

Development of the Blooming Together Program – A comprehensive model of maternity care incorporating evidence based behavioural change strategies for women with obesity to achieve a healthy pregnancy weight

Final Research Report

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Table of Contents

Ex	ecu	utive	Sum	mary	i		
Αd	ckn	owle	edgen	nents	iv		
Αl	br	evia [.]	tions	and Attachments	v		
G	ove	rnar	nce st	ructures	. vii		
O	ver	view	of th	nis report	viii		
1		Intr	oduct	tion	1		
	1.1		Ove	Overall aim of the Research			
	1.2		Objectives				
	1.3	3	Polic	Policy context			
	1.4	4	Impe	etus for the Research	2		
2	Literature Review						
				issue of maternal obesity			
	2.2			ling maternal obesity			
	2.3	2.3 Rev		ew of antenatal interventions to limit GWG	8		
	2.3.1		1	Reviews and meta-analyses of available data	8		
	2.4	4	Criti	cal appraisal of the literature	9		
		2.4.	1	Approach	9		
		2.4.	2	Criteria	9		
	2.4		3	Critique of interventions	. 12		
		2.4.	4	Summary of critique of interventions	. 15		
3	Method			ology	. 17		
	3.2	1	Pre-	Consultation Phase	. 17		
		3.1.	1	Recruitment	. 17		
		3.1.	2	Data collection	. 18		
	3.2	2	Deve	elopment Phase	. 19		
	3.3	3	Cons	sultation Phase	. 19		
		3.3.	1	Recruitment	. 19		
	3.3.2		2	Data collection	21		
	3.4 Ref		Refir	nement Phase	21		
	3.4		1	Health care providers' feedback on Participant Guide	22		
		3.4.	2	Target group feedback on Participant Guide	22		
4	Results				24		
	4.2	1	Pre-	Consultation Phase	24		
		4.1.	1	Results: Sample	24		
		4.1.	2	Results: Focus groups with CRG	24		
	4.1.3		3	Output of Pre-consultation Phase	. 29		

	4.2	2 [Development Phase	29					
		4.2.1	Results: Sample	29					
		4.2.2	Results: Written feedback from CRG	29					
		4.2.3	Output of the Development Phase	30					
	4.3	3 (Consultation Phase	30					
		4.3.1	Results: Sample	30					
		4.3.2	Results: Post-session focus groups	32					
		4.3.3	Results: Post-session evaluation survey	33					
		4.3.4	Outputs of Consultation Phase	34					
	4.4	l f	Refinement Phase	34					
		4.4.1	Sample: Target group feedback on Participant Guide	35					
		4.4.2	Results: Target group feedback on Participant Guide	35					
		4.4.3	Sample: Health care provider feedback	38					
		4.4.4	Results: Health care provider feedback	38					
5		Proje	ct Outputs	41					
	5.1	L E	Blooming Together Program	41					
	5.2 Par		Participant Guide	43					
	5.3	3 1	Facilitator Guide	43					
	5.4	1 1	Program branding	43					
6		Discu	ission	45					
7		Future Research: Blooming Together Program Pilot and Trial51							
8		References							

Executive Summary

Why was this research done?

The maternity system is seeing increasing numbers of pregnant women with obesity. This is a consequence of more women of childbearing age being overweight or obese. This population is at a greater risk of adverse obstetric and neonatal outcomes (including gestational diabetes, hypertension, pre-term birth, macrosomia, shoulder dystocia) compared with normal weight pregnant women. The situation is compounded by these women becoming progressively more overweight with each subsequent pregnancy due to excessive gestational weight gain (GWG) and unsuccessful weight loss inter-pregnancy. This research addresses a gap in service delivery for pregnant women with obesity at King Edward Memorial Hospital (KEMH) as well as in secondary hospital settings and the community; with the aim of supporting these women to achieve a healthy pregnancy weight and reducing obstetric and neonatal complications.

What were the aims of the research?

The primary aim of this research project was to develop an acceptable maternity model of care for obese women incorporating evidence based behavioural change strategies to achieve a healthy pregnancy weight.

How was this research done?

A comprehensive literature review was conducted to provide an evidence base for the development of the model of care. This was followed by the formation of a Consumer Reference Group (CRG). The membership of the CRG included fourteen (14) obese women who received their antenatal care at King Edward Memorial Hospital (KEMH) in Perth Western Australia. The purpose of the CRG was to ensure that the project was overseen by representatives of the target group and that the final product of the research was aligned with the needs of this group.

Two (2) focus groups were conducted with the CRG: one in the north metropolitan area of Perth (n=6) and the other in the south metropolitan area (n=8). The participants were asked to comment on and discuss their previous experiences of maternity care, their knowledge, understanding and attitudes regarding healthy lifestyles and Body Mass Index (BMI); as well as suggestions for ways that a model of maternity care could help them to achieve a healthy pregnancy weight.

The results of the focus groups and the literature review were used to draft the content for the model of care. This draft content was then sent back to the CRG for further comment to ensure that what was discussed in the focus groups was accurately reflected in the draft model of care. The draft program content was then divided into five (5) separate "sessions" reflecting different stages of pregnancy. These sessions were as follows: Session one at 19-21 weeks gestation; Session two at 24-26 weeks gestation; Session three at 28-30 weeks gestation; Session four at 34-36 weeks gestation; and Session six at 6-8 weeks postnatal. The CRG named the maternity model of care 'Blooming Together'.

Each of the five (5) individual sessions was trialled and re-trialled with participants who were recruited from KEMH. The sessions were facilitated by a Clinical Midwife and a Dietitian. A total of 40 women attended one or more of the trial sessions. Most of these women attended one session only while some attended one antenatal session and the postnatal session. At the completion of each of the sessions participants were asked to fill out a self-administered questionnaire and to participate in a focus group to provide feedback on the session. Each of the sessions were amended and re-trialled with a different group of women.

Feedback from the session trial and retrials resulted in the preparation of the draft Participant Guide for the Blooming Together Program. This Guide was then circulated to relevant health care providers (a total of 14 across a number of disciplines including Dietetics, General Practice, Obstetrics, Midwifery, Psychology, Exercise Physiology, and Physiotherapy) and interested members of the CRG and participants who had attended at least one session (a total of 9 women). This feedback was incorporated into the final Participant Guide and an accompanying resource, the Facilitator Guide was also produced.

What did this research find?

The feedback from the CRG and from participants of the session trials provides overwhelming evidence of the importance of the provision of a tailored maternity model of care for pregnant women with obesity.

The CRG focus groups revealed a complex relationship between these women and their weight. The CRG reported low satisfaction with the care they had received previously at KEMH. This was a result of feeling that they were provided with insufficient support and little practical information to help them to achieve a healthy pregnancy weight. Some reported that the care they had received undermined their motivation to achieve a healthy pregnancy weight. Overall, the CRG reported that the approach of health professionals at KEMH during their maternity care could make them feel defensive, unsupported, upset and/or angry. It is well documented in

the literature that health care providers feel limited in their ability to provide tailored lifestyle education due to time constraints, and a lack confidence in delivering this information particularly to patients who are obese.

The focus groups and interviews with the target group showed a high level of acceptability of the Blooming Together Program, both the content and group format. Participants reported that being surrounded by peers considered in 'the same boat' contributed to their level of comfort and receptiveness to the key messages of the program. The participants valued sharing their experiences with the group and learnt from hearing about other's experiences. They also reported an increased level of confidence in making changes to their behaviour as a result of hearing about peers' successes.

The positive response of the participants in regard to continuity of care was consistent with the literature. The participants felt having the same health care providers throughout their care encouraged more personal accountability and thus motivation for behavioural change. In addition, the individual strategies that made up the program such as ongoing goal-setting and tracking of pregnancy weight was seen as important to the women in terms of their own accountability to achieving a healthy pregnancy weight.

The feedback from the CRG and other the value of conducting honest and open discussion around BMI, explaining in detail how healthy pregnancy recommendations came about and how these relate to prepregnancy BMI.

Overall the research findings reinforced the importance of a comprehensive maternity model of care designed specifically for obese women to support the achievement of a healthy pregnancy weight.

What were the outputs of the research?

The major output of this research was the development of the Blooming Together Program (BT Program). The BT Program is a group-delivered maternity model of care incorporating evidence-based behavioural change strategies to achieve a healthy pregnancy weight. It has been designed within a continuity of care model to provide obese pregnant woman with a comprehensive antenatal model of care.

The BT Program is delivered as eight (8) group sessions and one-on-one appointments at 16 weeks and from 37 weeks to birth (following the routine antenatal care schedule). The sessions are run by two midwives and a dietitian: one midwife and one dietitian to facilitate the group lifestyle education component and another midwife to conduct the antenatal check-up during the session. Some sessions will also have a visiting Physiotherapist or Lactation Consultant. The participants will receive medical consultation where indicated.

Each session provides discussion and activities relevant to the gestation of the women and based on evidence from the medical, dietetic, psychological and exercise physiology literature. The BT Program is supported by a Participant Guide, a draft Facilitator Guide and a number of supporting resources.

Acknowledgements

This project has been undertaken by the Collaboration for Applied Research and Evaluation at the Telethon Institute for Child Health Research with the support of the Women's and Newborns' Health Network and Women and Newborn Health Service.

First and foremost, acknowledgement goes to our Consumer Reference Group (CRG) who freely gave their time, energy and enthusiasm; and who contributed greatly to the development of the major output of this project: the Blooming Together Program. Special thanks also to all the women who participated in our session trials and provided valuable feedback, insight and recommendations to ensure that the Program meets the needs of our target group. Furthermore, thanks goes to the project steering committee who gave their time to provide expert guidance on the research plan and progress.

Acknowledgement also goes to Tanyana Jackiewicz (Manager, Collaboration for Applied Research and Evaluation) for her wise guidance and editorial assistance.

Abbreviations and Attachments

Abbreviations

BMI = Body Mass Index

BLOOM = Better Lifestyle and Obstetric Outcomes for Mothers (BLOOM) Program

BT Program = Blooming Together Program

KEMH = King Edward Memorial Hospital

HCP = Health Care Provider

GWG = Gestational Weight Gain

GP = General Practitioner

HPW = Healthy Pregnancy Weight

PW = Pregnancy Weight

WNHS = Women and Newborn Health Service

List of Attachments

Attachment 1: Critical analysis of the literature (table)

Attachment 2: WNHS Low Risk Midwives Clinic with Medical Consultation Clinical Guidelines 1.1.2.2

Attachment 3: Consumer Reference Group recruitment - Confirmation letter

a) North CRGb) South CRG

Attachment 4: Consumer Reference Group focus group instrument

Attachment 5: Consumer Reference Group draft program content feedback instrument

Attachment 6: Consultation Phase recruitment tools

a) Invitation letter

b) Project information sheet

Attachment 7: Consultation Phase confirmation letter

Attachment 8: Post-trial evaluation survey instrument

a) Session 1b) Session 2c) Session 3d) Session 4

Attachment 9: Post-trial focus group instruments

a) Session 1b) Session 2d) Session 4e) Session 5

c) Session 3

Participant Guide Attachment 11: **Facilitator Guide** Attachment 12: Health care provider feedback instruction sheet Attachment 13: Trial participant and CRG feedback on Participant Guide feedback instrument Attachment 14: Participant Guide interview instrument

Attachment 15: Pregnancy weight tracker

Attachment 10:

Attachment 16: Blooming Together brand identity design brief

Attachment 17: Blooming Together brand identity components

> a) Participant Guide cover page e) Session cover pages

b) Facilitator Guide cover page f) Letterhead

c) Introductory information cover page g) PowerPoint template

d) Contents page

Governance structures

Steering Committee

A Project Steering Committee was established to guide the research. Membership of the Committee included Professor Yvonne Hauck (Curtin University, Women and Newborn Health Service [WNHS]), Ms Anne Rae (King Edward Memorial Hospital [KEMH]), Ms Hanna Burbidge (KEMH), Mr Kim Clark (TICHR), Ms Barbara Lourey (KEMH), Dr Lisa Gibson (TICHR) and Ms Tanyana Jackiewicz (TICHR). The Project Managers, Ms Anna Fletcher (Senior Research Officer, TICHR and Dietitian, KEMH) and Ms Joan Jones (Clinical Midwife and Midwife Educator, KEMH) met regularly with the Steering Committee to discuss and assess project process, progress, and review documents.

Consumer Reference Group (CRG)

A consumer reference group (CRG) was formed to help guide the development of the program content and format. Please refer to subsequent discussion on the CRG.

Ethics

This project was granted ethics approval from the Women and Newborn Health Service Ethics Committee on 4 October 2011.

Overview of this report

This report provides a description of a qualitative research process that led to the development of the Blooming Together Program (BT Program). This included establishment of a consumer reference group (CRG), recruitment of pregnant women with obesity to provide feedback on the program; the trialling of sessions, the conduct of focus groups and interviews with session trial participants and CRG members; and the input of health care providers (HCPs) involved in delivering maternity care to obese women.

This report has seven sections. Section 1 provides an overview of the guiding aims and objectives of the research, and sets the scene and context in which the research was conducted. This is then followed in Section 2 with a critical analysis of the evidence base that guided the development of the BT Program. Section 3 provides a summary of the methodology used in informing the development of the BT Program that includes the following phases also presented in figure 1.1:

- Pre-Consultation Phase that involved the formation of and consultation with a Consumer
 Reference Group (CRG). The membership of the CRG included obese women who received their
 antenatal care at King Edward Memorial Hospital (KEMH). The purpose of forming the CRG was
 to ensure that the project was overseen by representatives of the target group and that the final
 product of the research was aligned with the needs of this group.
- Development Phase that involved the consolidation of information from the literature review (the evidence base) and the pre-consultation phase which led to the development of a draft program (session content).
- Consultation Phase that involved the trialling of the session content as five (5) group sessions with members of the target group.
- Refinement Phase that involved the production of the complete Blooming Together Program
 (known as the Participant Guide) and seeking feedback from the CRG, trial participants and HCPs
 as to the content, appropriateness and usefulness of the Program. A supportive resource (the
 Facilitator Guide) was also drafted. The Guides will be finalised following the pilot of the
 program in its entirety in the next phase of the research for which funding is being sought.

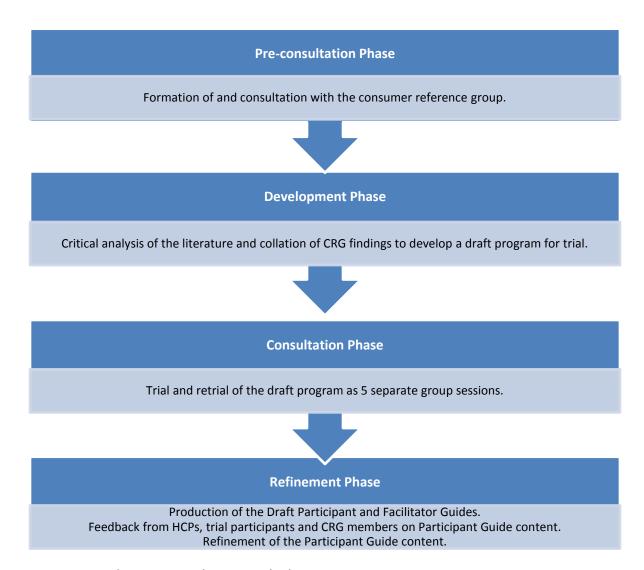


Figure 1.1: Blooming Together research phases.

Section 4 details the results of each of the phases of the research whilst Section 5 includes a complete list of all the outputs as a result of this research. Section 6 then provides a discussion on the outcomes of the research and this is followed by a brief discussion on the future piloting and trial of the complete BT Program in Section 7.

1 Introduction

The maternity system is seeing increasing numbers of pregnant women with obesity. This is a consequence of more women of childbearing age being overweight or obese. This population are at a greater risk of adverse obstetric and neonatal outcomes (including gestational diabetes, hypertension, pre-term birth, macrosomia, shoulder dystocia) compared with normal weight pregnant women [1]. This situation is compounded by these women becoming progressively more overweight with each subsequent pregnancy due to excessive gestational weight gain (GWG) and unsuccessful weight loss inter-pregnancy. There is emerging evidence that maternal obesity and large GWG can have an impact on the health of the fetus with lasting effects into childhood and adulthood [1].

1.1 Overall aim of the Research

The aim of this project was to develop a comprehensive model of maternity care incorporating evidence based behavioural change strategies to support obese women to achieve the healthiest weight possible for their pre-pregnancy BMI. For the purpose of this research, the healthiest weight possible is referred to as a 'Healthy Pregnancy Weight' (HPW).

1.2 Objectives

The following objectives guided the project:

- [1] To undertake a comprehensive literature review on obesity in pregnancy with a focus on antenatal interventions that aim to address the management of maternal obesity.
- [2] To consult with pregnant women with obesity on the appropriate approach and content of a program that addresses HPW for women who are obese.
- [3] To design a draft program based on the first two objectives.
- [4] To trial the components of the draft BT Program (session content) with pregnant women with obesity to determine acceptable program content and delivery.
- [5] To consult with pregnant women with obesity and health care providers (HCPs) on the draft BT Participant Guide.
- [6] To develop a draft Facilitator Guide to support the delivery of the BT Program.

1.3 Policy context

This research project was funded by the Western Australian Department of Health with the support of the Women's and Newborns' Health Network (WNHN).

The Project is in-line with the key action areas as identified in the National Preventative Health Strategy [2]. These include addressing maternal and child health, enhancing early life and growth patterns and strengthening the ability of the primary healthcare workforces to support people making healthy choices.

This project also progresses a number of the strategic objectives of the Western Australian Health Promotion Strategic Framework [3]. Addressing the issue of obesity in pregnancy is in-line with the objectives of "eating for better health", "a more active WA", and "maintaining a healthy weight'.

The Program developed as part of this research also addresses the following goals outlined in the policy framework provided by the Improving Maternity Services: Working Together Across Western Australia report [4]:

- Improve the health and wellbeing of women and their unborn babies through better preconception and early pregnancy care;
- Improve women's experience of pregnancy primarily through continuity of carer, a collaborative team approach, some community-based care and providing consistent evidence-based information; and
- Better inform women of the benefits of breastfeeding whilst supporting mothers in their chosen mode of infant feeding.

1.4 Impetus for the Research

This research addresses a gap in service delivery for pregnant women with obesity both at KEMH as well as in secondary hospital settings and the community. The current environment at KEMH (defined by competing resources, later booking appointments due to extended care by community GPs and difficulties in providing comprehensive dietetics follow-up) makes the existing programs (as described below) limited in their effectiveness in managing the weight of obese women in pregnancy. Furthermore, there is neither a team nor a consistent approach to maternal obesity at KEMH which means that messages and behaviours in regard to healthy pregnancy weight are not reinforced. This lack of dedicated coordinated care pathways for pregnant women with obesity in both tertiary and secondary hospital settings has provided the impetus to investigate alternate ways of delivering maternity care for this target group that addresses HPW.

The environment that led to the framing of this project included the following characteristics of maternity care for pregnant women with obesity in Western Australia:

- Most pregnant women classified as category II and III obese (BMI of ≥35kg/m²) are referred to KEMH for specialised maternity care (since this research project commenced regional hospitals have increased their capacity to birth women up to a BMI of 45kg/m² and hence, although King Edward Memorial Hospital, as a tertiary maternity hospital will continue to see women with complicated pregnancies, more women with high BMIs are now able to receive their maternity care at secondary hospitals).
- In 2011/12 class II and III pregnant women with obesity represented 24% of all women who deliver at KEMH (Refer to Table 1.1).

30.00 % of pregnant women with BMI > 35 kg/m 2 24.03 25.00 22.62 21.46 21.10 19.24 20.00 16.77 16.44 15.00 10.00 5.00 0.00 2005/2006 2006/2007 2007/2008 2008/2009 2009/2010 2010/2011 2011/2012 **Financial Year**

Table 1.1 Percentage of pregnant women delivering at KEMH with a BMI > 35 kg/m² from 2005-2012

Source: KEMH STORK database

• Obese women who receive their maternity care at KEMH are currently offered the Better Lifestyle and Obstetric Outcomes for Mothers (BLOOM) program. The BLOOM program includes an initial 45 minute consultation with a Dietitian which occurs at their booking antenatal appointment if possible or later (if less than 36 weeks gestation). This consultation involves a detailed diet history and provision of the BLOOM lifestyle information with some follow-up provided where possible and indicated. The women are also directed to additional information

online. The BLOOM resources are freely available online and are used by HCPs across Western Australia and are well-regarded by both patients and HCPs.

Please note: BLOOM is the existing maternal obesity management program currently run at KEMH; Blooming Together (BT) is the program that has been developed as a result of this research.

2 Literature Review

2.1 The issue of maternal obesity

The prevalence of overweight and obesity in the Australian population has steadily increased over time from 56.3% of adults in 1995, 61.2% in 2007–08 and 62.8% in 2011-12 [5]. Of particular concern is the increasing numbers of women entering pregnancy obese. Currently it is estimated that 46 per cent of Australian women of childbearing age are overweight or obese [5]. Additionally, figures at a large tertiary maternity hospital (Mater Mothers' Hospital, Brisbane) report that 33 per cent of their obstetric patients were either overweight or obese between 1998 and 2002 [6]. McIntyre and colleagues (2012) [7] also report that a redistribution has occurred within the classes of obesity with a three-fold increase in class II and III obesity observed during the period of 1998 and 2009.

Maternal obesity (BMI≥30kg/m²) is a widely recognised risk factor for a series of adverse maternal, fetal and neonatal outcomes and these risks rise with increasing BMI. During pregnancy, mothers are at greater risk of experiencing pre-eclampsia [8], gestational diabetes [6] (and increased risk of developing Type 2 diabetes in the future), miscarriage [9] and stillbirth [8]. During labour women are at greater risk of needing their labour induced, having a caesarean section [6] and experiencing birth trauma. Maternal obesity also poses difficulties for fetal monitoring [10], labour analgesia and general anaesthesia [11]. Furthermore, postpartum obese women more frequently suffer from thromboembolic disease, haemorrhage, postcaesarean wound infection [6], respiratory and genital tract infections and mortality [1]. The increased fetal/neonatal risks associated with maternal obesity relate to prematurity, congenital anomalies [12], macrosomia/large for gestational age [6], shoulder dystocia [13], admission to neonatal intensive care units [6] and perinatal death [8].

The long-term risks of obesity in childhood and future metabolic disease are strongly associated with maternal BMI, GWG and high infant birth weight [14] with growing evidence on the role of the developmental origins of health and disease [15]. Excess GWG particularly amplifies the risk of caesarean section, macrosomia, postpartum weight retention and higher maternal and child BMI in the long-term [16-18].

This paints a costly picture for the Australian Health System both in caring for obese patients during pregnancy including their increased risk of complications as well as the future health care of these women and their children [19]. There is a critical need to find an effective method of reducing maternal obesity that improves pregnancy outcomes and the long-term health of obese mothers and their infants.

2.2 Tackling maternal obesity

A considerable amount of work has gone into reducing the burden of maternal obesity and improving outcomes for obese women and their infants through developing GWG guidelines and interventions to help adherence to these guidelines.

The GWG guidelines have been developed based on the weight ranges that incur the best health outcomes for mother and child based on the mother's pre-pregnancy BMI. The currently most widely used guidelines were developed by the Institute of Medicine in 1990 and re-examined and modified in 2009 [20]. These updated guidelines provide one weight gain recommendation for all obesity categories (I-III) of 4-7kg GWG. Similarly they discourage weight loss during pregnancy, regardless of the severity of obesity citing insufficient evidence that weight gains below the current IOM guidelines for this population would not lead to SGA and poor neurological outcomes in the infants [21]. In contrast, however, the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) stratify the recommendations into different classes of obesity, recommending a zero kilogram (0kg) gain and up to four kilogram (4kg) weight loss for class III obesity.

The support for greater GWG restriction and weight loss in the higher classes of obesity is building [20, 22-28]. Treating each obesity class separately is in line with the differing levels of risk associated with each class [7, 29], particularly in light of the increasing proportion of class II and III obese childbearing women [7].

A systematic review of interventions aimed at preventing excessive GWG [30] found that, across seven studies, 63-74% of obese women gained more than 9 kg during their pregnancy, exceeding both the IOM and RANZCOG guidelines. This adherence is significantly lower compared with women entering pregnancy with a normal BMI [31]. A study by de Jersey et al (2012) [32] had similar findings. This further highlights the need for an effective weight management intervention for obese women during pregnancy to help them to achieve the GWG recommendations.

In order to develop an effective weight management intervention for obese women, an understanding of the drivers of GWG is important. Some of the key determinants of excessive GWG are reported to be high prepregnancy BMI, higher energy intake, reduced physical activity, lack of advice on and/or understanding of appropriate weight gain and psychological aspects (including symptoms of depression, anxiety, low self-esteem and body-image dissatisfaction) [33-38].

Obese women are likely to have poor dietary [39] and physical activity behaviours [40]. This is despite evidence that suggests that in pregnancy there is an increase in motivation to improve their lifestyle for the

health of their child. One of the barriers cited in making sufficient lifestyle changes is a lack of knowledge around the impacts their lifestyle can have on the health of their unborn child and a lack the confidence to make the required changes [41]. This suggests the need for interventions that not only educate women about the role of maternal obesity, diet, physical activity and GWG in pregnancy but also increases women's self-efficacy in making behavioural changes [41].

An Australian study by de Jersey and colleagues (2012) found that at 16 weeks, 47 per cent (%) of women in the study were unsure of the weight gain recommendations appropriate for them [32]. Sixty-two per cent (62%) of women reported that the HCPs caring for them during the most recent pregnancy 'never' or 'rarely' offered advice about how much weight to gain. The reason for this lack of knowledge could be due to either a failure in the delivery of relevant and consistent information by health care providers (HCPs) or an issue with how the information was received by the woman.

A number of studies have reported that health care providers (HCPS) may feel that they do not have the capacity to address weight-related issues effectively [41-49]. This could be the result of a number of factors. One reason reported was the perceived difficulty in raising the subject of GWG with obese women and avoidance behaviours out of fear of offending their patients and consequently damaging rapport [41, 48]. A recent Australian study found that, in tertiary hospitals, obese women are likely to see a number of clinicians and rarely the same midwife reducing the level of responsibility felt by each HCP to address the issue of GWG [50].

Additionally, with the time-constraints relevant to busy antenatal clinics today, the time required to sensitively address maternal obesity and provide the necessary information for women to make healthy changes could also be a deterrent, particularly with the absence of consistent evidence-based national guidelines for the management of obesity in pregnancy [48, 51].

Misconceptions can impact on how a woman receives information on GWG gain and lifestyle advice from HCPs. These misconceptions include the over-estimated energy requirements in pregnancy ("eating for two" myth), the safety of exercise in pregnancy, the risks associated with maternal obesity in pregnancy, the value of BMI as a measure of healthy weight for height in determining GWG [52, 53]. Some obese women had experienced a critical and offensive approach of HCPs when being educated about lifestyle issues and weight which could cause significant distress [54, 55]. Weight stigma and the associated de-personalisation of care and feeling unfairly labelled as unhealthy based on weight alone have been identified as factors that contribute significantly to the poor maternity experience of obese women, including how supported and understood they feel [41, 42, 52, 54].

Furthermore, it has been reported that some HCPs are not aware of the updated GWG guidelines and could unwittingly be recommending excessive GWGs to their obese patients [56-58].

Research has also found a positive correlation between pre-pregnancy BMI, GWG, anxiety and depressive symptoms. This suggests a possible association between weight and psychosocial vulnerability [36, 59]. Combining this vulnerability with the other significant barriers to positive lifestyle change in this population highlights the need to address the psychosocial aspects when attempting to promote a healthy weight gain [39, 60].

Overall, these findings reveal that there are deficits in the current maternity care system for obese women. There is an increased pressure on maternity staff to care for these women without the necessary training and resources. This environment is not conducive to ensuring the care delivered is not only woman-focussed, non-judgmental, supportive and consistent but also effective at addressing the barriers to behaviour change and promoting the achievement of a HPW. This highlights the need for a change that meets the needs of obese women without putting an excessive burden on the system. This change involves the design and implementation of comprehensive interventions that successfully target GWG in pregnant women with obesity.

2.3 Review of antenatal interventions to limit GWG

There have been many interventions aimed at GWG. These have been targeted at the general population of pregnant women; as well as interventions specifically for overweight and pregnant women with obesity. Despite this however, it is still unclear as to the elements of a successful intervention that result in reductions in GWG within the appropriate guidelines that in turn result in improved obstetric and neonatal outcomes.

2.3.1 Reviews and meta-analyses of available data

A number of reviews and meta-analyses have been conducted of interventions to minimise GWG in pregnancy [30, 61-67] which have found a modest difference in mean GWG. Oteng-Ntim and colleagues found, from their review and meta-analysis of 10 RCTs of a range of different interventions targeted to pregnant women, a mean reduction in GWG of 2.21 kilograms (95% CI) in overweight and obese women. Of these interventions, those that combined antenatal lifestyle education (diet and physical activity) with personalised guidance were found to be most effective at restricting GWG in overweight/obese women with an observed trend towards reducing the prevalence of gestational diabetes (GDM). The randomised

controlled trials (RCTs) in this meta-analysis did not provide robust evidence for a reduction in caesarean section rates, large for gestational age (macrosomia) or any other change in birthweight. This, as the authors point out, could be a result of inadequate power due to small sample sizes. Thangaratinam and colleagues' (2012) systematic review of interventions to reduce or prevent obesity in pregnant women, however, did find a statistically significant decrease in the prevalence of pre-eclampsia in obese women [66].

2.4 Critical appraisal of the literature

A critical appraisal of the key interventions was undertaken to inform the development of the evidence based Blooming Together Program.

Eligibility for inclusion in this critical appraisal included the following:

- involved an experimental design
- involved diet only or both diet and physical activity education,
- were published between 2001 and 2013 and
- included obese women in the analysis.

Please note: Exercise only or weight-monitoring only interventions were excluded because systematic reviews and meta-analyses have found them to be less effective than diet or combined diet and physical activity interventions[66, 68].

2.4.1 Approach

Of the reviewed studies 11 were randomised controlled trials (RCTs) [31, 69-78] and three (3) were non-randomised controlled trials (non-RCTs) [79-81]. These studies varied in their delivery and their research focus.

Of the RCTS, eight (8) were both diet and physical activity focused, with four (4) individually-delivered [31, 74-76], two (2) were both group and individual-based [72, 77], and two (2) were solely group-based [73, 78]. Three (3) of the RCTs were diet focused and individually delivered [69-71]. Of the non-RCTs reviewed all were diet and physical activity focused, one (1) was individually-delivered [81], and two (2) were individually-based with an optional group exercise class [79, 80].

2.4.2 Criteria

Interventions were assessed according to a series of criteria. These criteria were developed after reviewing the literature on the self-reported maternity experiences of pregnant women with obesity and on an initial

review of the effective and ineffective behavioural interventions published in the literature. The justification for each criterion is described below.

1. Targeted interventions to pregnant women with obesity

Targeted interventions designed to limit GWG in obese women are found to be more effective than universal interventions [65]. It is suggested that targeted interventions are more likely to address the factors specifically contributing to excess GWG in obese women [82]. This is understandable in light of the often complex relationship obese women have with their weight [45]. The risk of damaging rapport with obese women is high (which could result in disengagement with the service) without a specific and considered approach to education around GWG [83]. Furthermore, a good rapport between HCP and patient is paramount when addressing sensitive topics such as weight management in pregnancy.

2. Initiation in early pregnancy (< 16 weeks gestation)

A review of the literature supports that early intervention initiation results in better GWG outcomes [62]. The later an intervention begins the greater the opportunity for excess GWG prior to beginning the intervention. In contrast, the earlier an intervention begins the sooner the participants are educated regarding the GWG goals and armed with the strategies to help meet these goals through early adoption of healthy lifestyle behaviours.

3. Frequency of counselling

More frequent counselling spread-out over the antenatal period offers greater opportunities to reiterate key aspects of the intervention to participants and regular monitoring of progress translates to behavioural change on the pathway to reducing GWG [65]. When counselling is combined with tailored/personalised advice, this further improves the ability of the participant to adopt healthy lifestyle behaviours resulting in improved outcomes [65]. Furthermore, obese women report that regular contact with a HCP results in a feeling of greater accountability for their actions and this translates to improved motivation to make behavioural changes [84].

4. Continuity of carer

The benefits of continuity of carer to the quality of patient care are well-established [85]. It has been a key focus area for the improvement of Maternity Services in Western Australia and Australia on the whole [4, 86]. The value of continuity of carer for the management of maternal obesity is particularly clear [85]. The complex relationship that obese women have with their weight can complicate the delivery and reception of lifestyle information and advice around GWG [84]. Continuity of carer allows a

level of rapport and familiarity to be built between a HCP and a pregnant woman which encourages open communication, and the opportunity to progress patient care from the base level of a general medical check-up to ongoing tailored advice to the patient's specific pregnancy experience [41]. This has been reported to translate to greater patient empowerment and satisfaction with care [87, 88].

5. Group-delivered

Interventions that are mainly delivered in a group context have been found to enhance weight loss in non-obstetric populations compared to individually-delivered therapies. Group delivered interventions are also associated with improved maternal satisfaction with care [84, 89, 90]. The benefit of group-based interventions is suggested to be related to the social support they provide and the opportunity to draw on the group as a dynamic resource. Being surrounded by people in similar situations and seeing them successfully make progress in the behaviours of interest as well as hearing about their experiences has the potential to enhance participants' levels self-efficacy in achieving behaviour change[41]. Furthermore, obese women report feelings of embarrassment and shame regarding their weight and also feel as if others (normal weight people) would not understand their situation [41, 42, 52].

6. Personalised/tailored counselling

Interventions that tailor education and advice to participants are shown to be more effective. Tailored information requires the participant to share their experiences and current behaviours that allows a more personalisation provision of advice[45]. As a result, participants feel more listened to, supported and viewed as an individual [85]. This can translate to improved patient-carer rapport and a more positive environment conducive to behavioural change [85]. De-personalisation of care can, for example, manifest as generic/standardised advice based on an individual's overweight status (e.g. eat less, exercise more) which perpetuates the weight stigma that is reportedly present in the current maternity care system [41, 42, 52]. This is associated with maternal dissatisfaction with care and decreased confidence and motivation to change behaviours [41, 52]. Tailoring of advice also allows the lifestyle education to be pitched at a level that the participant is able to relate. This is supported by a well-used model of behavioural change, the trans-theoretical or stages of change model [91]. This model is based on tailoring information according to where the individual is placed on a five-step spectrum of readiness for change and the integration of this behaviour change into everyday life. Tailored counselling can also involve feedback on performance, of which, positive reinforcement for achievements is particularly beneficial [92].

7. Address psychological determinants of GWG

A psychological approach can be defined as a more holistic intervention that recognises the role of psychological factors in weight-status, diet and physical activity behaviours. Maternal levels of stress and anxiety/depression, body image satisfaction and self-esteem are found to be determinants of GWG and potential barriers to successful behavioural change[30]. Psychological approaches can also address participants' motivation and/or confidence to make behavioural changes, thereby improving self-efficacy [91, 93]. Interventions that address strategies to manage the psychosocial issues alongside physical activity and dietary behavioural change are suggested to be more effective both in the short and long-term [20, 30, 63].

8. Inclusion of self-monitoring and goal-setting behavioural techniques

Self-monitoring and goal-setting are key behavioural change techniques across the literature and particularly in weight management [92, 94, 95]. A literature review conducted by Brown and colleagues (2012) found that goal-setting appeared a promising aspect of behavioural change and reducing WG [96]. Moreover, Hill et al's review of behavioural change techniques used in interventions to minimise GWG found self-monitoring to be a common characteristic of more effective interventions [97] which was further supported by Streuling and colleagues in their meta-analysis of physical activity and diet counselling interventions [65].

2.4.3 Critique of interventions

Overall, 14 interventions were critically analysed (See Attachment 1).

Success in reducing GWG

Six (6) of the interventions were effective at reducing GWG in obese women with five(5) RCT designs [69-73] and one (1) a case-control non-randomised study [79]. The reduction in GWG ranged from 1.6 to 9.1 kilograms (average = 4.6 kg) compared to the control groups. Eight (8)of the studies were ineffective at reducing GWG in obese women, this included six (6) RCTs [31, 74-78] and two (2) case-control trials [80, 81].

Targeted interventions to pregnant women with obesity

Of the six (6) effective interventions [69-73, 79] all were targeted to obese women with one (1) also including overweight women [71]. Only one (1) of the ineffective interventions targeted obese women [78] and one (1) that included both overweight and obese women [81]. The remaining four (4) were universal interventions.

Initiation in early pregnancy (< 16 weeks gestation)

Three (3) out of the six (6) effective interventions were initiated at less than 16 weeks gestation [69, 72, 73] with one beginning slightly later for some participants, ranging from 13 and 17 weeks gestation [70].

The majority of ineffective interventions began after 16 weeks [74, 81] or timing of intervention initiation was not reported [31, 75-77]. Two (2) of the ineffective interventions did begin before 16 weeks [78, 80] however other factors led to the unsuccessful result.

Reporting on some of the interventions was inadequate which made it difficult to determine when the intervention was first initiated. For example, Thornton et al (2009) reported recruitment gestation ranged between 12 and 28 weeks and no further details were supplied apart from the intervention being delivered at routine antenatal appointments [69]. Furthermore, the study by Claesson et al (2008) provided a vague description of the timing of intervention initiation in "early pregnancy" [79] and another study neither reported on the eligible gestation for recruitment nor timing of intervention initiation [71].

Frequency of counselling

The frequency of counselling was difficult to assess in a number of the interventions reviewed. Of the interventions that reported sufficient detail about counselling frequency, the effective interventions overall offered a greater number of contacts with HCPs compared to the ineffective interventions. Two (2) of the effective interventions [71, 79] and two (2) of the ineffective studies [31, 75] only explained that the intervention was conducted at routine antenatal appointments however the number of appointments attended was not reported [31, 75]. This suggests a medium frequency of contact however this conclusion cannot be assured from the information available. The successful Quinlivan study (2011) had a stepped-care approach where participant's psychological wellbeing was assessed by a clinical psychologist and further intervention (an individualised solution-focussed treatment plan) was offered where indicated [71]. The researchers did report that 82 per cent (%) of participants had one (1) follow-up appointment which suggests a potentially medium to high counselling frequency. The effective interventions that did report on frequency of counselling were rated medium to high however quality of reporting was still variable. The frequencies reported ranged from four (4) appointments with a dietitian [73], an additional four (4) to six (6) group education sessions [72] to 10 appointments with a dietitian [70] and "at least one appointment with a dietitian" with ongoing review of their food diary by physicians at their routine appointments [69].

For the ineffective interventions that reported counselling frequency this ranged from low to medium contact. Hui and colleagues (2012) included two (2) consults with a dietitian (rated low)[77], two (2) studies offered five (5) brief appointments [74, 80] and Guelinckx (2010) included three (3) sessions (1 hour each) with a nutritionist [78]. The study by Phelan and colleagues (2011) offered one (1) consult with a dietitian with three (3) follow-up phone-calls (made by research assistants) which would be a medium level of

contact. However, for those that exceeded the GWG guidelines in any month received an extra two (2) calls each month until their GWG was corrected [76]. One of the interventions offered one appointment each with a dietitian and kinesiologist. No follow-up was alluded to therefore it appears to have offered a low frequency of counselling [81].

Continuity of carer

Continuity of carer was another element that was poorly reported in the studies reviewed. Only three (3) of the effective interventions [71, 73, 79] and none of the ineffective interventions clearly provided continuity of carer. The other three (3) effective interventions are unknown whether they provided continuity of carer however the terminology used does suggest in some the studies that the same care provider could have been used. Two of the ineffective interventions clearly did not offer continuity of care [76, 81].

Group-delivery

Group components were included in three (3) of the six (6) effective interventions. Of these one (1) was solely group delivered [73] and the others provided an optional group exercise session [72, 79]. Attendance was not reported by Claesson (2008) however in Vinter's study (2011) participants attended on average 10.4 hours out of a possible 20 hours of the group exercise seminars [72, 79]. Of the ineffective interventions, three (3) included a group element. One study included three (3) group education sessions facilitated by nutritionist which were poorly attended [78]. The studies by Kinnunen (2007) and Hui (2012) included optional group exercise and for both attendance was not reported [77, 80].

Address the psychological determinants of GWG

The psychological determinants of GWG were, overall, poorly addressed in all of the interventions except one (1) of the effective interventions [71]. This study provided clinical psychology consultations for each participant to assess symptoms of depression and anxiety in order to determine whether these impact on eating patterns. Individualised solution-focused treatment plans were prescribed where indicated. Of the ineffective interventions two (2) may have addressed some psychology aspects however the extent is unclear. Guelinckx et al (2010) included education around the management of emotional and binge eating but did not report to have used any specific behavioural change techniques [78]. Althuizen and colleagues (2013) based their intervention on problem-solving treatment for primary care which was likely to have included some stress and anxiety management strategies however, this was also not apparent [74].

Self-monitoring and goal-setting behavioural change techniques

Of the effective interventions, three (3) provided both goal-setting and self-monitoring behavioural change techniques [69, 70, 73], one (1) just goal-setting [72] and for one (1) study (by Quinlivan et al, 2011) it is unclear whether either technique was used [71]. It is likely that some behavioural techniques were used in

Quinlivan's intervention (2011) since it included a psychological intervention (solution-focussed treatment plan)[71]. Of the ineffective interventions, five (5) of the eight (8) used both goal-setting and self-monitoring [74-77, 81], two (2) used goal-setting only [31, 80] and one (1) did not report the use of any particular behavioural change techniques [78].

All of the interventions included a range of different behavioural modification strategies including the following: Provide information on consequences of behaviour in general [69, 72, 79]; action planning [72]; review of behavioural goals [72]; feedback on performance [31, 70, 75]; modelling/demonstration of behaviour [77, 79, 80]; instruction on how to perform behaviour [72, 79]; identification/problem solving [75]; rewards contingent on successful behaviour [31]; facilitate social comparison; plan social support/social change [76]; and motivational interviewing [73, 79].

2.4.4 Summary of critique of interventions

Targeted interventions designed specifically for pregnant women with obesity were clearly a common characteristic of the effective interventions and rare in the ineffective interventions. This supports the conclusion that the maternity experience and needs of obese women are different to normal weight women, needing a specific approach to their care that only targeted interventions can offer.

It is difficult to comment on the importance of early gestational age at initiation of the intervention due to inconsistent reporting. From the information available the effective interventions were more often initiated earlier in pregnancy with three (3) initiated prior to 16 weeks. Those that did not clearly report the initiation date were possibly initiated as early as 6-12 weeks for an unknown proportion of participants. The exact role of reaching women early in pregnancy and successful GWG reduction cannot be ascertained from these studies.

On the whole, the effective interventions did seem to offer a greater number of counselling appointments. These interventions more often provided continuity of carer which could be responsible for greater success in GWG management. Furthermore, the benefit of goal-setting and self-monitoring appears to be realised in interventions that offer frequent counselling, and even more so if there is continuity of carer. This could be due to ongoing feedback to participants that allows recognition of effort and achievement, a greater sense of accountability, translating to more value placed on self-monitoring and working towards personal behavioural goals.

The psychological aspects have been largely neglected by GWG interventions in recent systematic reviews [30, 97]. In practice this translates to a failure to address the behavioural, psychological, cognitive and situational barriers to the behaviours changes required to help meet the GWG guidelines. The findings of this critical analysis mirror those findings where studies do not address the psychological determinants of GWG or do so ineffectively. One intervention provided education strategies on management of emotional and binge eating which is a pertinent issue for obese women. This study did not target obese women and was delivered in a group environment (i.e. normal weight, overweight and obese participants all together). Considering the maternal experience of obese women, a group environment with pregnant women of a range of weights and sizes is not likely to be effective in that this environment does not encourage the sharing of mutual experiences of being an obese woman which are seen as the strengths of a targeted group environment.

Overall, the current state of the intervention literature does not provide an accurate picture of the potential of group-delivered interventions in managing GWG in obese women. The main advantages of group-based counselling and education were not able to be realised for a number of reasons. Firstly, group sessions were poorly attended or attendance was not measured. This may be because the group sessions were in addition to routine antenatal care translating to a greater participant burden. Moreover, it was unclear whether the same group of women attended the sessions together which would affect the group dynamic. Furthermore, the group based components were commonly in the form of optional exercise classes which may not allow for the level of group interaction that incurs a benefit for participants.

Finally, this literature review has identified a number of gaps in the literature in regard to approaches to managing GWG in obese women which include:

- The lack of interventions that are embedded in the provision of antenatal care (that is a maternity model of care for pregnant women with obesity);
- The absence of evidence on continuity of carers responsible for administering the intervention;
- The inconsistent nature of group-delivered care with the same group of participants;
- The failure to address the psychological determinants of GWG;
- The lack of consumer-participation in the design of GWG interventions;
- The lack of clearly reported approach to lifestyle education and counselling; and
- The absence of formal evaluation of the acceptability of interventions.

The findings from this literature review, including the identified gaps in the literature, served as a valuable guide to the development of Blooming Together.

3 Methodology

This project involved a phased approach to program development.

Data collection occurred in four phases:

- Pre-consultation Phase involving focus groups with the Consumer Reference Group (CRG);
- Development Phase involving a comprehensive review of the literature and written feedback from the CRG on the first draft of the Program (session content and schedule);
- Consultation Phase involving the conduct of five (5) sessions of the draft Blooming Together (BT)
 program with the target group to ensure that the program is acceptable to and meets the needs of
 pregnant women with obesity.
- Refinement Phase which involved written feedback on the Program from relevant health care
 providers (HCPs), and interview feedback from members of the CRG and trial participants (recruited
 during the Consultation Phase).

3.1 Pre-Consultation Phase

The aim of the Pre-consultation Phase was to ensure that the program meets the needs of the target group. A CRG was formed with obese women who had recently received their antenatal care at KEMH. The principal role of the CRG was to inform and guide the development of the Program. Two focus groups were conducted with members of the CRG.

3.1.1 Recruitment

Eligible women were identified from the KEMH Nutrition and Dietetics Department's record of women who were offered the existing maternal obesity intervention program (BLOOM) resources. The KEMH Dietitians also recommended particular patients they felt would be interested in being involved. The maternal health database (STORK) was used to check each woman's eligibility according to the following criteria:

- Over the age of 18;
- Fluent in conversational English (no requirement for an interpreter);
- Suitable for 'midwifery care with medical consultation' as per WA Women and Newborn Health Service (WNHS) Clinical Guideline no 1.1.2.2 (refer to Attachment 2);
- Absence of a serious medical illness diagnosis;
- No neonatal death or serious complications; and
- Received their antenatal care at KEMH.

Those women who had delivered their babies between two (2) and six (6) months prior and who met the above criteria were telephoned and invited to be part of the CRG. The women who agreed to be involved were sent a confirmation letter and meeting details (refer to Attachment 3) and were followed up with a telephone call.

In order to get a mix of socio-economic levels the research team decided to form two different CRGs located in the northern (Joondalup area) and southern (Rockingham area) metropolitan suburbs of Perth. The researchers identified women located in the north and south catchment area by their resident postcodes.

3.1.2 Data collection

Two (2) focus groups were conducted with the CRG: one in the north metropolitan area of Perth (n=6) and the other in the south metropolitan area (n=8). The north focus group was conducted at Mullaloo Heights Primary School (Mullaloo) whilst the south was conducted at South Coastal Women's Health Service (Rockingham).

The focus groups were facilitated by the Project Managers and attended by a member of the Steering Committee (Dr Lisa Gibson). Informed consent was obtained from the CRG members and each participant was given a \$40 Myers/Coles voucher for their contribution. Refer to Attachment 4 for the focus group instruments.

Each focus group was digitally recorded, transcribed and thematically analysed.

The participants were asked to comment and discuss their:

- Satisfaction with maternity care they received previously;
- Knowledge and understanding about a healthy lifestyle;
- Attitudes towards a healthy lifestyle;
- Understanding about the risks associated with having a high BMI in pregnancy;
- Satisfaction with lifestyle education provided during their maternity care;
- Perceived barriers to having a healthy lifestyle;
- Attitudes towards group-delivered, lifestyle-focussed antenatal care; and
- Suggestions to improve maternity care for themselves and others like them.

3.2 Development Phase

The aim of this phase was to ensure that the session content accurately reflected the feedback provided by the CRG in the Pre-consultation Phase of the research. This data collection phase involved receiving written feedback from the CRG on the draft session content.

Those CRG members who provided verbal consent to provide ongoing feedback on the Program were contacted and the draft program content and feedback instrument (refer to Attachment 5) was emailed or posted to them with a reply-paid envelope. The results of this data collection are presented in Section 4.2.2.

The major output of this phase was a draft Blooming Together (BT) program content that was ready to be trialled in five (5) separate "sessions" with the target group.

3.3 Consultation Phase

The Consultation Phase involved the conduct and retrial of five (5) sessions of the draft Blooming Together (BT) program with the target group to ensure that the program content and format is acceptable to and meets the needs of pregnant women with obesity. Each session was developed for a different stage of pregnancy (refer to Section 4.2.3 for the pregnancy stage break-down).

Participants were invited to attend a session and at the completion of the session they were asked to complete a self-administered questionnaire and to participate in a focus group to provide feedback on the session. The participant feedback on the first trial informed the amendment of the session content where which was then re-trialled with different women.

3.3.1 Recruitment

Participants were recruited to attend a session or the retrial of a session. The inclusion criteria for the session trials were:

- BMI ≥30 kg/m²
- Over the age of 18
- Fluent in conversational English (no requirement for an interpreter)
- Suitable for 'midwifery care with medical consultation' as per WA Women and Newborn Health Service (WNHS) Clinical Guideline no 1.1.2.2
- Absence of a serious medical illness diagnosis

- Gestation of ≤ 30 weeks at time of session trial

These criteria reflect the characteristics of the women for which the program was designed.

The recruitment protocol was developed after meeting with the Clinical Triage Midwife of the KEMH antenatal clinic. The protocol involved using the list of obese women identified from their GP referral letter that the Clinical Triage Midwife prepares for the KEMH Nutrition and Dietetics Department. This list was forwarded to the Project Managers at the beginning of each recruitment period. The Project Managers used the maternal health database (STORK) to check the eligibility of the identified obese women according to the above criteria.

Women who met the criteria above were mailed a recruitment letter to introduce the research, provide a project information sheet and advised that they could decline to be involved in any part of the research by mailing a return 'opt-out' slip (refer to Attachment 6). Those who had not returned an 'opt-out' slip after two weeks were then telephoned and invited verbally to attend a specific session trial. For those who agreed to participate in the session trial, the details were posted to them (refer to Attachment 7) along with directions for parking and to the trial location, and, if required, a parking permit and crèche information.

The original recruitment process proved overly time-consuming. In an effort to improve recruitment efficiency, the Research Team enlisted the help of the KEMH Dietitians to assist in recruiting eligible women referred to the BLOOM Program (the current program offered by KEMH). The BLOOM Program Dietitian checked the medical notes to determine the woman's eligibility and then provided her with a verbal description of the project and a project information sheet. The woman was assured that declining to be involved in the project would not affect her current care at KEMH. If the woman was interested in being involved, she was asked to complete a consent form to provide permission for the Project Managers to contact her.

Recruitment was also affected by a trend of booking appointments occurring later in pregnancy. This was likely to be due to the KEMH policy encouraging GP-shared-care arrangements in an effort to reduce the Antenatal Clinic load. This had the effect of reducing the number of women attending the Antenatal Clinic and hence the available pool of eligible pregnant women for this trial. In order to access these eligible women whose first appointment at KEMH was later in pregnancy an additional amendment to the original recruitment protocol was made to include a telephone call to replace the mailed recruitment letter.

The Research Team aimed to recruit at least ten (10) individuals for each session with the expectation that around four (4) of these women would not attend the session. Recruitment for the postnatal session

involved invitations to women who had previously attended an antenatal trial session and who were between six (6) and 15 weeks postnatal.

Each participant was given a Coles/Myer gift voucher for attending a session. The value of this voucher varied. Initially it was \$30 (for the first two trials) however this was increased to \$50 when attendance was low.

3.3.2 Data collection

Each session was conducted by two facilitators: a Clinical Midwife and Dietitian (Program Managers for this research project). Each session was also attended by an external qualitative researcher and scribe, primarily present to conduct the post-trial focus group along with observing the group dynamics and take notes on the conduct of the session for use in refining the content and delivery.

Each session was conducted as if it was being run as part of a formal Program. A post-trial evaluation survey (refer to Attachment 8) was completed by participants and offered an anonymous means of providing feedback on the session content. The tool included rating the level of value of the different topics (1= not very valuable, 5 = very valuable) with space for additional comments.

After each of the session trials, the facilitators left the room, while the external qualitative researcher (with the support of a scribe [KEMH midwifery student]) conducted a focus group with the participants to ask them questions about the session. Each focus group was approximately 30 minutes in duration. Refer to Attachment 9 for the focus group instruments.

The output of this phase was the draft Participant Guide and Facilitator Guide.

3.4 Refinement Phase

The aim of the Refinement Phase was to fine-tune the Program content. This data collection phase involved receiving feedback on the Participant Guide from health care providers (HCPs) (detailed in section 3.4.1.) and CRG members and participants who had previously attended a trial session of the Program (detailed in section 3.4.2). Telephone interviews were conducted and written feedback was received.

The output of this phase was the Participant Guide and accompanying draft Facilitator Guide (refer to Attachment 10 and 11, respectively).

3.4.1 Health care providers' feedback on Participant Guide

Health care providers (HCPs) with expertise in the area of maternity care were consulted in regard to the content of the Participant Guide. This included asking HCP's about the appropriateness of the information; terminology used; and whether any specific information could be included or improved.

The relevant HCP groups identified were Obstetricians, Midwives, Psychologists, Sports Physiologists, Physiotherapists and Dietitians with experience working in maternity care (or caring for women in pregnancy), both internal and external to KEMH. A convenience sampling method was used directed by recommendations made by the Project Steering Committee.

An invitation letter and project information sheet was emailed to each identified HCP (n=14). Those that agreed to provide feedback were sent the feedback instruction sheet (refer to Attachment 12) and a draft of the Participant Guide with an embedded feedback instrument. These were made available in either electronic or hard copy. Some HCP's provided feedback verbally.

3.4.2 Target group feedback on Participant Guide

The consumer reference group (CRG) and previous trial participants were contacted via telephone or email to invite them to review the Participant Guide. Three women from the CRG and six women who had participated in an antenatal and/or postnatal trial accepted the invitation to provide feedback on the participant booklet.

Each participant was provided with:

- The Draft Blooming Together Participant Guide;
- Blooming Together Feedback instructions;
- A feedback form to provide guidance with providing their feedback (refer to Attachment 13). This
 form asked participants to rate (using a 5-point Likert Scale) how much they agreed with statements
 regarding the content of each session. Some short answer questions were also included and
 participants were encouraged to annotate the Participant Guide.
- A draft of the Blooming Together Program branding for their review and opinion;
- A reply-paid envelope to return the Participant Guide after the telephone meeting if they have made a number of written suggestions.

A telephone interview was conducted by one of the Project Managers (Joan Jones) using an interview instrument (refer to Attachment 14) and each interview was digitally recorded with the permission of the woman. In order to reduce the interview length of the interview only the statements that the respondent did

not agree with (i.e. the participant guide was not effective at achieving) were further investigated using prompting questions. The interviews were between 45-60 minutes. It proved difficult to achieve the interview in one single session due to family commitments and responsibilities so often a second interview was required to complete the feedback.

As an acknowledgment for their time in providing feedback on the Participants Guide, the women who participated in the interview were each given a \$50 voucher.

The results of this data collection phase are detailed in section 4.4.2.

4 Results

4.1 Pre-Consultation Phase

This phase involved consultation with the CRG through the conduct of two focus groups. The purpose of this consultation was to ensure that the BT Program is acceptable to and meets the needs of the target group.

4.1.1 Results: Sample

The CRG (n=14) well represented both experienced (multiparous) and inexperienced (primiparous) mothers and age groups, ranging from 23 to 41 years of age with varying classes of obesity. The majority were postnatal with three antenatal women and all were within six (6) months of childbirth.

Table 4.1 provides information on the membership of the consumer reference group (please note: the CRG also provided feedback during the Development Phase and the Refinement Phase of the research).

Table 4.1 CRG sample demographics

Number of members	14
Age range	23-41
Average age	31
Antenatal	3
Postnatal	11
Primiparous	8
Multiparous	5
BMI range (kg/m²)	31-59
BMI average (kg/m²)	45

4.1.2 Results: Focus groups with CRG

The key findings from the CRG focus groups are presented below according to themes identified during the focus groups.

Satisfaction with maternity care

The women reported mixed experiences with the care they received at KEMH: some had a very positive experience whilst others were ambivalent or notably negative. The results suggest that what affected their experiences the most was how their health care provider (Dietitian, Doctor/GP, Obstetrician, Midwife, Child Health Nurse) treated them and how supported they felt.

Treated differently/judged and their own attitude towards their size

When asked about whether they felt that they were treated differently due to their size a few respondents felt KEMH health care providers did treat them differently and these women attributed this to an assumption that because they had a high BMI they would have pregnancy complications.

"Sometimes I feel that, because you are bigger, have a higher BMI, they assume you are going to have more issues. I don't have any problems, heart issues; I have easy births so I feel it is a waste going all the way there."

"I just think if I had been a skinny person, they would not have said that. I think it was just that she looked at me and went 'you've got bad lifestyle choices, she's obviously going to make bad lifestyle choices for her kid, so we better tell her that she's going to make her kid fat'"

"You're putting effort in as best you can at home and then to come in. Because I lost 10 kilos from my pregnancy, I was really strict with my diet, I wasn't very good with my exercise and I had gestational diabetes and my blood sugar levels were generally between 3 and 3.5, like they were really low, and the Dietitians were really good they sort of encouraged and said you're doing really well but I went to see one of the doctors and he looked at me and he didn't look at my chart and he said "well you need to start exercising more and eating less" and he said "I'm not going to do an ultrasound because we obviously won't be able to hear the baby" and all this sort of stuff. And he was really, and every other doctor had done an ultrasound and in the week that I'd seen him I'd lost two kilos in like a week and a half, I had lost more weight than I probably should have, but he was telling me I had to eat less and I thought 'you're not even looking at my chart, you're just looking at me and judging me..."

One respondent shared a stressful experience with her child health nurse who told her that by formula feeding her baby they will be fat for life:

"I can't breastfeed either; I tried for the first five or six weeks but never got any milk come in. I was pumping every three hours on the breast pump but nothing ever came. So she's just gone to the bottle but as soon as my, I know this isn't a Dietitian thing, as soon as I went to my child health nurse she basically said 'If you feed your baby formula it will put on weight and will never lose the weightit will be fat for the rest of its life because you lose breast milk fat but you don't lose formula fat'. And that's really upsetting to me because I'm already paranoid about her trying to have a healthy lifestyle..."

Knowledge about a healthy lifestyle

Participants were asked about their understanding of a healthy lifestyle. Most reported that a healthy lifestyle included diet and exercise, eating well (such as fruits, vegetables and drinking water) and avoiding foods considered high-risk (listeria). The importance of emotional wellbeing was also acknowledged and in particular how diet is affected by your emotional wellbeing. Keeping a balance between work and home life was also considered important for a healthy lifestyle. Not smoking during pregnancy was also mentioned.

Uncertainty with regard to the safety of exercise in pregnancy was shared by a number of participants. This was exacerbated by receiving varying recommendations from different sources including HCPs. One respondent was told to not do any more exercise than they were doing before they became pregnant. Another respondent thought that exercise intensity should not exceed that of walking.

There were mixed responses with regard to expectations of pregnancy weight gain. Some expressed fear of gaining too much weight in pregnancy, others wanted to gain the minimal amount while others gained between 16 and 30 kg. One respondent said that "you can put any amount on really". There was some concern expressed regarding gaining enough weight to support healthy fetal development. Another respondent felt that she was the only one who had to watch what she ate in pregnancy.

Information regarding pregnancy weight recommendations varied – some women were not informed, others were told figures ranging from zero kg to seven (7) kg to "minimal".

Attitude towards a healthy lifestyle

When asked about what was important about living a healthy lifestyle many reported that this motivation stemmed from ensuring the health of their child. Diet was also seen as important when breastfeeding but not so much when not breastfeeding. One respondent was aware that a healthy lifestyle in pregnancy reduces the risks for mother and baby during pregnancy and birth. A few respondents felt that even though they do not look after themselves they still want to ensure the health of their child.

"I'm an idiot about my weight but I'm not going to force-feed Hungry Jacks down my baby's throat. I would like to myself get thin and healthy and I would like to promote that for my kid..."

The participants were asked about physical activities and many responded that they preferred activities such as walking, swimming and playing with their children. It was expressed that they were more likely to engage in incidental activities rather than formal/planned exercise as this was easier to fit into their lives.

Respondents were more likely to engage in activities within a close proximity to their home and felt it would be helpful to be given a list of places that provide pregnancy-safe exercise classes as well as those suitable for post-birth that may have crèche facilities and/or include the baby.

"I was exercising before I was pregnant and I think if someone had told me, and I'd never exercised, if someone told me to start off really small and told me what to do, or there was a group of overweight group of mothers to go and join I would be more likely to go. But if they said go and do half an hour of exercise each day, I don't think you're likely to go."

One participant said she doesn't want to worry about weight in pregnancy and prefers focussing on weight loss once the baby is born.

Satisfaction with lifestyle education

Women's experience of lifestyle education was also mixed. Some indicated that they received negative reinforcement regarding their weight and lifestyle from maternity care professionals, including one who was offended and upset by the way a doctor spoke to her about her weight: "you're too fat to have a baby". There was an alternate view however, in that some women considered that maternity care was not a forum that they would expect to receive support on issues associated with their weight.

There was a mixed response regarding their satisfaction with dietetics consults and level of information. Overall women liked the BLOOM program and appreciated the positive reinforcement the Dietitians provided however would have liked more direction. A number of participants said that the Dietitian at KEMH provided them with a pack (BLOOM) that they found interesting however felt more (quick and easy) recipes and meal ideas would have been helpful, especially as a working mum with little time. Many felt that they would benefit from receiving more information and practical advice such as suggestions for healthier options, more menu plans, and quick and healthy recipes. Another respondent added that a series of information would have been helpful as well as links to other useful sites (e.g. Diabetes Australia). Two respondents said that they would like more tailored information such as alternatives for different foods, while another said that their Dietitian gave them some good ideas for alternative foods. Some of the women expressed concern regarding not eating enough potentially negatively affecting the baby's growth indicating a lack of knowledge of nutrition in pregnancy.

Barriers to having a healthy lifestyle

Most participants reported that they faced difficulties in maintaining a healthy diet and exercise regime due to work commitments (working full-time), family commitments (younger children to care for, household chores), and challenges of pregnancy (morning sickness, fatigue, pain, immobility). Another issue raised was of making excuses to not exercise or eat well, such as being too busy or tired as well as simply being pregnant – which they recognised as not acceptable.

Attitude towards group-delivered, lifestyle focussed antenatal care

Overall participants were supportive of the group model of care with private medical checks and open general lifestyle discussion/education. Many felt that it would enable expectant mothers to discuss their thoughts and feelings with like-minded others. Some also felt it would be an improvement in their care and felt it made sense to use the waiting times associated with antenatal clinic appointments for something worthwhile.

The following comments were provided in regard to continuity of carer aspect of the group model of care:

"Yeah you don't have to reiterate, because when I went they say 'how are you' and you say well I've had a bleed at 8 weeks then 10 weeks, you spend most of your appointment explaining stuff they should actually already know"

"And even just to build that confidence to be a bit more open with them, that's the only thing I think the public system lacks."

Some participants however, identified that the group model of care would not suit all expectant mothers, particularly if it was their first pregnancy. When asked about having partners present, many of the participants thought it was not ideal and could be seen as potentially restrictive of the conversation topics and how comfortable some women would feel to share their experience and be honest. However there was recognition of the importance of partners to also be educated about healthy lifestyle in pregnancy and for the family for the long term.

Suggestions to improve their maternity care

When asked about what they would like in a group-maternity care program the following responses were provided:

- A greater explanation of what a high-risk pregnancy means and how it relates to BMI.
- A more sensitive and respectful approach to address their BMI.
- Greater continuity of care to increase level of accountability, self-confidence and rapport with care
 providers. Respondents felt that continuity of carer would allow the development of rapport,
 accountability and more tailored care. They recognised the importance of this in their care: not
 having to repeat basic information about their medical history; to feel comfortable disclosing the
 truth; recognition for their achievements related to diet and physical activity and to feel more
 accountable for their actions.
- There was clear interest in the role of maternal lifestyle during pregnancy and breastfeeding on the future health of the child. Participants felt that discussing this relationship in more detail would be a good motivation to eat well.

- Greater and more consistent guidance regarding gestational weight gain (starting earlier pregnancy)
 and more support and practical suggestions to manage their gestational weight gain including
 nutrition and physical activity information.
- Providing antenatal care closer to home. The time required to travel to KEMH and find parking was identified as a significant barrier to attendance.

4.1.3 Output of Pre-consultation Phase

The output of the Pre-consultation Phase was the first draft of the program content broken down into the following session schedule:

- Session 1 –19 to 21 weeks gestation
- Session 2 24 to 26 weeks gestation
- Session 3 28 to 30 weeks gestation
- Session 4 34 to 36 weeks gestation

Feedback on this draft content was then sought from the consumer reference group and this resulted in further changes to the session schedule.

4.2 Development Phase

The Development Phase involved consolidation of information from literature and from the information collected as part of the Pre-consultation Phase, into the development of a draft program (session content). This draft content was then sent back to the CRG to seek written feedback on its acceptability.

4.2.1 Results: Sample

Please refer to section 4.1.1 for a description of participants who made up the CRG.

4.2.2 Results: Written feedback from CRG

The key feedback received from CRG members on the draft program content included the following:

- Participants thought that it was valuable to have both first-time and experienced mothers in the same group. They considered it beneficial to discuss the reasons behind over-eating, non-hungry eating and particularly emotional eating and management strategies; as well as managing the mood swings in pregnancy.
- Participants recognised the need for information about healthy eating pregnancy and value of having a meal plan to follow ("helps you to stay on track"). They felt that information would have been valuable to them during their pregnancy.

- Some wondered whether specific nutrition needs such as low iron status would be well managed in the group situation. The participants would still have their individual appointment with the midwife and doctor. Where needed they may require an individual appointment with the Dietitian for a more detailed diet history and medical nutrition therapy just as they would get in routine care.
- One CRG member raised a concern regarding particular personality types within the group where
 those who are more outgoing may make it harder for more timid people or primiparous women to
 share their thoughts and concerns. They commented on the need to ensure enough time in the
 session to ensure each participant has a chance ask their questions.
- Participants recommended the inclusion of a list of places that have exercises that include the baby.
- The suggested name for the program (Blooming Together) was also determined through consultation with the CRG and approved by the steering committee.

4.2.3 Output of the Development Phase

The Development Phase resulted in the amendment of the first draft of the program to include a postnatal session at 6-8 weeks. The amended program schedule was:

- Session 1 19 to 21 weeks gestation
- Session 2 24 to 26 weeks gestation
- Session 3 28 to 30 weeks gestation
- Session 4 34 to 36 weeks gestation
- Session 5 6 to 8 weeks postnatal

These sessions were then trialled with the target group and improved through the Consultation Phase.

4.3 Consultation Phase

This phase involved session by session delivery of the Program (as described in section 4.2.3) with a group of maternity consumers recruited through KEMH. Focus groups were conducted immediately after each of the sessions to provide an opportunity for the participants to provide feedback on the sessions in an effort to refine and improve the content and delivery of each session. Participants were also asked to complete a self-administered questionnaire.

4.3.1 Results: Sample

A total of 75 women were recruited and 40 women attended one or more of the five (5) sessions trialled. The age range of the women who attended the antenatal sessions was between 21 and 43 years with the

average age of 31 years. The average gestational age was 28 weeks; with 13 women being primiparous and 21 women multiparous. The average BMI was 42. The age range of the women who attended the post natal trial was between 24 and 43 years; with equal number of primiparous and multiparous and a BMI average of 40. Table 4.2, 4.3 and 4.4 provides information on women who participated in the trial sessions and focus groups conducted during the Consultation Phase.

Table 4.2 Trial session schedule and numbers for recruitment and attendance

Session	Trial number	Date	No. recruited	No. attended
Session 1	Trial	Mar 2012	10	7
(antenatal)	Retrial	May 2012	8	2
Session 2	Trial	June 2012	8	5
(antenatal)	Retrial	Aug 2012	5	6
Session 3	Trial	Oct 2012	7	3
(antenatal)	Retrial	Oct 2012	7	4
Session 4	Trial	Nov 2012	8	3
(antenatal)	Retrial	Nov 2012	9	4
Session 5	Trial	Feb 2013	6	3
(postnatal)	Retrial	Feb 2013	7	3
		TOTAL	75	40

Table 4.3 Demographics of the antenatal session trial sample (n=34)

Age range	21 – 43
Average age	31
Gestational age range (weeks)	14 – 36
Average gestational age (weeks)	28
Primiparous	13
Multiparous	21
BMI range (kg/m²)	31-66
BMI average (kg/m²)	42

Table4.4 Demographics of the postnatal session trial sample (n = 6)

Age range	24-43
Average age	32
Stage postnatal range (weeks)	6-21
Average stage postnatal (weeks)	13
Primiparous	2
Multiparous	2
BMI range (kg/m²)	35-46
BMI average (kg/m²)	40

4.3.2 Results: Post-session focus groups

The following section provides a summary of the key themes that arose from the focus groups.

Group-based obesity-specific maternity care

Participants acknowledged the program would be very useful for weight management and awareness from the beginning of pregnancy. Participants said the group sessions supported their particular challenges and situation (in relation to their BMI) during pregnancy:

"I felt they understood me because I'm big...".

"I just find it makes you feel not so singled out because there are other people going through the same issue".

"I think it's good to have a group, because you know there are other people that are at the same level as you".

Participants stated that they enjoyed sharing concerns and ideas in an open forum. It was expressed by a number of participants that they valued the support the groups would provide pregnancy and the postnatal period.

"There is not always the time in clinic to go through some of the discomforts as you feel that it's annoying and you don't want to bother the staff."

Session content

Participants felt they better understood why a pregnancy was deemed 'high-risk' due to maternal obesity "if the tangible risks are explained". One respondent suggested the session content made her feel self-aware "because pretty much every single section that was covered today was about me, which was quite good." Further, all participants indicated topics covered in the session were appropriate in content and duration. Participants felt the weight tracking tool was a good indicator of healthy weight gain/loss (refer to Attachment 15). Weighing yourself as part of the pregnancy journey was seen "as a process" and "something that you have to do. "You've got to be realistic about yourself when you are pregnant" and weight status is "knowledge that I think you need, but you don't want to hear.

Participants also indicated that being reminded about weight was important because they previously had not focused on weight gain or loss;

"Just focusing on the fact you are pregnant...".

The barriers to healthy eating were "a great eye opener".

Participants really valued the goal setting as "you don't think you have anything to change until you really think about it". Participants indicated the healthy eating component of the education session provided impetus for change; specifically the 'teaspoons of fat' activity.

Specifically, they appreciated "when you see it visually like that":

"I would cook with the fat on then take the fat off while I was serving it out and if I was served fat I would not eat it. But that makes a big difference. I never knew that... So now, when I am in the shops, I will look at the quality of meat... I have to an extent, but that's really bringing it home"

Respondents valued the barriers to physical activity worksheet as it provided an opportunity to diagnose why they are not making physical activity a priority:

"I think it's good because sometimes you're not doing things and not really thinking why".

Session structure

One respondent highlighted her desire to continue attending sessions after pregnancy "to check in after you have had the baby... because that's when you are breastfeeding too".

In particular, one respondent indicated they would be happy for each session to last 2.5 hours:

"I reckon there was a lot of useful information and another half an hour would be fine because I'm coming from quite far away. So by the time you drive and find parking and everything, just to come for an hour to an hour and a half..."

4.3.3 Results: Post-session evaluation survey

A brief evaluation survey was completed by participants following each session which included rating the value of the session content using a 5-point Likert Scale (Not very valuable '1' to very valuable '5') and the opportunity to provide written comments.

The value of the session topics were rated highly overall with most receiving a rating of 4 (range of 2-5). One participant who attended the first trial rated the discussion around the gestational weight gain (GWG) recommendations, and the effects of GWG on a baby's future health, as well as the recommendations for physical activity, as a '2' (not valuable) without providing any comments. All other session attendees rated these topics as valuable. The written comments provided by the other participants recognised the importance of discussing the background of the different GWG recommendations in order for women to understand the recommendations and not feel discriminated against (unfairly labelled as unhealthy). Additionally, two participants felt like too much time was spent on BMI whereas another person wanted more detailed information.

The other topic rated '2' (not valuable) by a participant was the discussion around gestational diabetes (GDM) and glucose tolerance test (GTT) (session 2, trial 2) without an accompanying comment. This section was rated as valuable by all the other attendees.

Some participants commented that they would like more practical and detailed information on particular topics such as recipes and physical activity (aspects that would be covered in other sessions that they did not attend). Another request was for the sessions to be longer to allow "more time for talking and group interaction".

The pregnancy weight tracker was rated as particularly valuable. The comments indicated that they would like to be provided with the weight tracker at the start of pregnancy, and they recognised the benefit of having a visual of their progress with regard to pregnancy weight. The label-reading, goal-setting, portion-size and the mindfulness exercises were also rated as valuable activities.

4.3.4 Outputs of Consultation Phase

A Participant Guide was developed as a result of all the feedback provided by the participants in each of the sessions through the self-administered questionnaire and participation in the focus group.

The following documents made up the Participant Guide:

- Introductory booklet To be given to women prior to signing up for Blooming Together Program
- Session 1 19 to 21 weeks
- Session 2 22 to 23 weeks
- Session 3 24 to 26 weeks
- Session 4 28 to 30 weeks
- Session 5 31 to 32 weeks
- Session 6 34 to 36 weeks
- Session 7 6 to 8 weeks postnatal

4.4 Refinement Phase

All sessions were modified, where appropriate, according to the feedback provided by participants in the previous phases of the research: Development Phase and Consultation Phase. These sessions were then combined to form the Blooming Together Participant Guide.

The completed draft of the Blooming Together Participant Guide was sent to a number of women previously involved in the session trials as well as from the CRG. The Participant Guide was also sent to HCPs for feedback and comment.

4.4.1 Sample: Target group feedback on Participant Guide

A total of nine (9) women provided feedback on the Participant Guide; three (3) of these were CRG members and six (6) women had attended at least one (1) of the session trials.

Figure 4.1 provides information on the representation of the CRG members and other trial participants in providing feedback on the Participant Guide.

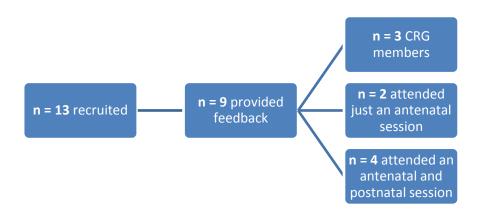


Figure 4.1. Level of participation of respondents who provided feedback on the Participant Guide

4.4.2 Results: Target group feedback on Participant Guide

The following is a summary of feedback provided by participants on the draft Participant Guide. The Participant Guide was modified according to this feedback. The methodology for this data collection phase in detailed in section 3.4.5

Overall impressions of the group model of maternity care model

Participants felt that it was beneficial having combined antenatal care and lifestyle education, particularly a group specifically for obese women. This was seen to make these women feel better cared for. The value of avoiding the clinic waiting time in clinic and replacing it with education was recognised; however one respondent felt that the model of care may be perceived as being too time consuming to those who are not familiar with the typical waiting times at the KEMH Antenatal Clinics.

Timing of sessions

The participants provided feedback regarding when the topic of healthy pregnancy weight is best introduced in the program. Many felt that it would be beneficial to know about healthy pregnancy weight earlier in pregnancy in order to avoid excessive weight gain.

In regard to the postnatal session, one respondent did feel that women may need more time to recover from their birthing experience. The vast majority of respondents, however, felt that follow-up at 8-10 weeks was a suitable time for the postnatal session.

Facilitators

The feedback from all the sessions was that they were all supportive of a Midwife and Dietitian facilitating the program. The attendance of a physiotherapist at two of the sessions was also supported. There was feedback as to time spent on safe exercise practice including demonstrations and pictures of safe exercises. There was a mixed response regarding having a clinical psychologist involved in the group. One participant commented that psychology service should be offered as individual counselling on a needs only basis.

Attendance of partners at the group

The participants felt that it would be good to have one session early on in the pregnancy that partners or other support person (e.g. mothers) can attend. They identified that it would be beneficial for the support people to be aware of the importance of being active and eat healthily in pregnancy as well and managing pregnancy weight so they can support the pregnant women to do this.

\Explanation of the risks related to having a high BMI

Participants reported that they felt it was important to explain what a high-risk pregnancy means and how it relates to maternal BMI. These participants indicated that this should be covered early in the Program. One respondent was not aware of the increased risks during labour and delivery and felt knowing this would have been valuable to her. Another respondent was surprised at the risks related to miscarriage and fetal abnormalities.

Healthy pregnancy weight

The majority of participants felt that the information on healthy pregnancy weight gain and BMI was valuable however one respondent did feel that there was too much focus on BMI and another was confused by how to calculate it. Some participants suggested that the pregnancy weight tracker (PWT) would be very beneficial to have from the beginning of pregnancy because later introduction of the PWT could lead to distress if you first receive it at 20 weeks gestation and have already gained outside of the recommended

guidelines. The PWT was seen as a good way of taking control of their own health and no longer feeling they had to "hide from the scales". Being weighed at each session was seen as a positive thing.

Goal-setting

Goal-setting was seen as helpful to keep themselves 'on track', 'accountable' and motivating. One respondent felt that it was difficult to think on the spot to develop personal goals that fitted the SMART criteria. Another respondent suggested that the group make a common goal that as a group they can work towards together. It was also suggested that more focus be put on doing physical activity as a family including recording how much time is spent being active as a family each week including incidental activity.

Dietary information

The BLOOM meal plan and menu ideas were seen as a valuable resource that provided clear portion sizes and family-friendly meals. One respondent felt that the meal plan may be difficult for a working woman to follow. Another respondent thought that BLOOM portion sizes were not relevant for her partner who is male, and felt that it would not be enough food for him. The hunger scale was considered a useful tool, particularly if presented as a fridge magnet. Respondents also felt being given regular menu plans would be helpful. The photos showing fat content of different meals and suggested healthy modifications to recipes was also considered as helpful. The FoodCents exercise on balancing the type of food purchases according to the eat more, eat sometimes and eat less.

Stress management

This was seen as a valuable aspect of the program. Participants reported that the information on how to effectively use support systems serves as a good reminder. There was interest in having more information relating to stress management and understanding the emotional effects of pregnancy hormones. There was a mixed response to the relaxation breathing activity, with suggestions that it would be helpful but not suitable to all participants.

Breastfeeding

Participants felt that the information on breastfeeding was appropriate and considerate of women's different intentions for infant feeding. Most participants felt that a lactation consultant visit during one of the later sessions to discuss breastfeeding techniques and support for breastfeeding would be useful.

4.4.3 Sample: Health care provider feedback

A range of health professionals (HCPs) were approached to provide feedback on the draft Participant Guide. Refer to Table 4.5 for more information.

Table 4.5 Information on health professionals who provided feedback on the draft Participant Guide

	Number	Number	Internal	External
	recruited	provided	to KEMH	to KEMH
		feedback		
Exercise Physiologist/	3	3	1	2
Physiotherapist				
Dietitian	2	2	1	1
Psychologist	1	1	0	1
Midwife	3	1	1	0
Obstetrician	3	0	0	0
GP	2	1	1	0
Total	14	8	5	3

4.4.4 Results: Health care provider feedback

Feedback from a range of HCPs was brief but constructive. All of the HCPs reported that the participant guide was of high quality, contained information that would be useful to the target group and seemed to be a promising intervention in the management of maternal obesity in pregnancy.

The Sports Physiologists and Physiotherapist suggested specific recommendations for aerobic and strength-based exercise in pregnancy for obese women. They stipulated that caution and proper instruction needs to be taken with abdominal and strength exercises as there is limited research for the benefits of these exercises during pregnancy and some increased risks with participation. They suggested that emphasis should to be put on aerobic exercise (i.e. walking, cycling, swimming), which is more accessible for women with a high BMI. A more accurate method of measuring exercise intensity was also suggested; using 'Borg's rate of perceived exertion' rather than heart rate.

The Dietitians had helpful additions and amendments to the nutrition components of the sessions. One of the nutrition activities that looked at the balance of the amount of money spent on the different food groups using FoodCents was simplified through using an online resource rather than manual calculations. Some re-

shuffling of the order of topics was also suggested to better complement others covered in the session (i.e. 'healthy food choices' with 'label reading').

The Psychologist's input primarily refined the writing and ensured a positive and motivational tone. A change to the timing of the postnatal session was suggested from 6-8 weeks to 8-10 weeks. The reason stated was that the session may be more beneficial for the women to receive after their GP check-up at 6 weeks. This will allow time for normal adjustment post-birth and the women may be more receptive to thinking about their own health, diet and physical activity levels. The presence of partners was not seen as an issue unless only one or two participants brought their partners which could lead to other women in the group to feel self-conscious in discussions having a male in the room that they do not know.

The utility of the session resources were commented on by most HCPs. They are summarised below.

- The healthy pregnancy wheel (promoting life balance)
 - Overall considered a beneficial resource.
 - One comment suggested that initially mothers may dismiss the wheel as being unrealistic to do all this for themselves as well as care for others however others felt that it is "simple and attainable".
 - Some suggested changes to the section titles:
 - "'Keep a positive mind-set' and 'keep stress levels manageable' sound a bit scientific and if you do fully understand them, difficult to achieve if you aren't positive or are stressed."
 - Change the 'minimising your pregnancy weight gain' to be clearer and provide a more positive message. This section was changed to 'have a healthy pregnancy weight' to meet these criteria. However, there was concern that 'healthy weight' could be misinterpreted.
 - To include regular attendance at antenatal appointments or receiving regular checkups through pregnancy
- The Pregnancy weight tracker
 - The HCPs all felt this tool would be valuable.
 - o It was suggested that detailed and clear instructions regarding its use would be required.
 - o The benefits of monitoring your weight in pregnancy should also be emphasised.

HCPs agreed that the program would be successful in raising women's awareness of the risks associated with their BMI. Two HCPs felt that including the risks to themselves and their baby may be alarming to some but that it was important for them to be aware of these risks.

One health professional felt that the participant guide focused too much on BMI and pregnancy weight however the majority felt it provided a good amount of information. HCPs felt the variability in gestational weight gain according to BMI categories was explained clearly and accurately. Feedback also stated that the way the information presented would not lead women to feel stigmatised or discriminated against for having a BMI.

A comment from one of the GP obstetricians suggested that the program would appeal to well-educated, English-speaking women who are likely to be motivated however, that "there is a lot of good ideas, strategies, problem-solving so something there for everyone".

5 Project Outputs

5.1 Blooming Together Program

The major output of this Project is the Blooming Together Program (BT Program). The BT Program is a maternity model of care for obese women incorporating evidence based behavioural strategies to achieve a healthy pregnancy weight. It has been designed within a continuity of care model to provide obese pregnant woman with a comprehensive antenatal model of care.

The BT Program is supported by a Participants Guide, a draft Facilitators Guide and a number of supporting resources.

The BT Program is delivered as eight (8) group sessions and one-on-one appointments at 16 weeks and from 37 weeks to birth (following the routine antenatal care schedule). The sessions are run by two midwives and a dietitian: one midwife and one dietitian to facilitate the group lifestyle education component and another midwife to conduct the antenatal check-up during the session. Some sessions will also have a visiting Physiotherapist or Lactation Consultant. The participants will receive medical consultation where indicated.

Each session provides discussion and activities relevant to the gestation of the women and based on evidence from the medical, dietetic, psychological and exercise physiology literature.

The following table (Table 4.6) provides information on the format and content of each of the group sessions. Each of these sessions can be held in a clinic, General Practice, or Community Centre and are facilitated by the Midwife and Dietitian. A Clinical Midwife will also attend most sessions to provide individual one on one routine antenatal care to the participants. A Physiotherapist will also attend some of the sessions.

Table 4.6. Blooming Together Program Outline

	Gestation	Group Session Content	Routine antenatal care	Visiting HCP
1	12 to 15 weeks	Program overview The healthy pregnancy wheel Healthy pregnancy weight Exploring Body Mass Index Importance of healthy pregnancy weight Steps to controlling pregnancy weight	Yes	None
-	16 to 18 weeks	No group session	Yes booking appointment	None
2	19 to 20 weeks	Life balance review Nutrition and pregnancy Optimising baby's environment and health Physical activity in pregnancy Self-monitoring Goal-setting	Yes	Physiotherapist
3	22 to 23 weeks	Stress management in pregnancy Barriers to healthy eating Increasing incidental activity Plans for infant feeding	Yes	None
4	24 to 26 weeks	Check-in and life balance review Problem solving barriers to physical activity Gestational diabetes and the role of lifestyle Diet and GDM	Yes	None
5	28 to 30 weeks	Emotional eating Binge eating Reading food labels Problem-solving barriers to a healthy family lifestyle	Yes	None
6	31 to 32 weeks	Check-in and life balance review Mindfulness strategies Simple ways to balance meals Healthy eating – planning for busy times Physical activity in later pregnancy Healthy body image	Yes	None
7	34 to 36 weeks	Healthy eating on a budget Infant feeding tips Healthy eating during the postnatal period Resuming physical activity post-birth Making the most of support systems	Yes	Lactation Consultant
-	37 weeks - birth	No group session. Individual appointments or telephone call with BT Midwife for check-ups and to provide support to maintain key behaviour changes	Yes	None
8	8 (postnatal session 8 to 10 weeks)	Common concerns in the postnatal period Emotional wellbeing and support systems Body image Exercise post-pregnancy Re-cap - healthy eating in the postnatal period Role modelling for the future	No	Physiotherapist

5.2 Participant Guide

The 'Participant Guide' refers to individual session booklets provided to participants at the beginning of each respective session. A ring binder is provided to allow easy storage of the session booklets and accompanying handouts and resources (refer to Attachment 10 for a copy of the Draft Blooming Together Participant Guide).

The Participant Guide is designed to be brief enough to be easily read and referred to within the sessions with sufficient detail to be a stand-alone resource that participants can keep and refer back to in the future.

5.3 Facilitator Guide

The 'Facilitator Guide' has been designed to support the delivery of the BT Program (refer to Attachment 11).

The guide is written for both novice and experienced BT facilitators. Each session of the Participant Guide is supported by the Facilitator Guide comprising the following:

- 'Session preparation',
- A brief 'Session overview' that can be used to help guide the experienced facilitator and
- Detailed 'Facilitators' notes' (including suggested scripts) for less experienced facilitators.

This guide is currently in draft form and will be subject to further amendment during the piloting of the Program in a hospital and community setting. Funding for this pilot is currently subject of an application to the Western Australian Department of Health.

5.4 Program branding

A brand identity for Blooming Together was created to ensure the resulting Blooming Together Program resources are recognisable as a cohesive package that visually appeals to the target group and promotes a sense of belonging to the BT Program. This is anticipated to encourage commitment to the Program.

A design brief (refer to Attachment 16) was developed to guide Block Branding Agency (Perth) in creating the Blooming Together brand identity. This outlined the purpose of the program, the target audience and the messages to be communicated through the branding. It was important that the branding reflected the supportive nature of the program whilst at the same time having a contemporary feel.

The branding components of the Blooming Together Program consist of:

- a Blooming Together logo;
- cover pages for the Participant and Facilitator Guides;
- cover pages for each of the sessions;
- a bespoke typeface for the session content; and
- a letterhead and PowerPoint presentation template

Refer to Attachment 17 for a copy of the brand identity components.

6 Discussion

This qualitative research project developed in consultation with pregnant women with obesity has produced a tangible outcome of an evidence-based maternity model of care aimed at supporting pregnant women with obesity to achieve a healthy pregnancy weight. The major output of this project is the Blooming Together Program: an eight session Participant Guide with accompanying Facilitator Guide.

Program Development

The development of the program was well and truly guided by the target group which is considered a vital part of developing a weight management program that meets the needs of pregnant women with obesity [45, 52, 98]. The research process was iterative in that it involved ongoing refinement and amendment according to feedback provided by a range of participants. The BT program development process commenced with the establishment of a Consumer Reference Group (CRG). The CRG provided guidance and advice on their maternity experience and the development of an acceptable model of care for pregnant women with obesity. A draft program was developed using evidence from the review of literature and the CRG input. The draft program was trialled with the target group which resulted in further modification of the session content and the development of a Participant Guide. Health care providers were consulted with regard to the content of this Guide as were members of the CRG and previous trial participants. Seeking feedback from both the end-user and end-administrator at multiple time-points in the development of BT is likely to have contributed to the program's overall acceptability and feasibility.

Maternity Experiences reported by the CRG

The CRG provided valuable insight into the experience of obese women in pregnancy. Overall the CRG reported low satisfaction with the care they had received previously at KEMH. This appeared to be the result of feeling that they were provided with insufficient support and little practical information to help them to achieve a healthy pregnancy weight, experiences also documented by Johnson and colleagues (2012)[84]. Some reported that the care they had received acted to undermine their motivation to achieve a healthy pregnancy weight.

Participants described their previous experiences of maternity care as inconsistent and impersonal. These women identified that a lack of continuity of care compromised the ability to develop a rapport with their carers. Some women felt time was wasted repeating basic pregnancy-related information thereby reducing the scope for questions and tailored lifestyle education. Women also reported that they felt HCPs made assumptions regarding their lifestyle and subsequently labelled them as 'unhealthy' without spending the time to ask the woman about their lifestyles. This feeling of being judged and/or stigmatised for their body size is reflected in the literature [42]. Some felt as if they were lectured regarding their lifestyle and were not given positive reinforcement or recognition for progress they were trying to make with their lifestyle. This

reduced their level of empowerment and motivation to make lifestyle changes thereby undermining their own efforts to achieve a healthy pregnancy weight [55].

The responses of members of the CRG in the focus group revealed a complex relationship between these women and their body size. Many women reported embarrassment/shame about their size. How these women then responded to an unfamiliar HCP raising the topic of their weight was also influenced by this complex relationship. This meant that little of the advice or information provided during routine antenatal care actually translated into behavioural change for these women. This was further compounded by some of the women indicating that they believed their weight was not under their control indicating a level of helplessness in dealing with their weight.

The CRG participants highlighted a range of experiences with HCPs around the issue of BMI in pregnancy. Some HCPs completely avoided the issue of their weight, providing no lifestyle education or information regarding the recommendations for healthy pregnancy weight. Others attempted to educate women regarding weight management in pregnancy however this was done by making assumptions regarding the woman's exercise and dietary patterns (without actually asking the women). This left the woman feeling defensive and unfairly labelled. The insensitive approach by HCPs was not as common but when it did occur it resulted in the women feeling judged, upset and/or angry which was similarly reported in the literature[42, 52, 53]. This was often associated with the HCPs using terms such as 'fat' or 'obese' and scaring them regarding the health of their child in pregnancy without providing constructive information as to how to manage their weight in pregnancy.

The CRG reported that, overall, the approach of the HCPs they experienced at KEMH tended to make them feel defensive, unsupported, upset and/or angry. This had the effect of making communication awkward, difficult and potentially damaging particularly in the circumstances where the HCP is uncertain as to how to approach the topic of weight in pregnancy. The lack of confidence in addressing gestational weight with obese women is well reported in the literature [42-48, 52]. The CRG members reported that their experiences made them provide surface justification of their size claiming that they were both active and ate healthily and that their size is simply a result of their genes, remaining unchanged despite food restriction and/or more exercise, despite knowing deep-down that improvements could be made.

It is unclear whether this reaction of the target group is a result of the approach of HCPs, or whether women with a high BMI interpret their experiences differently due to insecurities regarding their size, or, a combination of both of these aspects [84]. Regardless, it is well documented in the literature that HCPs do feel limited in their ability to provide tailored lifestyle education due to time constraints, and lack confidence in delivering this information particularly to patients who are obese [49, 84]. It is also recognised that

continuity of carer, that allows rapport to be built, benefits both the delivery and reception of sensitive lifestyle-related information as well as increasing satisfaction with care [85, 87].

The feedback from the CRG and participants of the session trials provide overwhelming evidence of the importance of a targeted model of maternity care for obese women. The BT Program has addressed these concerns of pregnant women with obesity by providing a model of care that acts to build rapport, understands the sensitivities required when discussing topics of weight and healthy lifestyle, and provides timely advice to empower women to manage their weight in pregnancy.

Participant experience of the Blooming Together Program

Focus groups and interviews with the target group showed a high level of acceptability of the Blooming Together Program, both content and format. The group model of maternity care addressing issues specific to obese women was seen as a highly valuable aspect of the program. Participants reported that being surrounded by peers considered in 'the same boat' contributed to their level of comfort and receptiveness to the education. They valued sharing their experiences with the group and learnt from hearing about other's experiences. Also reported was an increased level of confidence in making changes to their behaviour as a result of hearing about peers' successes.

The positive response of the participants in regard to continuity of care was consistent with the literature. [41, 87, 88] The participants felt that seeing the same HCP through their antenatal and postnatal care would increase their level of rapport and accountability and thus motivation for behavioural change. The accountability provided by ongoing goal-setting and tracking of pregnancy weights included in the program was considered particularly valuable.

Feedback from the CRG and other participants reinforced to the facilitators the importance of the Program focusing on the basics of BMI; conducting honest and open discussion around BMI, explaining in detail how healthy pregnancy recommendations came about and how these relate to pre-pregnancy BMI. In addition, participants reported that the sessions addressing strategies to improve emotional health along with their diet and physical activity levels were important. The participants appreciated the holistic approach to their care as well as multidisciplinary facilitators with attendance by a Physiotherapist who they could ask specific questions regarding pregnancy, diet and physical activity.

Challenges

Development of session content

The development of the session content was a dynamic, iterative process. The Program changed considerably from the initial idea to the end product of a comprehensive evidence-based group-delivered maternity care program designed to promote a healthy pregnancy weight. The research team strived to strike a balance between what could realistically be implemented in the current resource-limited environment whilst ensuring the program can be effective in improving the health outcomes for pregnant women with obesity and their babies as well as being acceptable by the target group.

Acceptability of the program for the participants involved ensuring that the schedule allowed for:

- Timely and sufficiently detailed lifestyle education and practical advice;
- Integrated antenatal check-ups and lifestyle education;
- Adequate time for group discussion and sharing of experiences; and
- An acceptable number and length of sessions.

In order for the intervention to be feasible in the public health system the sessions roughly followed the routine schedule of antenatal care. The research team identified that early referral and education regarding healthy pregnancy weight was vital to minimise the total amount of weight gained in pregnancy[62]. For this reason, the BT program begins earlier in pregnancy than the schedule followed by KEMH: at 12-14 weeks rather than at the booking appointment around 19 weeks' gestation. The research team has plans to explore an effective brief intervention for GPs to minimise gestational weight gain in the first trimester of pregnancy, the addition of a session to include support people and an extended postnatal program..

The program was developed in response to needing an effective intervention for weight management in pregnancy and a more comprehensive and supportive approach was deemed necessary to achieve this. A comprehensive model of maternity care incorporating antenatal care and lifestyle education in a series of eight x 2.5 hour group sessions which is run by three health care providers (two Midwives and a Dietitian) and additional visits from a Physiotherapist and Lactation Consultant will require greater resources than the current provision of care. The next step of this research is to explore the cost effectiveness of the intervention focusing on the savings to the health system in reducing obstetric and neonatal complications.

Recruitment

Successful recruitment of women for this research required significant thought, time and a particularly sensitive approach. The Research Team had to deal with the realities that pregnant women are busy, often tired, may or may not be on maternity leave and have other children in their care. Furthermore, the trial sessions were in addition to the women's antenatal care and therefore required an extra trip to KEMH which

was associated with extra travel time and difficulty with parking. These issues made the approach to recruitment even more important. The recruitment letters and project information sheets were carefully worded and presented, and telephone calls were made by the facilitators themselves. This ensured that the tone of the recruitment was in-line with the program's approach: sensitive, supportive, non-judgmental and woman-focussed.

Limitations

The use of the formative trial design meant that each session was run as stand-alone sessions; which meant that participants provided feedback on sessions in isolation rather than as part of a complete program. The artificial nature of how the sessions were run meant that pre-requisite knowledge that would have been gained from preceding sessions was not possible. The facilitators attempted to provide a context for each session and where possible included relevant background knowledge (e.g. the risks related to having a high BMI, the importance of healthy pregnancy weight, how to set effective goals). This meant that the true value of the session content was also likely to have been underestimated by participants, despite already rating it highly. The accumulative knowledge acquisition, practising skills and strategies, building social support and their experience progressing with behaviour change are all aspects that will be achieved through the program pilot.

Furthermore, the program was designed for each session to be run consecutively with the same group of women all living in a similar area (locally to the women's health centre or hospital that the program is run) and at a specific gestational stage (within 3-4 weeks of each other). This environment was not achievable for the formative trial where each session was conducted with women who did not know each other, were at varying gestational stages and lived as far North as Northam and as far south as Rockingham. Regardless of this significant limitation, the participants of the sessions demonstrated significant bonding and even shared contact details. This indicates the great potential for rapport building between participants and their peers as well as with facilitators in the pilot trial of the program.

The other potential limitation relates to the membership of the CRG. Pregnant women with obesity were recruited to the CRG to help improve maternity care for this high risk group. This may have skewed the membership of the CRG towards those women who had negative experiences at KEMH because of a desire to share those experiences. Women who had good or neutral experiences at KEMH may not have been as motivated to join the CRG or to participate in the session trials and hence their views would not have been representatively captured by this research. The CRG findings did offer a mix of both positive and negative experiences of their maternity care.

Conclusion

The thorough and considered approach in developing the BT Program involving input and feedback by members of the target group provides an excellent foundation for ensuring that the Program will be an acceptable model of maternity care for obese women and has the potential to reduce adverse obstetric and neonatal outcomes in these high risk women.

7 Future Research: Blooming Together Program Pilot and Trial

The output of this research is a maternity model of care for obese women incorporating evidence based behavioural change strategies to achieve a healthy pregnancy weight. The next phase of the research will involve conducting a pilot study to examine the effect of the intervention on maternal infant outcomes and the feasibility of implementing the BT program in a hospital and a community setting. In addition, an economic evaluation will be valuable in determining the cost of delivering the intervention and the likely cost savings in terms of the maternal and infant outcomes both in the short-term (e.g. caesarean section rate, breastfeeding initiation/prevalence) and the long-term (e.g. future maternal and child obesity).

In an effort to progress this pilot, the Research Team has met with a number of health service providers to explore possible future pilot sites. Advice was provided by the Women's and Newborns' Health Network Leads that a community-based location for the pilot would be an important adjunct to a tertiary hospital-based pilot due to a move towards community-delivered antenatal care. The Research Team also considered it important to engage and collaborate with a community-based women's clinic as this arena would maximise the benefits from a group-delivered program with regards to ongoing peer-support and the ability to provide tailored information to the local area. The Research Team have met and had ongoing contact with Woodbridge Women's Clinic in Rockingham who agreed, if funding was provided, to be the community-based pilot site. A meeting was also conducted with Rockingham General Hospital that established an intention to work collaboratively to establish the BT program as a model of maternity care.

The next step of this program of work involves the conduct of an RCT to evaluate the efficacy of the intervention with respect to the medical, psychological and behavioural outcomes for the mother and child in both the short-and long-term. In addition to this, the Research Team recognises the need for a comprehensive approach to the addressing pregnancy weight among obese women. With this in mind, work has been undertaken to identify appropriate support for GPs to offer accurate pregnancy weight education and support to obese women in early stages of pregnancy.

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