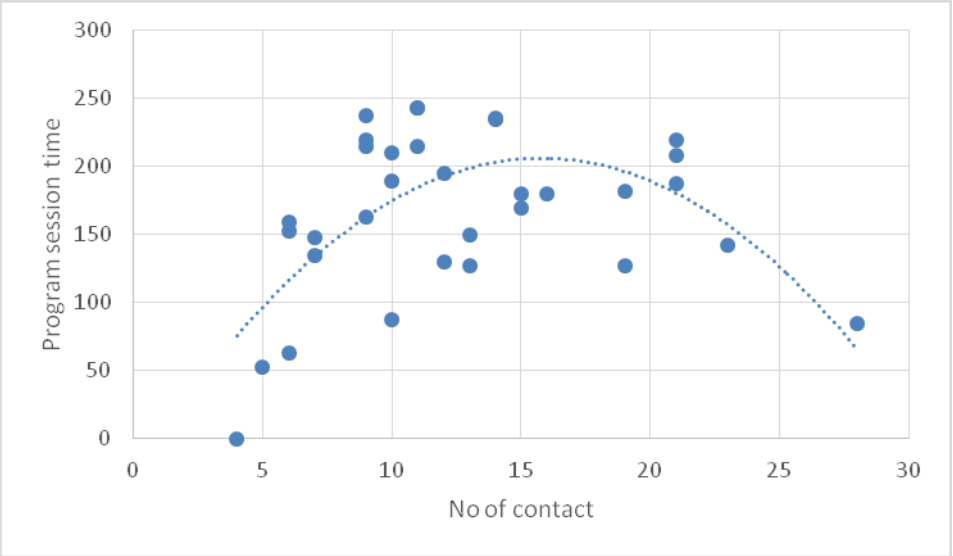

Figure 4: Relationship between reminding contact and program session time

Table 9: Preliminary efficacy

Paired *t*-tests of study outcome measures.

Outcome (unit; n)	Difference	Standard deviation	95% CI Lower	95% CI Upper	*p*-value
Weight (kg; 19)	-1.97	3.98	-3.89	-0.06	0.044*
BMI (kg/m^2; 18)	-0.82	1.68	-1.66	0.01	0.054
Waist (cm; 19)	-0.88	5.52	-3.54	1.77	0.494
Hip (cm; 19)	-2.61	2.93	-4.02	-1.19	0.001*
Waist:Hip (cm; 19)	0.13	0.05	-0.01	0.04	0.282
Systolic blood pressure (mmHg; 19)	-0.52	9.43	-5.07	4.02	0.810
Diastolic blood pressure (mmHg; 19)	4.23	11.19	-1.16	9.63	0.116
Fasting plasma glucose (mmol/l; 17)	0.19	0.65	-0.14	0.53	0.236

**Significant at α=0.05*

Proportion (%) of participants meeting the FIN DPS goals at baseline and T2.

Goal	Baseline	T2
No more than 30% energy from fat	2/30 (6.7%)	1/16 (6.2%)
No more than 10% energy from saturated fat	1/30 (3.3%)	1/16 (6.2%)
At least 15 g/1,000 kCal fibre intake	3/30 (10.0%)	3/16 (18.8%)
At least 30 minutes/day moderate intensity	15/28 (53.6%)	10/16 (62.5%)
At least a 5% reduction in body weight	N/A	4/19 (21.0%)

QUALITATIVE POST INTERVENTION

Participant responses in qualitative, post intervention telephone interviews showed that the program provided a positive experience. Particularly useful aspects, as reported by the

participants, were program accessibility and flexibility (autonomy in deciding time of calls and program topic order), participant workbooks, fortnightly goal setting, ongoing problem solving with coach support, building a relationship with coach and being accountable for the goals.

Discussion

Of the 86 women approached or who contacted the study team, 10% did not meet the eligibility criteria. A further 33% declined to participate. Of those eligible, 33 provided baseline measurements and were included in the study. Baseline characteristics of the participants are presented in Table 3.

ACCEPTABILITY

Almost all women (90%) found the program to be an overall positive experience, particularly in their interactions with the coaches. The most cited aspects of the program considered most useful in helping behavioural change were information in the handbook (37%), the goal setting component of the intervention (30%), and accountability to the coaches (17%). The most cited favourite aspect of the intervention was the telephone sessions (53%), followed by accountability (30%) and receiving support and motivation (27%).

All but one participant saw the telephone intervention as the best fit with their lives, mainly due to accessibility and childcare needs. Telephone was also the preferred option when compared with the internet by many participants (37%). Some (30%) suggested at least one or two face-to-face group sessions, mainly for peer interactions.

The use of the internet was perceived to be a less effective form of communication, and being less engaging. This was also apparent with regard to the online questionnaires, particularly the post intervention follow up questionnaires, which were only completed by 58% of participants.

Data collection proved more difficult, and required numerous reminders and 'nagging' from the research team to visit GP and to complete online surveys, more so at follow up. However, baseline measurements were completed as these were required before participants commenced the program.

The website and forum were not found to be used by the participants, with 60% not visiting the website and only 17% posting questions/comments on the website forum.

FEASIBILITY

The average duration of each session was 28±7 minutes. On average, each session was costed at $28 per participant, which included staff time and the cost of telephone calls. The average cost of the program for each participant was $177 and an additional $25 was spent on organising the sessions. The total program cost for all participants was $5671, of which $4945 was the staff time and $726 was the cost of the telephone calls, with additional $826 involved in organising sessions.

The overall cost effectiveness of the program was not able to be determined as a control group was not included in this pilot study nor a proxy control in usual care to act as a comparison. Whether the intervention reduces participant's health care resource usage was not able to be determined.

Pushing low interest participants by putting more effort in encouraging them to complete the intervention did not help nor was it feasible. More reminding, by means of phone calls, SMS and email, and rescheduling, was required, but did not help to improve their exposure to the program. On average it took 13 scheduling contacts (telephone call, SMS or email) to deliver six sessions. Each participant was contacted 2.7±2.1 times (range 0.9-10.0) to schedule for each session, or a total of 13.9±6.1 times (range 4-28) to schedule sessions for the entire program. It took 4.7±3.1 min (range 1-15mins) to organise one session for each participant, or a total of 24.5±11.3 (range 6-57) minutes for the entire program per participant.

Aside from the first session which were nearly double in duration compared to all the other sessions, there was no time-trend on increasing or decreasing staff time per session (including time to organise sessions) from the first to the last session.

Only 15% required intervention sessions out-of-hours (after 5pm calls). A total of 47% of the

sessions were delivered between 8:30am and 1pm, 38% were delivered between 1pm to 5pm. Almost all sessions (97%, 199/205) were delivered on weekdays.

PARTICIPATION RATE

Of the 33 women recruited, 23 (70%) completed the program and 10 discontinued. Attendance to the program was high with 87% of participants receiving the program as scheduled. A total of 76% completed all seven sessions, with 82% completing at least six sessions. Attendance was well sustained throughout the intervention, from 97% attendance at Session 1 to 81% at Session 7.

Engaged participants had lower BMI (28.0±4.9 vs 34.4±6.9 kg/m^2, p=0.009), shorter session duration (26.8±5.5 vs 33.8±8.7 mins, p=0.014) and received less staff contact to organize each session (1.9±0.8 vs 5.5±2.9 contacts per session, p=0.019).

With engagement effort defined as the total time taken to organise each session, those without a university degree required greater effort to engage (5.8±3.2 vs 3.5±1.5 minutes per session, p=0.014). Higher BMI was also associated with greater engagement effort (r=0.45, p=0.011). High engagement effort were significantly correlated with less sessions completed (r=-0.802, p<0.001).

There was no significant relationship between engagement effort and age, household income, education level, number of children, self-regulation, perceived social support, depression and quality of life.

Engaged and non-engaged participants did not differ in age, country of birth, household income, level of education, number of children, depression, quality of life, self-regulation, and social support.

BARRIERS TO PARTICIPATION (REASONS FOR NON-PARTICIPATION)

Of those declining to participate in study at initial contact, refusal reasons included time, work, belief that they were not at risk and that their lifestyle is already healthy.

The most common perceived barrier to the participating in the telephone coaching sessions included time constraints (27%), difficulty with childcare commitments (20%) and difficulty getting motivated (13%).

ATTRITION RATE

All 33 participants provided baseline clinical data from the GP clinic, but only 19 (58%) provided the final measurements from the GP clinic.

With completers defined as those who provided the final body weight at the GP clinic. completers had lower BMI (27.21±4.45 vs 32.15±6.17, p=0.017) and received more sessions (6.9±0.3 vs 3.7±2.9, p=0.003). There was a trend for participants born outside of Australia being more likely to complete the final measurements compared to those born in Australia (79% vs 44%, χ^2=3.802, df=1, p=0.05).

Non completers had more reminders to attend GP clinic appointment, and received more staff contact to organise each phone sessions. Completers and non-completers did not differ in age, household income, education level, number of children, self-regulation, perceived social support, depression and quality of life. The small number of participants in this pilot prevents sub-group analyses to determine the effects of participant factors on engagement. However, the intervention attendance and engagement rates in this telephone-based lifestyle-modification program were much higher than in the MAGDA face-to-face, group-based program.

Conclusion

Group-based lifestyle-modification programs have been shown to be effective in delaying the progression to T2DM for the older population. This is not the case for post-partum women who had GDM during pregnancy, due to barriers for attendance, such as childcare and travel. It is also difficult to address individual needs in a group setting. Telephone-based interventions, however, can address these difficulties. TeleMAGDA examined whether a telephone-based intervention was feasible and acceptable to postpartum mothers.

TeleMAGDA showed a strong fidelity to the program, with three quarters of participants completing all seven sessions. Almost all participants found that the program was a positive experience, with the telephone intervention giving the best fit to their lives. Telephone delivery is also a relatively inexpensive way of delivering a lifestyle-modification program, provided that participants have a strong interest in completing the full program.

TeleMAGDA showed that delivering a diabetes-prevention program by telephone to postpartum women with a history of GDM is both feasible and acceptable, but the effectiveness of that program in reducing diabetes risk factors was not able to be determined due to the small sample size of the pilot. Further studies will be required.

References

1. AIHW. How common is diabetes [Internet] Canberra: Australian Institute of Health and Welfare [updated 20131/9/2014]. Available from: http://www.aihw.gov.au/how-common- is-diabetes/.

2. Cowie CC, Rust KF, Byrd-Holt DD, Eberhardt MS, Flegal KM, Engelgau MM, et al. Prevalence of diabetes and impaired fasting glucose in adults in the U.S. population: National Health And Nutrition Examination Survey 1999-2002. Diabetes Care. 2006 Jun;29(6):1263-8.

3. Soriguer F, Goday A, Bosch-Comas A, Bordiu E, Calle-Pascual A, Carmena R, et al. Prevalence of diabetes mellitus and impaired glucose regulation in Spain: the Di@bet.es Study. Diabetologia. 2012 Jan;55(1):88-93.

4. Dunstan DW, Zimmet PZ, Welborn TA, De Courten MP, Cameron AJ, Sicree RA, et al. The rising prevalence of diabetes and impaired glucose tolerance: the Australian Diabetes, Obesity and Lifestyle Study. Diabetes Care. 2002 May;25(5):829-34.

5. AIHW. Diabetes impacts [Internet] Canberra: Australian Institute of Health and Welfare; [updated 20131/9/2014]. Available from: http://www.aihw.gov.au/diabetes/impacts/#exp.

6. Goss J. Projection of Australian health care expenditure by disease, 2003 to 2033. Canberra: Australia Institute of Health and Welfare, 2008 Cat. no. HWE 43.

7. American Diabetes A. Diagnosis and classification of diabetes mellitus. Diabetes Care. 2012 Jan;35 Suppl 1:S64-71.

8. Moses RG, Morris GJ, Petocz P, San Gil F, Garg D. The impact of potential new diagnostic criteria on the prevalence of gestational diabetes mellitus in Australia. Med J Aust. 2011 Apr 4;194(7):338-40.

9. Wendland EM, Torloni MR, Falavigna M, Trujillo J, Dode MA, Campos MA, et al. Gestational diabetes and pregnancy outcomes--a systematic review of the World Health Organization (WHO) and the International Association of Diabetes in Pregnancy Study Groups (IADPSG) diagnostic criteria. BMC Pregnancy Childbirth. 2012;12:23.

10. Vrachnis N, Antonakopoulos N, Iliodromiti Z, Dafopoulos K, Siristatidis C, Pappa KI, et al. Impact of maternal diabetes on epigenetic modifications leading to diseases in the offspring. Exp Diabetes Res. 2012;2012:538474.

11. Kim C, Berger DK, Chamany S. Recurrence of gestational diabetes mellitus: a systematic review. Diabetes Care. 2007 May;30(5):1314-9.

12. Knowler WC, Barrett-Connor E, Fowler SE, Hamman RF, Lachin JM, Walker EA, et al. Reduction in the incidence of type 2 diabetes with lifestyle intervention or metformin. NEJM. 2002 Feb 7;346(6):393-403.

13. Laatikainen T, Dunbar JA, Chapman A, Kilkkinen A, Vartiainen E, Heistaro S, et al. Prevention of type 2 diabetes by lifestyle intervention in an Australian primary health care setting: Greater Green Triangle (GGT) Diabetes Prevention Project. BMC Public Health. 2007;7:249.

14. Ratner RE, Christophi CA, Metzger BE, Dabelea D, Bennett PH, Pi-Sunyer X, et al. Prevention of diabetes in women with a history of gestational diabetes: effects of metformin and lifestyle interventions. JCEM. 2008 Dec;93(12):4774-9.

15. Lie ML, Hayes L, Lewis-Barned NJ, May C, White M, Bell R. Preventing type 2 diabetes after gestational diabetes: women's experiences and implications for diabetes prevention interventions. Diabet Med. 2013; 30: 986-93.

16. Lim SS, Norman RJ, Clifton PM, Noakes M. Weight Loss and Attrition in Overweight and Obese Young Women During a 36- Week Internet-Based Lifestyle Intervention. Journal of Obesity & Weight Loss Therapy. 2014; 4: 235.

17. Toth-Capelli KM, Brawer R, Plumb J, Daskalakis C. Stage of change and other

predictors of participant retention in a behavioral weight management program in primary care. Health Promot Pract. 2013; 14: 441-50.

18. Østbye T, Krause KM, Lovelady CA, et al. Active Mothers Postpartum: a randomized controlled weight-loss intervention trial. American journal of preventive medicine: 2009; 173-80.

19. Nitzsche N, Schulz H. On the feasibility of a regular training with the Wii Fit Plus in women after pregnancy. Journal fur Gynakologische Endokrinologie. 2010; 20: 12-16.

20. O'Toole ML, Sawicki MA, Artal R. Structured diet and physical activity prevent postpartum weight retention. Journal of Women's Health (15409996). 2003; 12: 991-98.

21. Kinnunen TI, Pasanen M, Aittasalo M, Fogelholm M, Weiderpass E, Luoto R. Reducing postpartum weight retention - A pilot trial in primary health care. Nutrition Journal. 2007; 6.

22. Norman E, Sherburn M, Osborne RH, Galea MP. An exercise and education program improves well-being of new mothers: a randomized controlled trial. Physical Therapy. 2010; 90: 348-55.

23. Dunbar JA, Jayawardena A, Johnson G, Roger K, Timoshanko A, Versace VL, Shill J, Philpot B, Vartiainen E, Laatikainen T, Best JD, Janus ED.Scaling up diabetes prevention in Victoria, Australia: policy development, implementation, and evaluation. Diabetes Care. 2014 Apr;37(4):934-42.

24. Goode AD, Reeves MM, Eakin EG. Telephone-delivered interventions for physical activity and dietary behavior change: an updated systematic review. Am J Prev Med. 2012 Jan;42(1):81-8.

25. O'Hara BJ, Phongsavan P, Venugopal K, Eakin EG, Eggins D, Caterson H, King L, Allman-Farinelli M, Haas M, Bauman AE. Effectiveness of Australia's Get Healthy Information and Coaching Service®: translational research with population wide impact. Prev Med. 2012 Oct;55(4):292-8.

26. Eakin EG, Winkler EA, Dunstan DW, Healy GN, Owen N, Marshall AM, Graves N, Reeves MM. Living well with diabetes: 24-month outcomes from a randomized trial of telephone-delivered weight loss and physical activity intervention to improve glycemic control. Diabetes Care. 2014 Aug;37(8):2177-85.

27. Nicklas JM, Zera CA, Seely EW, Abdul-Rahim ZS, Rudloff ND, Levkoff SE. Identifying postpartum intervention approaches to prevent type 2 diabetes in women with a history of gestational diabetes. BMC Pregnancy Childbirth. 2011;11:23.

28. Graves N, Barnett AG, Halton KA, Veerman JL, Winkler E, Owen N, et al. Cost-effectiveness of a telephone-delivered intervention for physical activity and diet. PloS one. 2009;4(9):e7135.

29 Schwartz R. Self-efficacy: Thought,control and action. Washington, DC: Hemisphere, 1992.

30. Schwaezer R, Fuchs R. Self-efficacy and health behaviours. Predicting health behaviour: research and practice with social cognition models. Buckingham, UK: Open University Press, 1996.

31. Bandura A. Social foundation of thought and action: A social cognitive theory. Englewood Cliffs, NJ: Prentice-Hall, 1986.

32. Bandura A. Self-efficacy: The exercise of control. New York: Freeman; 1997.

33. Feste C, Anderson RM. Empowerment: from philosophy to practice. Pat Edu Counsel. 1995 Sep;26(1-3):139-44.

34. Prochaska JO, Velicer WF. The transtheoretical model of health behavior change. AJHP. 1997 Sep-Oct;12(1):38-48.

35. Rappaport J. Terms of empowerment/exemplars of prevention: toward a theory for

community psychology. Am J Com Psychol. 1987 Apr;15(2):121-48.

36. Funnell MM, Anderson RM. Patient empowerment: a look back, a look ahead. The Diabetes Edu. 2003 May-Jun;29(3):454-8, 60, 62.

37. Oettingen G, Hönig G, Gollwitzer PM. Effective self-regulation of goal attainment. Int J Edu Res. 2000;33(7-8):705-32.

38. Tuomilehto J, Lindström J, Eriksson JG, Valle TT, Hämäläinen H, Ilanne-Parikka P, Keinänen-Kiukaanniemi S, Laakso M, Louheranta A, Rastas M, Salminen V, Uusitupa M; Finnish Diabetes Prevention Study Group. Prevention of type 2 diabetes mellitus by changes in lifestyle among subjects with impaired glucose tolerance. N Engl J Med. 2001 May 3;344(18):1343-50.

39. Shih ST, Davis-Lameloise N, Janus ED, et al. Mothers After Gestational Diabetes in Australia Diabetes Prevention Program (MAGDA-DPP) post-natal intervention: study protocol for a randomized controlled trial. Trials. 2013; 14: 339.