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Using health psychology theory in the design and evaluation of a complex weight management intervention.

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Presentation aims

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- To highlight best practice in the design and evaluation of complex public health interventions, with particular attention to the application of theory.

- To describe the process of designing and evaluating a theory-based intervention using the example of a complex intervention to support weight management during pregnancy and postpartum.

Background

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- Around 1 in 5 pregnant women in the UK have obesity.
- Associated generally with poorer health, as well as increased risk of adverse outcomes in pregnancy and birth for mothers and babies.
- Antenatal care costs may be 5–16 fold higher.
- Increased hospital stay of 4.43 days on average.
- Infant admission to neonatal care was 3.5 times higher.

Background

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Maternal risks

- Hypertension
- Gestational Diabetes
- Increased caesarean section rates
- Increased induction of labour
- Venous thromboembolism
- Increased postpartum haemorrhage

Foetal risks

- Pre-term birth
- Admission to neonatal unit
- Birth defects e.g. spina bifida
- Stillbirth
- Macrosomia

References: Callaway et al 2006, Bhattacharya et al 2007, Larsen et al 2007, Sebire et al 2001, Usha Kiran et al 2005, Bianco et al 1998

Background

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- Excessive gestational weight gain and postpartum weight retention can lead to long-term obesity and risks in successive pregnancies.
- Excessive maternal weight gain is associated with childhood obesity at 3 years and continuing into adolescence.
- Pregnancy thought of as a '**teachable moment**' but provides unique challenges for weight management and intervention.
- No UK guidance on pregnancy weight gain and referral options limited.

What makes an intervention complex?

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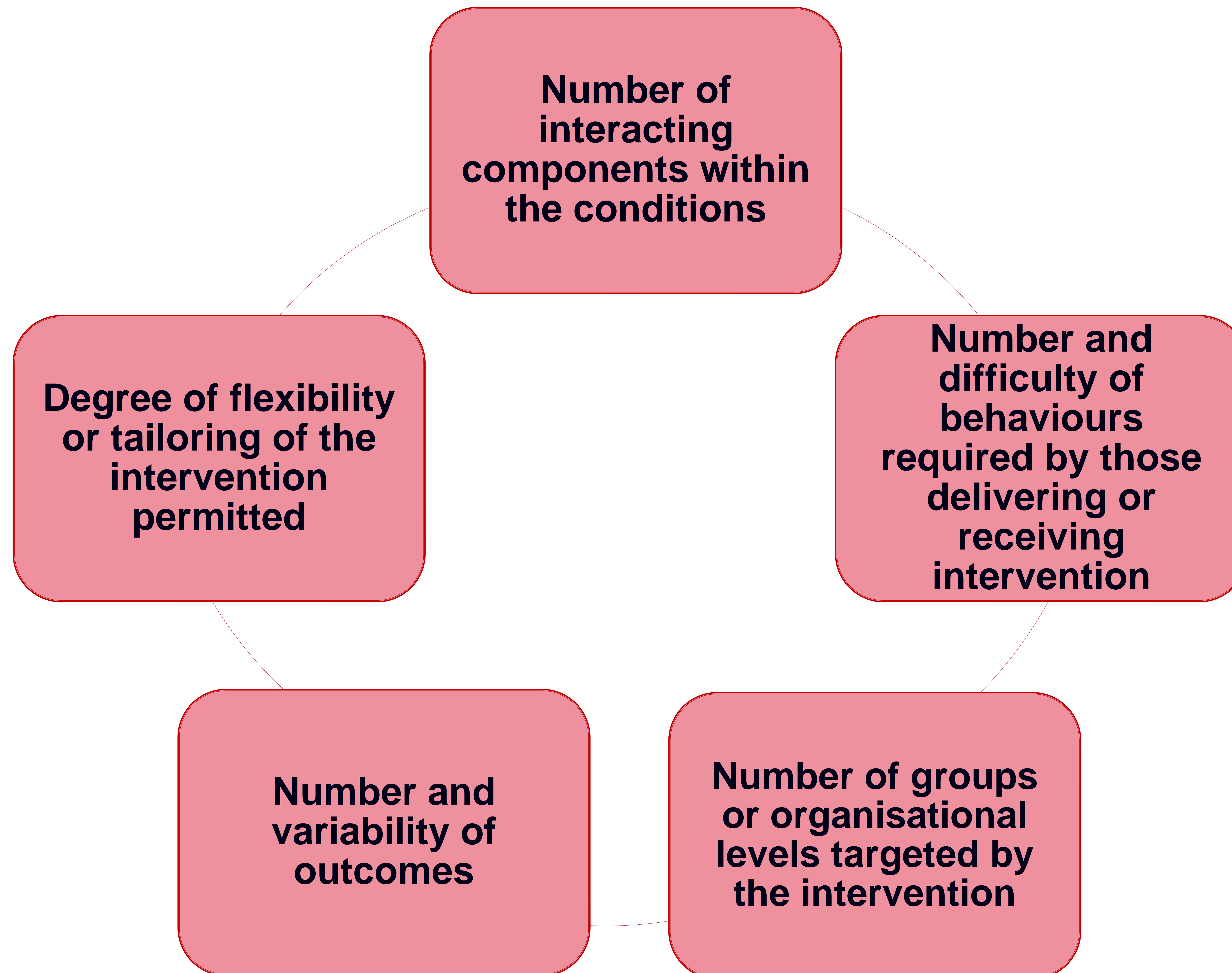

MRC Guidance on Complex Interventions

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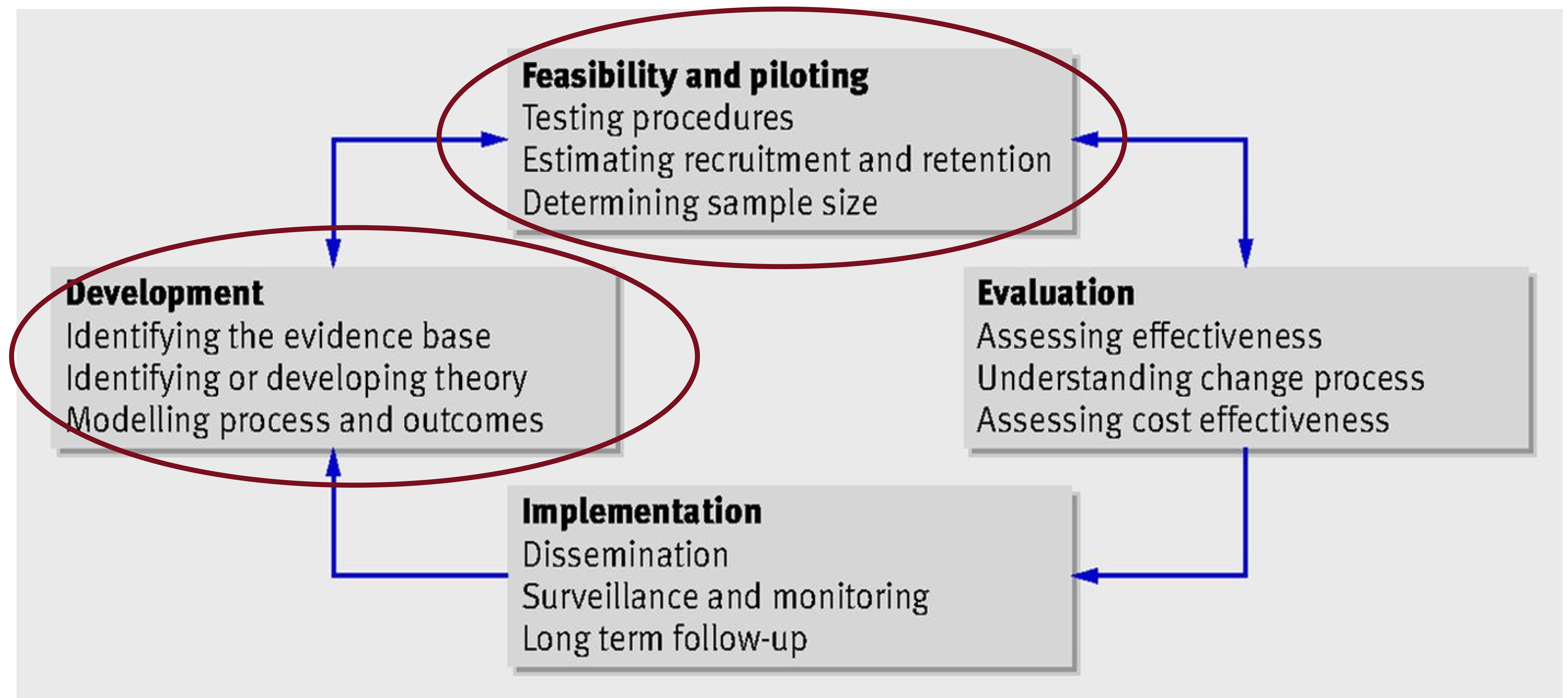

Reference: Craig et al. BMJ 2008;337:bmj.a1655

Healthy Eating and Lifestyle in Pregnancy (HELP) Trial Development

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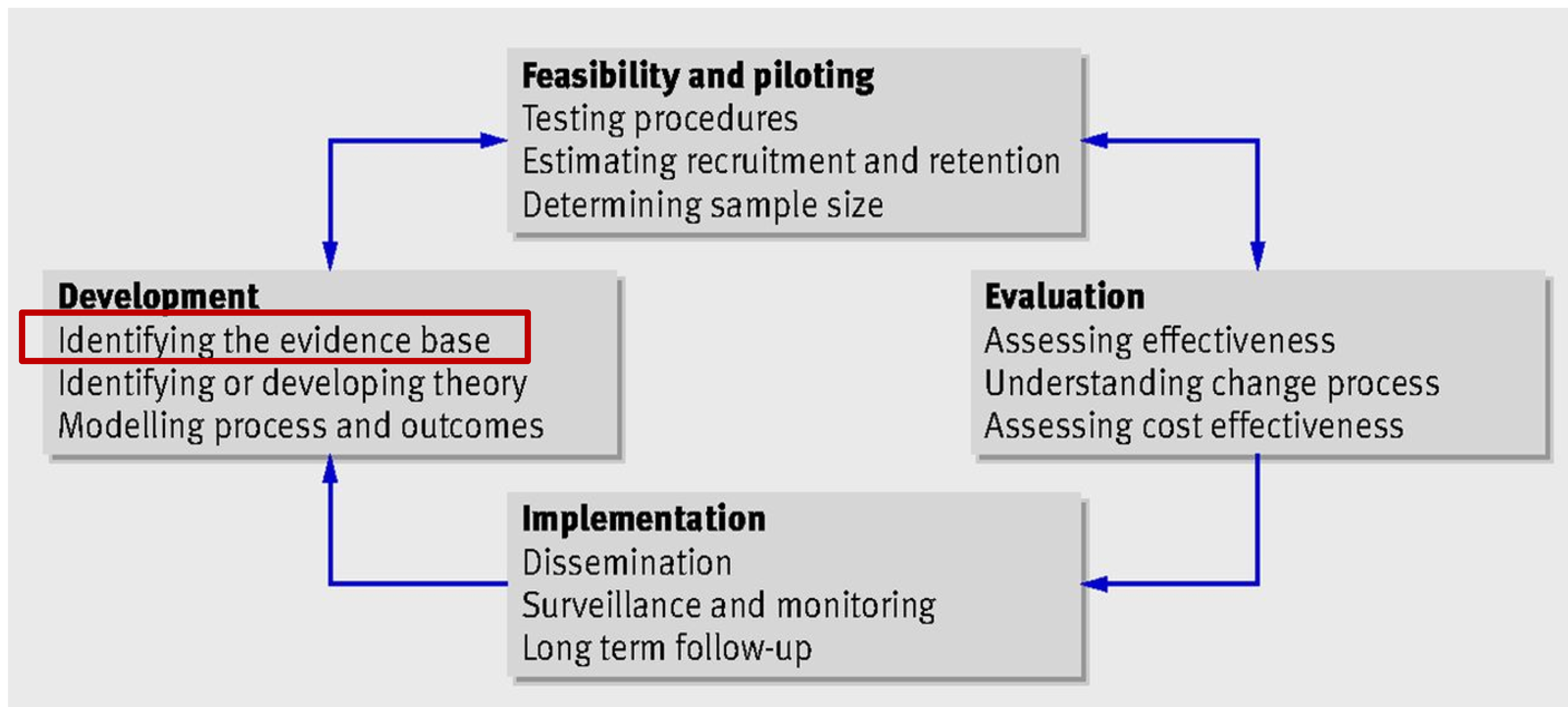

Development- identifying the evidence base

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Literature review- Qualitative evidence

Clinicians

- often uncomfortable discussing weight-related issues.
- training needed.
- referral options are limited.

Women beliefs

- about obesity and pregnancy and the risks.
- diet and physical activity in pregnancy.
- lack of information/ support given by health professionals.
- barriers including lack of sense of control/ social support/ motivation.

Development- identifying the evidence base

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Literature review- Quantitative evidence

- Effective evidence-based interventions were not available:
  - some evidence from meta-analyses that diet and exercise interventions could have a moderate positive effect on weight-related outcomes
  - limited evidence for further benefits on infant and maternal health
  - but poor quality trials with small sample sizes, loss to follow-up high, poorly described interventions and short term follow-up, no health economic data.
  - **few theory-based trials.**

Healthy Eating and Lifestyle in Pregnancy (HELP) Trial Development

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Feasibility and piloting
Testing procedures
Estimating recruitment and retention
Determining sample size

Development
Identifying the evidence base
Identifying or developing theory
Modelling process and outcomes

Evaluation
Assessing effectiveness
Understanding change process
Assessing cost effectiveness

Implementation
Dissemination
Surveillance and monitoring
Long term follow-up

HELP pilot study

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- Referral to commercial weight loss groups recommended by NICE and shown to be effective in short term but long term evidence lacking.
- Intervention group held in antenatal clinic in University Hospital Wales run jointly by a midwife and slimming world consultant.
- Non-randomised single arm feasibility study which recruited 148 women to take part.
- Assessed feasibility and acceptability outcomes, including recruitment and retention rates, as well as indicative positive effects.

HELP pilot study- key findings

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- Recruitment feasible (some alterations in main study)
- Feasible to deliver the intervention
- Intervention acceptable to women
- Retention needed improving – retention strategy developed for main study
- Positive indicative effects:
  - Higher initiation and continued breastfeeding
  - Fewer elective caesareans in women attending group
  - Women not attending group had two times greater weight gain

HELP pilot study- qualitative findings

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"Last time I put on 4 stone and had diabetes, this time I am in control"

"The other Mums and I swapped ideas and as a group found out new ideas and things to try. I really feel that without the group I would've put on an enormous amount of weight, especially because the SPD meant I wasn't able to exercise. I would like to thank X, Y and the other Mums-to-be for their support. I would've given up without them."

"I felt I had no choices when they told me I was too big but coming to group and keeping control of my weight has given me my confidence back"

HELP intervention

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Healthy Eating programme

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Slimming World's 'Extra Easy'

- A flexible weight management and healthy eating programme
- In line with current government recommendations including the "Eat Well Plate".
- Practical skills and strategies for managing behaviour change are discussed, including meal preparation and overcoming barriers.

Physical Activity programme

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Walking programme

- Focused on gradually increasing walking.
- In-line with The Royal College of Obstetricians and Gynaecologists and government recommendations.
- Included:
  - individual step targets reviewed throughout.
  - information and advice on pregnancy-appropriate exercise.
  - warning signs to terminate exercise or seek medical advice.
  - pedometer and walking diary to encourage and track physical activity.

Healthy Eating and Lifestyle in Pregnancy (HELP) Trial Development

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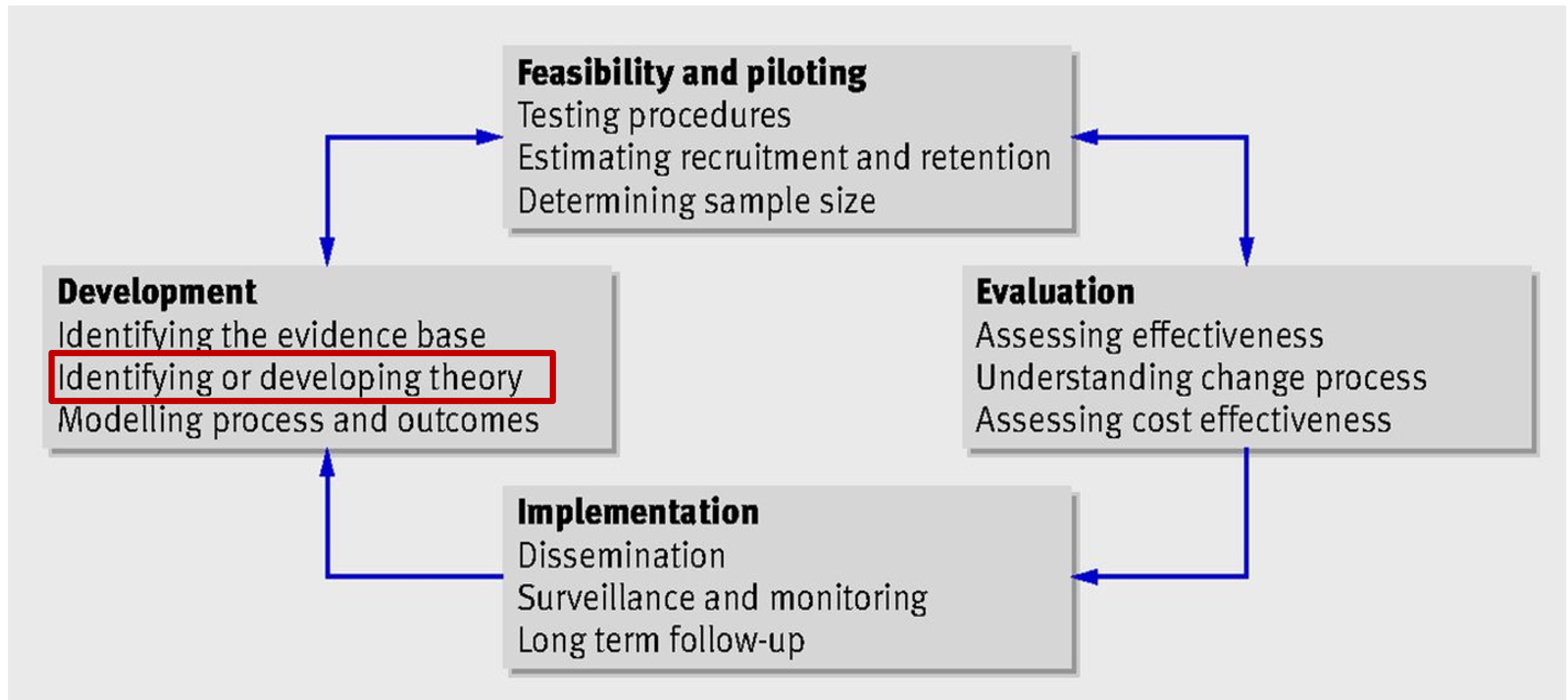

Identifying or developing theory

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How does the intervention work?

Why did the intervention not work?

"Only through understanding causal mechanisms can we design more effective interventions and apply them appropriately across groups and settings" (Craig et al, 2008)

Behaviour change techniques

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- Replication of interventions depends on having a good understanding of the nature and content of those interventions.

- Clarification of **what was delivered**- the 'active ingredients' or behaviour change techniques (BCTs) and **how it was delivered** (i.e. who delivered, to whom, how often, for how long, in what format, and in what context) is required.

- Several taxonomies developed to help define these components:
  - **2008:** 26 item BCT taxonomy
  - **2011:** 40 item BCT taxonomy for diet and physical activity behaviour change
  - **2013:** 93 item BCT taxonomy v1

www.ucl.ac.uk/health-psychology/bcttaxonomy/ www.bct-taxonomy.com

Behaviour change techniques (BCTs) for diet and PA: The CALO-RE taxonomy (2011)

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1. Provide information on general consequences of behaviour	11. Prompt review of outcome goals	21. Provide instruction on how to perform the behaviour	31. Prompt anticipated regret
2. Provide information on individual consequences of behaviour	12. Prompt rewards contingent on effort/ progress towards behaviour	22. Model/ Demonstrate the behaviour	32. Fear Arousal
3. Provide information about others' approval	13. Provide rewards contingent on successful behaviour	23. Teach to use prompts/ cues	33. Prompt Self talk
4. Provide normative information	14. Shaping	24. Environmental restructuring	34. Prompt use of imagery
5. Goal setting (behaviour)	15. Prompting generalization of a target behaviour	25. Agree behavioural contract	35. Relapse prevention/ Coping planning
6. Goal setting (outcome)	16. Prompt behaviour self-monitoring of behaviour	26. Prompt practice	36. Stress/ emotional management
7. Action planning	17. Prompt self-monitoring of behavioural outcome	27. Use of follow up prompts	37. Motivational interviewing
8. Problem solving	18. Prompt focus on past success	28. Facilitate social comparison	38. Time management
9. Set graded tasks	19. Provide feedback on performance	29. Plan social support/ social change	39. General communication skills training
10. Prompt review of behavioural goals	20. Provide information on where and when to perform the behaviour	30. Prompt identification as role model/ position advocate	40. Stimulate anticipation of future rewards

HELP theory development

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Informed by the pilot study findings:

- increased self-efficacy to manage weight in pregnancy.
- social support a valued aspect of group including information. sharing, modelling of behaviours.

Informed by existing evidence base underpinning SW programme:

- motivational support.
- outcome expectancies.
- goal setting and problem solving.

HELP theory development

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Informed by NICE guidance on obesity and behaviour change:

- self-monitoring and feedback.
- goal setting.
- planning.
- social support.

Informed by previous interventions to limit GWG:

- providing information.
- motivational approaches.
- self-monitoring.
- rewards contingent on success.

HELP theory development

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Informed by evidence of effective BCTs for dietary and physical activity behaviour change and weight loss in non-pregnant populations:

- **include self-regulation BCTs aligned with control theory.**
- self monitoring of behaviour and outcome combined with one or more other self-regulation BCTs.
- provision of instructions.
- relapse prevention.
- prompting practice.

References: Michie et al 2009; Dombrowski et al 2010

HELP theory development

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Social Cognitive Theory (Bandura, 1986)

HELP theory development

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Social Cognitive Theory (Bandura):

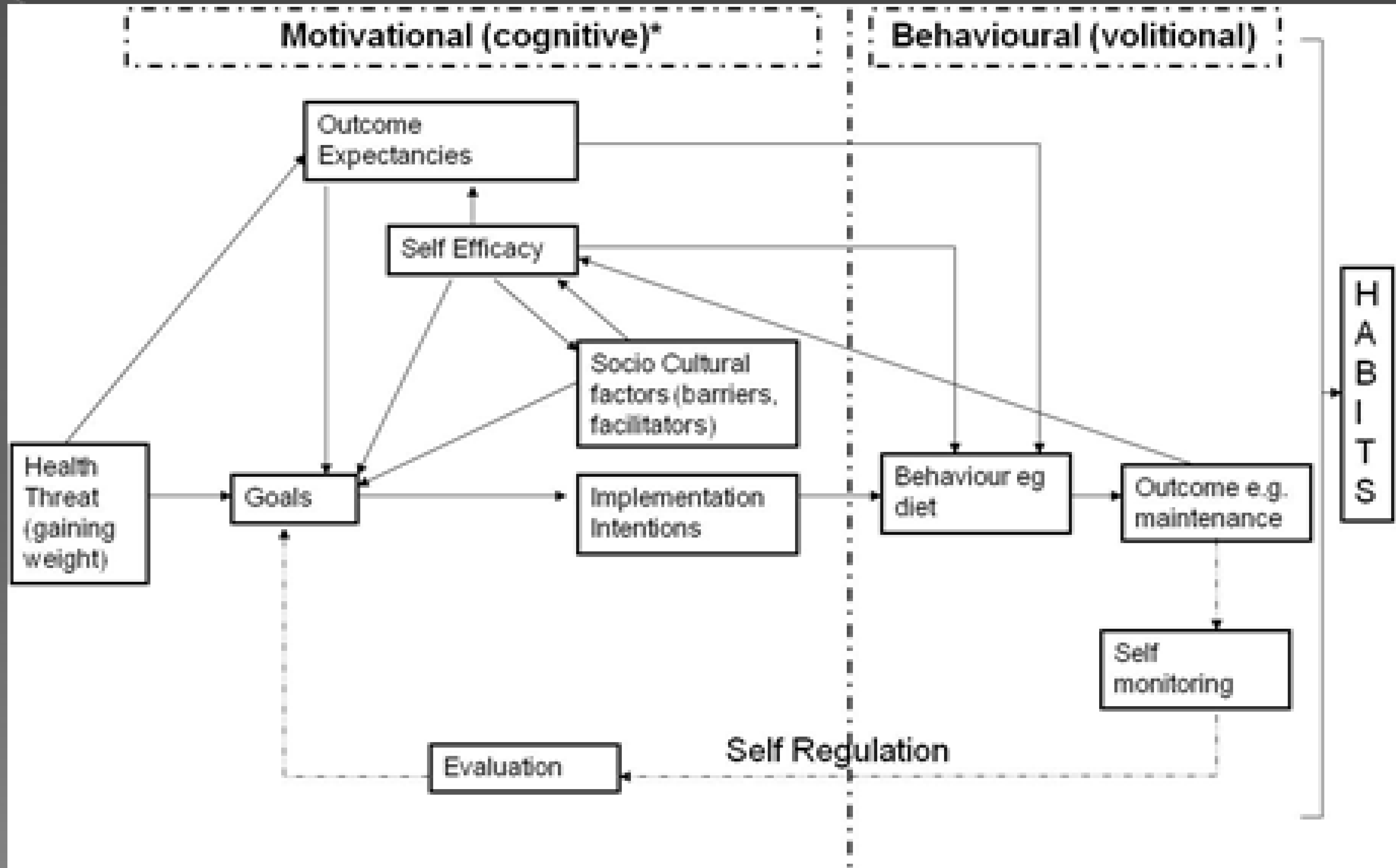
- self-efficacy, intrinsic motivation, goals
- outcome expectations
- social support/ modelling

Control theory (Carver & Scheier)

- self-regulation
- goal directed
- feedback and reinforcement
- action planning

Plus:

- increasing skills and knowledge and implementation intentions


Motivational (cognitive)*
Behavioural (volitional)
Outcome Expectancies
Self Efficacy
Socio Cultural factors (barriers, facilitators)
Health Threat (gaining weight)
Goals
Implementation Intentions
Behaviour eg diet
Outcome e.g. maintenance
Self monitoring
Evaluation
Self Regulation
HABITS
*Moderated by autonomy
Theory diagram, v1

Logic models

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"A systematic and visual way to present and share your understanding of the relationships among the resources you have to operate your program, the activities you plan, and the changes or results you hope to achieve"

(WK Kellogg Foundation 2004)

INPUTS	INTERVENTION	INTERMEDIATE GOALS	BEHAVIOURS / OUTPUTS	OUTCOMES
Slimming World	Give dietary information Encourage peer support Encourage goal setting, Implementation Intentions (IIs) and Problem Solving Share tips Support self efficacy Boost motivation Give information on physical activity Provide encouragement Provide professional support Encourage self regulation / monitoring Give feedback and reinforcement	Set goals Implementation intentions (IIs) Increase skills and knowledge Increase motivation Increase self efficacy Establish peer support (in group and externally) Increase self monitoring Increase problem solving	Eat more fruit and veg Eat more fibre Eat less fat Eat less sugar Do more exercise Less time in sedentary behaviour Planning to achieve goals (IIs) Attend group Monitor progress re: diet and exercise goals Problem solve Reflect, set ongoing goals Self-regulation and monitoring	Weight loss at 12 months Moderated weight gain in pregnancy Habit formation Increase self efficacy and self image Increase problem solving and planning skills Increase healthy eating Increase Physical activity Increase knowledge Increase motivation Improved health outcomes for Mum and baby General improvement in other lifestyle factors
Midwife	Give safety advice Provide professional support Encourage peer support Give pregnancy specific diet and exercise advice Give pregnancy and lifestyle advice Weight change monitoring Encourage goal setting Boost self efficacy Give feedback and support	Increase knowledge Increase self efficacy Establish peer support (in group and externally)		
Physical Activity	Give feedback and reinforcement Encourage self regulation / monitoring Boost self-efficacy Establish baseline and encourage physical activity Give safety advice Give pedometers and walking diary Encourage goal setting Give information on physical activity in pregnancy Encourage peer support Encourage goal setting, IIs and problem solving Boost motivation	Set goals Implementation intentions (IIs) Increase skills and knowledge Increase motivation Increase self efficacy Establish peer support Increase self monitoring Increase problem solving		

MEASURED IN PROCESS EVALUATION

MEASURED IN DATA COLLECTION TOOLS AND /or DATA COMPARED BETWEEN CONTROL AND INTERVENTION GROUPS

Aim

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To evaluate the usefulness of this theory based weight management intervention for pregnant women with obesity, in terms of the hypothesised mechanisms of action and the contextual factors impacting effectiveness.

Methods- study design

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Women are approached in antenatal clinic

- BMI≥30
- 12-20 weeks gestation
- ≥18 years old

Informed consent and baseline data collected

INTERVENTION	*ALL*	*CONTROL*
Routine care plus leaflet on diet and exercise		Routine care plus leaflet on diet and exercise
Attend intervention group sessions to 6 week postpartum	**Follow-up:** 36 week gestation	
	Follow-up: 6 week postpartum	
Intervention phone calls: 3 month postpartum 6 month postpartum	**Follow-up:** 6 month postpartum	
	Follow-up: 1 year postpartum	

Participant interviews and Intervention Facilitator focus groups

Methods- measures

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Primary outcome

BMI (12 months after giving birth)

Secondary outcomes

- pregnancy weight gain
- waist circumference, waist-hip ratio
- pregnancy and birth clinical outcomes
- diet, physical activity, health related quality of life, general health
- child weight and breast feeding

Methods- measures

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Hypothesised **mediators** of intervention

- self efficacy
- social support
- intrinsic motivation
- self regulation
- self monitoring

Potential **moderators** of intervention

(eg demographics, ethnicity, parity, mental health, smoking status and weight loss history)

Cost information for cost effectiveness analysis

- resource usage
- personal costs of healthy lifestyle

Process Evaluation

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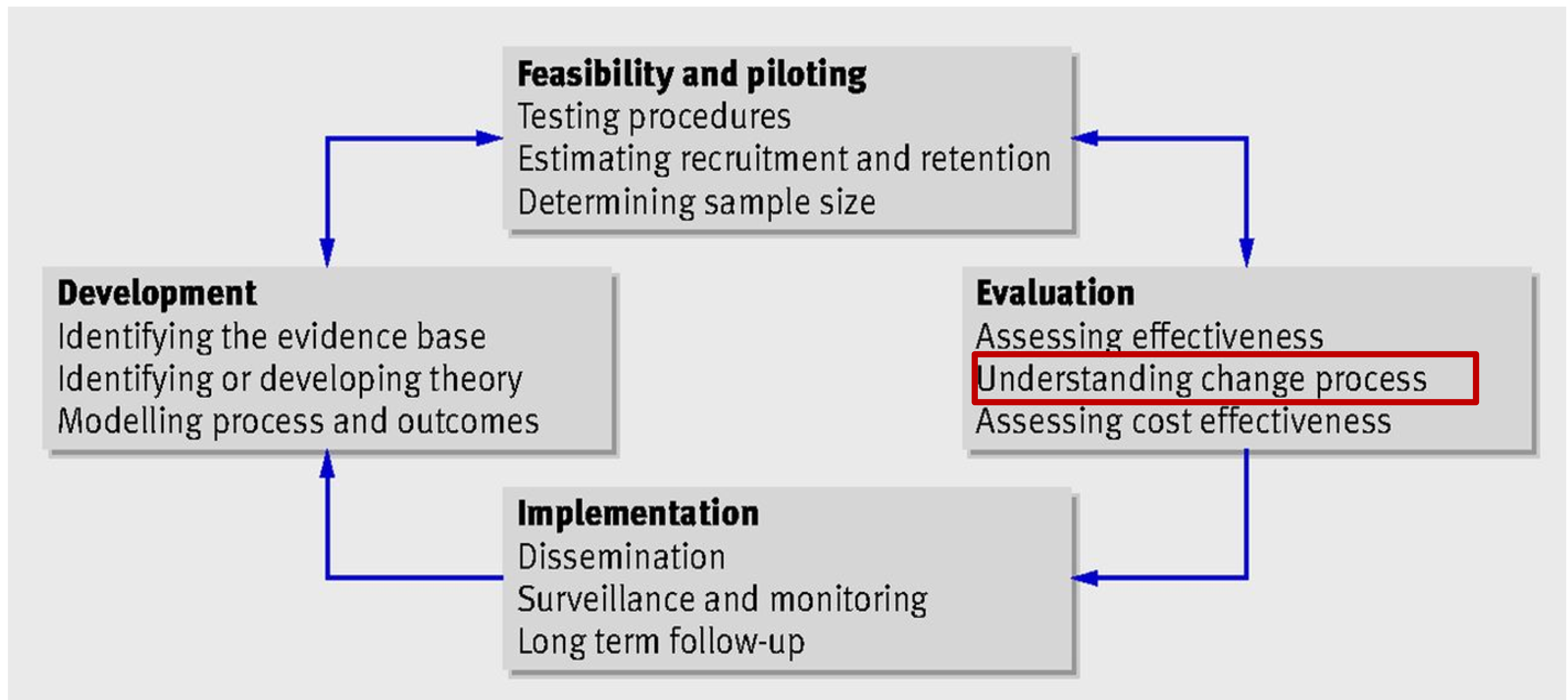

Process Evaluation

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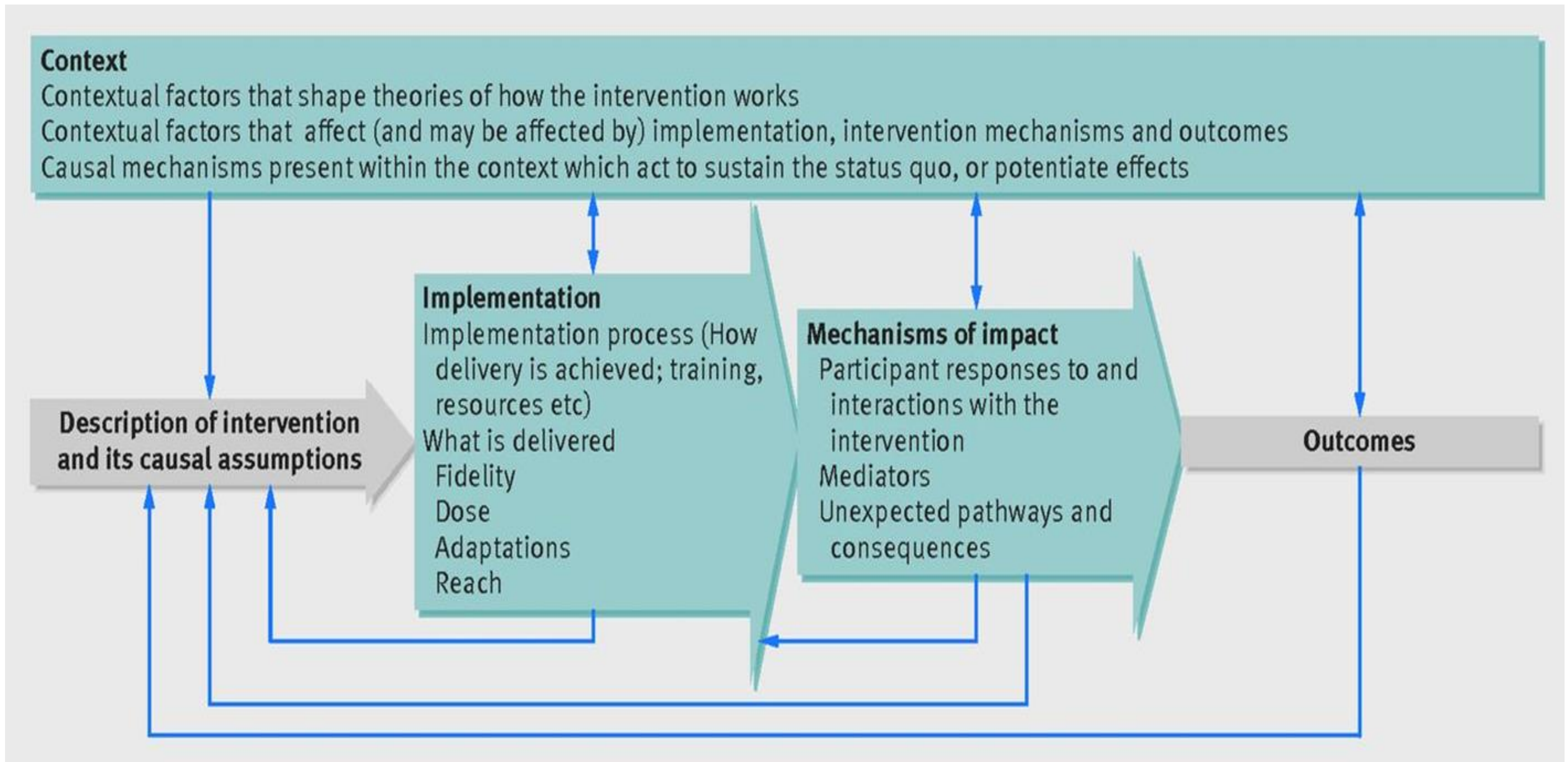

Reference: Graham F Moore et al. BMJ 2015;350:bmj.h1258

HELP trial process evaluation framework

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IMPLEMENTATION	SOURCES
Reach Exposure Fidelity Recruitment Retention Contamination	Participant interviews at 6 and 12 months Focus groups with intervention facilitators Participant questionnaires Mediation analyses Attendance records Intervention session summaries/ observations Pedometers/ step diaries Recruitment/ retention records
CONTEXT	
THEORY TESTING	

Methods- planned analysis

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Primary and secondary outcomes

- Multilevel modelling and ITT comparing intervention and control groups.
- Complier average causal effect (CACE) analysis to assess the effect of the intervention in those who complied.
- Exploratory analyses of differential intervention effects i.e. moderators e.g. parity.
- Mediation analysis.
- Cost-effectiveness analysis.

Interviews and focus groups

Thematic analysis

Other process evaluation data

Descriptive statistics

Results- evaluation of theory.

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Participant interviews

- 27 intervention participants and 18 control participants at 6 months.
- 13 intervention participants and 3 control participants at 12 months.

Focus groups

- 3 Focus Groups (9 Slimming World Consultants; 10 Intervention Midwives).

Results- interviews

Valued aspects of the intervention

Group environment and shared experiences

"We were all focused on one thing, all like picking each other up when we'd had bad weeks… they were very supportive because we all had that common goal" (Intervention 6m PP)

Weekly weighing and self-monitoring

"Having that every week and there wasn't a massive focus on weight loss… there's loads of help and loads of encouragement and em I did think having a diary it was really important cos it just kept you on track"
(Intervention 6mPP)

Group facilitators and social support

"Dieting during pregnancy I'd heard all these stories like you can't do this, you can't do that… because there was both the midwife and the dietician (Slimming World consultant) *there you knew that you would always get the answer that you needed and what was appropriate"*
(Intervention 6mPP)

Results- interviews

Wider impact

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"I incorporated it (the advice) *into my family life and made them all eat the same… it was a change of routine for everybody… My husband is more of a pie and chip man… so I think since I've gone there and I've started to change my diet, his diet is starting to, to change as well"*
(Intervention 6m PP)

"When you're pregnant you can easily over do it… I'm more conscious about my weight now and you know losing the weight and not getting overweight because I'm pregnant or because I just had a baby"
(Intervention 1y PP)

Results- interviews

Adherence / Compliance

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Pregnancy and postpartum

"My pregnancy was awful…first 3 months I had morning sickness… after that I was on crutches and then pretty much I was housebound so, I was in constant pain all through the last few months of my pregnancy… I was either indoors or in hospital" (Intervention 6mPP)

Those that didn't fit in

"I don't class myself as a huge person and I don't think physically I look the weight that I am… I know this sounds awful but you can have the attitude of the large women they eat burgers all day when that wasn't my lifestyle anyway" (Intervention 6m PP)

Support important throughout

"I just don't think they're bothered to be honest, like... with my partner.. he's like um "Well, just cos you're doing a diet, doesn't mean I have to like do one. So it's like "Well, yeah, cheers for the support." (Intervention 6mPP)

Results- interviews

Transition from group

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"We weren't getting out and em we weren't doing as much... takeaways which you know eating things like that so it, it, that's how easy it is to just put it back on by going back to that... I think being so tired em when you've just had a baby" (Intervention 1yPP)

"I gained a lot from it really [HELP group], *I was actually sad when it ended. I've carried on going to Slimming World… I've gone on to lose 5 stone. Definitely it helped me through that pregnancy cos when I had the baby I'd lost a stone and a half. I didn't go back* [to Slimming World] *straightaway having a new baby and everything I thought really it would be better if we could have continued longer than the 6 weeks after… that three month I put a few stone back on. I've realised I do need that extra help going to Slimming World because on my own I've not been able to do it. I think once you've had a weight problem you've always got a weight problem you've always got an issue with your eating and you've got to keep on track"* (Intervention 1yPP)

Summary- interviews

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- Important aspects from the perspective of participants:
  - Social support & shared experiences within the group.
  - Role of the midwife for support and reassurance.
  - Weekly motivation through monitoring.
- The intervention could change attitudes and confidence to control weight in pregnancy.
- Symptoms of pregnancy and external social support can negatively impact adherence.
- Group based intervention is not acceptable to all.
- Longer term support required post birth and a refocus of goals.

Results- focus groups

Intervention elements

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- Diet

  SW9 It was more about equipping them with ideas really that they could take on board and it was their choice whether they wanted to engage in them

- Physical activity

  SC2: I don't think I made them aware that the physical activity was as important to the diet.

  MW1: the pedometers I didn't feel were of a novelty value... particularly later on in pregnancy because, cos a lot of the ladies are big anyway and there tummies expanding, they didn't really have any way to anchor the pedometer to.

  MW1: I have questioned the value really of the exercise element of the study because I didn't really feel that anyone really increased their physical activity.

Results- focus groups

Impact

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Participants:

MW3: They're more confident to be able to make better choices. They feel better about themselves and it just becomes a sort of cycle ….

SC2: it's the sharing and empathising with each other and having been in similar situations and things… obviously its closer which is nicer cos there's fewer people so they were more able to form bonds that they might not necessarily do in a bigger group

Interventionists:

SC2: And it gave me confidence in me own groups then to, more confidence with pregnant ladies who just come to the normal groups

Results- focus groups

Improvements

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- Future groups

MW8: After the 6 week they can still continue into a specific post natal group

SC5: I, I would maybe separate the ante-natal's and post-natal's …

SW9: They can see in that 3 months then they're going to see the benefits and feel the benefits far far stronger

Summary- focus groups

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- Facilitators positive towards intervention and its impact on participants.
- Reiterated the role of self-efficacy both for participants and for themselves in providing advice.
- Intervention not delivered as designed.
- Emphasised importance of long-term ongoing support and how to improve postnatal support.

Discussion

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- Adopting guidance recommendations in the design and evaluation of complex interventions can help:

  - Evaluate the intervention in terms of implementation

  - Advance our theoretical understanding for future interventions:
    - Importance of social support- internal and external to group, and sustained beyond intervention.
    - Self-regulation important and monitoring of weight and behaviours should be applied in future.
    - Self-efficacy playing a role both for women and facilitators.

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Questions?

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