

**PROMOTING PHYSICAL ACTIVITY AMONG
POSTNATAL WOMEN: THE MORE ACTIVE MUMS
IN STIRLING (MAMMiS) STUDY**

by

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ABSTRACT

BACKGROUND: Adults benefit from participating in physical activity (PA) for chronic disease prevention and treatment. Postnatal women are encouraged to commence a gradual return to PA 4-6 weeks after giving birth, with participation in line with PA guidelines. The potential benefits of postnatal PA include weight management, improvements in cardiovascular fitness and psychological wellbeing. There has been limited high-quality information about the efficacy, feasibility and acceptability of PA interventions in postnatal women and few studies in the UK. Behavioural counselling interventions informed by behaviour change theory have been shown to successfully increase PA in low-active adults. Physical activity consultations (PACs) use structured and individualised behavioural counselling to enhance individuals' motivation for change, and improve self-management skills. This approach may support adoption of PA in low-active postnatal women with research demonstrating that modifiable socio-cognitive factors influence PA behaviour. This thesis reports on the efficacy of a postnatal PA intervention, the More Active MuMs in Stirling (MAMMiS) study on change in PA behaviour. Efficacy of the intervention was tested in a randomised controlled trial. The effect on secondary health and wellbeing outcomes and PA cognitions targeted by the intervention and feasibility results are also reported.

METHODS: The intervention comprised a face-to-face PAC of around 35-45 minutes and 10-week group pramwalking programme. Non-attenders to the pramwalking group received a support telephone call. A follow-up PAC (15-20 minutes) was delivered after three month assessments. The first PAC involved raising awareness about benefits of PA, developing self-efficacy for change, setting goals and action planning PA, developing strategies for overcoming barriers, encouraging self-monitoring, prompting social support and selecting/changing the environment to support PA. The second PAC involved feedback about changes and preventing a return to sedentary habits. The pramwalking group met weekly for

walks of 30-55 minutes at a brisk pace, providing opportunities to demonstrate moderate-intensity walking and to encourage and support PA behaviour change. The control group received an NHS leaflet, which encouraged PA after childbirth.

Postnatal women (six weeks to 12 months after childbirth) were identified through a variety of NHS-based and community-based strategies plus local advertisements and word-of-mouth. The primary outcome measure was evaluation of PA behaviour change using the Actigraph GT3X/GT3X+ accelerometer, an objective measure of PA behaviour; self-reported moderate-vigorous physical activity (MVPA) was measured using a recall questionnaire (Seven-Day Physical Activity Recall) and cardiovascular fitness using a submaximal step-test (Chester step-test). Secondary health and wellbeing measures were; anthropometric (i.e. weight and body mass index (BMI)) and body composition (measured using a bioelectrical impedance), psychological wellbeing (measured using the Adapted General Wellbeing Index) and fatigue (measured on a 100-point visual analogue scale). PA cognitions were measured via a questionnaire with constructs adapted from previous studies. All were taken at baseline (prior to randomisation), three and six months follow-up from baseline. Process measures were used to investigate intervention fidelity and feasibility. Acceptability was investigated in a post-trial interviews, conducted by a researcher not involved in the trial.

RESULTS: Sixty-five postnatal women (average 33 years old with an infant 24 weeks old) were recruited (77% of those eligible). There was a 91% rate of retention at six months; participants who missed a follow-up assessment were younger (30 versus 34 years old) and had younger infants (21 versus 34 weeks old). Participants were less deprived and older compared with postnatal women in Scotland. Objectively measured PA behaviour did not change in response to the intervention. There was no between-groups difference in change in mean counts/minute from baseline to three months ($p=0.35$, 95% CI -73.50, 26.17, $d=0.22$) or three to six months ($p=0.57$, 95% CI -39.46, 71.18, $d=0.13$). There was no change in MVPA

minutes/day in either group from baseline to three (intervention =-0.70, IQR -9.86, 8.36; control =1.65, IQR -4.79, 8.21) or three to six months (intervention =0, IQR -1.13, 1.10; control =0, IQR -9.86, 8.23), with no between-groups difference baseline to three ($p=0.43$; $r=0.10$) or three to six months ($p=0.75$, $r=0.09$). Results for relative MVPA were similar. Median steps/day from baseline to three months did not change in the intervention group (0, IQR -1619.44, 1047.94) and increased by 195.95 (IQR -1519.55, 1691.03) among controls. The between-groups difference was non-significant ($p=0.37$, $r=0.18$). From three to six month follow-up steps/day increased in the intervention group and not in controls (0, IQR -1147.50, 1303.52), this between-groups difference was also non-significant ($p=0.35$, $r=0.16$). From baseline to three months self-reported MVPA declined in the intervention group (15 minutes/week; IQR -111, 15) and increased in the control group (30 minutes/week; IQR -68, 75): a non-significant between-groups difference, with a small effect size ($p=0.71$, $r=0.22$). From three to six months a decline in self-reported MVPA was found in controls (53 minutes/week; IQR -41,-101) and no change among the intervention group (0, IQ range -26, 71); a significant between-groups difference with a small effect size ($p=0.04$, $r=0.26$). There were no differences between the groups for the change in aerobic capacity from baseline to three months or three to six months with no evidence for change over time in aerobic capacity or fitness category in either group. Change in secondary outcomes did not differ between the groups from baseline to three or three to six months (although fatigue did improve in the intervention group relative to controls from baseline to three months). Considering PA cognitions, outcome expectancies declined in both groups from baseline to three months and continued to decline only in the intervention group from three to six months, a between-groups difference with a small effect size ($p=0.03$, $r=0.26$). Self-efficacy increased in the intervention group from baseline to three months and declined in the control group with a small effect size for the between-groups difference ($p=0.03$, $r=-0.27$). An increase in action

planning was seen among the intervention group but not controls from baseline to three months ($p < 0.01$, $r = -0.34$). Both groups showed an increase in coping planning and action control; the change was larger among the intervention group relative to controls (i.e. $p < 0.01$, $r = 0.44$, $r = 0.43$, respectively). Increased self-efficacy and action control were maintained from three to six months in the intervention group. Coping planning increased relative to controls ($p < 0.01$, $r = 0.41$) and action planning increased among controls from three to six months ($p < 0.01$, $r = 0.39$). Intervention fidelity and feasibility was good. All intervention participants received the initial PAC and adoption of self-management strategies was high for ‘thinking about the benefits of PA’, ‘action planning’ and ‘self-monitoring’, between baseline and three months. Most participants attended at least one walk (61% attended five or more), 89% of planned walks were conducted with no evidence of poor attendance due to season. Walks were conducted at a brisk pace and met moderate-intensity thresholds.

DISCUSSION: MAMMiS aimed to recruit low-active healthy postnatal women to test the efficacy of a PAC and group pramwalking intervention. There was no evidence for an intervention effect on PA or on secondary health and wellbeing outcomes. Compared to previous postnatal studies the study sample were relatively active at baseline, there was large variability in accelerometer-measured PA and evidence for fluctuating PA habits. There were positive impacts of the intervention on PA cognitions, which published studies have shown mediate PA behaviour change and postnatal women perceived benefits from taking part. The intervention was feasible, although due to the sample being older and more affluent compared with the general population of postnatal women in Scotland, this would need to be considered if implementing the intervention. Given the importance of PA for health and the challenges of both engaging postnatal women and for postnatal women wanting to be physically active, the findings from MAMMiS provides important evidence to inform future choices about trial design and intervention approach in postnatal PA promotion trials.

TABLE OF CONTENTS

	<i>Page</i>
INTRODUCTION	27
Structure of this thesis	32
CHAPTER ONE	
1. LITERATURE REVIEW: PART ONE	
1.1 Chapter Preface	33
1.2 Physical activity	33
1.2.1 Physical activity recommendations for health and wellbeing in adults	35
<i>1.2.1.1 Recommendations for postnatal populations</i>	36
1.3 Benefits of postnatal physical activity	37
1.3.1 Postnatal weight management	37
<i>1.3.1.1 Role for physical activity in supporting postnatal weight management</i>	38
1.3.2 Postnatal cardiovascular fitness	40
1.3.3 Physical activity for postnatal psychological health and wellbeing	42
1.4 Measuring physical activity	44
1.4.1 Physical activity measured via physiological proxy	45
<i>1.4.1.1 Measuring cardiovascular fitness</i>	46
<i>1.4.1.1.1 Submaximal fitness tests</i>	47
1.4.2 Methods that subjectively measure physical activity	48
<i>1.4.2.1 Daily diaries</i>	48
<i>1.4.2.2 Recall questionnaires</i>	49
1.4.3 Methods that objectively measure physical activity	50
<i>1.4.3.1 Doubly labelled water</i>	50
<i>1.4.3.2 Heart-rate monitors</i>	51

1.4.3.3	<i>Motion sensors</i>	52
1.4.3.3.1	<i>Accelerometers</i>	54
1.4.3.3.1.1	<i>Types of accelerometers</i>	54
1.4.3.3.1.2	<i>Reliability and validity of accelerometer activity counts</i>	55
1.4.3.3.1.3	<i>Accelerometer estimated energy expenditure</i>	57
1.4.3.3.1.4	<i>Cutpoints for measuring intensity of physical activity behaviour</i>	58
1.4.3.3.1.5	<i>Acceptability/feasibility for measuring physical activity in the field</i>	60
1.5	Participation in physical activity during the postnatal period	60
1.5.1	Postnatal physical activity participation compared with pre-pregnancy	61
1.5.1.1	<i>Effect on leisure-time physical activity participation</i>	61
1.5.1.2	<i>Effect on total physical activity participation</i>	62
1.5.1.3	<i>Effect on walking participation</i>	63
1.5.2	Are women active enough in the year following childbirth?	64
1.5.2.1	<i>Adherence to physical activity guidelines during the postnatal period</i>	64
1.5.2.2	<i>Intensity of postnatal physical activity participation</i>	65
1.6	Modifiable factors influencing postnatal physical activity participation	65
1.6.1	Beliefs about the benefits of being active/outcome expectancies	68
1.6.2	Barriers, social support and self-efficacy	69
1.6.3	Self-regulatory self-efficacy	70
1.6.4	Modifiable factors and health behaviour change theory	70
1.6.4.1	<i>Theory of Planned behaviour</i>	71
1.6.4.2	<i>Socio-cognitive theory</i>	73
1.6.4.3	<i>Transtheoretical model</i>	74
1.6.4.3.1	<i>Decisional balance, processes of change and self-efficacy</i>	76
1.6.4.4	<i>Health Action Process Approach</i>	79

<i>1.6.4.5 Relapse Prevention Model</i>	81
1.7 Behavioural counselling interventions targeting physical activity change	83
1.7.1 Behavioural counselling interventions targeting physical activity change	83
<i>1.7.1.1 Considerations for physical activity consultations in postnatal populations</i>	84
1.8 Summary of Chapter One	93
CHAPTER TWO:	
2 EFFICACY OF PHYSICAL ACTIVITY INTERVENTIONS IN POSTNATAL POPULATIONS: SYSTEMATIC REVIEW, META-ANALYSIS OF RANDOMISED CONTROLLED TRIALS AND CONTENT CODING OF BEHAVIOUR CHANGE TECHNIQUES	
2.1 Chapter Preface	94
2.2 Aims of the review	94
2.3 Methods of the review	94
2.3.1 Search strategy and inclusion/exclusion criteria	94
2.3.2 Study selection	95
2.3.3 Data extraction and quality assessment	99
2.3.4 Meta-analytic approach	99
2.3.4.1 <i>Effect size calculation</i>	100
2.3.5 Behaviour change techniques coding and analysis	102
2.4 Results of the review	103
2.4.1 Measurement of physical activity and walking behaviour	105
2.4.2 Methodological quality assessment	105
2.4.3 Evidence Synthesis	105
<i>2.4.3.1 Physical activity promotion interventions in healthy inactive postnatal women</i>	105
<i>2.4.3.2 Postnatal weight management interventions</i>	106

2.4.3.3 <i>Physical activity promotion in clinical populations</i>	107
2.4.3.4 <i>Other postnatal health and well-being studies</i>	108
2.4.4 Meta-analysis results: What is the efficacy of postnatal physical activity interventions on change in physical activity (exercise) and walking behaviour?	117
2.4.5 Behaviour change techniques coding	121
2.4.5.1 <i>Are specific BCTs more common in efficacious interventions?</i>	122
2.4.5.2 <i>Do theory based interventions targeting postnatal women use more, or specific types of, BCTs compared with non-theory based interventions?</i>	122
2.5 Discussion of the review	126
2.5.1 <i>What is the efficacy of postnatal physical activity interventions on change in physical activity (exercise) and walking behaviour?</i>	126
2.5.2 <i>Are specific BCTs more common in efficacious interventions?</i>	128
2.5.3 <i>Do theory based interventions targeting postnatal women use more, specific types of, BCTs compared with non-theory based interventions?</i>	129
2.5.4 <i>Limitations</i>	129
2.6 Conclusions and future research	131
2.7 Summary of Chapter Two	132
CHAPTER THREE	
3 METHODS OF THE MAMMiS STUDY	
3.1 Chapter Preface	134
3.2 Background	134
3.2.1 Developing, implementing and evaluating interventions	135
3.2.2 Aims of the MAMMiS study	137
3.2.2.1 <i>Research objectives</i>	137

3.2.2.2 <i>Research Questions</i>	138
3.3 The MAMMiS intervention	139
3.3.1 Intervention procedures	145
3.3.1.1 <i>First physical activity consultation</i>	148
3.3.1.2 <i>Walking groups</i>	150
3.3.1.2.1 <i>Planning for walking groups</i>	151
3.3.1.2.2 <i>Walking procedures</i>	152
3.3.1.3 <i>Second (follow-up) physical activity consultation</i>	153
3.3.1.4 <i>Comparison (control) information condition</i>	153
3.4 Evaluation approach	153
3.4.1 Study design	153
3.4.1.1 <i>Randomisation</i>	154
3.4.1.2 <i>Blinding</i>	154
3.4.1.3 <i>Sample size</i>	155
3.4.1.4 <i>Recruitment and setting</i>	156
3.4.1.5 <i>Inclusion/exclusion criteria</i>	160
3.4.1.5.1 <i>Assessing current physical activity levels</i>	161
3.4.1.5.2 <i>Assessing medical contraindications</i>	162
3.4.1.5.3 <i>Feedback from screening</i>	162
3.4.1.6 <i>Enrolment</i>	163
3.4.1.7 <i>Ethical considerations</i>	164
3.4.2 Evaluation methods	165
3.4.2.1 <i>Evaluations procedures</i>	166
3.4.2.1.1 <i>Procedures for outcome assessments</i>	170
3.4.2.1.1.1 <i>Accelerometer procedures</i>	170

3.4.2.1.1.2	<i>Self-reported physical activity</i>	174
3.4.2.1.1.3	<i>Cardiovascular fitness</i>	175
3.4.2.1.1.4	<i>Weight, body mass index and body composition</i>	177
3.4.2.1.1.5	<i>Psychological wellbeing and fatigue</i>	178
3.4.2.1.1.6	<i>Physical activity cognitions</i>	179
3.4.2.1.1.6.1	<i>Outcome expectancies, self-efficacy and intentions to be active</i>	180
3.4.2.1.1.6.2	<i>Action planning and coping planning</i>	181
3.4.2.1.1.6.3	<i>Self-regulatory measures (action control)</i>	182
3.4.2.1.1.7	<i>Process data collection</i>	182
3.4.3	Data Analysis	185
3.4.3.1	<i>Missing data imputation</i>	185
3.4.3.2	<i>Cleaning and validation of accelerometer data</i>	186
3.4.3.2.1	<i>Data cleaning</i>	187
3.4.3.2.2	<i>Data validation</i>	188
3.4.3.3	<i>Data processing prior to analysis</i>	190
3.4.3.3.1	<i>Accelerometer data processing</i>	191
3.4.3.3.2	<i>Self-report and physiological proxy data processing</i>	192
3.4.3.3.3	<i>Physical activity cognitions data processing</i>	192
3.4.3.4	<i>Statistical analysis: assumptions</i>	193
3.4.3.4.1	<i>Testing assumptions with statistical testing procedures</i>	193
3.4.3.4.2	<i>Options for data that does not meet assumptions</i>	195
3.4.4	Post-trial interviews	196
3.4.4.1	<i>Aims and research questions</i>	196
3.4.4.2	<i>Study design and methods</i>	197
3.4.4.2.1	<i>Design and setting</i>	197

3.4.4.2.2	<i>Participants and sampling</i>	197
3.4.4.2.3	<i>Interviewer</i>	198
3.4.4.2.4	<i>Interview schedule</i>	198
3.4.4.2.5	<i>Data analysis</i>	199
CHAPTER FOUR		
4 RESULTS OF MAMMiS STUDY		
4.1	Chapter Preface	200
4.2	Results from the screening and recruitment process	200
4.2.1	Recruitment to the study and eligibility screening	200
4.2.2	Eligibility screening	202
4.2.3	Representativeness of women who expressed an interest in the study	204
4.2.3.1	<i>SIMD decline of women expressing an interest in the study</i>	204
4.2.3.2	<i>Urban/rural classification of women expressing an interest in the study</i>	206
4.2.3.3	<i>Age of mothers at the time of childbirth among women expressing an interest in the study</i>	207
4.2.4	Representativeness of enrolled participants compared to the eligible sample	207
4.2.4.1	<i>SIMD decile: comparing the eligible sample and recruited participants</i>	208
4.2.4.2	<i>Age of women at time of childbirth: comparing the eligible sample and recruited participants</i>	209
4.2.4.3	<i>Age of youngest child at eligibility assessment: comparing the eligible sample and recruited participants</i>	209
4.2.4.4	<i>Stage of physical activity change: comparing the eligible sample and recruited participants</i>	210
4.2.5	Summary of recruitment and eligibility screening results	210

4.3 Results of the study flow and baseline participants characteristics	211
4.3.1 Participant flow through the study	211
4.3.2 Baseline characteristics of the sample	213
4.3.2.1 <i>Clinical and health behaviour characteristics</i>	213
4.3.2.2 <i>Weight-related characteristics</i>	215
4.3.2.3 <i>Characteristics that changed over time: from baseline to three and six months assessment</i>	216
4.3.2.3.1 <i>Working status</i>	216
4.3.2.3.2 <i>Breastfeeding status</i>	216
4.3.3 Study withdrawal	217
4.3.4 Summary of baseline characteristics and participant flow through the study	218
4.4 Results of the accelerometer data cleaning and validations	219
4.4.1 Data cleaning results	219
4.4.2 Data validation results	221
4.4.2.1 <i>Baseline data validation results</i>	223
4.4.2.2 <i>Follow-up validation results (three and six months)</i>	224
4.4.2.3 <i>Number of valid days at three and six months</i>	224
4.4.3 Summary of the data cleaning and validation results	226
4.5 Results from the primary outcomes: effect on physical activity	226
4.5.1 Normality checking for accelerometer measured physical activity	226
4.5.2 Accelerometer measured physical activity	227
4.5.2.1 <i>Baseline physical activity measured by accelerometer</i>	232
4.5.2.2 <i>Change in counts per minute from baseline to three and six months</i>	232
4.5.2.3 <i>Change in absolute time spent in moderate-vigorous physical activity</i>	233
4.5.2.4 <i>Change in proportion (%) of time in moderate-vigorous physical activity</i>	234

4.5.2.5 <i>Change in steps per day</i>	235
4.5.3 Change in self-reported moderate-vigorous physical activity	236
4.5.3.1 <i>Representativeness of the measurement week</i>	238
4.5.4 Cardiovascular fitness change	239
4.5.4.1 <i>Proportion of participants in each fitness category</i>	240
4.5.5 Summary of physical activity outcomes	242
4.6 Secondary outcomes: effects on physical and psychological health	243
4.6.1 Anthropometric measures and body composition	243
4.6.1.1 <i>Weight and body mass index</i>	243
4.6.1.2 <i>Body composition</i>	246
4.6.1.3 <i>Proportion of overweight and obese participants</i>	247
4.6.2 Psychological wellbeing and fatigue	248
4.6.2.1 <i>Fatigue</i>	249
4.6.3 Summary of health and wellbeing outcomes	250
4.7 Effect of the intervention on physical activity cognitions	251
4.7.1 Internal consistency and distribution	251
4.7.2 Change in physical activity cognitions as a response to the intervention	252
4.7.2.1 <i>Outcomes expectancies and intentions</i>	252
4.7.2.2 <i>Self-efficacy, planning measures and action control</i>	255
4.7.3 Summary: change in physical activity cognitions	258
4.8 Intervention feasibility and fidelity	259
4.8.1 Fidelity checking for physical activity consultations	260
4.8.2 Participant's use of self-management strategies	261
4.8.3 Attendance at pramwalking groups	264
4.8.3.1 <i>Seasonal effect</i>	265

4.8.3.2	<i>Intensity, distance and duration of walks</i>	265
4.8.4	Summary of intervention feasibility and fidelity	266
4.9	Results of the post-trial interviews	267
4.9.1	Participants	267
4.9.2	Main themes	268
4.10	Summary of Chapter Four	275
CHAPTER FIVE		
5	DISCUSSION OF THE RESULTS OF THE MAMMiS STUDY	
5.1	Chapter Preface	279
5.2	Effects of the intervention on physical activity behaviour	279
5.2.1	Changes in physical activity in the context of a reasonably active sample	281
5.2.2	Previous findings in postnatal populations	284
5.2.2.1	<i>Physical activity measurement and blinding in intervention trials</i>	285
5.2.3	Perceived impacts of participating in the trial on physical activity	287
5.2.3.1	<i>Changes in lifestyle activities and cutpoints used for measuring activity intensity</i>	289
5.2.3.2	<i>Fluctuating physical activity among postnatal women</i>	290
5.3	Changes in physical activity cognitions following the intervention	291
5.3.1	Effects of the intervention on outcome expectancies and intentions	291
5.3.2	Effects on self-efficacy, planning and action control	294
5.4	Effect of the intervention on secondary measures	298
5.4.1	Change in weight, BMI and fat mass	298
5.4.2	Effects on psychological wellbeing and fatigue	300
5.5	Strengths, limitations and implications from the MAMMiS study	302
5.5.1	Strengths of the study	302

5.5.2	Limitations of the study	303
5.5.3	Implications of the study	307
5.5.3.1	<i>Implications for physical activity intervention approaches with postnatal women</i>	307
5.5.3.2	<i>Implication for trial design and measurement</i>	309
5.5.3.2.1	<i>Identifying and recruiting low-active postnatal women to physical activity trials</i>	310
5.6	Conclusions	312
	REFERENCES	314

LIST OF TABLES

<i>Table</i>	<i>Title</i>	<i>Page</i>
1	Actigraph accelerometer cut-points equations	57
2	Stages of physical activity behaviour change (Markus & Simkin, 1993)	74
3	Processes of Change applied to physical activity behaviour	76
4	Physical activity behavioural counselling interventions conducted among women with young children	86
5	Table of study characteristics	109
6	Methodological quality ratings	114
7	Total number of studies with behaviour change techniques (BCTs) present/probably present in the intervention and comparison conditions and in efficacious and theory based studies ¹	124
8	Intervention performance objectives, practical strategies and target constructs from behaviour change models	143
9	Study inclusion and exclusion criteria	161
10	Timing of data collection at baseline, three and six months	168
11	Specifications of the GT3X and GT3X+ accelerometers	171
12	Body Mass Index definitions (WHO, 2000)	178
13	Defining accelerometer non-wear periods in the MAMMiS study	188
14	Expressions of interest by recruitment method	201

15	Type of recruitment source by area	202
16	Proportion of postnatal women in the study from each SIMD decile compared with Scotland-wide deliveries in 2010	205
17	Proportion of postnatal women in the study from each SIMD decile compared with NHS Forth Valley deliveries in 2010	205
18	Proportion of postnatal women in the study by Urban/Rural classification	206
19	Age range of mothers at the time of childbirth in the MAMMiS study compared with the Scotland-wide and NHS Forth Valley live birth population in 2011	207
20	Comparison of least and most deprived SIMD deciles among eligible participants by enrolment status	208
21	Comparison of least and most deprived SIMD deciles among all those expressing interest in joining the study by eligibility status	209
22	Baseline socio-demographic, clinical & health behaviour characteristics	213
23	Weight characteristics at baseline	215
24	Comparison between assessed and declared accelerometer wear-periods for n=61 participants at baseline	221
25	Wear-time information for the baseline dataset (n=65)	223
26	Wear-time information for the three months dataset (n=60)	225
27	Wear-time information for the six months dataset (n=59)	226
28	Accelerometry results for intervention and control participants at baseline, three and six months follow-up using the full dataset	228

29	Accelerometry results for intervention and control participants at baseline, three and six months follow-up using the per protocol dataset	230
30	Self-reported total weekly minutes of moderate-vigorous physical activity*	237
31	Mean aerobic capacity reported as estimated VO ₂ max (mlsO ₂ /kg/min) at baseline, three and six months	240
32	Participants in each fitness category at baseline, three and six months (intervention)	241
33	Participants in each fitness category at baseline, three and six months (control)	241
34	Anthropometric results at baseline, three and six months follow-up	244
35	Psychological wellbeing at baseline, three and six months	249
36	Fatigue score at baseline, three and six months by group	250
37	Normality testing for psychological variables	252
38	Physical activity cognitions at baseline, three and six months follow-up	254
39	Independent skill ratings for recorded consultations	261
40	Use of self-management strategies from the consultation during the period between baseline and three months follow-up (n=29)	263
41	Use of self-management strategies from the consultation during the period between three and six months follow-up (n=27)	264
42	Time/proportion of time spent in low, moderate and vigorous intensities during pramwalking	266

43	Sampling matrix for intervention group interviews (up to $n=20$)	268
44	Sampling matrix for control group interviews (up to $n=15$)	268

LIST OF FIGURES

<i>Figure</i>	<i>Title</i>	<i>Page</i>
1	Review study selection procedure and reasons for excluded articles	98
2a	Meta-analysis: frequency of physical activity	118
2b	Meta-analysis: volume of physical activity	119
2c	Meta-analysis: volume of walking	119
3a	Funnel Plot: volume of physical activity	120
3b	Funnel Plot: frequency of physical activity	121
2	Map of Central Stirling showing common walking routes	149
3	Map of Larbert/Falkirk/Grangemouth showing common walking routes	150
4	Recruitment process for the MAMMiS study	159
5	Outcome assessments and intervention process	169
6	Flow through the eligibility screening process	172
7	Flow of participants through the MAMMiS study	203

8	Results of the accelerometer data cleaning and validation	221
9	Accelerometer counts per minute at baseline, three and six months in the intervention and control group*	233
10	Absolute MVPA (minutes per day) at baseline, three and six months in the intervention and control group*	234
11	Proportion (%) of time spent in MVPA (relative to total wear-time) at baseline, three and six months in the intervention and control group*	235
12	Median steps per day at baseline, three and six months in the intervention and control group	236
13	Self-reported total weekly minutes of moderate- vigorous physical activity	238
14	Proportion of participants reporting how their physical activity levels differed from usual habits during each measurement period	239
15	Mean aerobic capacity (estimated VO ₂ max) at baseline, three and six months in the intervention and control group	240
16	Median weight (kg) at baseline, three and six months	245
17	Median Body Mass Index at baseline, three and six months	245
18	Median % fat mass in at baseline, three and six months	247
19	Proportion of overweight and obese participants at baseline, three and six months between the intervention and control group	248
20	Mean psychological wellbeing at baseline, three and six months	249

21	Median outcome expectancies score at baseline, three and six months*	253
22	Median self-efficacy score at baseline, three and six months*	255
23	Median action planning score at baseline, three and six months*	256
24	Median coping planning score at baseline, three and six months*	257
25	Median action control score at baseline, three and six months*	258

LIST OF APPENDICES

<i>Appendix</i>	<i>Title</i>	<i>Page</i>
1	PRISMA checklist for the systematic review	352
2	Review search terms	355
3	Table of physical activity and walking outcome measures from systematic review and meta-analysis	356
4	Risk assessment form for pramwalks	362
5	MAMMiS study leaflet	363
6	MAMMiS study information sheet	364
7	MAMMiS accelerometer wearing times diary and instructions	368
8	Physical activity cognition measures	370
9	Physical activity consultation rating form	373
10	MAMMiS Interview study semi-structured topic guide	376
11	Participants use of self-management techniques (themes)	379
12	Graph showing spread of minutes of weekly MVPA in the MAMMiS study and Rogers study	382

INTRODUCTION

There are significant physical and psychological health and wellbeing benefits from participating in regular physical activity (PA). Evidence accumulated over the past half century has established the strong evidence that regular PA reduces all-cause mortality risk (Mokdad, Marks, Stroup, Gerberding, 2004), with insufficient physical inactivity among adults representing the 4th leading risk factor of global mortality (Alwan, 2010). PA is also critically important for chronic disease prevention and treatment (Hardman & Stensel, 2009). The evidence base for a positive effect of PA has been thoroughly discussed in numerous systematic reviews (Haskell et al., 2007; Oja, Bull, Fogelholm & Martin, 2010). In particular, Oja et al (2010) found PA contributes significantly to the prevention and treatment of a range of disabling physical and psychological conditions, including: cardiovascular disease (CVD), cancer, type 2 diabetes mellitus (T2DM), obesity, osteoporosis and depression.

Despite the importance of being regularly physically active for general health and wellbeing, the proportion of adults reporting sufficient activity levels is small. In Scotland, in 2010, 67% of women reported failing to meet the recommended minimum amount of PA (Townsend et al, 2012). These figures are similar throughout England and Wales, the United States and Australia (Australian Bureau of Statistics, 2011; Townsend et al., 2012; Tucker, Welk & Beyler, 2011). These figures are self-reported and therefore may be underestimating the scale of the problem. Adults PA levels measured with accelerometers have found much higher proportions are failing to reach PA guidelines (96% of women in the US: Tudor-Locke et al, 2010 and 94% of women in England: Townsend et al, 2012). Furthermore, women are more likely to remain inactive over time compared with men (Barnett, Gauvin, Craig & Katzmaryzyk 2008).

Women experience health and wellbeing benefits from increasing their PA levels (Brown, Burton & Rowan, 2007; Danaei et al., 2009). A prospective cohort of over 200,000

women followed over a 30-year time-span has demonstrated a protective effect of PA on women's risk of adverse cardiovascular morbidity and mortality, ischemic stroke, T2DM, and in preventing the onset of a range of cancers, including, breast, colorectal and pancreatic cancer (Hu et al., 2001; 2003; Manson et al., 1999; Michaud et al, 2001; Nocon et al., 2008; Rockhill et al, 1999). PA is also an important part of the treatment regime for many preventable health conditions. In particular, among women diagnosed with cardiovascular disease, cancer and T2DM, participation in regular PA is associated with greater chance of survival and better condition management (Taylor et al., 2004, cited in Hardman & Stensel, 2009; Hu et al., 2001). In relation to obesity, several longitudinal studies have identified that regular PA is associated with reduced weight gain in women over time (Littman et al., 2005; Weinsier et al., 2002, both cited in Hardman & Stensel, 2009). Increasing PA in combination with dietary management has been found to be effective for achieving a clinically significant reduction in weight, abdominal or visceral fat (Kay & Singh, 2006; Ohkawara, Tanaka, Miyachi, Ishikawa-Takata, & Tabata, 2007; Shaw, Gennat, O'Rourke & Del Mar, 2006). Following weight loss, greater PA participation is associated with effective prevention of weight regain in women (Mekary, Feskanich, Hu, Willett, & Field, 2010).

Studies have suggested that decreased time spent being physically active is associated with transitions in women's lives, with childbirth, pregnancy and childrearing as potentially negative influences on PA participation (Allender, Hutchinson, & Foster, 2008; Bell & Lee, 2005; Bellow-Riecken & Rhodes, 2008; Brown & Trost, 2003; Vrazel, Saunders & Wilcox, 2008). Increased caregiving responsibilities may make it more difficult for women to be physically active (Hamilton & White, 2010; Vrazel et al., 2008). Increases in caregiving are a central feature of becoming a parent, and are especially pertinent when parenting young children (under five years old). This appears to be negatively associated with PA participation (Hamilton & White, 2010; Sternfeld, Ainsworth & Queensberry 1999); with some evidence

that women are affected more than men (Schmitz et al., 1999). A recent review of activity levels in parenthood found that overall time spent being physically active was lower in mothers compared with non-mothers (Bellows-Riecken et al., 2008). Survey research and focus groups conducted with mothers of young children suggest having children leads to decreased participation in PA with sports and exercise participation particularly affected (Hamilton & White, 2010; Verhoef & Love, 1994).

The term ‘postnatal women’ can be used to cover the period from six weeks up until the year following childbirth (Mottola, 2002). At this time women might particularly be at risk of insufficient activity if activity declines during pregnancy (Borodulin, Evenson & Herring 2009; Cramp & Bray, 2009a; McIntyre & Rhodes, 2009; Pereira et al., 2007; Schramm, Stockbauer & Hoffman, 1996; Symons Downs & Hausenblaus, 2004). Research has found postnatal women participate in less exercise and sports PA and more activities related to household duties and caregiving (Borodulin et al., 2009; Treuth, Butte & Puyau 2005); these activities may not be at sufficient intensity to confer health benefits (Stamatakis, Hammer & Lawlor, 2009). Participation in regular PA is considered important during the postnatal period for the promotion of maternal health and wellbeing (Pivarnik et al., 2006; Artal & O’Toole, 2003). In particular, postnatal PA may be beneficial for weight management after childrearing, improving cardiovascular fitness, and increasing psychological wellbeing. Longer-term the benefits from being physically active postnatally may relate to the importance of women maintaining a physically active lifestyle across the lifespan. For example, among postnatal women who go on to have future pregnancies, PA may play a role in preventing maternal obesity and gestational diabetes mellitus (GDM) (Weissgerber, Wolfe, Davies & Mottola, 2006). Regular PA participation is protective of long-term cardiovascular mortality, obesity and prevention of progression to T2DM among women diagnosed with GDM during pregnancy (Ben-Haroush, Yogev & Hod, 2004 cited in

Lobner et al., 2006; Kim, Newton & Knopp, 2002). Given the potential benefits of being regularly physical active and the risks of inactivity postnatally, there was a perceived need for effective PA behaviour change interventions to be developed and tested in postnatal populations. There have been limited interventions research conducted in healthy but low-active postnatal women for the purposes of PA change (Albright, Maddock & Nigg, 2009; Cramp & Brawley, 2006; Fjeldsoe, Miller & Marshall, 2010; Montgomery, 2010; Watson, Milat, Thomas & Currie, 2005). Furthermore, work that has been conducted has had methodological weaknesses, including insufficient power (Fjeldsoe et al., 2010), no control group (Albright et al., 2009; Montgomery, 2010) or matched controls only (Watson et al., 2005), reliance on self-report measures of physical activity behaviour change and only measuring immediate post-intervention effects (Albright et al., 2009; Cramp & Brawley, 2006; Fjeldsoe et al., 2010). Limited attention has been paid to whether interventions effectively changed proposed psychological mediators of PA change, despite the importance of this for optimising interventions in the future.

Reviews of randomised controlled trials (RCTs) support the use of behavioural counselling interventions to promote sedentary adults to increase their participation in PA (Eakin, Glasgow & Riley 2000; Foster, Hillsdon, Thorogood, Kaur & Wedatilake, 2005; Kahn et al., 2002). PA counselling (US) or PA consultation (UK) (i.e. PAC) is a behavioural counselling approach, which uses structured and individualised session(s) to enhance individuals' motivation for change, and their cognitive and behavioural self-management skills necessary to enact change (Calfas et al., 2002; Loughlan & Mutrie, 1995). PACs are informed by theories of behaviour change (e.g. the Transtheoretical Model (TTM), Socio-Cognitive Theory (SCT) and Relapse Prevention Model (RPM)) and take cognizance of psychological factors, which have been empirically shown to be associated with PA behaviour, and in some cases mediators of intervention effects (Baruth et al., 2010; Rhodes &

Pfaeffli, 2010). Several RCTs have shown individual and group-based consultations to be effective in the promotion and maintenance of physical activity in non-clinical and clinical groups (Baker et al., 2008; Calfas et al., 2002; Hughes, Mutrie & MacIntyre, 2007; Kirk, Mutrie, MacIntyre, Fisher, 2004a; Lowther, Murtrie & Scott, 2002; Simons-Morton et al., 2001). Regarding healthy low-active postnatal women, PACs have not been tested in the UK.

Furthermore, there has been interest in developing structured group-based PA through pramwalking as a method for increasing PA in postnatal populations (Currie, Boxer & Develin, 2001; Currie & Develin, 2002; Rowley, Dixon & Palk, 2007; Wagg, 2010; Watson et al., 2005). However, evaluation studies have mainly been conducted among postnatal women in Australia (Armstrong & Edwards, 2003; 2004; Develin & Currie, 2000; Watson et al., 2005), with limited information about the transferability of this approach to the UK context. One concern with pramwalking relates to differences in climate and season compared with Australia. There is mixed evidence regarding seasonality effects on participation in PA (Tucker & Gilliland, 2007), however, studies exploring facilitators and barriers to PA among postnatal women, report poor or extreme weather conditions as a barrier to being physically active (Evenson, Aytur & Borodulin, 2009). Two small pilots of UK pramwalking groups have been reported, both of which have been facilitated by health visitors (Rowley et al., 2007; Wagg, 2010); neither study investigated efficacy and there is limited research regarding feasibility and acceptability for promotion of postnatal PA behaviour change.

This thesis reports on a trial to test the efficacy of a PAC plus group pramwalking intervention for changing PA behaviour among postnatal women. The background, development, implementation and evaluation of this trial: the More Active MuMs in Stirling (MAMMiS) study is the focus of this thesis.

Structure of this thesis

This thesis is split into five Chapters. Chapter One discusses recommendations and benefits of postnatal PA and measurement issues in PA research. I also discuss postnatal PA participation, modifiable influencers of PA participation and the contribution of models of behaviour change to understanding and changing PA. Chapter One also considers how theory-based behavioural counselling approaches can be used to change PA behaviour. Physical activity counselling/consultations (PACs) utilise behaviour change techniques to promote PA and individuals are supported to develop self-management strategies associated with successful change. Chapter Two is a systematic review and meta-analysis of previous postnatal PA interventions. I consider previous studies that have promoted postnatal PA through behavioural counselling and structured group exercise, including pramwalking groups and lifestyle management interventions including dietary components. Content coding of the behaviour change techniques included in previous postnatal trials was also conducted. These chapters provide the rationale for the approach taken to developing, implementing and evaluating the postnatal PA promotion intervention: the More Active MuMs in Stirling (MAMMiS) study, which is the focus of the rest of the thesis. Chapter Three describes the methods and methodology used. MAMMiS was a pilot trial, which was designed to conduct a powered investigation of efficacy of the intervention in addition to exploring feasibility and acceptability of the approach. It is important to conduct this initial work to provide information prior to conducting a full large-scale trial. Chapter Four presents the result from this work and Chapter Five presents a discussion of the findings from the trial in light of previous and more recent research. The outcomes, and strengths and limitations of the MAMMiS study are discussed in this chapter. Chapter Five ends with concluding remarks and suggests implications for PA research and interventions in postnatal populations.

CHAPTER ONE

1. LITERATURE REVIEW: PART ONE

1.1 Chapter Preface

This chapter contains a literature review, which provides the initial background for this thesis. This literature informed the development of the MAMMiS study. I conceived of, and conducted, all of the relevant literature searching, reading, analysis and synthesis. This was conducted under supervision from Dr Hughes and Dr McInnes. This review refers to literature primarily published up to early 2011 as the study was being developed during the period December 2009-February 2011. Relevant literature published from 2011 onwards is discussed in Chapter Five in relation to the findings from the MAMMiS study.

Firstly, this chapter consider PA, how it is defined and recommendations for PA in the postnatal period. I briefly consider the evidence that performance of regular PA is important for postnatal women, particularly considering weight management, cardiovascular fitness and psychological wellbeing. Secondly, I consider approaches to measuring PA in field-based settings. Accurate measurement of PA is important for assessing response to behaviour change interventions. I then consider evidence that PA is insufficient among postnatal women, exploring the importance of declines in leisure-time PA following pregnancy and as a result of childrearing, and the significance of intensity of postnatal PA behaviour. Finally, I discuss factors influencing postnatal PA and the importance of behaviour change theory for developing and evaluating interventions that promote PA change.

1.2 Physical Activity

PA has been defined by Caspersen, Kenneth, Powell and Christenson (1985) as: “any bodily movement produced by skeletal muscles that result in energy expenditure (EE)” (cited in Strath et al., 2013 p.2260). PA is a broad term, encompassing planned or structured exercise

and incidental EE arising from activities of daily living. PA is often referred to within a set of *domains* for example, occupational, leisure-time, domestic and transportation. Leisure-time PA and exercise are often used synonymously as both describe recreational activities undertaken explicitly for health benefit. The dimensions of PA include mode of activity and intensity, frequency and duration of performance. These have been defined by Strath and colleagues (2013): *mode* is the “specific type of activity being performed” (e.g. walking, gardening, cycling) and/or the physiological/biomechanical demand/types (e.g. aerobic versus anaerobic activity)”; *intensity* is the “rate of EE...an indicator of the metabolic demand of an activity”; *frequency* is the “number of sessions [bout] per day or per week”, *duration* is the amount of “time (minutes or hours) of the activity bout during a specified time frame” (p. 2261).

1.2.1 Physical activity recommendations for health and wellbeing in adults

Worldwide, a number of recommendations for PA participation for health and wellbeing have been published (Bull and the Expert Working Groups, 2010; Haskell et al., 2007; World Health Organisation (WHO), 2010). Although recommendations vary slightly, in terms of the frequency, duration and intensity of PA that is recommended; consensus suggests that adults should work towards a minimum accumulation of 2½ hours of at least moderate-intensity PA per week. Using the American College of Sports Medicine (ACSM) guidelines, Haskell et al. (2007) suggests moderate-intensity activity is equivalent to a brisk walk and “noticeably accelerates the heart rate” (p.1425). For enhancing cardiovascular fitness, vigorous-intensity activities such as running or jogging are recommended, based on a minimum performance of 20 minutes, at least 3 times per week. Moderate and vigorous intensity activities can be combined to reach the recommended weekly duration, and PA can be accumulated in as little as ten-minute bouts throughout the day. For weight management (i.e. to prevent weight gain, or regain following weight loss) guidelines recommend at least 60 minutes of at least

moderate-intensity aerobic activity per day. In 2010, the Chief Medical Officers (CMOs) for England, Scotland, Northern Ireland and Wales published guidelines for the recommended PA participation required for optimal health and wellbeing (Bull et al., 2010). It was recommended that adults should work towards the minimum of 150 minutes of moderate-intensity activity per week (or 75 minutes of vigorous-intensity activity) with ideally PA performed on most days. Being regularly physically active in line with guidelines has been shown to have beneficial effects on health and wellbeing (Li et al., 2006; Woodcock, Franco, Orsini & Roberts, 2010), however, there is evidence for a dose-response effect such that greater changes in participation in PA are likely to afford even greater effects on health and wellbeing (Bull et al., 2010; Haskell et al., 2007).

1.2.1.1 Recommendations for postnatal populations

The American College of Obstetricians and Gynecologists (ACOG) and the Royal College of Obstetricians and Gynaecologists (RCOG) guidelines recommend a gradual return to PA after the first 4-6 weeks of giving birth (Artal & O'Toole, 2003; RCOG, 2006). Women with uncomplicated pregnancies and births can participate in PA without a postnatal check-up (Artal & O'Toole, 2003). However, hormonal, physical and behavioural effects of pregnancy, breastfeeding, childbirth and caring for an infant all impact on mothers' physiological, physical and emotional readiness for activity (Mottola, 2002). Recovery from pregnancy and childbirth vary according to individual clinical factors, environmental considerations and prepregnancy state. These factors can include (but are not limited to): prior psychological vulnerability, pre-existing medical conditions, antenatal wellbeing, type of birth, postnatal support, choice of feeding method(s), physical health and fitness, urinary incontinence, financial wellbeing, family relationships, neonatal health and wellbeing and return to work etc. (e.g. Burgio et al., 2003; Leigh and Milgrom, 2008; McVeigh, 2000; Tulman, Fawcett, Groblewski & Silverman, 1990). For breastfeeding women, guidelines suggest expressing or

feeding prior to vigorous-intensity exercise (Artal & O'Toole, 2003). This improves comfort during exercise and ensures there are no problems with infant palpability of breast milk. A review by Larson-Meyer (2002) concluded that there was no evidence for a detrimental effect of acute or regular PA of a moderate-intensity on breast milk volume, composition, palatability to infants or infant growth, however with vigorous-intensity exercise there was evidence breast milk is less palatable to babies due to lactic acid build up. Overall, recommendations suggest postnatal women should commence a gradual return to PA following the general guidance for adult populations.

1.3 Benefits of postnatal physical activity

This section considers some health and wellbeing benefits of PA in postnatal populations. In particular I consider the effects of PA in relation to postnatal weight management, cardiovascular fitness and psychological wellbeing.

1.3.1 Postnatal weight management

Maternal obesity rates have risen in recent years (Heslehurst, Rankin, Wilkinson & Summerbell, 2010). Additionally, failure to lose pregnancy weight during the postnatal period is a significant predictor of long-term obesity (Rooney, Schauburger & Mathiason, 2005). There is evidence that women tend to retain weight following pregnancy, however there are inconsistencies regarding the amount of weight retention attributable to pregnancy, partly due to measurement differences across studies. Reviews suggest average weight increase in the short (6-18 months) term is 0.5 – 1.5 kg from prepregnancy (Gunderson, 2009); long-term weight retention averaging 0.5 – 3kg (Gore, Brown & West, 2003).

Some women are more at-risk of retaining pregnancy weight. 'At-risk' groups (i.e. those retaining ≥ 5 kg above prepregnancy weight) are more likely to have been overweight or

obese at the onset of pregnancy or have gained excessive gestational weight (EGW)¹ (Gunderson,2009; Ohlin & Rossner, 1994; Olson, Stawderman, Hinton & Pearson, 2003; Rooney & Schauburger, 2002). Other risk factors are socio-demographics (e.g. being older, socioeconomically disadvantaged and belonging to a non-white ethnic group), psychosocial factors (e.g. being unmarried, higher PND score, poor sleep habits, less negative attitudes towards weight gain and body dissatisfaction) and behavioural factors, such as sedentary behaviour, PA, smoking and dietary habits and breastfeeding status (Gore et al., 2003; Oken, Taveras, Popoola, Rich-Edwards & Gillman, 2007; Gunderson et al., 2008; Olson et al., 2003).

Retained postpartum weight may contribute to a cumulative effect of pregnancy on weight gain (Williamson et al, 1994 cited in Gore et al., 2003). Women who are obese in first and subsequent pregnancies are at significantly greater risk of obstetric complications, such as gestational diabetes and pre-eclampsia; these conditions are associated with increased fetal and maternal mortality and morbidity (RCOG, 2007) Greater long-term weight increases, alongside declines in PA participation, have been found in primiparous (women who have given birth to at least one child) compared with matched nulliparous women (i.e. who have not given birth) (Smith et al., 1994; Wolfe, Sobal, Olson & Frongillo, 1997). It is clinically important to address postnatal weight retention and support weight loss amongst women who are overweight or obese. Evidence discussed below suggests that PA may play a role in supporting postnatal women to manage their weight after childbirth.

1.3.1.1 Role for physical activity in supporting postnatal weight management

¹Excessive gestational weight gain during pregnancy is defined differently in different research. However, the most cited reference is the Institute of Medicine guidance from the United States, which recommends weight gain in normal weight women of 1 pound (lb) per week and 0.5 or 0.6lbs per week for overweight and obese women in the second and third trimester (Institute of Medicine, 2009 cited in Siega-Riz, Deierlein & Strube et al, 2010).

Observational and intervention studies have found evidence for a role for PA in postnatal weight management. Postnatal women with a normal or low prepregnancy BMI who 'often' took part in PA that 'makes you sweat or breathe hard' at six months postnatally retained less weight at one year compared with postnatal women who were physically active 'less than often' (Olson et al., 2003). This pattern was more pronounced if women were overweight or obese prepregnancy. Ohlin and Rossner (1994) found postnatal women who were ≥ 5 kg heavier at one year compared with prepregnancy were more likely to be rated as 'inactive' (defined as engaging in mainly TV watching and reading during leisure-time and participating in less than 4-6 hours of light leisure-time PA per week) compared with women who gained less than 5 kg. Rooney and Schauger (2002) found that postnatal 'exercisers' were significantly lighter five years after pregnancy (on average they had gained 4.5kg compared with prepregnancy, whilst in 'non-exercisers' this gain was 6.7kg). It was unclear whether self-reported postpartum behaviour predicted long-term weight retention or whether active postpartum women were more likely to remain active in the longer term, leading to less age-related weight gain over time. Observational studies have used self-reported behaviour to assess the effects of PA on weight management after childbirth, which may be less robust compared with objective methods. Interventions that randomise postnatal women to groups provide a more rigorous test of the effects of PA on postnatal weight management.

A Cochrane review (Amorim, Linne & Lourenco, 2007) has compared the effect of PA behaviour change with studies that included dietary change components only and dietary components plus PA. The authors found no additional beneficial effect of PA over dietary management strategies for weight loss. However, among interventions using both PA and dietary management, postnatal women showed greater fat mass reduction measured via bioelectrical impedance. Earlier intervention studies had found no effects on postpartum weight-loss (Dewey, Lovelady, Nommsen-Rivers, McCrory & Lonnerdal, 1994) or body

composition (Lovelady, Nommsen-Rivers, McCrory & Dewey, 1995) among inactive postnatal women assigned to an aerobic exercise programme for up to 12 weeks. However, Dewey et al. (1994) noted there was no impact of the intervention on change in total EE (TEE), suggesting women did not adhere to the exercise programme or substituted their remaining leisure time with a greater amount of sedentary behaviour. Also the study sample was not recruited on the basis of overweight or obesity, which may help explain the nil effects observed. Lovelady, Garner, Moreno & Williams (2000) found overweight postnatal women were significantly more likely to achieve a normal BMI following a 10-week programme of vigorous-intensity activity four times per week alongside calorie restriction of 500kcal below average daily intake. In Lovelady et al. (2000) there was no exercise only control group for comparison.

Overall, evidence from observational longitudinal studies and intervention studies have suggested that taking part in PA during the postnatal period may be important for weight management after pregnancy. There is limited evidence that dietary restriction and PA in combination leads to greater postpartum weight loss, compared with dietary restriction in isolation, however, PA change may improve body composition.

1.3.2 Postnatal cardiovascular fitness

Studies have suggested women who continue with an active lifestyle during pregnancy maintain much of their cardiovascular fitness postnatally (Cotton et al, 1993 cited in (Pivarnick et al., 2006). Where a decline in fitness is found, change in patterns of PA during pregnancy and the postnatal period may explain this. Treuth et al. (2005) measured cardiovascular fitness and PA behaviour in 124 non-pregnant women, of whom 76 subsequently became pregnant. They found aerobic capacity decreased at six week postpartum (compared to prepregnancy). At 27 weeks postpartum participants across all BMI categories showed some improvement in aerobic capacity but levels were still lower than prepregnancy

values. Self-reported total PA EE was similar at 27 weeks postpartum compared with prepregnancy, however, participants decreased participation in more aerobically challenging PA (e.g. sports, cycling and water based activities) and increased time spent in home activities and in low-intensity walking. These changes may have accounted for the lower postnatal aerobic capacity found. Greater aerobic fitness predicts physical health-related quality of life during the postnatal period (DaCosta et al., 2009) and longer-term, there are implications of aerobic fitness for cardiovascular-related mortality.

A small number of intervention studies have shown postnatal cardiovascular fitness can be improved by increasing PA participation. Armstrong and Edwards (2003; 2004) and O'Toole, Sawicki & Artal (2003) have all shown improvements on measures of cardiorespiratory fitness following 12-week programmes consisting of either group pramwalking of moderate-intensity 2-3 times per week (Armstrong & Edwards, 2003; 2004) or weekly EE goals of 150 kcal/day (O'Toole et al., 2003). At the 12-week follow-up point Armstrong & Edwards (2003; 2004) found pramwalking participants had moved from the low/borderline fitness categories to the adequate/good categories, whilst the control groups had either remained or declined in fitness and had low/borderline cardiovascular fitness. Likewise, 12-week increases in aerobic capacity were found in the intervention group in O'Toole et al. (2003) but not in the control group, with these maintained at one year postpartum. These studies provide some evidence that aerobic fitness gains can be made, and sustained, among postnatal populations who increase their participation in PA. However, an important criticism of these studies is that all three had small sample sizes (between 20 and 40 participants) and there was a high drop-out rate in the study by O'Toole et al. (2003).

Overall, the evidence for a beneficial impact of postnatal PA on cardiovascular fitness is currently still unclear, although studies in the general population show that modest increases in frequency, duration and intensity of aerobic activity for 12 weeks produce gains

in aerobic capacity (Stephens, Kirby, Buckworth, Devor & Hamlin, 2007). Even a weekly increase of 60 minutes of brisk walking has been shown to improve cardiovascular mortality rates among women (Manson et al., 1999).

1.3.3 Physical activity for postnatal psychological health and wellbeing

Postnatal women who have been physically active during pregnancy appear to experience better psychological wellbeing compared to inactive counterparts (Sampselle, Send, Yeo, Killion & Oakley, 1999). The study by Sampselle et al. (1999) found those who self-reported exercising vigorously during pregnancy had more favourable scores on measures of psychosocial wellbeing compared with those who did not exercise. Evidence that changing PA behaviour during the postnatal period contributes to increased postnatal wellbeing is not particularly strong. One intervention study measured changes in wellbeing following an intervention to increase PA (Norman, Sherburn, Osborne & Galea, 2010). The researchers evaluated an 8-week intervention delivered among mother recruited around 2 months after childbirth, which consisted of weekly light-moderate group exercise session (approx. 1 hour), with additional resources to promote PA at other times. Despite a positive effect of the intervention on psychological wellbeing (improvements in positive affect and reductions in postnatal depression score), compared with the control group at 12 weeks follow-up, the authors did not find an increase in self-reported PA behaviour. Therefore, improvements in wellbeing may have occurred due to the group setting in which the PA took place or due to the additional involvement of health professionals during the postnatal period.

There is an interest in PA for treating postnatal depression (PND). Within the first year after giving birth, around 10-15% of women experience PND (O'Hara et al, 1996 cited in Daley, Jolly & MacArthur, 2009). PND has potential short and long-term adverse consequences for mothers, children and families including reduced quality of life, increased risk of clinical depression and impaired maternal-infant interaction affecting child

development (Cooper & Murray, 1995; Beck, 1995, both cited in Daley et al., 2009). The National Institute of Health and Clinical Excellence (NICE) guidelines for antenatal and postnatal mental health recommend the use of PA (particularly in group settings) as a treatment modality in mild-moderate PND (National Collaborating Centre for Mental Health, 2007), however, the evidence base is not particularly strong.

A meta-analysis conducted by Daley et al. (2009) found limited evidence for the efficacy of PA as a stand-alone treatment option. The meta-analysis included five studies with three showing a significant change from pre-post-test on PND score (measured via the Edinburgh Postnatal Depression Scale: EPDS) that favoured the intervention group (Armstrong & Edwards, 2003; 2004; Heh et al., 2008 cited in Daley et al., 2009). However, two of these studies were conducted in group settings with no attempt to control for the impact of increased social support in relation to improved scores on the EPDS (Armstrong & Edwards, 2003; Heh et al., 2008 cited in Daley et al., 2009). In a later study by Armstrong and Edwards (2004) they did include a non-exercise social support group who met weekly over the 12-week study period. Compared with the earlier study conducted by the same research team the effects size for the change in EPDS score relative to controls at the end of the 12-week period was reduced but still significant. A further limitation identified in the review was the confounding of the exercise intervention with other forms of treatment for PND as most studies included participants who were taking medication or were engaged in some form of counselling or psychological therapy (Daley et al., 2009).

Despite the limited evidence for the efficacy of PA in the treatment of PND, this may be a more appropriate or readily available treatment option compared with medication or psychotherapy. Breastfeeding women may prefer to increase their PA levels rather than take prescribed medications due to concerns about unknown harmful effects (NICE, 2007). PA can also be used as an adjunctive therapy as it has many other beneficial effects and limited

negative side effects. Despite not finding a significant impact of a home-based exercise programme on overall PND score (DaCosta et al., 2009), physical and mental fatigue scores were significantly reduced in the intervention group compared with controls (Drista, DaCosta, Dupuis, Lowensteyn & Khalife, 2009). Change in physical fatigue was mediated by increased participation in exercise. Fatigue is an important factor in overall psychological wellbeing during the postnatal period, although as this study recruited women meeting criteria for PND it is not clear if this effect would hold amongst healthy postnatal women. Overall the effect of PA interventions on psychological health and wellbeing in postnatal women in general has not been sufficiently established due to a lack of research in this field.

1.4 Measuring physical activity

This section considers measurement of PA behaviour. It is important to accurately measure PA behaviour to understand whether activity levels differ between populations, to identify whether people meet PA guidelines and to identify the impact of PA change interventions.

PA is a complex, multifaceted behaviour and as such accurate measurement can be difficult. To measure PA in the field (i.e. non-laboratory, free-living conditions) the following objective methods are widely available: doubly labelled water (DLW), heart-rate monitors (HRMs) and motion sensors (e.g. pedometers and accelerometers). Objective measures measure physical or physiological signals of EE, such as heart rate (HR) or rate of acceleration. Although indirect calorimetry (EE is calculated based on the amount of oxygen consumed and carbon dioxide produced during activities) and participant observation are also considered objective measures of PA, they are not suitable for use in free-living conditions (Dishman, Washburn & Schoeller, 2001). Instead these approaches are often used for assessing validity of other PA measurement approaches in lab-based studies. Subjective methods require participant recall (e.g. self-report) or self-completion. These methods include

interviews, questionnaires and daily diaries. Habitual PA can be measured via cardiovascular fitness as a physiological proxy measure. Suitability of PA measurement approach includes considering issues such as cost, equipment requirements, participant burden and compliance, in addition to the validity and reliability of the measure. *Validity* refers to the extent to which a given method measures what it has been designed to measure (Field, 2013). Validity concerns the accuracy or precision with which the measure assesses PA behaviour. Most validity investigations utilise comparison with directly measured EE. DLW (discussed below) is often used as the criterion measure of PA in the field (Plasqui & Westerterp, 2007). *Reliability* refers to the consistency of a measure across the same test conditions, with repeated measurement required to determine test-retest reliability. Reliability is important to ensure that any true variation in PA is a result of implementation of an intervention rather than poor reliability over time (Field, 2013).

1.4.1 Physical activity measured via physiological proxy

Cardiovascular fitness is not a measure of PA participation *per se*, however has been used within studies as a proxy or surrogate measure. An individual's cardiovascular fitness is described in terms of their maximum aerobic (oxygen) capacity (VO_{2max}). The rationale for using cardiovascular fitness to measure PA stems from the relationship between increased PA participation (e.g. intensity, frequency and/or duration) and VO_{2max} (Garber et al., 2011). Reviews of studies that have examined the relationship between PA behaviour (measured both subjectively and objectively) and cardiovascular fitness; present strong evidence for a positive linear relationship (Bull et al., 2010; Haskell et al., 2007). Studies have also shown differences in VO_{2max} , following changes in participation in PA over time as the result of interventions. For example, a standard 12-week aerobic exercise prescription intervention has been found to show improvements in cardiovascular fitness among healthy sedentary individuals (Stephens et al., 2007).

Correlations between PA participation (measured by daily diary) and VO₂max are high (around 0.78-0.83), and are reportedly stronger in women compared with men (Paffenbarger et al., 1993 cited in Dishman et al., 2001); however, correlations with self-reported PA measured via recall questionnaires are poorer (Jacobs, Ainsworth, Hartman & Leon, 1993) and total PA participation does not have as strong a relationship with VO₂max as participation in vigorous intensity exercise (Aadahl, Kjaer, & Jorgensen, 2007). Also, despite the strong correlations between PA participation and cardiovascular fitness, approximately 30% of the variation in aerobic capacity is made of heritable characteristics and there is genetic variation in individuals' cardiorespiratory response to training (Dishman et al., 2001). Finally, the relationship between PA participation and VO₂max changes as individuals' age, with a stronger relationship in older participants compared with children, adolescents or younger adults (Dishman et al., 2001).

1.4.1.1 *Measuring cardiovascular fitness*

The recommended protocol for measuring cardiovascular fitness is via a maximal fitness test, which involves participants taking part in a graded exercise test within a laboratory setting. Participants are told to exercise (e.g. on a treadmill or stationary bike) with increasing increments in work rate until they reach exhaustion. Analysis of expired gases during the test provides a direct measure of VO₂max, which is expressed in litres of oxygen per minute, either as *absolute* VO₂max, which is the amount of oxygen the body uses during maximal effort, or as *relative* VO₂max, which takes account of body weight and is expressed as mlO₂/kg/min. A measure of relative VO₂max is preferable as it allows individuals with different body weight, or changes in body weight over time to be meaningfully compared (Haskell et al., 2007). One of the main disadvantages of maximal fitness test protocols is that they involve testing under laboratory conditions with expensive equipment and participants must exercise to exhaustion. This may not be practical in larger-scale studies, in non-

laboratory settings or in certain populations, for example, due to pain, fatigue or impaired balance (Noonan & Dean, 2000).

1.4.1.1.1 Submaximal fitness tests

Submaximal fitness tests are an alternative to maximal tests. Predictive submaximal tests estimate cardiovascular fitness (VO_2max), usually via heart-rate (HR) readings taken at two or more work rates (i.e. multi-stage tests). The prediction equations used in submaximal tests takes advantages of the relationship between HR, work rate and oxygen consumption. Reliability and validity of the prediction estimate is then confirmed using a maximal fitness test with gas exchange methods described above. The benefit of submaximal tests is that they do not require participants to exercise to exhaustion (Heyward et al., 2002 cited in Sykes & Roberts, 2004). When choosing a submaximal cardiovascular fitness test it is important to ensure it can be practically implemented and is suitable for the population being tested. One sub-set of submaximal tests, known as step-tests are also particularly useful as they require minimal equipment and training, so can be used in non-laboratory settings (Noonan & Dean, 2000). In step-tests the work rate is determined by step height and stepping rate and cardiovascular fitness is predicted using HR readings, either during the test or during recovery period (Watkins, 1984). There are a variety of reliable and valid step-tests available for predicting cardiovascular fitness with the well-researched tests being the Harvard Step Test (Brouha et al., 1944 cited in Watkins, 1984), Canadian Aerobic Fitness Test (CAFT) (Bailey et al., 1976 cited in Noonan & Dean, 2004) and the Chester Step Test (Sykes & Roberts, 2004).

The Harvard Step Test was originally developed with fit young men and therefore is considered unsuitable for untrained individuals (Watkins, 1984). Although the original testing procedures can be altered for female participant (known as the Queens College Step Test),

this has been criticised as it was developed on a treadmill, rather than using a stepping up protocol (McArdle et al., 1972 cited in Watkins, 1984). In contrast, both the CAFT and Chester Step test have been developed with men and women of various ages and the prediction equations used to estimate oxygen capacity have been shown to be reliable and valid when testing against maximal fitness tests (Buckley, Sim, Eston, Hession & Fox, 2004; Jette et al., cited in Noonan & Dean, 2000; Sykes & Roberts, 2004).

1.4.2 Methods that subjectively measure physical activity

Subjective measures rely on participant self-report to measure PA behaviour. Measurement is either via participant recall (i.e. individuals remember their past PA performance, usually over the previous week or month) or via daily diaries, which encourage participants to write down their PA behaviour as it happens. The main benefits from subjective methods are that they are inexpensive and require no specialist equipment. Subjective methods have been found to be readily acceptable to participants and can provide detailed information on the mode, intensity, frequency and duration and domains of PA. Subjective measures also allow certain types of PA to be captured that might not otherwise be available (i.e. swimming). They are ideally suited to collection in large-scale trials or epidemiological studies as they can be conducted via postal survey, telephone or face-to-face interview (Dishman et al., 2001). The main limitations for any recall or diary measure is that they are open to subjective inference from participants due to reliance on self-reports, which are affected by individual perceptions, emotions and memory (Adams et al., 2005; Sallis & Saelens, 2000). As PA is considered socially desirable, both daily diaries and recall questionnaires are open to participants overestimating their PA behaviour, to appear more active (Adams et al., 2005).

1.4.2.1 *Daily diaries*

Diaries offer an advantage over questionnaires that are implemented after PA takes place as they do not require participants to accurately recall their behaviour. Recall from memory can be problematic in certain populations, such as children or among older adults (Sallis & Saelens, 2000). However, daily diaries can be time consuming for individuals to complete and as such they can show poor compliance (Dishman et al., 2001). The main limitation of daily diaries is the impact they have on behaviour during completion. There is evidence that individuals completing diaries increase their PA behaviour in response (Dishman et al., 2001). For this reason diaries are not suitable for assessing change in intervention studies.

1.4.2.2 Recall questionnaires

Recall questionnaires, are a popular method of measuring PA behaviour in field settings, due, in part, to the ease of administration. There are numerous instruments (> 50) available for assessment in adult populations and three reviews published prior to 2010 had considered their reliability, validity and measurement properties (Prince et al., 2008; Sallis & Saelens, 2000; van Poppel, Chinapaw, Mokkink, Van Mechelen & Terwee, 2010).

van Poppel et al. (2010) and Sallis and Saelens (2000) have found recall questionnaires used in adult populations scored highly on measures of test-retest reliability (i.e. studies generally recorded interclass correlation coefficients (ICC) or kappa statistics at >0.70, or Pearson's correlations at >0.8; considered to represent a high level of reliability). Test-retest intervals ranged from 2 days to 18-21 months (van Poppel et al., 2010).

Regarding validity, all reviews have considered the extent to which recall questionnaires agreed with objective measures of PA behaviour. The evidence showed there was low-moderate agreements between subjective recall methods with objectively measured PA behaviour using DLW, indirect calorimetry, heart-rate monitors or motion sensors (Prince et al., 2008; Sallis & Saelens, 2001). Sallis and Saelens (2001) reported coefficients of

between 0.14 to 0.50 for recall questionnaires compared with PA measured via motion sensors and heart-rate monitors. Prince et al. (2008) found coefficients of -0.17 to 0.93 when comparing objective and self-report measures of PA, with correlations between the measures being poorer among female samples. The differences between self-report measures of PA compared with motion sensors was on average 138%, suggesting substantially higher levels of PA are self-reported than objectively measured with motion sensors; the same trend in females was identified when PA measured by HRM was compared with recall questionnaires. In contrast, compared with DLW measures, self-reported PA was significantly lower (-9% difference). This difference might be accounted for the fact that DLW includes non-PA components of EE and, as discussed below, that motion sensors may not detect some non-ambulatory activities accurately (Prince et al., 2008). Van Poppel et al. (2010) has recently considered 77 recall questionnaires finding 16 achieved ICC/kappa of at least 0.70, suggesting adequate agreement with an objective criterion measure most closely linked to the behaviour being measured by the questionnaire (i.e. pedometer for recall of walking behaviour).

1.4.3 Methods that objectively measure physical activity

1.4.3.1 Doubly labelled water

DLW is used to measure total EE in free-living conditions over a set measurement period, normally up to three weeks (Schoeller, 1988; Roberts, 1989). The process of measurement involves participants ingesting a liquid substance containing two stable isotopes of hydrogen and oxygen, which are eliminated from the body in water (e.g. through sweat, urine and saliva) and in carbon dioxide (CO₂). The differential rate of elimination of the isotopes of hydrogen and oxygen are used to estimate CO₂ production rate and EE is calculated using an established equation (Andre & Wolfe, 2007). The accuracy of DLW for measuring EE in

humans under free-living conditions has led some to consider it the ‘gold standard’ measure (Andre & Wolfe, 2007). Within large-scale population studies or trials DLW is not generally suitable due to the cost per participant of conducting the techniques and specialist equipment required for analysis (known as mass spectrometry). Furthermore, the protocol for measuring DLW is intrusive for participants as it involves ingesting a liquid, overnight fasting and regular blood, saliva or urine testing. DLW does not provide information on PA intensity, duration or frequency, which is often of interest.

1.4.3.2 *Heart-rate monitors*

HRMs are used to measure PA behaviour in the field due to the linear increasing relationship between HR and VO_2 during physical exertion. Previous research has shown HRMs are valid and reliable for estimating EE in free-living conditions as they compare favourably to measurement with DLW (Freedson & Miller, 2000; Racette, Schoeller & Kushner, 1995). HRMs are easier to use on a large-scale compared with DLW because the devices are relatively inexpensive. HRMs also provide a measure of activity intensity, frequency and duration as time spent in different activity intensities can be calculated using proportion (%) of maximum HR values. Researchers classify HR values obtained at <50% of maximum HR (HR_{max}) as low intensity, values between 50-70% as moderate and values >70% of HR_{max} as vigorous intensity as these have been shown to correspond to Metabolic Equivalent (MET) values associated with these intensities (McArdle, Katch & Katch, 2007). METs are multiples of the metabolic rate of activities compared to resting rate of EE (the energy costs of sitting quietly are roughly 1 MET). Individual variations, such as gender, fitness levels and taking certain medications (e.g. beta-blockers) can all affect the accuracy of measuring PA using HRMs. Due to these variations it is common to find different heart rate readings from individuals who are participating in the same activities. It is recommended that prior to heart-

rate monitoring researchers establish an individual calibration curve (i.e. showing the relationship between HR and VO_2 for each individual). This requires testing under laboratory conditions, usually via a maximal exercise test (Freedson & Miller, 2000). Following the initial testing session field-based assessment can proceed. Some trials have reported low-compliance with HRMs (Forrest et al, 2004 cited in Andre & Wolfe, 2007), perhaps due to the inconvenience for participants from wearing a device with a constricted chest strap over a long measurement period (i.e. a week) and complaints of skin irritation (Andre & Wolfe, 2007). Other concerns relate to the ability of HRMs to accurately measure light-intensity PA. Previous studies have shown the relationship between HR and VO_2 (from which EE is estimated) during light activities is often confounded due, in part, to internal or external states or activities that raise HR with no corresponding effect on VO_2 (e.g. experience of emotional stress, anxiety, caffeine intake, high ambient temperature, illness etc.) (Crouter, Albright & Bassett, 2004 cited in Andre & Wolfe, 2007).

1.4.3.3 *Motion sensors*

Motion sensors for measuring PA in the field include accelerometers and pedometers. This method of measuring activity is via the movement (or motion) of individuals during their day-to-day lives.

Pedometers are a simple motion sensor, which measures PA that occurs during walking. Pedometers typically contain one spring-suspended lever axis, positioned in a vertical plane (the pedometer is worn on the belt band at the waist); the resulting measurement is a direct count of the number steps taken by the individual while wearing the devices. A range of pedometers are available commercially; they are inexpensive, easy to use and have evidence of good validity and reliability for measuring walking behaviour (Crouter, Schneider, Karabulut & Bassett, 2003; Tudor-Locke, Ainsworth, Thompson & Matthews, 2002). Pedometers performed particularly well in terms of accuracy of step counting

(measured against participant observation) when participants walked at a pace that was at least moderate (e.g. during brisk walking and running) or during sedentary activities (such as sitting). However, during slow walking correlations were much poorer (Crouter et al., 2003, Tudor-Locke et al., 2002; Tyo, Fitzhugh, Bassett, Feito & Thompson, 2011).

Due to their easy operation, pedometers are a popular choice for measuring the impact of interventions in terms of change in walking behaviour (Bravata et al., 2007; Kang et al., 2009). One consideration is the need to conceal step count information from participants in order to reduce the possibility of participant reactivity affecting accuracy of measurement. Many pedometers have a screen displaying daily step counts and some studies have encouraged participants to record their steps in a diary, which researchers also collect for data analysis (e.g. Krummel, Semmens, MacBride & Fisher, 2010). Clemes, Matchett and Wane (2008) have shown this increases walking as a result of participants' viewing and being asked to self-monitor step counts.

Limitations of the use of pedometers for measurement are that they do not measure the intensity of walking, thus are unable to differentiate walking with running; pedometers provide no information regarding the frequency or duration of walking and they do not accurately measure PA without a step component (e.g. weight-lifting, cycling, sitting household activities etc.). Pedometers have been found to be less valid and reliable in certain populations, including the elderly and obese populations (Crouter, Schneider & Bassett, 2005; Melanson et al., 2004; Tyo et al., 2011). Pedometers are generally considered unsuitable for accurate measures of EE as they have been found to both under and overestimate the energy costs of walking behaviour when compared with DLW (Leenders, Sherman, Nagaraja & Kien, 2001). Step counts measured via accelerometers (discussed below) correlate with step counts measured by pedometers (Tudor-Locke et al., 2002).

Accelerometers offer a more sophisticated measure of PA behaviour and have the advantage of addressing some of these limitations of pedometers.

1.4.3.3.1 Accelerometers

Like pedometers, accelerometers are motion sensors that offer a direct measure of movement in real-time. Accelerometers operate on the premise that acceleration is proportionate to the muscular force during PA (Troost, McIver & Russel, 2005). Accelerometers can be worn on the wrist, back, lower leg or foot or trunk and generally measurement takes place in one, two or three direction (uni-, bi- and tri-axial accelerometers), respectively (omnidirectional multi-axis accelerometers are also available (Troost et al, 2005). The different accelerometer axes are the anterior-posterior (x), medio-lateral (y) and vertical (z) axis; uniaxial accelerometers operate on the z -plane, while triaxial accelerometers operate on x -, y - and z -planes. Regardless of positioning, or how many axes are measured, the most common unit of measurement from accelerometers is via *activity counts*, which are the product of the accelerometer sensor filtering the frequency and intensity of movements at set sampling intervals (known as epochs). Activity counts are normally expressed as counts per minute (counts/minute), which is proportional to the intensity and frequency of movements over the measurement time period. Also conversion of these counts to a more meaningful measure of PA behaviour can be conducted via EE prediction equations or conversion to time spent in different intensities using cut points. The development of the equations for predicting EE and cut points for intensity of activity will be discussed below, and also the reliability and validity of accelerometer outputs (i.e. activity counts, estimated EE and time spent in intensities); the range of accelerometers that are available for measuring PA are considered first.

1.4.3.3.1.1 Types of accelerometer

Over the past two decades a number of accelerometers have become commercially available. A review by Trost, McInver and Pate (2005) described eight commonly used accelerometers (Actigraph, Actical, Actiwatch, AcitTrac, Biotraininer Pro, Tristrac-R3D and RT3 and the IDEEA), all with various technical specifications, data storage capacities, battery life and computer interfaces. Different accelerometers require different data reduction and manipulation techniques to process and analyse the data.

1.4.3.3.1.2 Reliability and validity of accelerometer activity counts

Of the eight accelerometers described in the Trost et al. (2005) review, seven had reported reliability and validity data for measuring PA in adult populations with early studies demonstrating accelerometers could reliably measure PA. For example, the uniaxial Actigraph accelerometer (ActiGraph, Pensacola, FL 32502), formally Computer Science and Applications (CSA) (Actigraph 7164) showed acceptable test-retest reliability (also called intra-instrument reliability) when participants walked, jogged and ran at variables speeds in treadmill tests (Hendelman et al., 1995 cited in Trost et al, 2005). In tests of the same accelerometer under free-living conditions inter-instrument reliability (i.e. comparing different accelerometer devices of the same model) was high for activity counts (McClain, Sisson &, Tudor-Locke, 2007). Nichols, Morgan, Chabot, Sallis & Calfas (1999) found similar results for both inter-instrument and inter-instrument reliability on an early triaxial accelerometer (Tritrac R3D), while participants engaged in treadmill walking and running. However, comparisons between three accelerometers: the Actical, RT3 (formally Tritrac R3D) and Actigraph GT1M (formally 7164) during a mechanical setup using a hydraulic shaker plate found only the Actical and Actigraph had evidence of high intra and inter-instrument reliability considering activity counts (Esliger & Tremblay, 2006). The study by Esliger and Tremblay (2006) also considered test-retest variability and between instruments at different accelerations; reliability of the Actigraph was good regardless of speed of

movement. The GT1M model is a later version of the Actigraph accelerometer than the 7164 with improved sensors capable of distinguishing between acceleration due to standing upright and moving, however analysis of activity counts between these models suggests they are comparable, based on treadmill walking and running (John, Tyo & Bassett, 2010).

Regarding validity, activity counts from accelerometers have been shown to provide a useful and accurate measure of PA behaviour during lab-based assessments (Troost et al., 2005). In one study of the Actigraph (CSA) accelerometer there was a strong linear relationship between counts and criterion measures (VO_2 , HR and EE measured via indirect calorimetry) when young adult participants took part in treadmill walking or jogging at increasing speeds (Melanson & Freedson, 1995). However, one limitation of accelerometers is that when fast running is considered this linear relationship becomes compromised; accelerometer counts begin to level off at running speeds greater than six miles per hour (Rowlands, Stone & Eston, 2007). Accelerometers have also been shown to be less sensitive at very slow walking speeds (Tudor-Locke, Johnson, Katzmarzyk, 2009), Accelerometers cannot discriminate changes in gradient; correlations between counts and the criterion measures were not significant if speed was kept constant and the slope of the treadmill was increased linearly (Mendelson & Freedson, 1995; Nichols et al., 1999).

Counts from the Actigraph accelerometer have been found to positively correlate with free-living activities that are equivalent to those measured in the lab-studies, showing good agreement with oxygen uptake measured via indirect calorimetry (Hendelman, Miller, Baggett, Debold & Freedson, 2000). Comparisons between accelerometers have shown near identical correlations between adults' field-based activity counts measured using the Actigraph (CSA) and Trictrac RD3 with PA EE measured using a PA recall questionnaire (Leenders, Sherman & Nagaraja, 2000). However, this study did not use an objective criterion measure, therefore self-reports may not be a valid comparator. One study using an

objective monitoring method did find comparable agreement with VO_2 (measured using indirect calorimetry) during outdoor walking or indoor and outdoor household activities between the Actigraph CSA (uniaxial) and Trictrac RD3 (Triaxial) accelerometers (Hendelman et al., 2000), however this study was conducted under supervised conditions. In the field, when activities are measured over a week or more, agreement between accelerometer measured activity counts with PA EE as measured using DLW is more modest, although still significant (Adams et al., 2005).

1.4.3.3.1.3 Accelerometer estimated energy expenditure

A number of studies have developed prediction equations for estimating EE using accelerometer activity counts. The first prediction equation was derived from treadmill walking and running by Freedson, Melanson and Sirard (1998) using the first generation of the Actigraph (CSA) accelerometer. This was a linear regression model premised on the relationship between increasing counts on the vertical plane (measure of acceleration) and increasing metabolic costs (measure of EE) during locomotion. Linear prediction equations are reasonably accurate at estimating EE in healthy adults when considering normal or brisk walking and where there is no gradient, but during performance of indoor and outdoor household tasks, slow walking, fast running or considering overweight or obese adults they perform less well (Hendelman et al., 2000; Al-Jaloud, Hughes & Galloway, 2011; Lyden, Kozey, Staudenmeyer & Freedson, 2011). Hendelman et al. (2000) reported the CSA accelerometer underestimated the energy costs of tasks such as window washing, dusting, vacuuming, lawn mowing and planting a shrub. This is unsurprising as these activities involving carrying, pushing or a large amount of movement of the upper torso and arms and the Freedson equation was based on treadmill walking and running. Overall, there is no consensus on the best prediction equation to use for estimating EE and accelerometers continue to underestimate energy costs of activities carried out in free-living conditions.

1.4.3.3.1.4 Cut points for measuring intensity of physical activity behaviour

Activity intensity cut points can be used to determine the amount of time participants spend in different intensities during free-living conditions or investigate changes to the intensity of PA performance over time/in response to an intervention. A range of cut point thresholds derived from counts have been proposed for use in adult populations when measuring activity using the Actigraph accelerometer range (Table 1). As PA guidelines stress the importance of *at least* moderate-intensity PA for health benefit (Haskell et al., 2007), a simple method for classifying time spent in different activity intensities during free-living is useful.

Table 1. **Actigraph accelerometer cut-points equations**

References	Light intensity counts	Moderate intensity counts	Hard³ intensity counts	Very hard³ intensity counts
Freedson et al. (1998)	100-1951	1952–5724	≥5725	-
Hendelman et al. (2000)	≤190.6	190.7-7525.7	7525.8-14860.5	≥14860.6
Swartz et al. (2000)	≤573	574-4944	4945-9318	≥9317
Sasaki et al. (2011) ¹	≤2690	2691-6166	6167-9642	≥5725
Troiano et al. (2008) ²	100-2019	2020-5998	≥5999	
Note. Corresponding Values (METs): Light intensity <3 METs, Moderate 3–6 METs, Vigorous (e.g. Hard 7–8 METs, Very hard ≥9 METs) ¹ Suitable for use with triaxial (e.g. GT3X/GT3X+) Actigraph accelerometers only; ² Developed for the NHANES study but considered largely equivalent to the Freedson et al (1998) cut points ³ Hard and very hard intensity are commonly termed ‘vigorous intensity’.				

The first cut points were proposed by Freedson et al. (1998) using the Actigraph CSA accelerometer. Activity counts obtained during walking and running at different treadmill speeds were averaged and compared with MET values associated with the different intensity zones, measured simultaneously with indirect calorimetry. Studies have shown these activity based cut points reliably classified intensity of PA under test-retest conditions, although due to poorer correlations for moderate-intensity activities researchers recommend moderate-

vigorous activities are combined (McClain, Sisson &, Tudor-Locker, 2007). Lab-based studies have shown that classification of time spent in different PA intensities using the Actigraph CSA GT1M accelerometer were comparable (Kozey, Staudenmayer, Troiano & Freedson, 2010; John, Tyo & Bassett, 2010), although not with the newest models of Actigraph accelerometers (released in 2009/2010) when calculating intensity based on data from all three axes (Sasaki, Dinesh & Freedson, 2011). The GT3X accelerometers can be used in comparison to the CSA/GT1M but only when activity counts from the single vertical axis is used. Where all three axes are used Sasaki et al. (2011) proposed new thresholds (shown in Table 1) should be used to classify activity intensity, however no research has investigated the use of the newer cut points in free-living conditions.

The Freedson cut points were developed using treadmill walking and running, therefore there is concern the relationship between counts and activity intensities are less valid in field-based settings. Hendelman et al. (2000) and Swartz et al. (2000) developed cut points through assessing agreement between activity counts (measured using the Actigraph CSA accelerometer) and various criterion measures (e.g. portable gas exchange, DLW etc.), for example during indoor and outdoor household activities performed at a self-selected pace (Hendelmen et al., 2000; Swartz et al., 2000)

Ainsworth et al. (2000) compared the cut-points proposed by Hendelman, Swartz and Freedson against self-completed PA logs over a 21 day period in a mixed-gender sample. The showed the cut-points proposed by Swartz and colleagues correlated better with moderate-intensity activities recorded via the logs compared with the Freedson cut points, which underestimated time spent in moderate-intensity activities. The Hendelman et al. (2000) cut-points greatly overestimated moderate-intensity activities compared to the logs probably due to the very low cut-point threshold that was set for moderate activities. Regarding vigorous/hard intensity activities, there was no significant difference in the estimated

performance (minutes per day) using all the Hendelman, Swartz and Freedson cut points and all showed good correlations against the data gathered from the activity logs. The lower threshold for moderate-intensity activities proposed by Swartz et al. (2000) appeared to lead to more lifestyle activities (e.g. vacuuming, sweeping, mopping, washing windows, washing dishes and gardening from participants self-reports) being classified as moderate-intensity (Crouter et al., 2005).

1.4.3.3.1.5 Acceptability/feasibility for measuring physical activity in the field

Like pedometers, accelerometers are relatively small and light and can be correctly worn by participants with minimal instruction. Newer accelerometers also have larger memory capacities and technological advances, such as USB interface and analysis software. Accelerometers have become less expensive and this has made it possible to measure PA using accelerometers within interventions research. All studies using motion sensors to measure PA behaviour experience challenges related to adherence to protocols. Guidance for using accelerometers to accurately measure PA is available (Troost et al. 2005). Considerations include appropriate site of monitor placement, number of days of monitoring, choice of sampling interval, process for distribution and collection of monitors and filtering of data to account for participant nonwear time etc.). Some issues such as non-compliance, incorrect monitor placement and incomplete diary records have been identified in previous studies (Ward, Evenson, Vaughn, Rodger & Troiano, 2005), although data from large-scale population PA monitoring studies is encouraging, showing three-quarters of healthy adult participants adhere to required protocols for accelerometer wear-time (Hawkins et al., 2009).

1.5 Participation in physical activity during the postnatal period

This section considers participation in PA, in particular whether PA behaviour is lower postnatally relative to prepregnancy and what facets of PA participation are affected. It is important to consider whether postnatal women are insufficiently active in order to identify their suitability for interventions promoting behaviour change.

1.5.1 Postnatal physical activity participation compared with prepregnancy

Several studies have assessed changes in PA levels from prepregnancy into the postnatal period. Amongst studies comparing prepregnancy and postpartum activity participation, some have identified declines in PA (Albright, Maddock & Nigg, 2005, McIntyre & Rhodes, 2009; Pereira et al., 2007; Schramm et al., 1996; Symons Downs & Hausenblaus, 2004), whilst others have found participation remains unchanged, rebounds or even increases during the year following childbirth, compared with prepregnancy levels (Blum, Beaudoin & Canton-Lemos, 2004; Borodulin et al., 2009; Cramp & Bray, 2009a; Grace, Williams, Stewart & Franche, 2006; Treuth et al., 2005). Some of this variation is likely explained by differences in population characteristics among studies and due to different measurement approaches, with large variation in the type of PA included.

1.5.1.1 *Effect on leisure-time physical activity participation*

Pereira et al. (2007) found evidence for a decrease in PA at six months postpartum in a sample of over 1200 participants recruited during their first trimester of pregnancy. Total self-reported leisure-time physical activity (LTPA) fell from over nine hours per week at prepregnancy to eight hours per week postpartum; failure to completely return to prepregnancy activity levels was explained by a drop in both moderate and vigorous activity. Pereira and colleagues (2007) used a longitudinal prospective assessments of LTPA; but other studies have measured participants' PA behaviour retrospectively using cross-sectional designs.

Symons Downs and Hausenblaus (2004) measured LTPA behaviour of 74 postpartum women with an average time since childbirth of 3.5 months. They found a statistically significant decrease in participation in self-reported strenuous, moderate and mild LTPA postpartum compared with prepregnancy. Albright et al. (2005) also compared prepregnancy LTPA with current postpartum behaviour (average time since delivery 8.2 months). Participants self-reported habitual PA behaviour and were classed as either inactive/irregularly active or active at both time points in accordance with PA guidelines. Results showed 64.5% of participants were inactive/irregularly active postpartum. Of these, 43% were active prepregnancy. Among those reporting a decline in activity, 52% stated they had reduced the number of active days by three or more (Albright et al., 2005). This study had a large gap between assessment and retrospective recall of prepregnancy activity behaviours (i.e. up to 18 months); this large window between the behaviour occurring and measurement is problematic. However, the Albright et al study is supported by a more recent study conducted with mothers of young children up to the age of four (McIntyre & Rhodes, 2009). Assessing prepregnancy activity levels retrospectively, this study found 62% of participants were currently inactive, of which 31% self-reported PA prior to pregnancy. This contrasted with 27% who continued to be active postpregnancy and 11% who increased their activity. LTPA significantly declined from prepregnancy participation levels.

1.5.1.2 Effect on total physical activity participation

Studies including non-leisure physical activities have generally found total PA participation rebounds to prepregnancy levels during the year following childbirth. This may be because time spent in caregiving, household and gardening increases postpartum, whilst leisure-time and occupational activity decreases. As with the studies measuring LTPA the literature regarding total PA levels has methodological weaknesses, mainly due to PA measurement approaches.

Treuth and colleagues (2005) conducted a longitudinal investigation of changes in physical fitness, strength, and PA behaviour among healthy adult women. Of the 124 women recruited, 63 delivered a term singleton infant during the course of the study and took part in repeated measurements at six weeks and 27 weeks postpartum. The study found decreased participation in strength and conditioning, water-based, sports and occupational activities; however an increase in home activities was reported. Overall however, the author's found no significant change in total self-reported activity levels amongst postpartum women at six or 27 weeks compared with prepregnancy. Blum et al. (2004) also found patterns of PA differed across types of activity. PA from the prepregnancy period was retrospectively recalled and participants self-reported frequency of participation in 75-items from four activity domains (household and caregiving, sports/exercise, active living and occupational) using a 5-point Likert scale from "never" to "more than once a week". Overall there were no significant changes in total PA from prepregnancy among study participants at an average of 4.4 months following childbirth.

Borodulin et al. (2009) also found increased caregiving PA and decreased occupational PA but no overall change in total activity levels, compared with pre-pregnancy, at three months postpartum. This pattern held until 12 months following delivery. Borodulin and colleagues (2009) used a prospective design, recruiting a large sample (471 participants) at less than 20 weeks gestation, which is more methodologically sound compared with retrospective assessment. However, this included light-intensity activity along with moderate "somewhat hard" and vigorous activity "hard/very hard" intensity, which may explain why overall activity levels remained stable.

1.5.1.3 Effect on walking participation

There is some evidence that walking is less likely to decline postnatally relative to participation in exercise or sports participation and may be the primary form of LTPA among

postnatal women. Albright et al. (2005) found self-reported walking was reported as the main form of LTPA by 44% of postpartum women in their study, with no decline relative to prepregnancy walking. In contrast, aerobics class attendance, which was self-reported by 20% of participants prepregnancy, dropped to 8% following childbirth. Pereira and colleagues (2007) also found walking participation remained stable, despite the decline in moderate-vigorous LTPA. Walking may be a more acceptable form of LTPA for postnatal women, particularly among overweight or obese women who report physical discomfort during exercise or while using exercise equipment (Lambert et al., 2005). Walking is also associated with less perceived exercise barriers among postnatal women, particularly as this reduces the need for childcare, transportation to exercise facilities and monetary costs (Cramp & Bray, 2009b; Evenson et al., 2009; Lambert et al., 2005).

Walking may also be conducted for non-exercise purposes, for example for transportation and/or during lifestyle activities. There is limited evidence regarding overall walking behaviour of postnatal women but one study conducted by Wilkinson, Huang, Walker, Sterling & Kim (2004), (discussed in more detail below) has suggested step counts are relatively low postnatally (i.e. averaging less than 7000 steps day), which is indicative of a low-active profile (Tudor-Locke et al., 2009). However, as Wilkinson et al. (2004) was conducted at three months postpartum and in a low-income population, it may not be representative of postnatal women in general.

1.5.2 Are women active enough in the year following childbirth?

1.5.2.1 *Adherence to physical activity guidelines during the postnatal period*

The proportion of postnatal women achieving minimum guidelines recommendations for adults differs between studies, which have mostly been conducted in the US. Pereira et al, (2007) reported the most favourable figures for PA participation at six months postpartum,

with almost 80% of women self-reporting meeting PA guidelines. Albright et al. (2005) found only 35.5% of postnatal women self-reported meeting guidelines at 8.4 months postpartum. Grace et al. (2006) reported 50% of women were meeting PA guidelines at an average of 9.9 months postpartum. Among mothers of children under four years 40.2% self-reported currently meeting PA guidelines (McIntyre & Rhodes 2009).

1.5.2.2 Intensity of postnatal physical activity participation

Intensity of PA is an important consideration in relation to short and long-term health benefits of postnatal PA. Walking intensity is a far more important predictor of positive health and wellbeing (in women) compared to total walking duration (Schnohr, Scharling & Jensen, 2007; Hu et al., 1999; Manson et al., 1999). Furthermore, PA guidelines suggest *at least* moderate-intensity activity is associated with health benefits (Bull et al., 2010; Haskell et al., 2007). Studies discussed above found household, caregiving and walking activities were less likely to decline postnatally. Given individual variation of many household, caregiving and walking activities, these may not be performed at sufficient intensity to confer health benefit (Withers et al., 2006; Schnor et al., 2007; Stamatakis et al., 2009).

Accelerometry studies of the daily activity patterns of adults in developed countries suggest little time is spent in moderate and vigorous intensity activity (Ainsworth et al., 2000 cited in Norton, Norton & Sadgrove, 2010). At the time of conducting this literature review no research evidence had investigated PA behaviour among postnatal women using accelerometers. However, one study did use a recall interview and daily diary to measure activity levels at 3 months postpartum in low-income women in the US. This study suggests postnatal women also spend a large proportion of their day in sedentary and light intensity activities and little time in moderate or vigorous intensity activities (Wilkinson et al., 2004). Wilkinson et al. (2004) asked participants to self-report time spent in sitting, light, moderate

and vigorous activities in the last week. They found that postpartum women at three months from delivery spent 384 and 537 minutes per day in light-intensity and sitting activities, respectively. Moderate activities were reported as 16 minutes per day. Step counts for the measurement week averaged 6,262 steps per day, which is indicative of a low-active pattern of activity (Tudor et al., 2009). This suggests postnatal women were predominately active through light-intensity activities, including walking, since their step counts were not as low as some research has found in the sedentary general adult population (Tudor-Locke & Bassatt, 2004 cited in Wilkinson et al., 2004). Since the interview data was subjectively measured the same limitations discussed in relation to the general postnatal PA literature apply. Also the early measurement point (three months after delivery) means PA intensity might be expected to be lower than at later postpartum stages (Cramp & Bray, 2009a).

1.6 Modifiable factors influencing postnatal physical activity participation

This section considers modifiable factors associated with PA participation. Compared with non-modifiable factors, which are associated with poorer participation in PA (e.g. female gender, older age, low-income, poor education levels, non-white ethnicity etc.); modifiable factors are amenable to change through interventions (Allender, Cowburn & Foster, 2006; Sherwood & Jeffery, 2000; Trost, Owen, Bauman, Sallis & Brown, 2002). The strongest evidence suggests adults who are more physically active report higher self-efficacy, fewer perceived barriers to activity, greater motivation/intention to be physically active, greater levels of enjoyment, greater use of processes for changing behaviour (discussed below) and social support for PA (Allender et al., 2006; Baruth et al., 2010; Lewis, Marcus, Pate & Dunn, 2002; Sherwood & Jeffery, 2000; Steptoe, Rink & Kerry, 2000; Trost et al, 2002).

Research has shown that the following modifiable variables are associated with being more active during the postnatal period: having more positive outcome expectancies (Cramp

& Brawley, 2009), perceiving fewer barriers to being physically active (Pereira et al., 2007), general self-efficacy for being physically active (Cramp & Bray, 2009b), self-efficacy for overcoming barriers to activity (Cramp & Bray, 2009b) and self-efficacy for recovering from setbacks (Cramp & Brawley, 2009). Among mother of young children self-efficacy and perceptions of social support (Miller, Trost & Brown, 2002) have been identified as modifiable influences on PA behaviour. The best evidence comes from studies that have shown that change in PA behaviour is mediated by change in these modifiable factors (Cramp & Brawley, 2009; Miller et al., 2002). These are important findings because this provides strong evidence for targeting these factors in behaviour change interventions, specifically those which target individuals and include changing PA cognitions as a route to changing behaviour.

1.6.1 Beliefs about the benefits of being active/outcome expectancies

Studies with postnatal women have found they mention a range of potential benefits from being more physically active. These beliefs include: PA will help them to lose weight, sleep better, have more energy, to increase positive emotions and mood and to be stronger and toned (Evenson et al., 2009; Groth & David, 2008; Lambert et al., 2005; Symons Downs & Hausenblas, 2004). Studies of postnatal beliefs about PA benefits have included ethnically diverse samples, low-income and overweight/obese (OW/OB) participants (Groth & David, 2008; Lambert et al., 2005).

Cramp and Brawley (2009) found changes in PA participation in the context of stable outcome expectancies at post-intervention among postnatal women taking part in a behaviour change intervention (Cramp & Brawley, 2006). Participants were randomised to four weeks of community based exercise (aerobic and strength training) and educational classes with onsite childcare, followed by four weeks of home-based exercise (both groups), with the intervention receiving an additional six twenty minute sessions of behavioural counselling in

the first four weeks. The sessions introduced topics such as goal-setting, self-monitoring activity and planning to overcome barriers. The intervention group significantly increased both frequency and total minutes of MVPA. Only the intervention group maintained increased positive outcome expectancies at 8-week follow-up with the control group showing a decline in outcome expectancies. Significance testing showed outcome expectancies were not significant mediators of the changes in PA behaviour from baseline to post-intervention (Cramp & Brawley, 2009); this has been found previously among sedentary adult women (Steptoe et al., 2000).

1.6.2 Barriers, social support and self-efficacy

The most frequently cited barriers in postnatal populations are: lack of time, lack of childcare, low energy levels and lack of motivation for being active (Cramp & Bray, 2009b; Evenson et al., 2009; Pereira et al., 2007; Symons Downs & Hausenblas, 2004). Perceived barriers appear to affect both postnatal women's intentions to be active and their PA behaviour (Godin, Vezina & Leclerc, 1989; Cramp & Bray, 2009b; Pereira et al., 2007). Furthermore, social support, which may help with overcoming barriers, has been shown to be positively associated with PA behaviour among women with young children (Brown, Brown, Miller & Hansen, 2001; Cody & Lee, 1999; Miller et al., 2002). In focus groups, Groth and David (2008) found mothers endorsed lack of social support, particularly with childcare as a significant barrier to being physically active during the year following childbirth. Pereira et al (2007) found that reporting lack of childcare was a barrier to PA was associated with significantly increased odds of failing to meet PA guidelines at six months postpartum based on self-reports of LTPA participation. Longer working hours (indicative of lack of time) were also associated with inactivity postnatally. Physical discomfort or pain/injury, low self-esteem, lack of normative influences for PA, depression, lack of money, breastfeeding and the additional demands and inherent unpredictability of caring for a baby have also been

reported as barriers to postnatal PA (Evenson et al., 2009; Cramp & Bray, 2009b; Lambert et al., 2005; Symons Downs & Hausenblas, 2004).

Self-efficacy has been defined by Bandura (1997) as “the belief [i.e. confidence] in one's capabilities to organize and execute the courses of action required to produce given attainments” (p.3). Self-efficacy is consistently shown to be a significant predictor of PA behaviour among women (Sharma, Sargent & Stacey, 2005; with mediation of behaviour change following change in self-efficacy found following an intervention in women with young children aged 2-5 years; self-efficacy significantly predicted whether women self-reported meeting PA guidelines at 8-weeks follow-up (Miller et al., 2002). A longitudinal study by Cramp and Bray (2009b) found LTPA participation among postnatal women could be predicted at 12, 18, 24 and 30 weeks post-delivery by general self-efficacy for being active (i.e. how confident they were that they could be achieve at least 30 minutes of moderate-intensity aerobic PA one, two, three, four and five times each week over the following next six weeks) and barrier self-efficacy (i.e. postnatal women's confidence for overcoming personally relevant barriers to LTPA in the next six weeks). Both constructs were significant predictors of how much PA participants' self-reported over the following six weeks.

1.6.3 Self-regulatory self-efficacy

Self-regulation is a process whereby individuals use feedback about their own behaviour to determine success in meeting their goals/plans and overcoming their barriers (Schwarzer, 1992; Carver & Scheier, 1982). Self-regulation beliefs/skills have been found to be important mediators of PA behaviour change in the general population (Michie, Abraham, Whittington, McAteer & Gupta, 2009). Cramp and Brawley (2009b) suggest self-regulatory self-efficacy is the individuals level of confidence that they can “organise, plan and schedule regular physical activity” (p. 599); finding postnatal women's self-regulatory self-efficacy increased following the PA behaviour change intervention discussed above (Cramp & Brawley, 2006).

Mediation analysis showed it was the only factor to partially mediate the relationship between intervention group and PA change at the 8-weeks follow-up.

1.6.4 Modifiable factors and health behaviour change theory

Modifiable socio-cognitive factors (e.g. outcome expectancies, self-efficacy for overcoming barriers, self-regulatory efficacy) have been shown to be significantly associated with postnatal PA participation, with some variables mediating changes in PA behaviour. These factors are common to several models of health behaviour change which have been used extensively to understand and change PA participation (e.g. the Theory of Reasoned Action/Planned Behaviour (TRA/TPB), Socio-Cognitive Theory (SCT), Transtheoretical model (TTM) and the Health Action Process Approach (HAPA)) or prevent relapse from behaviour change (e.g. HAPA, Relapse Prevention Model (RPM)). Although, not an exhaustive list, the range of behaviour change models discussed do provide testable frameworks for predicting relationships between PA factors with PA behaviour (Michie, Johnston, Francis, Hardeman & Eccles, 2008; Biddle & Mutrie, 2008). Descriptions of these models and research testing the contribution of them to understanding postnatal PA behaviour change are discussed below. Interventions, which have been developed with reference to behaviour change models are discussed in Chapter Two.

1.6.4.1 *Theory of Planned behaviour*

The TPB (an extension of the earlier TRA) has been used to understand PA behaviour. The TPB explains behaviour through the concepts of behavioural intentions and perceived behavioural control (PBC), proposing both are direct determinants of behaviour (Ajzen & Fishbein, 1979, cited in Biddle & Mutrie, 2008). According to the model intentions are determined by the following social cognitive constructs: attitudes about the behaviour, and subjective norms. Attitudes are defined as evaluations about the positive and negative beliefs

individuals hold about performing the behaviour (e.g. activity is/is not important for health benefits or is/is not enjoyable), while subjective norms are defined as beliefs/behaviours significant others (e.g. family, peers, partner, doctor etc.) hold/do in relation to the behaviour in question and the extent to which the individual is motivated to comply with the beliefs of those people. PBC, defined as the perceived ease/difficulty of performing the behaviour (taking account of potential barriers), is predicted to influence the strength of the intention-behaviour relationship and to impact on behaviour directly.

One study has assessed the PA beliefs and behaviours of mothers of young children (aged 3 months-4 years old) cross-sectionally using TPB constructs and a subjective measure of LTPA with a retrospective recall for prepregnancy behaviour (McIntyre & Rhodes 2009). This study found that a number of behavioural beliefs related to PA barriers successfully distinguished ‘active continuers’ (i.e. women who maintained their activity levels from prepregnancy to motherhood) with ‘discontinuers’ (i.e. active prepregnancy but now inactive). The strongest effects were found for the beliefs PA “takes too much free time” and “relives stress”, with the former being significantly greater in discontinuers and the latter higher in continuers. Regarding norms, the belief that friends approved of PA, but not family members predicted greater LTPA (both predicted intentions to be active). Finally, in a regression analysis they found that 22% of the variance in frequency of LTPA was predicted by intention and PBC, with intentions being predicted by PBC, affective attitude and subjective norms.

Godin et al. (1989) found pregnant women’s intentions to participate in LTPA activity after childbirth were predicted by their attitudes, subjective norms, perceived barriers and PBC for postnatal PA. PBC was assessed by giving participants a list of possible barriers to being physically active and asking them to consider how easy or difficult it would be for them in their personal situation to be active after childbirth. The study found both attitudes

and PBC were significantly associated with intentions to be physically active during the postnatal period. Subjective norms did not predict intentions. Also, past behaviour was as strong a predictor of intentions as both attitudes and PBC.

The lack of longitudinal follow-up studies between self-reported postnatal PA intentions and actual behaviour is problematic due to the ‘intention-behaviour gap’; the well-documented difference between behavioural intentions and the prediction of behaviour (Biddle & Mutrie, 2008). For example, intentions and PBC measured prior to delivery directly predicted 1-year postpartum PA behaviour, but only 20% of the variance could be explained using the TPB constructs alone (Hinton & Olson, 2001). This is in line with research conducted in the general population, and women with young children, which has demonstrated that a significant amount of the variance in intention (up to 50%), but only 20-33% of the variance in actual PA behaviour is explained using TPB constructs (McEachan, Conner, Taylor & Lawton, 2011; McIntyre et al., 2009).

1.6.4.2 Socio-cognitive theory

SCT is another well researched theory in relation to PA behaviour and behavioural change. SCT proposes that interactions between personal/cognitive, environmental and behavioural factors influence performance of behaviour (Bandura, 1997). Personal/cognitive factors from the SCT include outcome expectancies (e.g. evaluative beliefs about the consequences of performing PA), affective beliefs (e.g. evaluations of enjoyment), biological interpretations (e.g. experiencing sweating) and self-efficacy. SCT proposes that personal/cognitive factors drive PA behaviour change, and maintenance of change, as individuals experience positive associations with performance of the behaviour (e.g. positive evaluations from oneself or others for pursuing weekly activity goals) and therefore make an effort to begin or continue to adopt those behaviours. This increases self-efficacy to overcome barriers they experience as a process of self-regulation of behaviour. Environmental factors (e.g. activity

opportunities, convenience of facilities and social support) are proposed to facilitate or hinder this reciprocal process (Conner & Norman, 2005).

SCT-informed behaviour change interventions have demonstrated increased participation in PA (DuVall, Dinger, Taylor & Bembem, 2004; Miller et al., 2002) including in a postnatal population (Fjeldsoe et al, 2010.). There is evidence for SCT constructs in predicting PA behaviour (Keller, Fluery, Gregor-Holt & Thompson, 1999), with evidence for mediating effects of self-efficacy in response to behaviour change interventions in the general population (Lewis et al., 2002) and among mothers with young children (Miller, et al., 2002). Although evidence for the importance of SCT constructs (in particular self-efficacy) is reasonably strong, this is largely limited to change in self-reported PA (Cramp & Bray, 2009b; Miller et al., 2002). The role of outcome expectancy beliefs and environmental factors (also constructs from SCT) have not been adequately established in postnatal populations.

1.6.4.3 *Transtheoretical Model*

Another commonly used model for understanding and changing PA behaviour is the TTM. Originally developed within the addictions field, the TTM suggests that individuals change via progression through a series of five stages: Precontemplation, Contemplation, Preparation, Action and Maintenance (Prochaska & DiClemente, 1994 cited in Biddle & Mutrie, 2008). Table 2 describes conceptualised movement through the stages in relation PA participation (Marcus & Simkin, 1993). Assigning individuals to stages depends on their intentions to be active or current and past performance of PA and the extent to which they participate in regular PA (defined in line with the PA guidelines); assessment of stage of change therefore includes both people's readiness to change and current behaviour (Marcus & Simkim, 1993). Importantly this process of movement through the stages is thought to be cyclical i.e. relapse from any *stage* is possible as people make attempts to move through the

stages (Marcus & Simkim, 1993). As shown in Table 2 maintenance is said to occur after behavioural habits are formed and behaviour has been maintained for six months.

Reviews of intervention studies conducted within the general population have found evidence that change in PA stage of change predicts change in self-reported PA behaviour (Marhsall & Biddle, 2001; Spencer, Adams, Malone, Roy & Yost, 2006). Among women with children, stage of change has been found to correlate with self-reported PA behaviour with the lowest total PA levels and least participation in MVPA found in the 'Precontemplation' group (Fahrenwald & Walker, 2003). PA participation rates increased at each stage progression until the 'Action' stage, whereby mothers met PA guidelines. Furthermore, there were no differences in PA behaviour between those in 'Action' and 'Maintenance' stages as would be predicted by the model. Despite the popularity of the TTM as a model for understanding PA behaviour change, and the evidence that the stage of change concept can differentiate individuals' self-reported and objective PA behaviour (Hellsten et al., cited in Armitage et al, 2009), critics point out that these cross-sectional studies offer insufficient evidence for stage segmentation (Sutton, 2000). Others point to the usefulness of the three other components from TTM, which are proposed mediators of movement between the stages of change, these are: decisional balance, processes of change and self-efficacy (Armitage, 2009). Interventions based on TTM components have successfully changed PA in sedentary individuals (Calfas, Sallis, Oldenburg & French, 1997; Marcus et al., 2007), which provides a better test of the model compared with association studies.

Table 2. Stages of physical activity behaviour change (Marcus & Simkin, 1993)

<i>Stage of Change</i>	<i>Definition applied to PA behaviour</i>
Precontemplation	Not regularly active* and no intention to become active in the next six months
Contemplation	Not regularly active but thinking about starting to be in the next six months
Preparation	Participate in some activity but not enough to be regularly active
Action	Regularly active but only began this in the past six months
Maintenance stage	Regularly active and has been so for longer than six months

*Normally defined in relation to PA guidelines (e.g. Haskell et al, 2007)

1.6.4.3.1 Decisional balance, processes of change and self-efficacy

The TTM components describe how to change PA behaviour. In common with other models, the TTM posits a role for positive (and negative) outcomes expectancies, that is, beliefs about the positive impacts (or pros in the TTM) of performing any given behaviour and beliefs about the potential negative impacts (or cons in the TTM) of performing the behaviour. Within the TTM these expectancy value judgements about the outcomes of PA are said to be compared so as to create an assessment or ‘weighing up’ of these outcomes; this is known as the decisional balance. Correlational research reviewed by Marshall and Biddle (2001) found that the decisional balance was associated with the stages of change: a more negatively weighted balance found in earlier stages (i.e. ‘Precontemplation’ and ‘Contemplation’), while a more positively weighted balance occurs in later stages and during ‘Preparation’ the decisional balance is said to be roughly equal. TTM therefore suggests that increasing the pros and reducing the cons for individuals in the first three stages of change would encourage stage progression. Among adults, positive changes in decisional balance have been shown to mediate changes in motivational readiness (i.e. intentions to be active) but not PA behaviour in response to behavioural interventions (Pinto, Lynn, Marcus, DePue & Goldstein, 2001; Baruth et al., 2010).

Self-efficacy is predicted to increase as individual’s progress through the stages of change and research shows that people in later stages have higher self-efficacy, which increases linearly (Marcus & Simkin, 1993). As discussed above, short and long-term mediation studies have suggested increased self-efficacy is predictive of change in subjectively and objectively measured PA (Calfas et al., 1997; DuVall et al., 2004), although among mothers with young children this is limited to self-reported change in PA (Miller et al., 2002).

Processes of change are the strategies from the TTM, which individuals adopt to change their behaviour (Marcus & Simkin, 1993). Table 3 details these applied to PA behaviour change (adapted from Marcus et al, 1992 and Prochaska et al 1992 as cited in Fahrenwald & Walker, 2003). Processes are grouped according to whether they target cognitive-affective or behavioural aspects of changing behaviour; the former are named *experiential* (i.e. processes 1-5 in Table 3), and the latter are *behavioural processes* (i.e. processes 6-10 in Table 3).

Table 3. Processes of Change applied to physical activity behaviour¹

<i>Process of Change</i>	<i>Definition</i>
1. Consciousness raising*	Conscious effort to seek new information and feedback about PA behaviour
2. Dramatic relief*	An affective experience or emotional reaction to the consequences of sedentary behaviour
3. Environmental reevaluation*	Cognitive and affective appraisal of how PA affects others
4. Self-reevaluation*	Both cognitive and affective assessment of values related to PA behaviour
5. Social liberation*	Awareness of increasing opportunities for PA behaviour
6. Counter conditioning**	A process of learning physically active behaviours to substitute for sedentary behaviours
7. Helping relationships**	Receiving care, trust, and support from others for PA behaviour change
8. Reinforcement management**	Self-reward for PA behaviour
9. Self-liberation**	A person's choice, commitment, beliefs, and goals related to PA behaviour change
10. Stimulus control**	Removing cues for unhealthy habits while adding prompts for healthy choices

Note.

*Experiential process, **Behavioural process. Processes definitions adapted from Marcus et al, 1992 and Prochaska et al 1992 as cited in Fahrenwald & Walker (2003)

Early research suggested that increasing process use is a feature of progression through the stages (Marcus & Simkin, 1993) and that people in an earlier stage of change should use experiential processes to help them progress; in later stages behavioural processes help with stage progression and relapse prevention (Biddle & Mutrie, 2008). Marcus et al (1996), cited in Hughes and Mutrie (2006), found differences in process use between healthy adults who remained physically active and those who were sedentary over a six month period (i.e. were stable). Comparison between stable individuals with ‘adopters’ (i.e. those who became more active) or ‘relapsers’ (i.e. those who became less active) showed increased use of all processes of change in the ‘adopters’ and a decrease in use of all behavioural processes in relapsers. Large-scale longitudinal studies and intervention research have shown that even in earlier stages behavioural processes appear to predict successful progression to later stages of change, change in PA behaviour and cardiovascular fitness (Calfas et al., 1997; Lowther, Mutrie & Scott, 2007),

Behavioural processes have shown to mediate subjectively and objectively measured PA behaviour in response to interventions (Baruth et al., 2010; Calfas et al., 1997; Lewis et al., 2002). Calfas et al. (1997) showed changes in use of behavioural processes of change mediated the relationship between allocation to PA intervention based on the TTM model and changes in accelerometer-measured PA behaviour at six weeks. Baruth et al. (2010) found behavioural processes mediated self-report PA behaviour and cardiorespiratory fitness up to a 24-month follow-up point following behavioural intervention.

Cross-sectional research has investigated TTM components in relation to postnatal PA behaviour. Keller, Allan and Tinkle (2006) measured stage of change and processes of change along with self-reported PA and weight variables among a largely Mexican cohort (71% out of 63 participants) of postpartum women in the US. They found no relation between participants stage of change with BMI, but did show that greater endorsement of two

processes: ‘environmental reevaluation’ and ‘consciousness raising’ significantly predicted greater participation in PA. As participants in Keller et al’s (2006) study had particularly low levels of activity the TTM predicts that use of these (experiential) processes would predominate as most would have been at earlier stages of change. However, the cross-sectional nature and use of self-reported PA behaviour is problematic. Also, the specific geographical context and ethnicity of participants from this studies means this evidence may not be transferable to the UK context (Keller et al., 2006).

1.6.4.4 *Health Action Process Approach*

As discussed, research has shown there is an intention-behaviour gap: as such motivations to be more active appear a necessary but not sufficient condition to enact behavioural change. The Health Action Process Approach (HAPA) has sought to explain how to overcome this gap, through the explicit addition of planning and self-regulatory strategies.

HAPA is a two-stage model developed by Schwarzer (1992), which proposes (in line with the models above) that motivational constructs (e.g. outcome expectancies, task/action self-efficacy and risk perceptions (i.e. “how much am I at risk from negative consequences if I do not engage in more PA”) are important determinants of individual’s intentions to be active (Schwarzer, 2008). However, the motivational stage culminates with the formation of a behavioural intention and individuals enter the volitional phase. The volitional phase proposes that individuals use planning strategies (i.e. action planning, coping planning) to successfully change actual behaviour. Action planning appears to be an extension of goal-setting, as individuals create personalised plans that specify *where, when and what* PA they will participate in over the coming week, while coping planning is a about explicit planning for setbacks; these help individuals overcome barriers to changing behaviour (e.g. having indoor and outdoor opportunities for PA in case of poor weather). HAPA also explains the

importance of individuals using feedback about their own behaviour to determine their success in meeting their plans and overcoming their barriers. This process is similar to the reciprocal process described in SCT. Sniehotta, Nagy, Scholz & Schwarzer (2006) propose that a feedback loop operates through which individuals self-regulate their behaviour. However, they use the phrase: 'action control' to describe this process, with the main aspects being: *awareness* of behavioural standards (i.e. how much activity should I be doing?), *self-monitoring* against these standards (i.e. noticing/keeping a record of my activity behaviour to see whether I am on track) and *effort* to reduce the discrepancy (i.e. notice I am not meeting my PA goals and make a sustained and concentrated effort to improve performance) (Sniehotta et al., 2006). Finally, self-efficacy for maintaining PA behaviour in light of experiencing barriers to change and for recovering from setbacks are also important during the volitional phase. The addition of planning and self-regulatory factors for explaining movement from intentions to successful behaviour change has been influential in our understanding of how to change PA behaviour (Schwarzer, 2008; Michie et al., 2009).

There is some evidence for the volitional stage constructs proposed in the HAPA model (Schwarzer, Schuz, Ziegelmann, Lippke & Luszczynska, 2007; Sniehotta, Scholz & Schwarzer, 2005a). One study with in-patients within a coronary heart disease rehabilitation centre, found individuals who utilised action and coping planning strategies were more likely to be physically active one, two and four months later (Sniehotta et al, 2005a); additionally, action control components predicted adherence to an exercise programme 8 weeks after discharge from cardiac rehabilitations (Sniehotta, Scholz & Schwarzer, 2006).

As discussed, in common with the other behaviour change models above, HAPA predicts self-efficacy is an important factor at both the motivational and volitional stages of behaviour change (Schwarzer, 2008). The model predicts greater self-efficacy leads to stronger intentions to be physically active, greater success with adopting changes in line with

an individual's PA plan and greater likelihood of individuals recovering from setbacks they experience in order to maintain a physically active lifestyle. Self-efficacy has been found to moderate the relationships between intentions, planning behaviour, self-regulation and PA. Among healthy adults who planned how they would be active, greater self-reported PA behaviour was found four weeks later, but only if their self-efficacy levels were sufficiently high at baseline (Lippke, Wiedemann, Ziegelmann, Reuter & Schwarzer, 2009). The change in postnatal women's self-regulatory self-efficacy found in Cramp and Brawley (2009) is in line with predictions regarding the volitional stage of the HAPA model.

1.6.4.5 Relapse Prevention Model

When individuals make behavioural change attempts (e.g. to become more physically active), there can be lapses in adherence to previously set goals and plans. Lapses from behaviour change feature in both the TTM and HAPA models (Schwarzer, 2008). However, to understand relapse from behavioural change attempts, the Relapse Prevention Model (RPM) has also been influential. Originating in the addictions field (e.g. Marlatt & Gordon, 1985 cited in Larimer & Palmer, 1999) RPM predicts that individuals are at 'risk' of relapse if they return to their previous sedentary habits akin to the manner in which a return to alcohol use among drinkers occurs following a period of abstinence. In summary, the model proposes that relapse occurs in response to 'high-risk situations', for example emotional, social and environmental circumstances, which act as threats to continuation of the desired behaviour. There is evidence that negative emotional states such as boredom and anxiety, pressure to be inactive from social contacts and increased workload have been linked to relapse following onset of PA in healthy women (Simkin & Gross, 1994). Other such predicted high-risk situations relevant to PA include poor weather, lack of time due to competing commitments,

illness and/or injury. Previous research has suggested many of factors are pertinent to postnatal populations (Evenson et al., 2009; Pereira et al., 2007).

Appropriate use of cognitive and behavioural strategies is related to lower risk of relapse among women from the general population (Simkin & Gross, 1994; Stadler, Oettingen & Gollwitzer, 2009). Simkin and Gross (1994) found participants likelihood of relapse over a 14-week period (defined in the study as a non-exercise period of three weeks or more) decreased among women who self-reported greater planned use of cognitive (e.g. I would think about the benefits of exercise) and behavioural (e.g. I would exercise with a friend) relapse prevention strategies in response to high-risk of relapse vignettes (e.g. a busy/stressful period at work). Stadler et al. (2009) demonstrated that using a simple mental contrasting technique (known as implementation intentions) increased the likelihood of maintenance of PA behaviour change following a brief informational and self-monitoring intervention. Implementation intentions are specific *if-then* plans, which encompass information on where, what, when and how behaviour will be performed when a given high-risk situation is encountered (Gollwitzer, 1999). Creation of an if-then plan is hypothesised to create a mental link between a high-risk situation and the desired behaviour (e.g. If I can't walk outside because of the weather, then I'll use my home exercise DVDs), which facilitates goal-attainment (Gollwitzer, 1999). Stadler et al. (2009) found women from the intervention group, who created *if-then* plans to overcome potential obstacles to being physically active, self-reported more activity at four months compared with the control group, who received information about the benefits of PA and a take-home diary for recording their behaviour. These findings are consistent with the predictions from the RPM and show simple coping planning techniques can be utilised in interventions to help individuals prevent relapse.

1.7 Behavioural counselling interventions to promote physical activity

This section considers how behavioural counselling interventions have been used to promote PA and the effectiveness of this approach. Previous PA interventions conducted among women with young children are reviewed.

1.7.1 Behavioural counselling interventions targeting physical activity change

Given the importance of targeting socio-cognitive factors, which have been shown to influence PA change, behavioural counselling interventions for low-active adults have grown in popularity during the past two-three decades. PA counselling (US) or PA consultation (UK) (i.e. PACs) are short-term goal-directed helping relationships between a ‘consultant’ and an individual client. PACs follow a semi-structured set of intervention techniques targeting cognitive, behavioural and social factors from psychological theory, however, they are also individualised to each participants’ own experience, so that personal benefits, barriers and activity goals are discussed (Louglan & Mutrie, 1995). PACs have mainly drawn from the TTM, SCT and RPM; as such the content of the conversation is targeted to discussing key components from these health behaviour change models. Guidelines for conducting PAC suggest it is important to raise awareness about the amount of PA required for health and wellbeing, increase awareness of benefits of becoming more active, set specific goals for changing PA behaviour, develop self-efficacy for making changes, discuss strategies for overcoming barriers to change, prompt social support for activity and prompt individuals to make change to their environment to make active options easier. Towards the end of the PAC or in follow-up PACs (once behaviour change has been attempted) most studies support individuals to identify and plan how to overcome barriers to longer-term maintenance of behaviour change, including risky conditions where relapse is likely. Relapse prevention strategies help participants identify their personal ‘high-risk’ situations that may

cause a lapse or relapse then develop plans to overcome these situations in order to continue with their goals for being physically active. As part of the delivery of a PAC, consultants require good communication skills, for example the ability to put clients at ease, build rapport, evoke motivation for change, actively listen and accurately express empathy for the client's situation (Rollnick, Butler, McCambridge, Kinnersley, Elwyn & Resnicow, 2005). PACs are explicitly person-centred as discussions are tailored to individuals' own circumstances and. PAC consultants are encouraged to avoid persuasion and to adopt a guiding, rather than directive style (Loughlan & Mutrie, 1995; Rollnick et al., 2005). This approach is consistent with theory and evidence that suggests behaviour change is more likely if individuals are supported to make behaviour change decisions for themselves (Rubak, Sanbaek, Lauritzen & Christensen, 2005). There is no consensus on the ideal intensity of PACs, although most studies have used at least one session of 30 minutes or more; a small number of face-to-face follow-ups within the first three months are also common (Brekcon, Johnston & Hutchison, 2008). Additional follow-ups (where used) often make use of telephone, SMS-text or email/print materials.

1.7.1.1 Considerations for physical activity consultations in postnatal populations

In section 1.5 I discussed evidence for the importance of constructs such as outcome expectancies, self-efficacy for being physically active, barriers to PA, social support and self-regulation among postnatal populations. This fits well with a PAC approach in which individuals consider their personal benefits of being active and are encouraged to set goals for changing their activity gradually and write a specific activity plan specifying where, when and what activity they will do. Setting specific, measurable, achievable, and realistic and timely (e.g. SMART) goals, and increasing difficulty of goals over time (graded tasks) encourage self-efficacy for change (Bodenheimer & Handley, 2009). Other strategies for

developing self-efficacy include demonstration of successful performance of the behaviour (e.g. modelling from similar others), experiencing mastery (i.e. having achieved previously set goals) and correctly interpreting physiological sensations (e.g. experiencing increased heart-rate during moderate activity as evidence of successful behavioural change rather than an inability to walk at increased pace) (Bandura, 1997). Discussion and development of strategies for overcoming barriers to change are likely to be particularly important for postnatal populations. For example, among postnatal women strategies for overcoming a lack of consistent childcare might include being physically active in the home environment with exercise DVDs or engaging in activity that was at least moderate-intensity by walking with their baby in a pram. Previous interventions have found walking can be effectively promoted using PAC approaches, including in combination with step count goals and provision of a pedometer for self-monitoring (Baker et al., 2008). As discussed above, walking, at a moderate-intensity is an acceptable form of postnatal exercise, which can lead to health benefits. Furthermore, the explicit discussion of social support for being active is relevant to postnatal populations (Miller et al., 2002; Fjeldsoe et al., 2010). Longer-term relapse prevention strategies may also support self-efficacy for continuation of behaviour change in spite of small lapses, which are likely to occur during the period of parenting a young child.

1.7.2 Effectiveness of physical activity counselling/consultations

Interventions utilising PAC methods have been developed and tested in the general population and clinical populations with evidence that they are effective for changing PA behaviour (Baker et al., 2008; Calfas et al., 1997; Hughes et al., 2007; Kirk et al., 2004a; Simons-Morton et al., 2001). Early reviews of PAC interventions found positive impacts on PA behaviour change variables but some had methodological shortcomings (Breckon, Johnston & Hutchison, 2008; Eden, Orleans, Mulrow, Pender & Teutsch, 2002; Kahn et al.,

2002). For example, many studies utilised short-term follow-ups and only reported change in stages of change and/or subjectively measured PA (van Sluijs, van Poppel & van Mechelen, 2004; Lowther, Mutrie & Scott, 2002). Studies have shown changes in objectively measured PA and physical fitness outcomes (Baker et al., 2008; Calfas et al., 1997; Hughes et al., 2007; Kirk et al 2004a). A review of the effectiveness of PACs for enhancing PA intervention in Type 2 diabetes found significant changes in self-reported and accelerometer measured PA following single or multiple sessions compared with standard diabetes care and/or provision of an information leaflet about exercise (Kirk, Mutrie, MacIntyre & Fisher, 2004b). Likewise, Hughes et al. (2007) found that participants who received a PAC at the end of a standard supervised exercise programme for cardiac rehabilitation were more likely to maintain established levels of MVPA at four, six and 12-month follow-ups. PA levels were measured using both self-report and accelerometers. Maintenance of changes to self-reported PA participation and cardiorespiratory fitness has been found in the longer-term (Simons Morton et al., 2001). Overall, PAC interventions can successfully change PA behaviour among healthy and clinical populations. While these results are encouraging it is not clear to what extent these would be replicable among postnatal women.

There has been a small number of PAC intervention studies conducted among women with young children and postnatal populations, specifically. Table 4 shows that studies (Clarke et al., 2007; Cody & Lee, 1999; Fahrenwald, Atwood, Walker, Johnson & Berg, 2004; Lombard, Deeks, Jolley, Ball & Teede, 2010; Miller et al., 2002) have successfully changed PA among women with young children through the provision of primarily PAC interventions drawn from theories of behaviour change (e.g. TTM, SCT, Self-efficacy theory). Studies have also included some form of group exercise component, which is popular as this provides opportunities for women with children to be active.

Table 4. **Physical activity behavioural counselling interventions conducted among women with young children**

Author, year	Study design/demographics	Intervention details	PA outcomes	Results
Clarke et al (2007)	<i>n</i> =93, US, Pre-post design Recruited overweight low-income women from WIC-centers with at least 1 child aged 1-4 years, Participant mean age = 27yrs, mean BMI = 35 kg/m ² .	Self-efficacy theory intervention. Eight weekly group PAC sessions with 30-minutes of exercise. Provision of a pedometer and weekly recording of step counts. Additional dietary components. Attendance rate= 74%.	Yamax Digiwalker pedometer measured walking/EE at baseline and 8 week FU (3 days of monitoring).	Significant increase in walking and EE.
Cody & Lee (1999)	<i>n</i> =32, Australia, Pre-post design Recruited women attending playgroups who were in ‘Contemplation’ or ‘Preparation’ stage of change with at least one child under 5 years old. Participant mean age = 32.4yrs.	TTM intervention. Ten weekly 1-hr exercise classes including PAC components. Participants received a handbook (information, planning and monitoring diaries, space for coping planning) Childcare provided.	Canadian Home Fitness Step Test at baseline and 10 weeks FU to measure cardiovascular fitness.	Significant increase in resting HR.
Fahrenwald et al (2004)	<i>n</i> =52, US, RCT design Recruited low-income women from WIC-centers with at least 1 child who were in ‘Contemplation’ or ‘Preparation’ stage. Participant mean age = 26.5yrs.	TTM intervention. Four bi-weekly 1-hr PAC calls and a brochure providing information: “examples of key pros & cons to PA, strategies to overcome frequently cited barriers to PA and sedentary habits”. <i>Control:</i> Breast self-examination intervention with the same number of contacts.	7-Day PAR measured PA. Sealed Digi-Walker* pedometer measured walking (3 days of monitoring) at baseline and 10-week FU (2-weeks post-intervention).	Significant increase in total & moderate PA and walking in intervention compared with control group.

Lombard et al (2010)	<i>n</i> =250, Australia, cluster-RCT design Recruited mothers from primary schools. Participant mean age = 40.4yrs, mean BMI = 27.8 kg/m ² .	SCT intervention consisted of a four 1-hr group PAC sessions (over 3 weeks with a 16-week booster session) delivered by a dietitian. Behaviour change strategies related to both diet & PA. Provision of pedometer and FU support via text messages. <i>Control</i> : One 30 minute lecture, information from PA guidelines (and dietary guidelines).	IPAQ measured PA and sealed Yamax Digiwalker pedometer measured walking baseline and 12 months FU (3-7 days of monitoring).	Significant increase in vigorous PA in intervention but not control group. No change in moderate PA and walking.
Miller et al (2002)	N=554, Australia, three-group cluster-controlled design Recruited women whose children were enrolled in Preschools and Childcare Centers (aged 2-5 yrs). Participant mean age = 33yrs, mean BMI = 25kg/m ² .	SCT intervention. Environmental/social change through 'lobbying' for childcare/timetable changes at local leisure facilities and facilitating mothers to arrange PA classes/groups and support for PA. PAC components delivered via networking and noticeboards (e.g. information about local PA opportunities and a print (8-page) booklet. <i>Control group 1</i> : Received the print booklet only. <i>Control group 2</i> : No intervention	Active Australia PA evaluation administered at baseline, 8-week and 5-months FU.	Intervention group more likely to be meeting PA guidelines compared with controls groups at 8-weeks only.

Note.

*50% of the intervention group sample wore the pedometer at pre and post-test.

7-Day PAR, Seven-day Physical Activity Recall; BMI, Body Mass Index; EE, energy expenditure; FU, Follow-up; HR, heart-rate; IPAQ: International Physical Activity Questionnaire; METs, Metabolic Equivalent Units; Mins: Minutes, PA, physical activity; PAC physical activity counselling/consultation; PP, Postpartum; SCT: Socio-Cognitive Theory, TTM, Transtheoretical model; UK, United Kingdom; US, United States; WIC, Women, Infant and Children; yrs, years old.

1.7.2.1 Results from non-controlled studies among women with young children

Cody and Lee (1999) found significant changes in resting heart rate but not HR response to exercise among preschool mothers, 10 weeks after commencing a PA intervention informed by the TTM. The intervention included weekly group exercise sessions (walking and low-impact dance aerobics) for 10 weeks at convenient locations and with onsite childcare. Discussions during classes also encouraged adoption of at least two additional exercise sessions with associated plans, which specified where, when and what activity participants would take part in. Social support was encouraged through asking participants to identify and commit to being active with friend(s). Relapse prevention strategies were discussed through encouraging participants to consider potential dropout situations and cognitive strategies to overcome these (e.g. self-talk). The researchers also found that mothers endorsed a greater number of PA pros and a lower number of PA cons at 10 weeks follow-up. Extent of social support provision from friends also increased. Despite these positive findings, there was a moderate dropout rate of 15%, with those who remained in the study being significantly more likely to attend the weekly exercise sessions. Also as researchers' assessed PA behaviour via physiological proxy at post-test only, it is not clear to what extent the intervention affected PA performance.

Clarke et al. (2007) observed changes in walking behaviour among women with preschool aged children following participation in group PAC sessions which included behavioural modification skills, a facilitated exercise session and supportive materials for self-monitoring behaviour change (e.g. pedometer and walking logs). Changes in walking behaviour (measured via a pedometer) were observed at 8-weeks follow-up among participants taking part in the intervention. However, as with the study conducted by Cody and Lee (1999), Clarke and colleagues (2007) did not include a control group, therefore it was unclear whether short-term changes could be attributed to the intervention components.

1.7.2.2 *Results from controlled studies among women with young children*

Fahrenwald et al. (2004) recruited 52 low-income women and randomised them to receive either a control breast self-examination condition or a PA telephone counselling intervention, which targeted TTM constructs over an 8-week period. Significant increases in self-reported PA behaviour were found in the intervention group compared with controls at the 10-week follow-up. There was also evidence from pedometer readings that walking behaviour at follow-up had increased following participation in the intervention. As with the PAC interventions described above, the intervention techniques were designed to impact on decisional balance, self-efficacy and use of cognitive and behavioural processes of change by asking participants to think about benefits to the family from the mother being more active, encouraging participants to set realistic PA goals and discussing plans for overcoming two personal barriers, including explicit discussion of support needs and names of supportive others. Despite the positive effects of the intervention on changing behaviour, the authors found no evidence for mediating relationships between the TTM constructs with change in PA behaviour (Fahrenwald, Atwood & Johnson, 2005), suggesting changes in PA observed may not have been caused by increasing pros for behaviour change, use of processes of change and self-efficacy as predicted by the TTM.

Lombard et al. (2010) found a significant increase in PA behaviour among mothers of primary school aged children who took part in a 12-month SCT behavioural counselling intervention when compared with mothers from matched control schools. The intervention took place over 12-months, with at least three initial group behavioural counselling sessions, a booster sessions and text and informational support up to the 12-month follow-up point. Intervention strategies targeted both PA and dietary change and included realistic goal-setting, training in self-monitoring, problem solving for overcoming barriers to change. The intervention also included long-term term training in strategies to prevent relapse back to

previously sedentary habits. However, although self-reported vigorous PA participation increased from baseline there was no change in moderate PA. Walking behaviour, as measured by sealed pedometer recordings did not change significantly either. Strengths of this study were the long follow-up period and the used of an objective method of measuring changes in PA behaviour. However, as intervention components were delivered throughout the 12-month period, it is not clear to what extent changes in behaviour would be maintained following removal of intervention support.

The study by Miller and colleagues (2002) was discussed in brief above. They found that making changes to the local environment (in line with SCT); in addition to behavioural counselling strategies, facilitated PA behaviour change among mothers of preschool aged children. As discussed, environmental barriers were directly addressed through encouraging local leisure-centres to adopt timetable changes that suited mothers and providing childcare to allow women to access exercise classes. The intervention also included facilitating convenient walking groups for mothers (the evidence regarding walking groups for promoting PA among postnatal women is discussed below). Behavioural counselling elements included discussions about accessing support for PA to increase self-efficacy for being active (partners were present during these discussions). Printed materials were also used to provide information and instruction about where and when to be physically active in their local community and how to overcome barriers to change. At the 8-week follow-up (immediately post-intervention), and 5-month follow-up, questionnaires assessed adherence to the PA guidelines using a self-report seven-day recall of PA. At 8 weeks participants taking part in the full intervention were significantly more likely to be meeting the PA guidelines compared with participants who received print information only or no intervention. However, this effect was not sustained at the five month follow-up.

Overall among the small number of interventions conducted among women with young children behavioural counselling approaches show promise for enacting changes in short-term self-reported PA participation. The evidence is limited as a number of studies have been non-controlled or have not demonstrated changes in objectively measured PA behaviour.

1.8 Summary of Chapter One

It is recommended that postnatal women participate in PA in line with the guidelines for the general adult population. Apart from the known general health and wellbeing benefits of being regularly physically active, participation in PA during the postnatal period may be important for postnatal weight loss and improved body composition, improved cardiovascular fitness (aerobic capacity) and better mental wellbeing; these health outcomes are sensitive to change in response to increasing PA. PA is a complex behaviour that encompasses many facets, making accurate measurement challenging. It is important to accurately measure PA change in interventions. There are advantages and disadvantages of the different approaches to measuring PA in field based settings. Physiological proxy measures, which assess change in cardiovascular fitness are available, with submaximal step-tests being suitable outwith laboratory conditions. Subjective methods, which rely on individual recall, are open to potential bias, however they provide detailed information on PA patterns and are easy to implement. . Recall questionnaires have demonstrated adequate reliability but the evidence is more mixed on whether they offer a valid assessment of PA behaviour in the field compared with objective methods. Of the objective measures available, accelerometers offer a valid and reliable, relatively inexpensive option for measuring PA behaviour in the field, with good evidence for participant adherence. There are limitations to the performance of accelerometers during other activities of daily living, slow-walking and fast-running. A range of EE prediction equations have been developed from accelerometer activity counts. However, there is evidence that prediction equations tend to underestimate the energy costs in free-living conditions. Time spent in PA intensities can be estimated from accelerometer activity counts, although there is no consensus on which cut points should be used for this analysis.

Some postnatal women may be insufficiently physically active, with declines in PA particularly affecting LTPA. Participation in postnatal PA is an under-researched area and many studies have been of poor methodological design. However, there is a perceived need for interventions that support postnatal women to increase PA in line with guidelines. The literature regarding modifiable factors influencing PA behaviours suggests that constructs from behaviour change theory are important for understanding PA behaviour change, although there is limited literature applied to postnatal women to date. Applied to postnatal populations there is particularly strong evidence for self-efficacy. Outcomes expectancies, perceived barriers, social support, planning and self-regulation may also be important socio-cognitive factors that can be targeted in behaviour change interventions.

Physical activity consultations (PACs) are short-term semi-structured behavioural counselling approaches which include a range of behaviour change techniques to target theoretically and empirically-based mediators of behaviour change. Delivery of a PAC usually involves face-to-face contact with individuals although other delivery mechanisms are available, regardless of this delivery requires appropriate communication skills. Previous research has suggested interventions using PACs have successfully changed self-reported and objectively-measured PA participation among sedentary adults. Among women with young children behavioural counselling interventions have resulted in significant changes to PA, although this evidence is still limited. To date, the evidence has not been reviewed among postnatal women.

CHAPTER TWO

2 EFFICACY OF PHYSICAL ACTIVITY INTERVENTIONS IN POSTNATAL POPULATIONS: SYSTEMATIC REVIEW, META-ANALYSIS OF RANDOMISED CONTROLLED TRIALS AND CONTENT CODING OF BEHAVIOUR CHANGE TECHNIQUES

2.1 Chapter Preface

To review evidence for the efficacy of postnatal PA interventions I conducted a systematic review and meta-analysis, which has been published (Gilinsky et al., 2014). This review was conducted in parallel with the development, implementation and evaluation of the MAMMiS trial, however the intervention studies included (published pre-2011) informed the background the MAMMiS study. I conceived of the review, and I developed and conducted the review in full. Three co-authors conducted second coding; one of methodologically quality, and two of content coding of behaviour change techniques (BCTs) in the interventions included in the review. A fourth author was available to resolve discrepancies.

Content coding of BCTs within behaviour change interventions is a relatively new approach. In Chapter One I discussed that a number of different behaviour change models have been used to inform research regarding the determinants of physical activity and development of behaviour change interventions. However, regardless of whether interventions are derived from a particular behaviour change theory (or none), they typically include a number of BCTs; described by Bartholomew, Parcel, Kok, Gottlieb, & Fernández as: *“methods (or processes) used for influencing change in the determinants of behaviors and environmental conditions”* (2006 p. 318). The rationale for this approach is that understanding the effective content of interventions will enable for more efficacious intervention development in the future (Michie, Fixsen, Gimshaw, & Eccles, 2009) and may

go further to identify links between BCTs and theory (e.g. Williams & French, 2012). Previous reviews, in healthy and obese adult populations, suggest BCTs can be identified using published coding systems, known as taxonomies of BCTs (Michie et al., 2013). Content coding has not been applied to postnatal physical activity, despite interventions using BCTs to influence behaviour change determinants, and interventions being reportedly theory-based (e.g. Albright et al., 2005; Fjeldsoe et al., 2010; Ostbye et al., 2009).

2.2 Aims of the review

This review addresses three research questions: *i*) What is the efficacy of postnatal physical activity interventions on change in physical activity (exercise) and walking behaviour? *ii*) Are specific BCTs more common in efficacious interventions? *iii*) Do theory-based interventions targeting postnatal women use more, or specific types of, BCTs compared with non-theory-based interventions?

2.3 Methods of the review

Recommendations from Cochrane were used to conduct the systematic review (Higgins & Green, 2011) and PRISMA guidelines were followed throughout the review process (Liberati et al., 2009). See Appendix 1 for details of how the review conforms to PRISMA guidance.

2.3.1 Search strategy and inclusion/exclusion criteria

Intervention studies were sought from electronic databases: MEDLINE, PsycINFO and CINAHL from (January 1980-July 2013). Search terms used were '*physical activity*' OR '*exercise*' OR '*walking*'. These were combined with '*postnatal*' OR '*postpartum*' OR '*after birth*' OR '*following pregnancy*' and '*intervention*' OR '*trial*'. Searches were limited to peer reviewed journals, English language, female and human populations. The search was originally conducted on each database separately for studies until 2011, with a repeated

search conducted for studies from January 2012 to July 2013 (date of last update). See Appendix 2 for the combined search (using EBSCO Host). Additional studies were sought through forward (via PubMed) and backward citation-search (reference list searches for all full-text downloads, and relevant reviews identified via the database search). The criteria for inclusion in the review were:

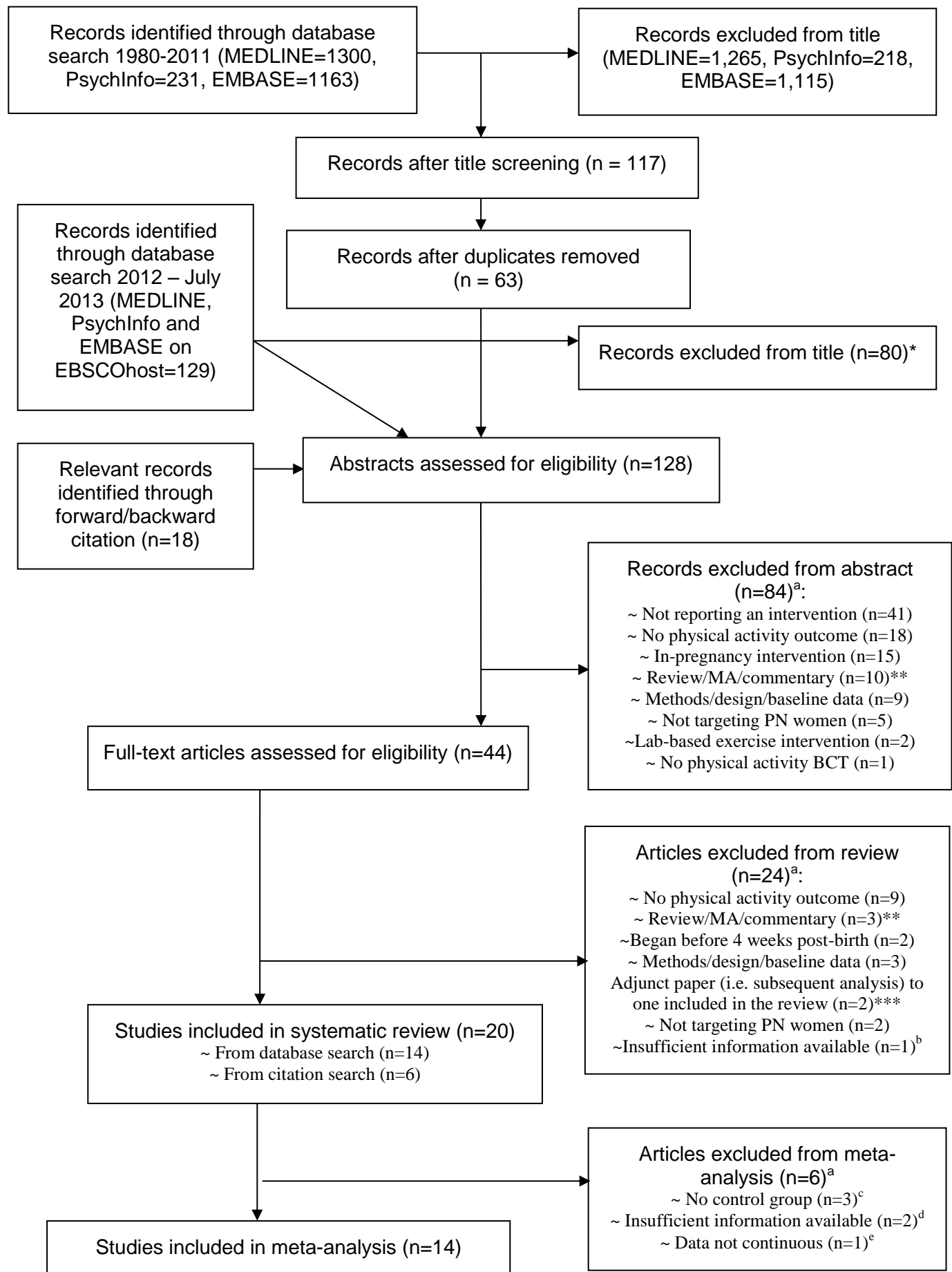
1. Population: Women who commenced intervention at least four weeks after birth (in line with ACOG guidelines) and within 12 months of birth. Antenatal interventions were excluded.
2. Interventions: Report of an intervention with at least one BCT directed towards changing physical activity behaviour. Studies were excluded if the intervention was conducted in an inpatient hospital setting as this review focuses on interventions which could be replicated within a community setting.
3. Comparisons/study design: Published studies meeting 1-4 level of evidence (Oxman, 1994), which was a minimum of pre-post intervention data, and those with any type of comparison group (e.g. usual care, information provision only or studies comparing two interventions). For inclusion in the meta-analysis, studies were required to have an intervention and control group (i.e. were randomised trials).
4. Outcomes: Studies with at least one physical activity behavioural outcome measure. Studies that only reported physical fitness measures (e.g. maximal V_{O_2} ml/Kg/min), stages of physical activity change or measures of attitudes, intentions or other beliefs about physical activity behaviour were excluded.

2.3.2 Study selection

Using the above search strategy, a total of 128 citations were identified and systematically screened based on the inclusion/exclusion criteria, with 44 full-text articles reviewed (see

Figure 1 for further details). Twenty intervention studies were identified for the systematic review, of which fourteen were appropriate for meta-analysis. Reasons for exclusion are provided in Figure 1. Every effort was made to acquire supplementary information to include data in the meta-analysis; this included contacting authors and accessing additional papers where relevant data was reported.

Figure 1. Review study selection procedure and reasons for excluded articles



Note.

^aSome articles were excluded for more than one reason

^bSurkan et al. (2010): authors were contacted but did not produce information required for inclusion in the review

^cAlbright et al. (2009), Lewis et al. (2011), Maturi et al. (2011): walking behaviour assessed in the intervention group only

^dLeermarkers et al. (1998); Watson et al. (2005): authors were contacted but could not produce data required for meta-analysis

^eMaturi et al. (2010) assessed total physical activity participation, reported as a dichotomous variable

*No duplicates as databases checked together.

**Reference lists of relevant reviews were checked for studies potentially meeting inclusion criteria (counted under forward/backward citations).

***Retained for reference purposes.

2.3.3 Data extraction and quality assessment

I conducted data extraction using a proforma developed for this review. Study characteristics, intervention characteristics and data collection methods were extracted from each study. Where available ‘health-enhancing’ physical activity behaviour change outcomes were extracted. Health-enhancing outcomes were those in line with physical activity guidelines, i.e. were of at least moderate-intensity (Haskell et al., 2007). Total physical activity was also extracted where studies did not specify intensity or did not report separate estimates for health-enhancing activity (this was mainly walking outcomes as these were often measured via total steps per day).

Two coders assessed methodological quality independently using criteria for judging bias in intervention studies recommended by Cochrane (Higgins & Green, 2011). Fifteen studies (75%) were double coded (citations from the first round of searching). The remaining five (25%), identified in the second search round (to July 2013) were single coded by the first author. Studies were coded adequate, not adequate, unclear or not applicable in relation to sequence generation, allocation concealment, blinding of outcome assessors, retention at follow-up and handling of data. Both authors used all of the quality indicators above to assign each study with an overall risk of bias rating of high, low or unclear. Disagreements were settled through discussion or by consulting a third reviewer who independently reviewed these studies. This occurred in one paper (Maturi, Afshary, & Abedi, 2011). Using Cohen’s Kappa (Cohen, 1968), inter-rater agreement was calculated as $k=0.60$.

2.3.4 Meta-analytic approach

The approach followed guidance from the Cochrane Handbook for Systematic Reviews of Interventions (Higgins & Green, 2011). We considered both postnatal physical activity (exercise) behaviour and postnatal walking behaviour separately. Frequency and volume of

physical activity were extracted as separate outcomes since both are independently associated with health outcomes (Haskell et al., 2007). Furthermore, this is in line with good practice for conducting meta-analysis whereby studies contributing more than one outcome measure should not be included in the same analyses to avoid additional weight being given to those studies within the pooled effect size (Lipsey & Wilson, 2001). Where there was a choice of outcome measure we used the measure most likely to correspond to the most ‘health-enhancing’ physical activity (i.e. at least moderate intensity physical activity/exercise behaviour) or authors were contacted to provide combined data. One exception was Reinhardt et al. (2012), which included several measures of physical activity change, of which both non-weighted moderate-vigorous intensity physical activity and total physical activity weighted by METmins were equally valid for inclusion; we included both outcomes but halved the respective sample size, therefore reducing the weight of each outcome in the pooled effect size. Walker et al. (2012) provided data separately for three ethnic groups (Hispanics, African Americans and Whites); these were treated separately. Bertz et al. (2012) had four groups and as such we conducted two effect size comparisons, between exercise intervention and usual care and between exercise and diet intervention compared with diet only. Details of the inclusion for the meta-analysis is in Appendix 3

2.3.4.1 Effect size calculation

The effect size statistic used was Hedges’ (adjusted) g , which calculates the difference between the intervention and control group on change in the outcome from baseline to follow-up (earliest post-intervention assessment as only two studies conducted further post-intervention follow-up). Participant numbers for both trial arms for each outcome measure were extracted at baseline and follow-up, plus means and standard deviations. We used the standardised mean difference (SMD) to combine data as this is the summary statistic

recommended when different measurement scales are used. The standard deviation from the follow-up point is used to standardize the mean differences between study groups. Cluster-randomised trials were included, with correction for the sample size to avoid bias from clustering. Correction involved calculating the ‘effective sample size’, which is the reported sample size corrected by using the ‘design effect’, calculated using the average cluster size (i.e. number of participants) within clusters and using an estimate of the intraclass correlation coefficient (ICC). The formula for calculating the ‘design effect’ used was $1 + (\text{average cluster size} - 1 \times \text{ICC})$, with the ICC was estimated as 0.05, from a previous primary care physical activity counseling trial (Elley, Kerse, Arroll & Robinson, 2003).

Analyses were conducted in RevMan 5.0. Heterogeneity was investigated using the chi-square (Q-statistic), based on observing a p-value of <0.05 , and the I^2 test, with levels $>50\%$ suggestive of substantial heterogeneity (in line with previous studies, e.g. Dombrowski et al, 2010). Calculations were conducted assuming a fixed effects model, with no evidence that random effects improved heterogeneity. The random effects model is reported below. Due to the small number of studies, moderator analysis was not conducted. Publication bias was investigated visually using funnel plots, drawn in Microsoft Excel with asymmetry of the plot indicating potential bias (volume of walking behaviour was not included as there were only four effect sizes). Statistical tests for estimating bias were not employed in the present review as they are insensitive to estimating publication bias when sample sizes are small and there is a large amount of heterogeneity within the meta-analysis (Sterne et al., 2011).

2.3.5 Behaviour change techniques coding and analysis

Three coders with professional qualifications in Health Psychology from the UK identified the BCTs used in studies included in this review. Seventy five percent of studies were triple coded and 25% were single coded. The 40-item CALO-RE taxonomy of BCTs was used

(Michie et al., 2011). During the review period this was the most up to date taxonomy for the target behaviour. Coders independently coded the intervention and control condition using a fixed-choice format to specify if BCTs were definitely present, probably present (when techniques may have been used but this was uncertain) or definitely absent. For weight management (or lifestyle) interventions, only techniques directed at physical activity were coded; though techniques targeted at weight outcomes (e.g. self-monitoring of weight change) were included if they might be expected to affect activity behaviour. Following coding, disagreements were discussed and resolved through discussion. Using Fleiss' Kappa for agreement among several raters (Fleiss, 1971), inter-rater reliability was $k=0.60$ (excluding Daley et al., 2008; this study was coded during a practice round).

Interventions were categorised as efficacious/non-efficacious, and theory/non-theory based. Efficacious interventions had at least one statistically significant ($p<0.05$) physical activity outcome from baseline-follow-up (for controlled trials this was the between-groups difference). We excluded one study from this analysis as it was not sufficiently powered (deRosset et al, 2013). Theory base was coded with reference to those mentioned in the published papers (studies only mentioning motivational interviewing (MI), and the study by Lioret et al. (2012), concerning the theoretical impact of parenting behaviours on infant outcomes were not counted as 'theory-based'). The median number of BCTs present in theory based versus non-theory based interventions was compared statistically using a Mann Whitney U-test. For comparisons between studies, we considered BCTs that were coded in at least 40% of studies (i.e. 8 of the 20 included in the review) to answer research questions two and three. This descriptive analysis is reported as the proportion of efficacious and non-efficacious studies, and theory/non-theory based studies, including those BCTs.

2.4 Results of the review

Detailed study characteristics are shown in Table 5. There were 13 RCTs, two cluster randomised trials, two controlled trials and three pre-post trials with a range of theory and non-theory based interventions tested in a range of postnatal populations: healthy inactive women, overweight women, low-income groups, first time mothers, those meeting criteria for postnatal depression (PND). Studies used a variety of different delivery modes for BCTs designed to promote physical activity, often including or solely targeting walking behaviour (i.e. face-to-face counselling, follow-up support calls, SMS-texts, DVDs and print materials etc.), with full details in Table 5. Comparison conditions varied, including usual care, a single information leaflet/booklet about physical activity, weekly educational mail-outs, structured exercise and educational classes without behavioural management strategies (Table 5).

2.4.1 Measurement of physical activity and walking behaviour

Detailed information regarding physical activity measurement is shown in Appendix 3, including domains used and the intensity and periods of reference for the measurement. Two studies used an objective method for assessing physical activity. Twelve studies used subjective measures requiring participant recall, with a variety of interview/questionnaire methods being employed; none were postnatal specific. Participation in physical activity was measured in the following units: energy expenditure (EE), frequency of physical activity, total volume of physical activity (i.e. number of active minutes/week, either additive or weighted, using METmins, which is a system of assigning values to time spent based on different activity intensities EE values) and participant classification (i.e. 'light', 'moderate' or 'vigorous' activity performers). Walking behaviour was separately reported in four studies and two studies only measured walking, again using either total minutes walked and/or frequency of walking as the unit of measurement. Four studies used pedometers or

accelerometers to measure pre-post walking behaviour (via daily step counts), normally averaged over the measurement week.

2.4.2 Methodological quality assessment

Overall methodological quality was poor. Nine studies were rated as having a high potential risk of bias. Methodological quality indicators were often inadequate (e.g. studies lacked randomly allocated controls, had high dropout rates, inadequate missing data handling and poor measurement approaches (Table 6). Five studies were rated unclear as essential information was unavailable from study reports. Six studies were rated as low risk of bias; all were RCTs with good retention rates and used objective measurement methods or blinded outcome assessors if self-reports were used. Although pedometers were used to measure daily step counts in three studies, this information was self-reported via an activity log and therefore open to participant influence.

2.4.3 Evidence synthesis

2.4.3.1 *Physical activity promotion interventions in healthy inactive postnatal women*

Six of the seven studies targeting healthy inactive postnatal women had significant effects on moderate-vigorous physical activity (MVPA) participation and/or walking behaviour (Albright et al., 2005; Cramp & Brawley, 2006; Fjeldsoe et al., 2010; Lewis et al., 2011; Maturi et al., 2011; Montgomery, 2010). This included post-test increases in volume (Albright et al., 2005; Cramp & Brawley, 2006; Lewis et al., 2011) and frequency (Cramp & Brawley, 2006; Fjeldsoe et al, 2010) of MVPA. Of these, only Fjeldsoe et al was rated as low risk of bias. Maturi et al. (2011) showed a significant increase in the proportion of participants classified as vigorously active following their intervention. Three of the four studies measuring change in walking identified positive outcomes (i.e. pre-post increased

average step counts; Maturi et al., 2011; Montgomery, 2010) or a significant increase in time spent walking for exercise among intervention participants mid-way through the intervention (6-weeks) but not at 13-week follow-up; Fjeldsoe et al., 2010). Watson et al. (2005) reported an increase in total weekly walking minutes (at least moderate intensity) among control group participants and not intervention participants following a 6-month group pram-walking intervention.

2.4.3.2 *Postnatal weight management interventions*

Nine studies were weight management interventions including physical activity promotion, these showed mixed outcomes, with only two poor or unclear quality studies (O'Toole, Sawicki, & Artal., 2003; Walker et al., 2012) showing a positive outcomes on physical activity. Leermakers, Anglin, & Wing (1998 and Kinnunen et al (2007 found no effect of interventions on total EE or physical activity METmins, respectively. In O'Toole et al's study (2003); EE from exercise and vigorous-intensity physical activity was significantly greater in intervention participants at 1-year follow-up, compared with controls. In Ostbye et al. (2009) there were no between-group differences in total volume of vigorous-intensity physical activity. There was no change in accelerometer-measured MVPA among intervention participants in the study by Craigie et al. (2011). Both Ostbye et al. (2009) and Craigie et al. (2011) were rated as showing low risk of bias but reported different interventions, and different populations (i.e. a low-income U.K. sample and a relatively affluent U.S. sample). A small scale (non-powered) weight management study (deRosset et al., 2013) involving Hispanic postnatal women with poor English skills, reported a small effect ($d=0.2$) among intervention participants relative to controls for change in frequency of physical activity participation. Walker et al. (2012) showed significantly increased frequency of MVPA participation among white postnatal women, who took part in an ethnic-specific weight loss

intervention, compared with white controls, however this effect did not hold for other ethnic groups. Bertz et al. (2012) found no impact on daily step counts between groups receiving an exercise intervention only (or in combination with dietary management) compared with usual care or dietary management intervention. In the weight management intervention conducted by Krummel et al. (2010), walking behaviour did not significantly increase at follow-up.

2.4.3.3 *Physical activity promotion in clinical populations*

Two studies (rated as unclear risk of bias) conducted in clinical populations did not demonstrate an effect of interventions on weekly frequency of moderate or vigorous physical activity among women meeting criteria for PND (Daley et al., 2007); or on total MVPA volume among postpartum women with previous gestational diabetes (Reinhardt et al., 2012). Daley et al. (2007) focused on promoting physical activity behaviour only, while Reinhardt et al. (2012) also targeted diet; and observed a reduction in BMI and improved dietary behaviours. Daley et al. (2007) did not show an effect on PND score due to low power, however, reported increased exercise self-efficacy at follow-up among intervention participants.

2.4.3.4 *Other postnatal health and well-being studies*

Norman et al. (2010) and Lioret et al. (2012) found no impact of their interventions on postnatal physical activity volume. Neither study sought to exclusively promote physical activity focussing on overall postnatal well-being (Norman et al., 2010) or parenting health behaviours (Lioret et al., 2012). Norman et al. (2010) was rated as a low risk of bias and did demonstrate improved postnatal well-being scores and subsequent risk for PND. Lioret et al. (2012) changed dietary behaviours in first-time mothers but was not effective at increasing participation in physical activity.

Table 5. Table of study characteristics

Author, year	Study demographics (n, country, design, study type, exclusions)	Intervention details (theories mentioned, delivery person, brief description, adherence to intervention, comparison)	BCTs definitely present ^a	BCTs probably present ^a
Physical activity promotion studies conducted in healthy inactive postnatal women				
Albright et al, 2005+	n=20, U.S.A., Pre-post design, PA promotion for healthy women taking part in less than 30 mins of MVPA per week, excluded if under 18/over 45 years old, less than 3 or greater than 12 months PP or due to chronic conditions.	TTM, 8-week SCT intervention delivered by trained health educators, consisted of 1 individual ‘counselling’ session, provision of a pedometer and weekly follow-up calls with print, DVD & email resources. 83% of scheduled telephone contacts were completed.	1, 2, 5, 8, 10, 16, 19, 20, 29, 33, 38	9, 23, 24, 40
Cramp & Brawley, 2006+	n=67, Canada, RCT design, PA promotion for healthy women taking part in less than 2 days mild-moderate PA per week, excluded if less than 6/greater than 52 weeks PP or due to medical contraindications or non-English speaker.	Targeting OE, SE, SR strategies etc. 8-week intervention delivered by trained counsellors. 4-week group exercise (x2 per week: 55-60mins) at fitness centre (childcare) & 20mins group-based ‘counselling’. 4-week self-guided workbook and 10min support call. Average participation rate 6/8 classes. <i>Comparison:</i> Group classes without behavioural management counselling.	5*, 8, 10, 15*, 16*, 19*, 20*, 21*, 22*, 26, 27*	-
Fjeldsoe et al, 2010+	n=88, Australia, RCT design, PA promotion for healthy women taking part in <30 min of MVPA on 5 days, excluded if >12 months PP, 2 nd or 3 rd trimester of pregnancy or no access to mobile phone or non- English speaker.	SCT intervention delivered by trained counsellor. 1 ‘counselling’ session, information packs, maps & vouchers. 42 SMS-texts sent over a 12-week period (3-5 per week), 11 ‘goal-check’ texts & support partner texts. 1 follow-up call (week 6). 78% responded to goal checks. <i>Comparison:</i> Information booklet about PA.	1*, 5, 7, 8, 10, 13, 16, 19, 20, 23, 27, 29	-
Lewis et al, 2011+	n=18, U.S.A., Pre-post design, PA promotion for healthy women, who exercised <90 mins per week, excluded if >6 months PP or medical contraindications or no physician/nurse-midwife consent prior to participation.	12-week TTM/SCT intervention delivered by health educators consisted of calls lasting 10-15mins, weekly (1 month) then bi-weekly (months 2 & 3). Exercise goals/discussion about logs (activity calendar) at each session. Activity logs were mailed to educators monthly. 83% completed three monthly activity logs.	5, 13, 16, 27, 29, 39	1, 2, 10, 21
Maturi et al, 2011+	n=70, Iran, Cluster RCT design, PA promotion for healthy inactive women, excluded if <18/>40 years old, <6 weeks or >6 months PP or if bottlefeeding or multiple births or not literate.	Non theory-based 12-week intervention delivered by researcher. 1 individual ‘counseling’ session to increase steps gradually by 500 per week until 5000 per day with pedometer & calendar. Information leaflet, texts & bi-weekly calls. <i>Comparison:</i> UC.	5, 9, 16, 19	1, 2, 12, 27

Author, year	Study demographics (n, country, design, study type, exclusions)	Intervention details (theories mentioned, delivery person, brief description, adherence to intervention, comparison)	BCTs definitely present ^a	BCTs probably present ^a
Watson et al, 2005	n=139, Australia, Matched controlled community design, PA promotion study for healthy women, excluded if >6 months PP, had a sick infant or non-English speaker.	Non theory-based intervention delivered by project officer and fitness instructor consisted of supervised group pram-walking sessions for 6 months in local community. 20% of participants walked at least once a fortnight. <i>Comparison: UC.</i>	20, 21, 22	-
<u>Postnatal weight management interventions</u>				
Bertz et al ^b , 2012	n=68, Sweden, RCT design, lifestyle intervention comparing effects of diet, PA & combined diet/PA on weight loss. Recruited lactating, PP women (8-12 weeks PP), excluded if BMI <25/>35kg/m ² , multiple births, no intention to breastfeed for 6 months, >20% infant energy intake complementary foods, LBW infant, medical illness (both mother & baby) or smokers	Non-theory based 12-week PA 'counselling' intervention delivered face-to-face by physical therapist over 2.5hrs (1.5hrs at start & 1hr at 6-week follow-up. Individual PA prescription (45-min brisk walk at 60-70% HRmax). Advice to gradually increase walking for first 4 weeks & booklets with exercise plans, HRM & strategies for managing barriers to change. Second intervention group also received dietary advice provided by dietician. 91% completed the intervention. <i>Comparison: UC.</i>	5, 8, 9, 16, 27	7, 17, 19, 20, 21, 22, 26
Craigie et al, 2011	n=52, U.K. (Scotland), RCT design, weight management trial recruiting overweight women from low-income areas, excluded if less than 6 or greater than 18 weeks PP or if pregnant.	MI 12-week intervention delivered by trained lifestyle counsellors. 3 individual 'counseling' sessions, provision of walking plans, weight-loss booklet, a pedometer & 3 follow-up calls between sessions. 100% of sessions & calls delivered. <i>Comparison: Information booklet about PA.</i>	5, 10, 16, 17, 38	7, 12, 19, 20
deRosset et al, 2013	n=24, U.S.A., RCT design, weight management trial. Recruited self-reported overweight/obese Hispanic women with limited English at 6-week PP visit, excluded if <21 years old, participating in another trial, poor family medical history.	Non-theory based 12-week group intervention delivered by bilingual 'interventionists' ^c using MI. Educational classes (60 mins each) on nutrition, exercise, goal-setting and coping skills, reminder calls prior to classes. Childcare & transportation. 75-80% weekly attendance. <i>Comparison: UC.</i>	1, 5, 8, 9, 21, 24, 35, 40	7
Kinnunen et al, 2007	n=92, Finland, Cluster-controlled design by baby clinic, weight management trial for all women receiving PP care starting at 8 weeks PP, excluded if <18 years old, multipara, type 1/2 diabetes, physical disability or history of psychiatric illness or non-Finnish speaker.	SoC (TTM) intervention delivered by public health nurses. 5 individual 'counselling' sessions (initial contact at 2 months PP 20-30mins, boosters 10-15mins at 3, 5, 6 & 10 months PP) at child health clinics & optional weekly group exercise (45-60mins). 90% of participants received all counselling sessions. Participation in group exercise (51%). <i>Comparison: UC.</i>	1, 5, 10, 20	6, 9

Author, year	Study demographics (n, country, design, study type, exclusions)	Intervention details (theories mentioned, delivery person, brief description, adherence to intervention, comparison)	BCTs <i>definitely</i> present ^a	BCTs <i>probably</i> present ^a
Krummel et al, 2010	n=151, U.S.A., RCT design, weight management trial recruiting all women who used WIC-centres, excluded <18 years old >24 months PP or underweight.	Targeted SE, SS, SR strategies etc. 1-year intervention delivered by a dietitian. 1 individual ‘counselling’ session then 10 x 60min monthly group class in local churches/children’s centres. Newsletters, calendars, feedback & self-monitoring booklets used. 47% of participants attended ≥ 1 session. <i>Comparison:</i> Group classes without behavioural management counselling.	5, 9*, 19, 36*	1*, 8*, 29*, 35
Leermakers et al, 1998	N=90, U.S.A., RCT design, weight management trial recruiting all women who gained EGW, excluded if <18 years old, <3 months or >12 months PP or currently lactating or BMI <22.	Non-theory based 6-month intervention. 2 group ‘counselling’ sessions, weekly/bi-weekly calls (5-15mins), 16 mail-outs (weekly: 12, bi-weekly: 4, monthly: 8 weeks), homework & progress checked. Homework (41%) & phone contacts (51%) completed. <i>Comparison:</i> Information booklet about PA.	5, 8, 9, 11, 16, 17, 21, 27	10, 19
Ostbye et al, 2009	n=450, U.S.A., RCT design, weight management trial recruiting overweight PP women, excluded if <18 years old, or unable to walk for a mile unassisted due to health conditions or non-English speaker.	SCT/Stage of readiness (TTM) 9-month intervention delivered by a fitness instructor. 10 group exercise classes (aerobics, strength & flexibility). Calls/in-person individual ‘counselling’ every 6 weeks (20mins), bi-weekly newsletters & sports stroller, pedometer, workbook etc. 38% class participation & 55% of calls received. <i>Comparison:</i> Information booklet about PA.	5, 6, 8, 20, 21, 22, 35	-
O'Toole et al, 2003+	n=40, U.S.A., RCT design, weight management trial recruiting overweight women or women who gained EGW, excluded if <6 weeks or >6 months PP or already enrolled in an exercise or diet programme or medical contraindications.	Non-theory based intervention over 1 year by dietitians & exercise physiologists. PA prescription (EE goal 150 kcal/day), weekly group educational sessions (12-weeks), then bi-weekly, then monthly, exercise brochure. No details on adherence. <i>Comparison:</i> Information booklet and 1hr educational session.	5*,9, 16* 21, 27	-
Walker et al, 2012+	n=71, U.S.A., RCT design (stratified by ethnicity), weight management trial for low-income Hispanic, African American & White women who retained ≥5kg weight at 6 weeks-12 months PP. Excluded if BMI<25, <18 years old, >3 children, poor English, no phone, medical	SCT 13-week group intervention delivered by registered nurses or health educators consisted of weekly ethnic-specific content on nutrition, physical activity & behavioural strategies for 2 hrs per week. Pedometers and notebook provided, with childcare & transportation available. 50% of participants followed up to 13-	5, 16, 21, 36	10, 35, 39

contraindications (e.g. HIV/AIDs, high BP, diabetes, depression) or non-singleton infant.

weeks attended 5-12 intervention classes. *Comparison:* UC.

Physical activity promotion/lifestyle studies conducted in clinical postnatal populations

Daley et al, 2007	n=31, U.K. (England), RCT design, PA promotion for treatment of PND in women with EPDS score of ≥ 12 taking part <30 mins of MVPA on 3 days, excluded if <16 or >12 months PP, inpatient treatment, pregnant or non- English speaker.	TTM 12-week intervention delivered by trained researcher consisted of 2 individual ‘counselling’ sessions (60mins each). Pedometer & diary provided & walk-&-talk session plus 2 follow-up calls (10 mins, weeks 3 and 9). 55% of participants returned exercise diaries. <i>Comparison:</i> UC.	5, 22, 16, 35	10
Reinhardt et al, 2012	n=38, Australia, RCT design, lifestyle intervention recruiting women with a diagnosis of GDM during pregnancy at 6 weeks PP, excluded if women had no access to phones or medical contraindications.	Theory-based (e.g. benefits of change, perceived barriers, SS etc.). 6-month MI intervention delivered by diabetes educators consisted of 10 phone calls of 10-30mins, weekly (5 weeks) then monthly (5 months), educational and self-help materials provided by mail. No details on adherence. <i>Comparison:</i> UC.	2, 8, 16, 18, 21, 27, 38	5, 6, 10, 33

Other postnatal/infant health and well-being studies including physical activity change components**

Lioret et al, 2012 ^d	n=542, U.S.A., Cluster-RCT design, lifestyle intervention for preventing childhood obesity and promoting behaviour change in parents. Recruited <i>first time</i> mothers at 3 months PP, excluded if poor English or infants with chronic physical health problems.	Parenting support theory/anticipatory guidance (encouraging child behaviours for obesity prevention by improving parenting skills, information about expected infant behaviours & role-modelling healthy lifestyles). Delivered by dietitian over 6 group face-to-face sessions (2 hours each) at first time mothers’ groups. Follow-ups via text & mailouts. No information on adherence. <i>Comparison:</i> UC.	2, 30	4, 20, 21, 24, 26, 28
Norman et al, 2010	n=161, Australia, RCT design, physical therapy and an education programme intervention to improve postnatal well-being for all women, excluded if psychiatric disorder or could not speak and read English independently.	Non theory-based 8-week intervention delivered mainly by a physiotherapist consisted of group exercise (weekly for 1 hr) with babies at a local hospital. Additional individual 30min session with a relevant healthcare professional. Diagrams of exercises & list of local gyms/community resource & additional educational components. 85% programme adherence. <i>Comparison:</i> UC.	15, 20, 21, 22	-

BP, blood pressure; DVD, Digital Versatile Disc; EPDS, Edinburgh Postnatal Depression Scale; EE, energy expenditure; EGW, excessive gestational weight; GDM, Gestational Diabetes Mellitus; GP, general practitioner; Hr, Hours; HR, Heart rate; HRM, Heart rate monitor; HV, health visitor; Kcal, kilocalorie; MI, Motivational Interviewing; LBW, low birth weight; mins, minutes; MVPA, moderate-vigorous physical activity; PA, physical activity; PND, postnatal depression; OE: outcome expectancies, PP, postpartum; SCT, Socio-Cognitive Theory; SoC, Stages of Change; SE, Self-efficacy; SMS, Short-Message-Service; SR, Self-regulatory; SS, Social support; TTM, Transtheoretical Model; UC, usual care; U.K., United Kingdom; U.S.A., United States of America; WIC-center, Women, Infant and Children center

Notes: +=the intervention was efficacious. *=BCT was also coded as present in comparison condition. (Cramp & Brawley, 2006; Fjeldsoe et al, 2010; Krummel et al, 2010; Leermaker et al, 1998; Ostbye et al, 2009; O'Toole et al, 2003; Watson et al, 2005) **=Although physical activity interventions and weight management trials consisted of lifestyle interventions in this group of studies we differentiated the studies based on the purpose of the trial (i.e. improved postnatal well-being: Norman et al, 2010 and promoting positive infant behaviours for childhood obesity prevention: Lioret et al, 2012)

^aFor the corresponding list of BCT names see Table 2. ^bFor Bertz et al (2012), all information regarding the intervention for this study refers to the groups receiving the exercise intervention (either alone or in conjunction with a diet intervention). ^cStaff were employed as part of an existing nutrition educational programme and were at least high school graduates with experience working in the population and from a similar socio-economic background. Non-paraprofessionals also delivered motivational calls, but paraprofessionals retained case management responsibility for participants. All staff received additional training in motivational interviewing as part of the intervention. ^dThe published paper provided limited information and the protocol paper was coded instead for this intervention. Although the study references theories these are in relation to the impact of parenting behaviour on behaviour change in offspring and are not included in analysis as truly 'theory-based'.

Table 6. **Methodological quality ratings**

Reference	Sequence generation	Concealed allocation	Outcome assessment	<i>RETENTION RATE</i>	Missing data handling	Overall risk of bias	Rationale
Albright, 2005	N/A	N/A	U	100%	N/A	High	Pre-post design lacking a control group
Bertz, 2012	A	A	A	91%	A	Low	High quality RCT design, low drop-out with objective measurement of physical activity
Craigie, 2011	A	U	A	69%	U	Low	High quality RCT design with objective measurement of physical activity change
Cramp, 2006	U	U	U	85%	N	Unclear	Unclear information across most areas
Daley, 2007	A	U	U	82%	N	Unclear	Unclear information across most areas
deRosset, 2013	A	A	U	100%	N/A	Low	Generally well conducted, blinding at baseline but not clear at follow-up (interviewer-assisted questionnaire)
Fjeldsoe, 2010	A	A	A	75%	A	Low	High quality RCT design, blinding at baseline, reasonable retention with ITT used
Leermaker, 1999	U	U	U	69%	N	Unclear	Unclear information across most areas
Lewis, 2011	N/A	N/A	U	81%	N	High	Pre-post design lacking a control group
Lioret, 2012 ¹	A	A	U	91%	N*	High	Unclear whether assessors were blinded and analysis approach introduced potential bias

Kinnunen, 2007	N	N	N	92%	A	High	Non randomly allocated control group
Krummel, 2010	U	U	N	42%	N	High	High dropout rate, self-report pedometer data and no information on missing data handling
Maturi, 2011	A	U	N	94%	A	High	Bias introduced through measurement approach
Montgomery, 2010	N/A	N/A	N	97%	A	High	Pre-post design lacking a control group
Norman, 2010	A	A	U	97%	A	Low	High quality RCT design, high retention rate but non-validated questionnaire measure used
Ostbye, 2009	U	A	A	80%	A	Low	Baseline measures completed prior to randomisation & blinding of outcome assessors.
O'Toole, 2003	U	A	U	83%	U	Unclear	No information on blinding and measurement approach poorly specified
Reinhardt, 2012	U	N	N	95%	A	High	Randomisation to groups known by researcher (and possibly participants) prior to baseline assessments
Walker, 2012	U	U	U	70%	N	High	RCT design indicators unclear and possible important differences among participants who withdrew
Watson, 2005	N	N	N	78%	U	High	Non randomly allocated control group

A: Adequate, N: Not Adequate, U: Unclear, N/A: Not applicable ¹Quality ratings derived after consulting protocol paper (e.g. Campbell et al, 2008)*Although retention rate was high a large number of participants were excluded due to missing data

2.4.4 Meta-analysis results: What is the efficacy of postnatal physical activity interventions on change in physical activity (exercise) and walking behaviour?

The meta-analyses were all conducted using random effects models. Analysis of frequency of physical activity (figure 2a, n=7 studies, n=9 effect sizes, with Walker et al., 2012 broken into three sub-groups) showed a significant increase favouring the intervention groups at post-test. The associated effect size was moderate (SMD = 0.53) with large confidence intervals ([95% CI: 0.05, 1.01], p=0.03). Testing with the Q-statistic ($\chi^2[8] = 49.86$, p<0.01) and I^2 index measure for the mean effect size (84%) suggests particularly high heterogeneity was present. Some of the heterogeneity improved if the largest study by Ostbye et al. (2009) was removed ($\chi^2[7] = 26.18$, p<0.01, $I^2=73\%$: (figure not shown). The effect size from this study, along with three others are outwith the expected 95% confidence intervals from the mean for the whole sample (shown in the funnel plot: 3b as outliers from the upper and lower plotted CI lines), demonstrating the significant heterogeneity among samples included in this analysis. The analysis for volume of physical activity (figure 2b, n=9 studies, n=10 effect sizes as Reinhardt et al. (2012) contributed two effect sizes to the analysis) was not significant (SMD = 0.15; [95% CI: -0.6, 0.35]; p=0.16) and showed moderate heterogeneity ($\chi^2[9] = 20.03$, p=0.02, $I^2 = 55\%$). Volume of walking behaviour (figure 2c, n=3 studies, n=4 effect sizes as two comparisons were used in Bertz et al., 2012) was also non-significant (SMD = 0.07, [95% CI: -0.21, 0.36], p=0.62) with no evidence of heterogeneity (see Figure 2c).

Figure 2a. Meta-analysis: frequency of physical activity

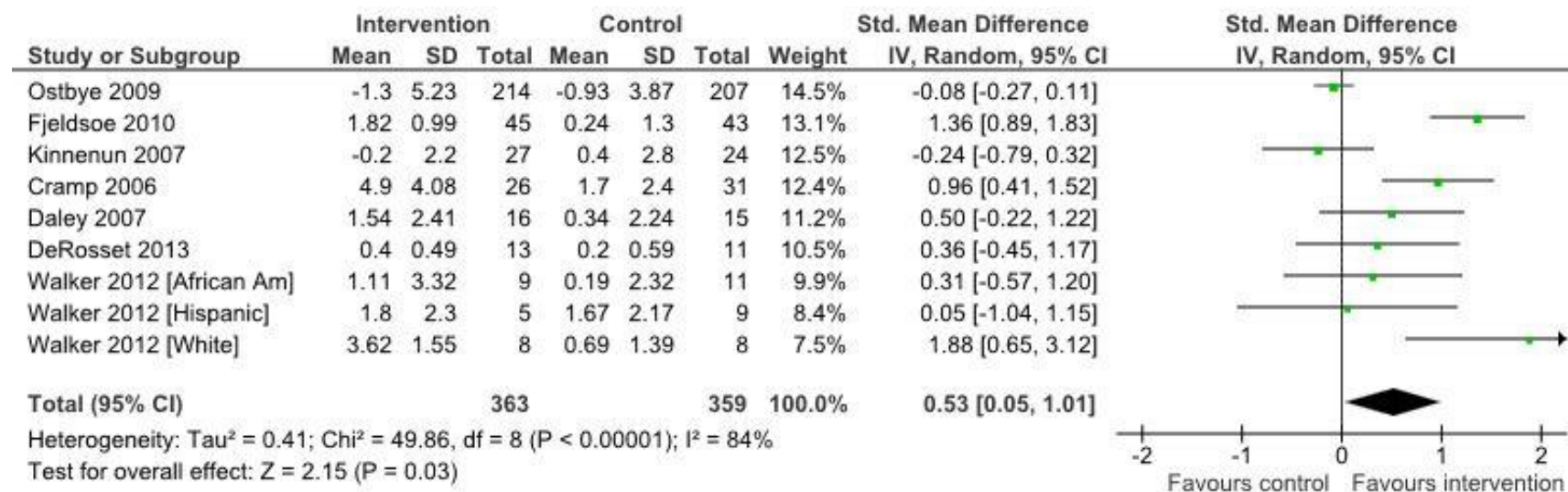


Figure 2b. Meta-analysis: volume of physical activity

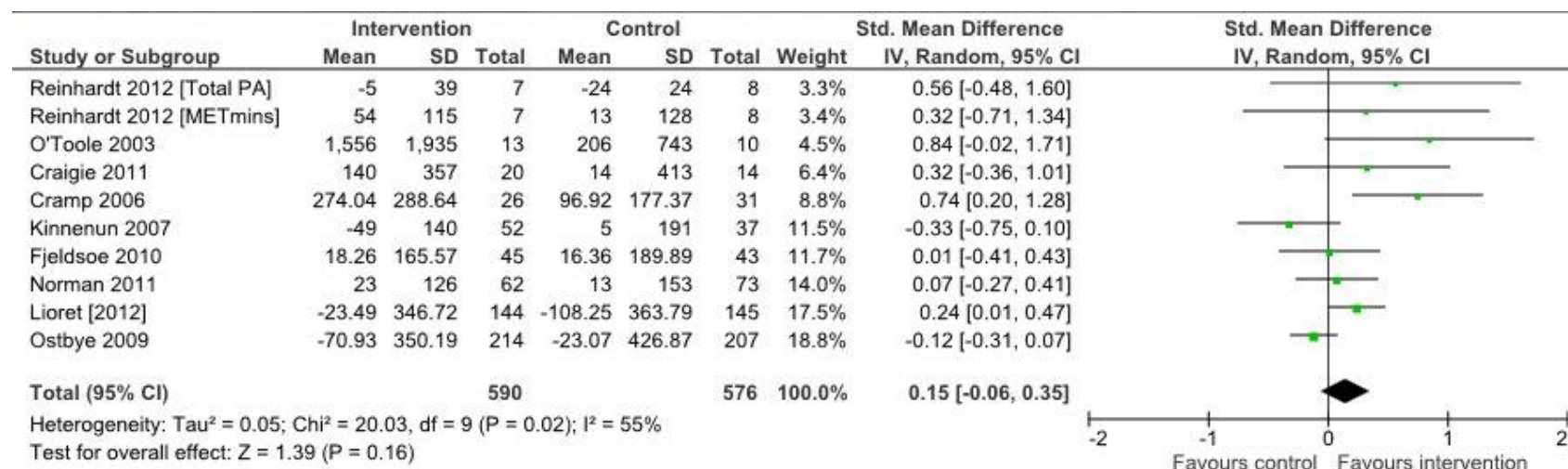
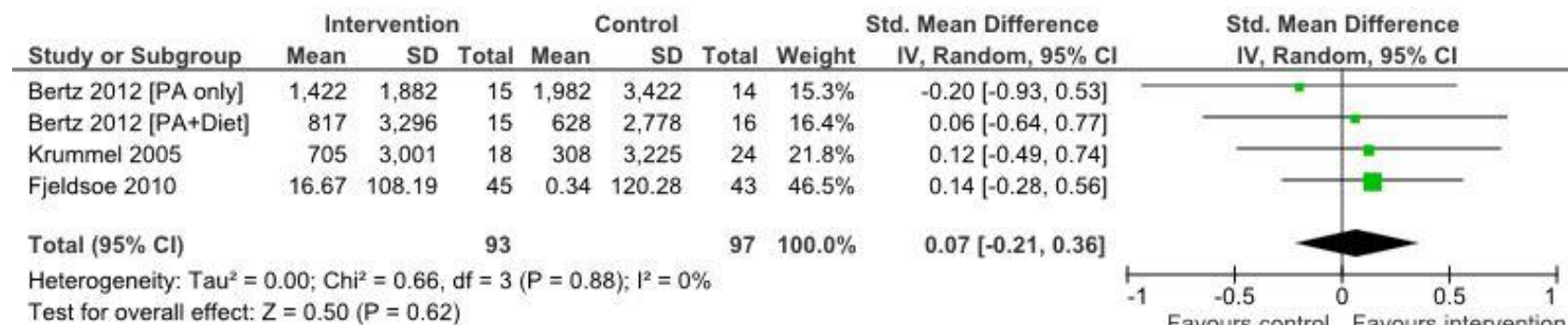
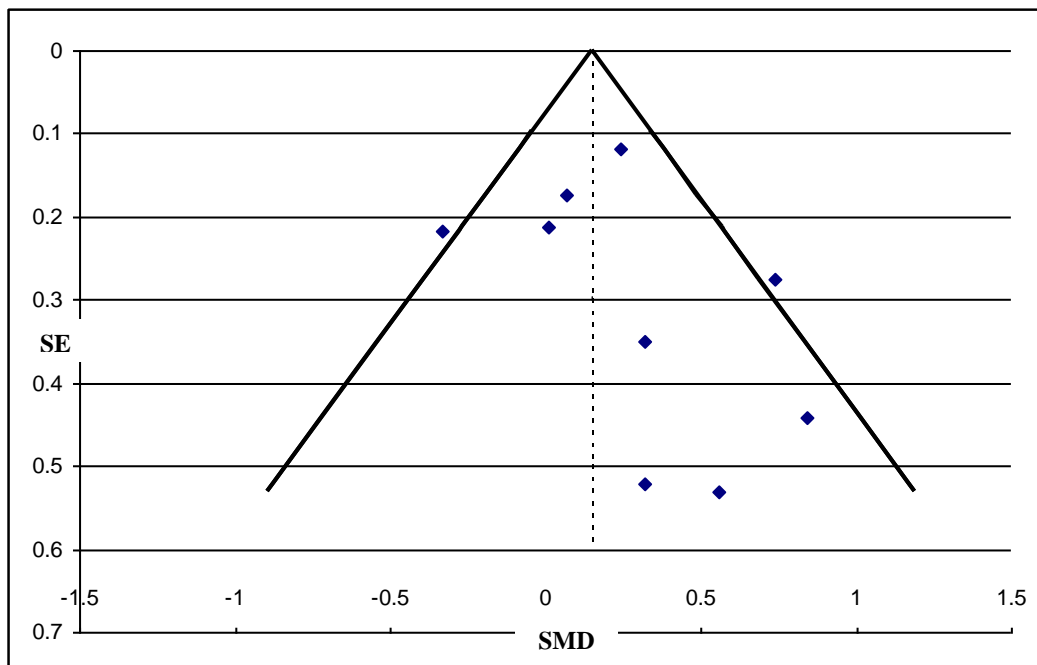


Figure 2c. Meta-analysis: volume of walking



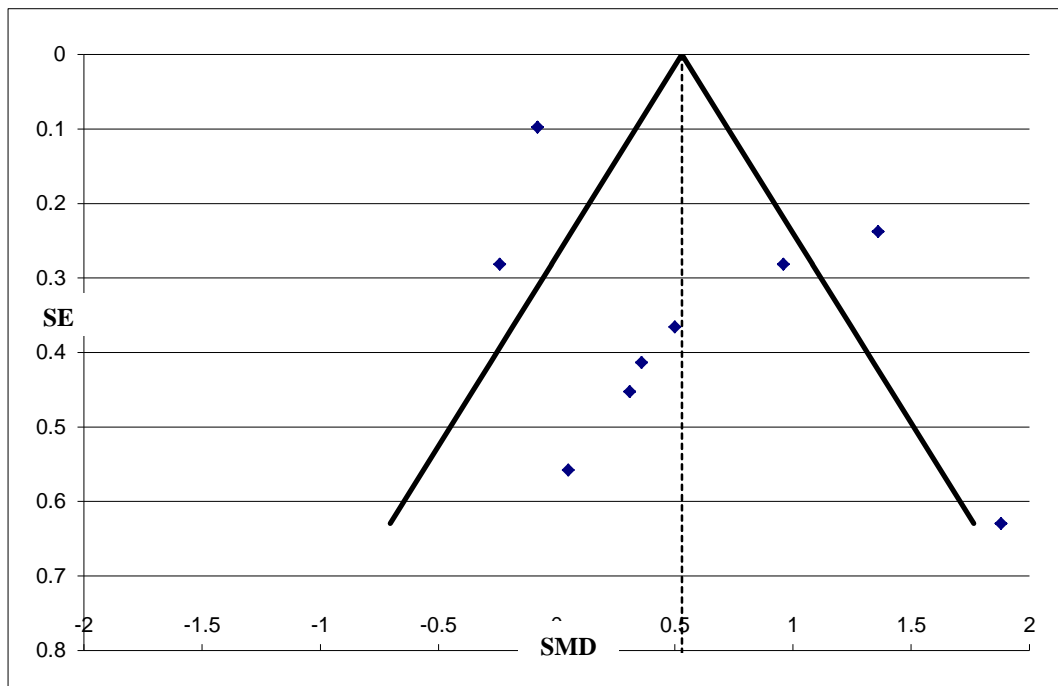
As shown in the funnel plot in Figure 3a, there was evidence for possible publication bias: in relation to volume of physical activity. Plotting the SMD effect size against the standard error (SE) showed asymmetry (i.e. clustering around the top and right of the funnel); suggesting studies with smaller samples may have been under-represented. The funnel plot for frequency (Figure 3b) could not be accurately interpreted due to heterogeneity in this outcome (Lipsey & Wilson, 2001).

Figure 3a. **Funnel Plot: volume of physical activity**



SE, Standard Error; SMD, Standardise Mean Difference

Figure 3b. **Funnel Plot: frequency of physical activity**



SE, Standard Error; SMD, Standardise Mean Difference

2.4.5 Behaviour change techniques coding

BCTs coded as definitely and probably present in each of the intervention and comparison conditions are shown in Table 7. We coded twenty intervention conditions and seven comparison conditions. The median number of BCTs coded as definitely present in interventions was five (range of 2-12 BCTs). Including probably present BCTs brought this to eight (range 5-15 BCTs). As shown in Table 7 among the 20 included studies in this review, 33 of the 40 BCTs specified in the CALO-RE taxonomy were coded as definitely or probably present in the interventions. The most prevalent BCTs (coded in $\geq 40\%$ interventions) are shown in Table 7 as shaded rows. These, in order of prevalence, were: ‘goal-setting (behaviour)’ ($n=17$ interventions), ‘prompt self-monitoring of behaviour’ ($n=13$), ‘provide instruction on how to perform the behaviour’ ($n=11$), ‘prompt review of behavioural goals’, ‘provide information on where and when to perform the behaviour’ (each in $n=10$ interventions), ‘barrier identification/problem solving’, ‘set graded tasks’, ‘use of

follow-up prompts’ (each in $n=9$ interventions), and ‘provide feedback on performance’ ($n=8$). These nine techniques accounted for 58% of codes applied across the 20 intervention conditions.

2.4.5.1 *Are specific BCTs more common in efficacious interventions?*

We compared the proportion of studies including each BCT coded in at least 40% of intervention conditions between efficacious ($n=8$: shown in Table 5 with a + next to the author’s name and date) and non-efficacious interventions ($n=11$). Table 7 shows efficacious interventions were more likely to have contained ‘goal-setting (behaviour)’, ‘prompt self-monitoring of behaviour’, ‘use of follow-up prompts’ and ‘provide feedback on performance’. In the case of self-monitoring and follow-up prompts, efficacious studies were more than twice as likely to contain these BCTs (Table 7). In contrast, ‘provide information on where and when to perform the behaviour’, ‘provide instruction on how to perform the behaviour’, ‘prompt review of behavioural goals’ ‘barrier identification/problem solving’ and ‘set graded tasks’, were equally or more likely to have been in non-efficacious interventions compared with efficacious interventions.

2.4.5.2 *Do theory based interventions targeting postnatal women use more, or specific types of, BCTs compared with non-theory based interventions?*

Theory based interventions had a slightly greater number of BCTs (median of 9) compared with non-theory based interventions (median of 8). However, this difference did not reach significance ($U(1) = 36.5$, $z = 0.98$, $p = 0.33$). Theory based interventions were more likely than non-theory based interventions to have included ‘goal-setting (behaviour)’ and ‘self-monitoring of behaviour’ (Table 7). The largest difference was for the techniques ‘prompt review of behaviour goals’ and ‘barrier identification/problem solving’. These were found 3-

4 times more often in theory based studies. 'Feedback on performance' and 'provide information on where and when to perform the behaviour' had equal prevalence in theory and non-theory based studies. 'Provide instruction on how to perform the behaviour', 'set graded tasks' and 'use of follow-up prompts' were more prevalent in non-theory based studies.

Table 7. Total number of studies with behaviour change techniques (BCTs) present/probably present in the intervention and comparison conditions and in efficacious and theory based studies¹

No.	Behaviour Change Technique	<i>N</i> studies with BCT in intervention	<i>N</i> studies with BCT in comparison	BCT when efficacious* (% studies)	BCT when non-efficacious* (% studies)	BCT when theory based (% studies)	BCT when non-theory based (% studies)
1	Information on consequences of behaviour in general	7*	2*	50	18	50	20
2	Consequences of behaviour to the individual	5*	0	38	18	30	20
4	Provide normative information about others' behaviour	1*	0	0	9	0	10
5	Goal setting (behaviour)	17*	2	100	73	100	70
6	Goal setting (outcome)	3*	0	0	27	30	0
7	Action planning	4*	0	13	18	10	30
8	Barrier identification/Problem solving	9*	1*	38	36	60	30
9	Set graded tasks	9*	1	38	45	30	60
10	Prompt review of behavioural goals	10*	0	50	55	80	20
11	Prompt review of outcome goals	1	0	0	9	0	10
12	Provide rewards contingent on effort/progress	2*	0	13	9	0	20
13	Provide rewards contingent on successful behaviour	2	0	25	0	20	0
15	Prompting generalisation of a target behaviour	2	1	13	9	10	10
16	Prompt self-monitoring of behaviour	13	2	100	45	70	60
17	Prompt self-monitoring of behavioural outcome	3*	0	0	27	0	30
18	Prompting focus on past success	1	0	0	9	10	0
19	Provide feedback on performance	8*	1	50	33	40	40
20	Information on where/when to perform the behaviour	10*	1	38	64	50	50
21	Provide instruction on how to perform the behaviour	11*	1	50	55	40	70
22	Model/ Demonstrate the behaviour	6*	1	13	45	30	30
23	Teach to use prompts/ cues	2*	0	25	0	20	0
24	Environmental restructuring;	3*	0	13	9	10	20
26	Prompt practice	3*	0	13	18	10	20
27	Use of follow up prompts	9*	1	75	27	40	50
28	Facilitate social comparison	1*	0	0	9	0	10
29	Plan social support/social change	5*	1*	50	9	40	10
30	Prompt identification as role model/position advocate	1	0	0	9	0	10
33	Prompt Self talk	2*	0	13	9	20	0
35	Relapse prevention/ Coping planning	6*	0	25	27	40	20
36	Stress management	2	1	13	9	20	0

38	Motivational interviewing	3	0	13	18	20	10
39	Time management	2*	0	25	0	20	0
40	General communication skills training	2*	0	13	0	10	10

¹20 intervention,7 comparison conditions. *Includes probably present. Shading=BCT present in $\geq 40\%$ of studies. *Analysis excluded deRosset et al. (2013). Techniques not present in studies: Provide information about others' approval; Shaping; Agree behavioural contract; Prompt anticipated regret; Fear arousal; Prompt use of imagery; Emotional control training.

2.5 Discussion of the review

2.5.1 *What is the efficacy of postnatal physical activity interventions on change in physical activity (exercise) and walking behaviour?*

There was evidence for a moderate effect of the interventions included in the review on increasing frequency of postnatal physical activity behaviour. As physical activity guidelines for adults recommend participation in activity that is at least moderate intensity on ‘most days’ (Bull et al., 2010; Egger et al., 1999; Haskell et al., 2007), this is a positive finding regarding efficacy of interventions in this population. However, due to differences in the measurement approaches we do not know whether the magnitude of change is clinically significant. Also these results should be viewed with caution as the pooled data came from studies that were highly heterogeneous. The pooling of results for volume of ‘health-enhancing’ postnatal physical activity and walking behaviour showed no evidence of effect; volume was moderately heterogeneous, and the funnel plots suggested that publication bias may have been an issue. Furthermore, the lack of effect for total volume may be due to a larger amount of measurement error in volume versus frequency of physical activity.

One unexpected finding from this review was the apparent difference in efficacy between interventions solely targeting physical activity and postnatal weight management interventions. Among high quality studies, postnatal weight management studies appeared ineffective in promoting physical activity. It might be that these interventions, which generally focus on both diet *and* physical activity, have a lesser impact on activity behaviour. Most of the physical activity interventions included in this review were conducted in healthy but inactive women, rather than overweight or obese populations, which were the populations targeted in weight management trials. Postnatal women joining weight management interventions may have different motivations than women joining purely for physical activity. Also obese or overweight individuals may require more complex interventions to enable

significant changes in behaviour. Among the general population there is evidence that compared with men; women preferentially adopt dietary control strategies as opposed to physical activity for weight loss (McElhone, Kearney, Giachetti, Zunft, & Martinez, 1999). In postnatal populations studies have shown endorsing distal outcome expectancies as important motivators (e.g. weight loss and fitness) is associated with being less physically active (Cramp & Brawley., 2009; Fjeldsoe et al., 2012); compared with proximal outcomes expectancies (e.g. improved mood, energy and sleep habits); these better predict self-reported postnatal physical activity (Cramp & Brawley., 2009). Furthermore, dietary restriction is sufficient for weight-loss following childbirth, although physical activity (alone or in conjunction with dietary change) is associated with improved body composition (i.e. greater fat-mass weight loss relative to fat-free weight loss; Amorin et al., 2006). When considering the studies included in this review, three weight management interventions and one study in a gestational diabetes population did not show change in physical activity but reported significant weight loss (Craigie et al., 2011; Leermakers, et al., 1998; Ostbye et al., 2009; Reinhardt et al., 2012), with most evidencing dietary changes, such as a decrease in daily calorie intake (Craigie et al., 2011), percentage of calories from fat (Leermakers, et al., 1998), fat, carbohydrate and high-sugar snacks intake (Ostbye et al., 2009; Reinhardt et al., 2012).

Considering results of previous BCT content coding reviews may help elucidate further reasons for these findings. A review of physical activity interventions among obese adults (Olander et al., 2013), found a limited relationship between change in self-efficacy and change in physical activity behaviour. This relationship is much stronger among non-obese adults (Williams & French, 2011). Also different BCTs were associated with change in self-efficacy, compared with change in physical activity among obese adult populations (Olander et al., 2013). An outstanding question this review is unable to answer is whether the lack of efficacious results for postnatal weight management interventions was due to the particular

population targeted or as a result of the selection of BCTs commonly used in interventions, since no studies included normal weight comparison groups. The two explanations need not be mutually exclusive and the findings from the review conducted by Olander and colleagues suggests a possible mismatch between the needs of overweight/obese postnatal populations regarding physical activity behaviour change, with the interventions which have been predominantly used.

2.5.2 Are specific BCTs more common in efficacious interventions?

A number of BCTs were used equally in efficacious and non-efficacious interventions. However, efficacious interventions included more BCTs including ‘goal setting (behaviour)’, ‘self-monitoring of behaviour’, ‘feedback on performance and ‘follow-up prompts’ were used more frequently in efficacious studies. The finding that BCTs associated with self-regulatory actions were much more apparent among efficacious interventions is consistent with earlier findings from within the general population (Michie et al., 2009; Williams & French, 2011) and from research in postnatal populations (Cramp & Brawley, 2009). Michie and colleagues (2009) found usage of the BCT ‘self-monitoring of behaviour’ explained a large proportion of the variance in effect sizes among studies included in their meta-analysis. Using meta-regression they found that studies including this BCT along with one of four other BCTs (‘intention formation’, ‘specific goal setting’, ‘feedback on performance’ and ‘review of behavioural goals’) were significantly more effective compared with interventions not including those BCTs. Use of ‘action planning’ was found to be associated with change in physical activity behaviour, among healthy adult populations in Williams & French (2011). Although ‘action planning’ was coded infrequently in the present review, the criteria for coding this BCT in the CALO-RE taxonomy suggests interventions must specify ‘when, where and how to act’ (Michie et al., 2011, Table 2). As authors of other

content coding reviews have noted, this level of explicit detail for coding is often not available within intervention descriptions (Michie et al., 2009; Olander et al., 2013; Williams & French, 2011). The high number of *probably* present codes applied to studies in this review is indicative of some of the difficulties faced coding BCTs within interventions.

2.5.3 *Do theory based interventions targeting postnatal women use more, or specific types of, BCTs compared with non-theory based interventions?*

When exploring BCT coding in relation to theory, there was no evidence from the present review that choice of theory (or indeed mention of theory) was necessarily associated with the number of BCTs included in interventions. Theory based studies did appear more likely to include the following two BCTs: ‘prompt review of behavioural goals’ and ‘barrier identification/problem solving. As discussed in Williams and French (2011), theories largely based on increasing self-efficacy as a route to behavioural change would be expected to adopt techniques associated with enhancing perceptions of successful past performance. Indeed, evidence from postnatal intervention trials suggests mediating effects on physical activity behaviour as a result of self-efficacy change (Fjeldsoe et al, 2012; Cramp & Brawley, 2009). However, despite the widespread inclusion of ‘barrier identification/problem solving’ in theory based physical activity interventions, according to the results of previous reviews (Ashford, Edmunds, & French, 2010), this BCT can result in decreased self-efficacy perceptions. This may tie into the social roles of postnatal women who are predominantly responsible for child care. This can often create even greater barriers than the general population, or parents less responsible for child care, particularly around structured exercise; therefore the identification of these barriers may contribute to further reduced self-efficacy (Bellows-Riecken & Rhodes, 2008; Evenson et al., 2009).

2.5.4 Limitations

As might be expected from the diverse studies included there was significant heterogeneity observed in the meta-analyses. Variation might be explained by differences in the study designs and characteristics of the included samples, i.e. combining healthy inactive, obese and clinical populations. Also there were large differences in the type of activity that was measured, i.e. in some studies leisure-time or 'planned exercise' activity only. Along with an over-reliance of self-report measures, which are known to poorly correlate with objective measures (Evenson, Herring, & Wen, 2012), and unclear reporting of physical activity measurement approach, this issue represents a limitation of the literature to date and make comparisons challenging. There were also differences in delivery modes and person, and in the intensity of interventions and adherence rates; variable postnatal stage and weight profiles of participants may have also played a role. In particular, intervention intensity is an important factor to consider when reviewing efficacy, which we could not conduct analyses on due to the difficulty classifying intensity, as interventions were delivered in a complexity of ways. It is also possible that the large sample size in the trial reported by Ostbye et al. (2009) may have diluted the overall meta-analyses effects due to a greater weighting of this non-significant trial. Also, low adherence levels were reported in this trial (average 38% attendance at classes), another potential confounder. In fact, adherence and retention rates were poor across many trials in this review, which has implications for research and practice with this population, who may be a more challenging group to engage in health promotion. The fact that not all eligible studies were able to be included in the meta-analyses due to authors not being able to provide necessary data also limits conclusions. Further, we did not include unpublished studies in the review so cannot be sure to have fully accounted for publication bias, with evidence for this found in our funnel plot for volume of physical activity. As only two studies were identified that conducted longer-term follow-ups we could

not assess whether postnatal interventions were efficacious beyond immediate post-intervention effects, which is an important research question.

This review used an empirically developed taxonomy of intervention techniques to code BCTs present in interventions targeting postnatal physical activity behaviour. Three coders independently coded all studies in this review, which is a significant strength; however the modest rate of inter-rater reliability was somewhat concerning. One previous review has reported a similar rate of agreement using the CALO-RE taxonomy based on two raters (Olander et al., 2013, who reported a Kappa of 0.68); however the review by Williams and French (2011) and the study by Michie et al. (2011) reported Kappas of > 0.8, and 0.79, respectively. It is difficult to assess whether the rate of inter-rater reliability in the present review is a result of limited or unclear intervention descriptions, coding descriptions from the CALO-RE taxonomy or due to the coders own skill level for coding, or a combination of all three issues. It is likely that agreement could be improved following training via improved specification of techniques, as has been confirmed by the primary team developing a taxonomy of BCTs (Michie et al., 2013; personal communication with Caroline Wood, BCT Taxonomy Project Research Associate on August 13th 2013).

2.6 Conclusions and future research

Currently there is evidence within postnatal populations suggesting physical activity participation in the short-term can be promoted among healthy inactive postnatal women. Postnatal physical activity frequency and volume were shown in healthy inactive women following interventions promoting change in social cognitive determinants of behaviour change including the use of self-regulatory strategies such as goal setting and self-monitoring, and use of feedback and follow-up prompts after initiation of behaviour change. Although theory based studies, were more likely to include ‘prompt review of behavioural

goals' and 'barrier identification/problem solving', this does not seem to be associated with short-term intervention effectiveness. Promoting physical activity within postnatal weight management interventions, whereby weight loss is the primary outcome does not seem to be effective. These conclusions are tentative because only a small number of studies were deemed to be methodologically at low risk of bias. Future studies would benefit from considering measurement issues carefully to ensure studies can be meaningfully compared, walking outcomes should be reported separately, and studies should employ high quality RCTs to test the impact of interventions on change in postnatal physical activity behaviour. Improved intervention descriptions including the use of recognised/standardised taxonomies would also improve our ability to assess the relationship between technique usage and change in physical activity behaviour. In the future, interventions targeting postnatal women for physical activity change should measure, and report on, whether change occurred in theory-based constructs that are being targeted as mediators of physical activity behaviour change (e.g. see Cramp & Brawley., 2009; Fjeldsoe et al., 2012).

2.7 Summary of Chapter Two

The systematic review and meta-analysis found both PA counselling and pedometer programmes have been successfully developed and tested in postnatal population, suggesting they may be an effective and feasible approach. There is less evidence for structured group exercise or pramwalking for PA behaviour change, although this has not been adequately investigated in a UK setting. Weight management/lifestyle interventions have also been used to promote PA change. Despite positive weight and dietary outcomes, these appear less effective for increasing participation in postnatal PA. Overall, the interventions research among women with young children and postnatal populations is relatively limited and

methodological quality was generally poor suggesting there was a need for further high quality interventions research.

CHAPTER THREE

3 METHODS OF THE MAMMiS STUDY

3.1 Chapter Preface

This chapter describes the methods and methodology of the MAMMiS study. The study aims, objectives and research questions are given and the intervention, implementation and evaluation approach used is described in detail. Dr Hughes and Dr McInnes conceived of conducting a trial in a healthy postnatal population and submitted an outline proposal for funding from the University of Stirling. However, I developed the research proposal in full (including research questions, methodology and analysis). I conducted the full trial on my own, under supervision from Dr Hughes and Dr McInnes. This included all stages from recruitment, data collection, intervention delivery, follow-up, analysis and write-up. The exception to this is two parts of process data collected as part of the trial. Firstly, the pramwalking data (i.e. the intensity of pramwalks); I supported an undergraduate student to conduct the data collection and analysis. Secondly, I conceived of the qualitative interview study that was conducted among participants upon trial completion; the rationale and methods used for that study are given in this chapter. However, a person independent of the trial conducted the interviews and thematic analysis, the results of which are summarised in Chapter four and discussed in Chapter five along with the primary MAMMiS trial results.

3.2 Background

Chapter One discussed that PACs are a behavioural counselling approach that has been successfully adopted in the UK among a range of healthy and clinical populations to increase adoption of PA for health and wellbeing benefit. This may represent a feasible and acceptable intervention for postnatal women who may be at risk of insufficient PA and who will benefit

from being active. Although interventions have successfully changed short-term self-reported PA behaviour among women with young children (Chapter One) and healthy low-active postnatal women most studies were of poor quality and not generalisable to postnatal populations in the UK (Chapter Two). Overall there were relatively few individual-level behaviour change interventions that were of a high-quality, which focused specifically on postnatal women. Poor methodological quality was as a result of studies not employing randomised controlled designs, not having sufficient power to detect change in PA outcomes, or using only subjective methods for measuring PA behaviour change. In Chapter One I discussed the limitations of using subjective measures. Furthermore, most previous interventions in postnatal populations have only measured immediate post-intervention effects. Given these findings it was considered that further high-quality interventions research was warranted. This chapter reports on the methods and methodology used to develop, implement and evaluate a postnatal PA intervention, utilising a PAC approach alongside pramwalking groups. The intervention targeted healthy low-active women in the 12 months following childbirth to increase participation in MVPA, which guidelines suggest promotes health and wellbeing benefits (Haskell et al., 2007).

3.2.1 Developing, implementing and evaluating interventions

The development and evaluation of the MAMMiS study was conducted within the framework of complex health improvement interventions research as outlined by the Medical Research Council (Craig et al., 2008). This guidance begins from the premise that interventions designed to improve health are generally complex to design, develop, deliver, evaluate and report (Craig et al., 2008). Furthermore, the guidance states that although there are specific stages in intervention development and testing; these rarely follow a neat linear pattern, but are more likely iterative and cyclical. However, there is consensus that it is good practice to develop interventions in a manner that is systematic and takes cognizance of relevant theory

and evidence (Michie, Fixsen, Grimshaw & Eccles, 2009; Davidson et al., 2003). Furthermore, according to the MRC framework, evidence required to address research questions at different stages of the development, implementation and evaluation, lend themselves to different research designs. The main types of studies are:

1. *Feasibility studies*: these evaluations consider feasibility issues for larger studies, for example, the willingness of participants to be recruited and randomised, response/adherence rates and numbers of eligible participants, in addition to ensuring the suitability of outcome measures and interventions. Feasibility studies do not require randomisation or adequate power, but are used to determine time and resource needed to conduct an appropriate evaluation of the proposed intervention.
2. *Pilot studies*: small scale versions of a larger powered study are used to test whether studies can be run as intended. Pilot studies focus on whether aspects in the main study will run as intended. A pilot study will assess the primary outcomes in addition to testing processes such as recruitment, randomisation, intervention delivery and follow-up.
3. *Evaluation (effectiveness) studies*: powered investigations testing the effectiveness of the intervention on the outcome of interest. Randomised controlled trials (RCTs) are generally considered the most rigorous study design (Moher et al., 2010) for evaluation studies testing interventions to improve health. RCTs include a randomly allocated control group, which the intervention is tested against, thereby reducing possible bias due to researcher influence, natural changes that occur over time and placebo effects (Grimes & Schulz, 2000; Schulz & Grimes, 2002; Moher et al., 2010). There are standards of trial reporting, which researchers should adhere to (the CONSolidated Standards Of Reporting Trials (CONSORT)); these provide internationally recognised recommendations for the conduct and reporting of RCTs

(www.consort-statement.org). Trial reporting standards are important to ensure the research is adequately explained and can be critically evaluated. Finally, it is important to consider whether interventions are potentially adoptable by the target setting and institutions during the early phase of development and testing (Glasgow et al., 2001).

The MAMMiS study was an evaluation trial of the effectiveness of the physical activity consultation and pramwalking intervention on increasing postnatal physical activity among postnatal women. However, each section below discusses how I considered all aspects from the MRC framework, including issues of feasibility and piloting when adapting the intervention, implementing and evaluating the intervention during the MAMMiS effectiveness trial. Before describing the intervention and trial procedures in detail, the aims, objectives and research questions addressed in the MAMMiS study are given below.

3.2.2 Aims of the MAMMiS study

The primary aim of the MAMMiS study was to use a randomised controlled design to evaluate the effect of a PA intervention comprising of PA consultation (PAC) and a 10-week pramwalking programme (intervention condition) on postnatal PA levels compared with a standard information (control condition) on change in postnatal PA behaviour at three (post-intervention) and six months follow-up (three months post-intervention). Secondary aims were to determine the effect of the intervention on postnatal health and wellbeing indicators. I also sought to determine whether the intervention changed PA cognitions, which were socio-cognitive constructs targeted by the intervention.

3.2.2.1 Research objectives

The research objectives for the MAMMiS study were:

1. Identify and recruit a suitable number of healthy low-active postnatal women to take part in a randomised controlled trial (RCT) to test the efficacy of the intervention.
2. Conduct baseline, three and six month follow-up assessments of the primary and secondary outcomes according to standardised protocols.
3. Deliver PAC and pramwalking groups to intervention participants in line with intervention plans.
4. Describe baseline demographic, clinical and health behaviour characteristics of the intervention and control group.
5. Analyse and report on the effect of PA consultation and a 10-week pramwalking programme compared with a standard information on:
 - a. Objectively measured PA behaviour
 - b. Self-reported PA behaviour
 - c. Cardiovascular fitness
 - d. Anthropometric variables of weight, BMI, body composition and the proportion of postnatal women who were overweight and obese
 - e. Psychological wellbeing and fatigue severity
 - f. PA cognitions
6. Collect process information to report on feasibility
7. Explore intervention acceptability from the perspective of the postnatal women participating in the trial

3.1.2.2 Research Questions

1. What are the response, consent and retention rates for a postnatal PA intervention trial?
2. What are the characteristics of the recruited participants?

3. Does PAC and a 10-week pramwalking programme lead to PA behaviour change among postnatal women compared with standard information on postnatal PA and is this maintained three months post-intervention?
4. Does PAC and a 10-week pramwalking programme improve physical health and general psychological wellbeing and fatigue severity compared with standard information on postnatal PA and is this maintained three months post-intervention?
5. Does PAC and 10-week pramwalking programme change PA cognitions compared with standard information on postnatal PA and are any changes maintained three months post-intervention?
6. Is PAC and 10-week pramwalking programme a potentially feasible and acceptable intervention for delivery among postnatal women?

3.3 The MAMMiS intervention

The intervention consisted of an adapted PAC to enact postnatal PA behavioural change through motivational and behavioural self-management strategies (intervention techniques) in a one-to-one face-to-face setting. Each specific intervention technique was designed to target the theoretical mediator(s) and/or construct(s) from theoretical models (as discussed in Chapter One) shown to be empirically important for physical activity behaviour change. Furthermore, many techniques were shown empirically to be associated with effective change in postnatal physical activity interventions within the systematic review presented in Chapter Two. However, there are also published guidelines which specify the general structure, content and approach of PA consultations (PACs), in addition to the prerequisite communication skills required for consultants. These skills can be developed in health professionals and lay people through training therefore future implementation of this approach is possible, perhaps through health visiting services, community leisure staff and or walkleader volunteers who work for local councils/charities.

Usually, participants take part in an initial and follow-up PAC; the latter typically delivered several weeks after the participant has commenced their behaviour change attempt. Table 8 below shows how the practical strategies from PAC guidelines were delivered and the timing and nature of delivery in the MAMMiS study, with further details discussed below. As discussed in Chapter Two, most studies have found contact with participants during the change attempt to be helpful, often this is achieved through one or more support telephone calls, SMS-texts or another method. In the MAMMiS study the addition of a pramwalking group for postnatal women was a practical approach used to facilitate contact during the behaviour change process. Furthermore, the group pramwalking programme provided an opportunity to demonstrate brisk walking pace and enhance environmental opportunities for PA. A further benefit of using this approach is that walking can be

conducted at a moderate-intensity pace, suitable for health benefit, but without associated childcare barriers. Locally, there was interest among health visitors and the Walk about Stirling project managers in developing and testing pramwalking groups; both were in a position to facilitate groups therefore this is a potentially feasible approach in this population.

Table 8 below describes how I delivered behaviour change techniques recommended in PAC guidelines (Hughes & Mutrie, 2006; Loughlan & Mutrie, 1995), alongside specification of techniques from a taxonomy of behaviour change for PA interventions (i.e. the 40-item CALO-RE taxonomy) (originally reported as part of conference proceedings by Ashford, French, Sniehotta, Bishop & Michie, 2009 and published by Michie et al., 2011). Behaviour change taxonomies are lists of a set of distinct techniques which aim to change behaviour. There are benefits to specifying the exact techniques used interventions and how they relate to behaviour change targets. In particular, this makes the intervention replicable, intervention fidelity can be assessed and intervention effectiveness can be investigated by assessing whether change in proposed determinants mediated the impact of the intervention on behaviour (Michie & Abraham, 2004; Michie et al., 2009). The CALO-RE taxonomy was the most up to date version at the time of intervention development. As shown in Table 8, I considered which constructs from health behaviour change theory the techniques used in the MAMMiS intervention would seek to change. This also guided the choice of PA cognition measures for the study (discussed in section 3.3.2.1.1.6, PA cognitions).

In summary, the MAMMiS intervention consisted of a face-to-face PAC, which was delivered at the start of a 10-week group pramwalking programme (see Figure 5 for the intervention process). A post-randomisation PAC of between 35-45 minutes was delivered (usually at the end of the second outcome assessment appointment). A follow-up PAC (15 to 20 minutes) was delivered following three months outcome assessments. Written materials were used throughout guide the structure of the PAC via a workbook, which I developed for

this study (enclosed as separate file). Detailed intervention procedures are discussed below and summarised in Table 8.

Table 8. Intervention performance objectives, techniques, practical strategies and target constructs from behaviour change models

Performance objectives#	Timing/ Nature of delivery	Description of practical strategies	Behaviour change techniques ¹ <i>Processes of change</i> ²	Mediators (Models of change)
1. Has knowledge of the benefits of increasing PA in relation to recommended standards	First 1-to-1 PAC	<ul style="list-style-type: none"> • Assessment of habitual PA behaviour • Provision of information about guidelines for PA³ • Counsellor discusses discrepancy. • Decisional balance discussion of the pros and cons of increasing PA • Postnatal-specific benefits discussed 	<ul style="list-style-type: none"> ❖ Provide information on benefits⁴ of behaviour in general ❖ Provide information on benefits of behaviour to the individual ❖ <i>Self-reevaluation</i> ❖ <i>Consciousness raising</i> ❖ <i>Environmental reevaluation</i> 	Outcome Expectancies (TPB*, SCT, TTM**, HAPA)
2. Makes a behavioural resolution to change behaviour to meet personal PA goals	First 1-to-1 PAC	<ul style="list-style-type: none"> • Set realistic 3-months PA goals. 	<ul style="list-style-type: none"> ❖ Goal setting (behaviour) ❖ <i>Self-liberation</i> 	Intentions/Goals (TPB, SCT, TTM*** HAPA)
3. Has opportunities, skills and environmental conditions in place to <u>change</u> behaviour to meet personal PA goals	First 1-to-1 PAC	<ul style="list-style-type: none"> • Local opportunities for PA are explored • Invited to weekly pramwalking group. • Social support and environmental change requirements negotiated. 	<ul style="list-style-type: none"> ❖ Provide information on opportunities⁵ for where and when to perform the behaviour ❖ Plan social support for changes ❖ Environmental restructuring ❖ <i>Social liberation</i> ❖ <i>Helping relationships</i> 	Perceived/opportunities/Socio-structural factors (SCT, TTM***)
	Weekly pramwalking group	<ul style="list-style-type: none"> • Discussion and demonstration of moderate PA through walking • Gradually increasing PA towards meeting goals. 	<ul style="list-style-type: none"> ❖ Provide instruction on how to perform the behaviour ❖ Model/demonstrate the behaviour ❖ Set graded tasks 	Self-efficacy (TPB****, SCT, HAPA, TTM)

3. (cont. from above) Has opportunities, skills and environmental conditions in place to <u>change</u> behaviour to meet personal PA goals.	First 1-to-1 PAC and throughout intervention period using resource book	<ul style="list-style-type: none"> Plans are formed to specify the behaviour, location, frequency and duration of weekly PA. 	<ul style="list-style-type: none"> ❖ Action planning ❖ Teach to use prompt/cues ❖ <i>Counterconditioning</i> 	Action planning (TTM**, HAPA)
	First 1-to-1 PAC	<ul style="list-style-type: none"> Active alternatives to previous inactive behaviours encouraged. Highlighting of barriers to fulfilling PA plans. Problem solving through personal strategies to overcome barriers. If-then constructions prompt action when barriers experienced. 	<ul style="list-style-type: none"> ❖ Barrier identification/Problem solving ❖ <i>Stimulus control</i> 	Coping planning (TTM**, HAPA)
	Throughout intervention period using resource book	<ul style="list-style-type: none"> PA monitoring using a diary and pedometer. 	<ul style="list-style-type: none"> ❖ Prompt self-monitoring of behaviour ❖ Prompt review of behavioural goals ❖ Provide rewards contingent on effort or progress towards behaviour 	Action control (SCT*****, TTM**, HAPA)
	Weekly pramwalking group	<ul style="list-style-type: none"> Group review of progress and praise at each pramwalking group session. 	<ul style="list-style-type: none"> ❖ Provide feedback on performance ❖ <i>Reinforcement management</i> 	
	Second 1-to-1 PAC	<ul style="list-style-type: none"> Feedback about PA behaviour in light of previous personal PA goals. Setting of 6-month PA goals. 		
4. Has opportunities, skills and environmental conditions in place to <u>maintain</u> personal PA goals and prevent relapse from regular PA.	Second 1-to-1 PAC	<ul style="list-style-type: none"> Highlighting of situations leading to possible relapse. Problem solving through personal strategies to overcome barriers. Highlighting importance of continuous use of self-management strategies. 	<ul style="list-style-type: none"> ❖ Relapse prevention/Coping planning ❖ Prompt self-monitoring of behaviour ❖ <i>Stimulus control</i> 	Relapse prevention (RPM, HAPA*****) Action control

Note.

Performance objectives are actions or states that are pre-requisites for adoption of the behaviour change (Bartholomew et al, 2001). HAPA, Health Action Process Approach; PA, PA, PAC, PA Consultation; RPM, Relapse Prevention Theory; SCT, Socio-Cognitive Theory; TPB, Theory of Planned Behaviour; TTM, Transtheoretical model. ¹From Michie et al (2011); ²From Hughes & Mutrie (2006); ³From Haskell et al (2007), ⁴'Benefits' has been used instead of 'consequences' from the original taxonomy to reflect the discussion of positive effects of increasing PA rather than the consequences of failing to change PA⁵.⁵'Opportunities for' has been inserted to reflect the provision of information about places where PA *could* be performed. The decision on where and when the participant *will* be physically activity is negotiated. *Attitudes in the model. **Covered under decisional balance ***Covered under processes of change. ****Perceived behavioural control in the model. *****The reciprocal structure of the SCT supports the use of a feedback loop as part of action control strategies. *****Coping planning in the model.

3.3.1 Intervention procedures

3.3.1.1 First physical activity consultation

The first consultation included the following techniques: awareness raising regarding the PA guidelines for adults (participant's self-reported baseline PA data was used to aid discussion of current activity levels. This was in line with the most recent guidelines, which were available at the time of the study (i.e. the ACSM guidelines). Becoming aware of the how much PA is recommended is part of developing a discrepancy between current behaviour and guidelines. This may encourage individuals to re-evaluate and seek further information, develop their intentions for change and provides a basis for setting goals and directing ones' behaviour change efforts. Thereafter I encouraged a discussion of the benefits of increasing PA (particularly moderate and vigorous-intensity activity). As recommended within guidelines for conducting a PAC, I used a decisional balance sheet early on during the consultation to encourage participants to discuss their personal reasons for wanting to be active (pros or benefits of activity) and some of the things stopping them being active currently (cons or barriers to activity). Enhancing participants perception that benefits from PA outweigh barriers is considered important for developing intentions and motivation for change (Hughes & Mutrie, 2006; Kirk et al., 2004b). Thereafter participants were encouraged to set specific short (weekly) and long-term (three months from that date) activity goals and were advised to create a suitable action plan to achieve their goals (participants wrote down where, when and what PA they would take part in the following week). Goal-setting was collaborative and participants were encouraged to ensure weekly goals were specific and measurable in line with principles of goal-setting (Locke & Latham, 1990, cited in Loughlan & Mutrie, 1995), i.e. participant's stated the number of days they would be active for at least 30 minutes. This

specificity is important as it is more likely to lead to goal attainment (Bodenheimer & Handley, 2009). Furthermore, developing a PA action plan is designed to help translate intentions into actual behaviour change (Schwarzer, 1992). During this process local opportunities for being physically active were discussed with participants (e.g. pram-friendly walking routes, leisure facilities with childcare facilities) and if required I provided information about such activities. Participants were encouraged to think about PA could fit into their everyday live through substituting inactive activities for more active ones. This may be more effective in a population who find structured exercise to be challenging to fit into their routine. During the process of setting goals, participants were encouraged to increase their activity levels gradually, starting with more modest goals and building on past success by adding in additional planned activities on a weekly basis to reach long-term goals. For example, a participant might set a long term goal being active for at least 30 minutes five times per week (in line with activity guidelines), but in their first week set a goal of two sessions of PA for 20 minutes each, adding both frequency and duration of sessions each week. Gradually increasing PA levels was designed to increase participant's self-efficacy for being physically active and coupled with self-monitoring (participants were asked keep a diary of their PA participation by writing down the number minutes they were active for each day), this allowed participants to monitor their PA progress during the intervention. Self-monitoring has been shown to be the most important predictor of success in PA behavioural change in the general population (Michie et al., 2009) and has been successfully used in relation to walking and PA behaviour change (Baker et al., 2008; Fjeldsoe et al., 2010).

In addition to their weekly activity goal, participants who intended to walk as part of their planned PA were encouraged to set step count goals and monitor steps per day

using a pedometer and write down their target step goals and actual steps in a diary. Both written diaries and pedometers have been shown to be effective for self-monitoring (Ayabe et al., 2010). To ensure a realistic step goal, all participants wore a sealed pedometer during the baseline measurement week; and by calculating their average daily step counts (e.g. total weekly step count/number of wearing days), I was able to provide information regarding the number of daily steps participants should aim for on their 'active days'. For example, a participant whose average baseline daily step count was 4,000 steps per day was encouraged to set a long-term step count goal of 7,000 steps per day on 3-5 days of the week (according to personal preferences and in line with their activity goal). The addition of 3,000 steps onto baseline was based on the premise that this is approximately equivalent to an additional 30 minutes of walking (Tudor-Locke et al., 2009). As with PA more generally, participants were advised to gradually increase their step count goal, in line with previous research, which has shown this to be an effective approach for increasing walking participation (Baker et al, 2008). To aid monitoring of walking behaviour, participants were given a pedometer (Omron, HJ-152, Walking Style One) and were advised on how to use it to monitor daily steps and record this in the diary provided (either in addition to or instead of their number of active minutes per day).

A further technique that was used throughout the PAC was teaching participants to use coping planning strategies to overcome barriers to implementing their PA plan. Barriers to being active were first discussed during the decisional balance exercise and as previously discussed many of the 'cons' or downsides of being active were the things that participants reported as stopping them from being as active as they would like (common barriers reported were: lack of time, no access to childcare and preferring to spend time with friends and family). To facilitate coping planning, participants were given advice

regarding individual-level environmental restructuring (e.g. making plans to meet friends on a day when the car is unavailable) and making use of available social support for changing their PA behaviour (e.g. ask their partner to look after their baby to attend a fitness class). Participants were introduced to the use of implementation intentions (Gollwitzer, 1999) ‘if...then plans’ as a suitable format for writing down their self-generated coping plans. This was used to help create a mental link between experiencing the difficult situation and the method for coping with that barrier (e.g. *if* the day I normally go out for my walk around the park is raining *then* I will do my home exercise DVDs instead). This included inclusion of implementation intentions as a technique for problem solving to overcome barriers to behaviour change, as this was based on recent research regarding their effectiveness in adult female populations (e.g. Stadler et al., 2009). At the end of the first PAC participants were invited to attend a pramwalking group in their local area each week for 10 weeks. Usually I would provide participants with the walking programme, which covered the next 4-5 weeks of planned walks in their area.

3.3.1.2 Walking groups

In the early stages of the trial, two group walks (i.e. walks took place on different days and times) were offered in the Central Stirling area, this was later reduced to one group as I had to develop groups in other regions once recruitment to the study was extended. For example, in Falkirk CHP two groups were established; one in the Grangemouth/Falkirk and the other Larbert/Stenhousemuir area. At the same time a large recruitment drive, in rural Stirlingshire resulted in a final group, which was established to cover participants from these areas. Figure 2 shows the area covered by the Central Stirling group(s), with the most common routes signposted. Figure 3 shows common walking routes throughout

the Grangemouth/Falkirk and Larbert/Stenhousemuir area. As the rural group walks were spread across a vast area throughout the northwest of Stirlingshire, walking routes are not shown. Walking groups were started when at least two participants were recruited from each area, and stopped when no new participants from that area were recruited to the trial. Walk cancellations were undertaken following local and/or national recommendations from police that travel across the region should be avoided unless necessary, although as discussed in Chapter Four this occurred infrequently. Under these circumstances, participants were normally notified on the morning of the walk of the cancellation by phone or SMS-text.

Figure 2. Map of Central Stirling showing common walking routes

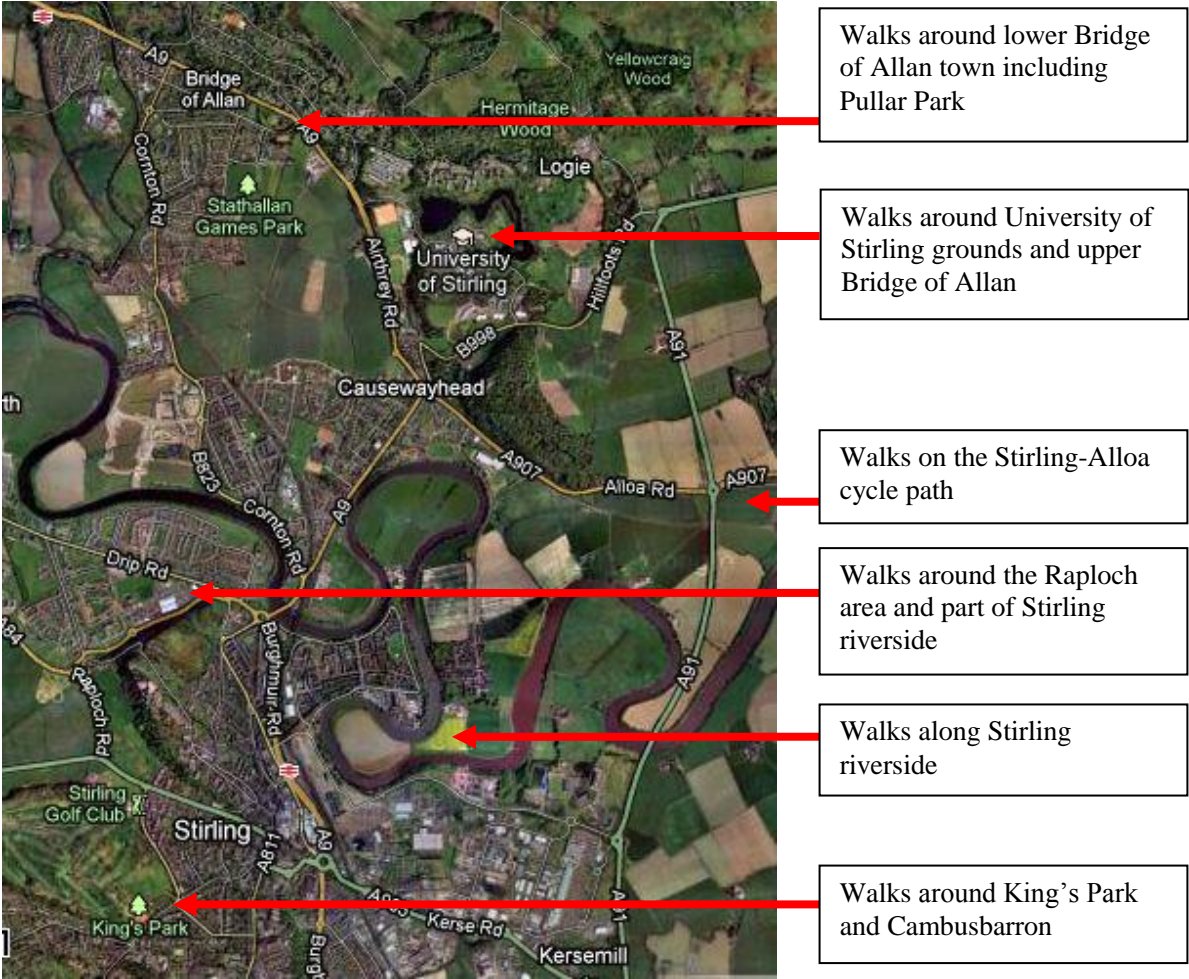
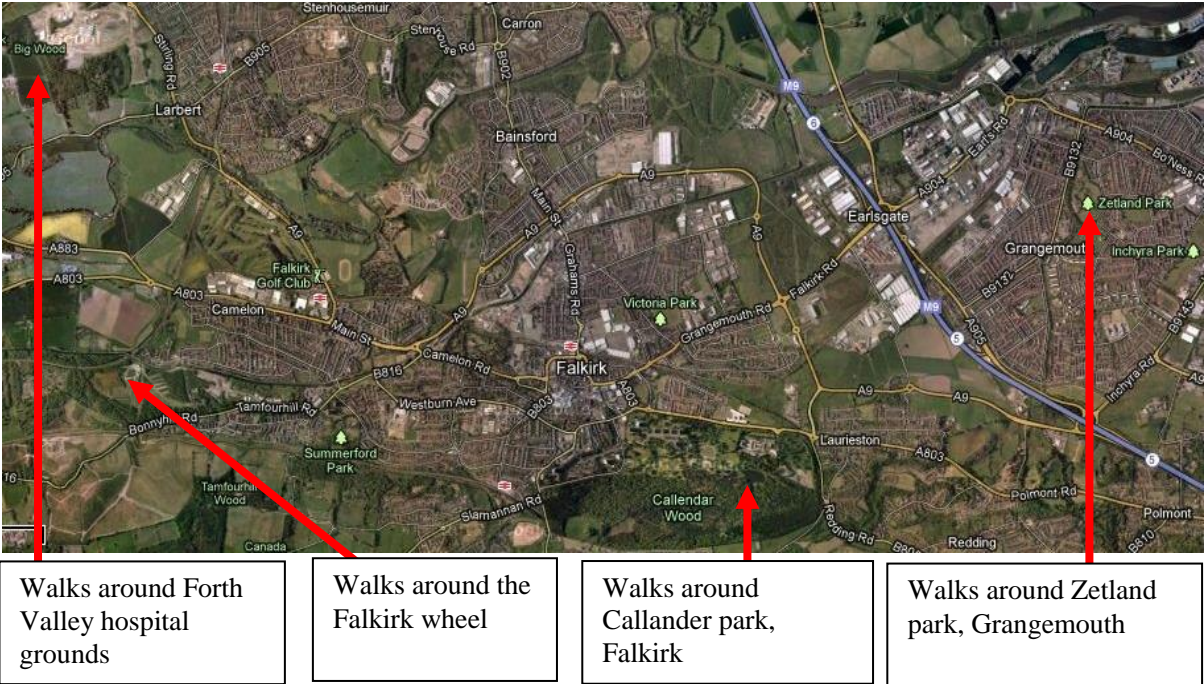


Figure 3. Map of Larbert/Falkirk/Grangemouth showing common walking routes



3.3.1.2.1 Planning for walking groups

Planning for the pramwalking groups involved a series of stages. Local routes were identified through links with local authority funded PA organisations (Active Stirling and the Falkirk Community Trust). Walking coordinators suggested routes, which I mapped and risk-assessed, making modifications to ensure they were suitable for mothers with prams. Risk assessment included gathering information on the quality of walking paths, likelihood of conditions being icy or slippery underfoot, proximity to roads and crossings, and transport options for getting to routes (Appendix 4). These procedures were important to ensure the safety of postnatal women taking part in the intervention. I also received walk leader training to facilitate groups.

The walking programmes was advertised as pramwalks, however walks that took place within the rural and outlying areas of Stirling were mostly unsuitable for prams due to the nature of paths and walking opportunities in this area. In order to support mother

and baby walks in this region, participants were asked if they would consider using a baby carrier, which all of the participants in the study had access to. Once I had identified and risk assessed routes, a walking programme was developed, however the day and time for the group was negotiated with participants as they were recruited into the study in order to maximise adherence to the intervention.

3.3.1.2.2 Walking procedures

Walks were conducted for 10 weeks at a moderate-intensity (e.g. brisk pace) for 30-55 minutes, and usually included a five-minute warm up and cool down at the start and end of each session. The rationale for the 10-week programme was to provide sufficient time for participants to gradual build up a walking habit in line with their physical activity goals and action plans (agreed during the first consultation). Previous research had shown improved fitness following 12 weeks of pramwalking (Armstrong et al., 2003, 2004).

Pace was monitored during most walks using an iPhone tracking app (unless poor signal or low battery prevented this), which provided details of time, distance and miles per hour (mph). During the PAC participants who anticipated difficulties attending the walking groups (e.g. due to childcare commitments for older children, transport difficulties or personal preferences) were encouraged, to plan alternative PA opportunities in line with their personal activity goals.

Participants who did not attend the pramwalking group in the first two weeks (either did not turn up on the day or had mentioned at the first PAC that they would not be able to attend) received a 10-minute support phone call encouraging efforts towards being more active. This offered an opportunity to support participants to adopt a problem solving approach to addressing initial barriers they were experiencing adopting PA in line with the plans set during the first PAC. Pramwalking also lasted 10 weeks to ensure

attendance had been completed prior to the first follow-up measurement period (3-months from baseline). This ensured any change in physical activity measured during the follow-up week was not attributable to merely attending the pramwalking group during the follow-up, effectively separating delivery and evaluation of the intervention (discussed below).

3.3.1.3 Second (follow-up) physical activity consultation

The second PAC took place after the three month follow-up measurement period, after the walking programme ended and three month follow-up assessments were undertaken. It was designed to build on the first by providing participants with feedback on their progress from baseline to three months. This personalised feedback used information from the self-report PA questionnaire and follow-up pedometer readings (where appropriate). These were gathered as part of the measurement protocol for the three-month assessment period. During the second PAC participants were reminded about the importance of utilising the motivational and self-regulatory strategies introduced during the first PAC and were encouraged to use these to continue with an active lifestyle through continuing to set goals, plan and monitor their activity as their circumstances changed (e.g. as their baby got older or they returned to work). This approach aimed to prevent participants returning to previous sedentary habits in line with the Relapse Prevention Model (RPM), which PAC guidelines suggests is an important part of follow-up consultations (Loughlan & Mutrie, 1995; Hughes & Mutrie, 2006). If participants had not increased their PA there was the option to explore barriers they had experienced and what strategies had been useful in overcoming these. Regardless of PA levels at three months follow-up, intervention participants were asked to write a specific goal for the six month-follow-up point, which recorded their aim for how many days per week they would be physically

active for at least 30 minutes. Participants who were mainly active through walking were able to set a step count goal for their aim to achieve an average number of steps per day.

3.3.1.4 Comparison (control) information condition

The intervention and control group both received a leaflet after baseline assessments. The ‘Active living during and after pregnancy’ leaflet was developed by NHS Health Scotland and provides information on the PA guidelines and suitable activities (e.g. brisk walking, swimming). The control group continued to receive standard postnatal management as appropriate and took part in all outcome measurements.

3.4 Evaluation approach

3.4.1 Study design

The MAMMiS study employed a single-site RCT design. To conduct a RCT with sufficient methodological rigor considerations must be given to elements of the research protocol such as methods of randomisation, allocation concealment and blinding. Previous research has found poorly implemented RCTs have overestimated trial effects (Schulz, 2000; Schulz & Grimes, 2002), which is detrimental to the accumulation of research evidence regarding the efficacy of interventions. There are published guidelines for conducting and reporting of RCTs. The MAMMiS trial was registered: Current Controlled Trials ISRCTN79011784 (<http://www.controlled-trials.com>) and the protocol was published in a peer-reviewed journal (Gilinsky, Hughes & McInnes, 2012). The study also included provision for post-trial interviews, with the aim of assessing acceptability of the intervention among postnatal women.

3.4.1.1 Randomisation

Randomisation was carried out using simple randomisation from a computer-generated sequence with block sizes of 4 and 6, generated by an independent person. In order to ensure concealment of allocation the same independent person placed group identifier cards (e.g. intervention or control) into numbered envelopes alongside a piece of card. This ensured envelopes could not be held up to the light to reveal group identification. Envelopes were sealed, numbered and stacked sequentially and participants were assigned an envelope according to the order in which they enrolled into the study. This process is known as sequentially numbered, opaque, sealed envelopes (SNOSE). This is not generally considered the best method for ensuring the process of randomisation and allocation is carried out without potential interference from researchers; central on-site allocation by an independent person is preferred (Doig & Simpson, 2005). However, the present study this method was used as most participants' appointments took place within their own homes, often outwith regular office hours.

3.4.1.2 Blinding

Blinding of participants and outcome assessors to study group is considered important for methodological rigor in RCTs (Moher et al., 2001). However, there are limitations to blinding within applied interventions research and due to factors such as equipment requirements, ethical issues and resource implications. Participant blinding is generally not possible in health improvement interventions. In the MAMMiS I was blinded at baseline as all assessments took place prior to randomisation (See Figure 5). This was not possible at follow-up assessment periods, therefore to minimise bias we implemented standardised study protocols for the collection of outcome measures and used objective

methods for assessing outcomes wherever possible. These procedures are detailed in the outcomes assessments section for each measure.

3.4.1.3 Sample size

It is important to estimate sample size prior to recruiting to a trial to ensure outcome data will be sufficiently powered to detect an effect of the intervention if one exists. Normally, power calculations involve using the standard deviations from previous studies with comparable interventions and outcome measures. However, as the MAMMiS study was the first complex health intervention to use accelerometers to measure change in PA levels among postnatal women, the sample size calculation used to assess recruitment numbers for the MAMMiS study was based on data from a previous study comparing a 12-week PA intervention in insufficiently active breast cancer survivors with usual care (Rodgers et al., 2009). Rodger et al. (2009) measured change in weekly minutes of MVPA from baseline to three months using accelerometers. Although the primary outcome in the MAMMiS study was raw accelerometry counts, unlike this raw data, which has no clinical relevance, an increase of 60 minutes of MVPA per week is clinically significant for women's cardiovascular health (Manson et al., 1999). Research has shown heart disease is the leading cause of mortality and morbidity among women worldwide (World Health Organisation, 2014). Physical inactivity across the lifespan has been shown to be the leading factor, which predicts relative risk for developing heart disease among women over 30 (Brown, Pavey & Bauman., 2014). An intervention showing an increase in physical activity of at least 60 minutes of MVPA per week would therefore be expected to have a beneficial impact on postnatal women's health.

Assuming power of 90%, 5% significance level with a two-sided unpaired t-test to detect change from pre to post-test between the intervention and control group using a

pooled standard deviation of 75 minutes/week (from Rogers et al., 2009); 31 participants per group were required in order to detect an effect of 63.83 minutes/week of moderate-vigorous PA (MVPA) participation using accelerometers. In line with similar PA interventions conducted within postnatal populations (Cramp & Brawley, 2006; Fjeldsoe et al., 2010), it was assumed there would be around a 20% dropout, therefore up to 76 postnatal women were sought over the recruitment period. The sample size calculation was verified by an independent statistician at the University of Stirling.

3.4.1.4 Recruitment and setting

Recruitment to research studies can be challenging and can take a long time. Often the study sample poorly represents the population of interest as people from more deprived backgrounds, younger people and ethnic minorities are less likely to take part in research (Yancey, Antronette, Alexander, Kumanyika & Shiriki, 2006; Goodman & Gatward, 2008). Anticipating such difficulties I recruited over a 13 month time-period (February 2011 until March 2012) from a NHS region within Central Scotland (NHS Forth Valley), which served a diverse range of communities (in terms of socio-economic status and urban and rural classification, although ethnic minorities are underrepresented). NHS Forth Valley comprises three Community Health Partnerships (CHPs) (Stirling, Falkirk and Clackmannanshire). The area covers a population of approximately 300,000 (“NHS Forth Valley: about us,” 2010) and in 2010 recorded 3,268 births. Recruitment was limited to two regions, Stirling and Falkirk, as health visitors in Clackmannanshire were already engaged in postnatal pramwalking, which would potentially lead to contamination. However, this underlies interest in this approach.

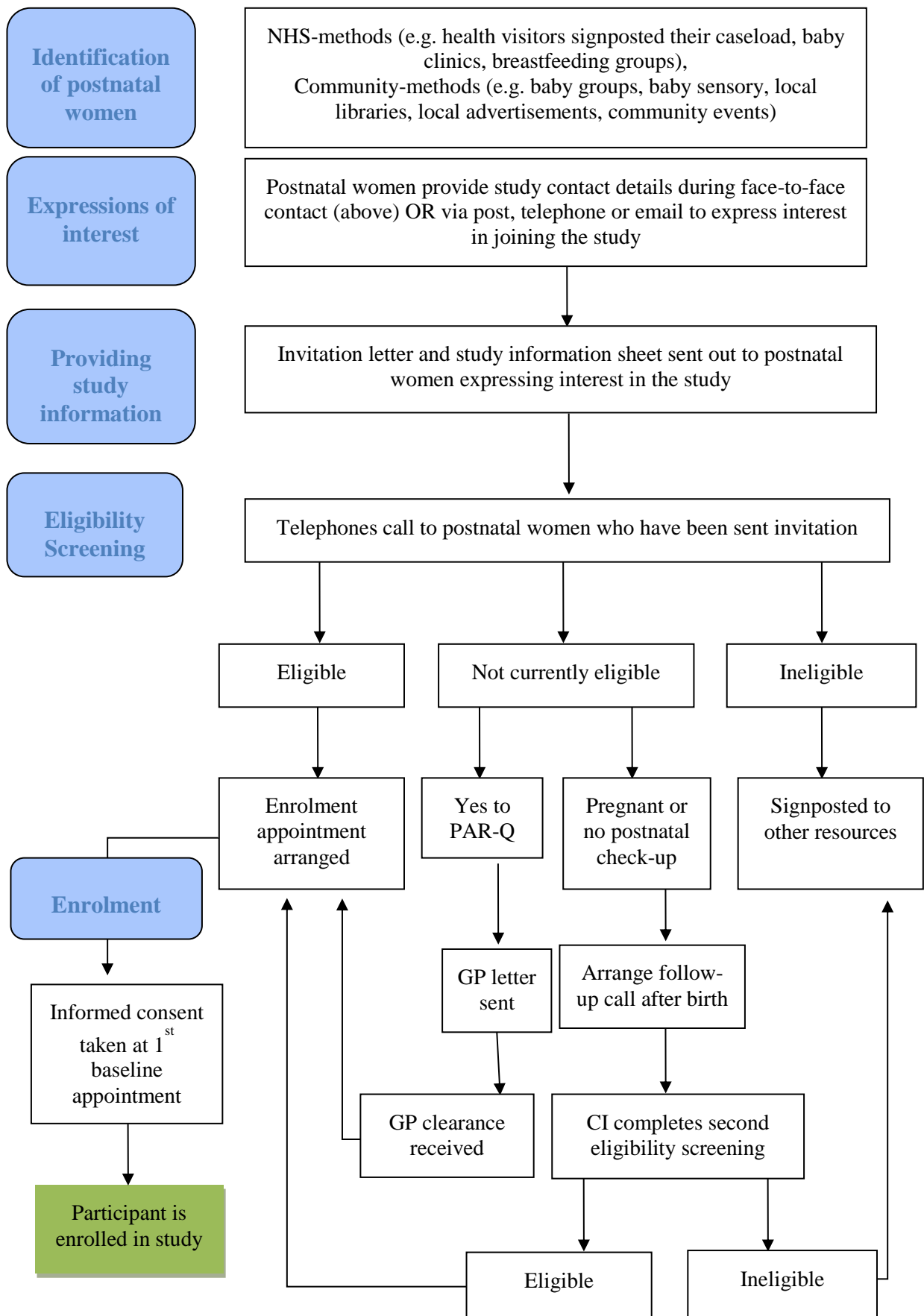
I adopted a variety of recruitment strategies. These included attendance at several baby and toddler groups, baby reading sessions within local libraries and baby sensory

classes (locally-run franchises running private classes for infants and toddlers, available across the recruitment regions). Advertisements were placed in local media and recruitment also relied on participant recommendations; I also attended other local community based events. The research team had good links with NHS contacts in order to facilitate identification of potential postnatal women for recruitment to the study.

The procedures used for identifying and recruiting participants into the MAMMiS trial are shown in Figure 4. To identify postnatal women who might be eligible to participate in the MAMMiS trial, both NHS and community-based methods were used. Different methods were used within different CHP regions due to the unique circumstances within each area. There was a central health visitor contact within Stirling CHP, who managed distribution of advertising materials to all health visitors. In contrast, in Falkirk CHP, individual health visitors were asked to come forward to provide opportunities for face-to-face contact with postnatal women via NHS baby clinics and breastfeeding groups in specific demographic areas. This approach was used in order to encourage participation from less affluent postnatal women who are traditionally less likely to take part in research studies (Goodman & Gatward, 2008). Study advertising materials were given to women during routine postnatal care (leaflet, Appendix 5) or placed on noticeboards in NHS premises (poster). Postnatal women were asked to provide their contact details to express interest in joining the study. I received contact information via a contact details form, email or telephone. A freepost envelope was included in each leaflet pack. A study website was developed to facilitate recruitment (www.mammis.weebly.com) and I widely disseminated advertising materials. During face-to-face contacts (i.e. during baby clinics) I took postnatal women's contact details in person. Contact details for potentially interested postnatal women were entered onto a

secure password protected database. Contact details were used to send postnatal women an invitation letter study information sheet (Appendix 6), which provided detailed information about participating in the study. The invitation letter informed each potential participant that they would be contacted by telephone to complete an eligibility screening process (described below) and that they would have an opportunity to ask any questions about the study. All postnatal women were telephoned, usually 3-5 days after posting the invitation letter and study information sheets. I made repeated effort to make contact by phoning interested women up to four times in order to ensure as many of those initially expressing interest in the study completed the eligibility screening process (Figure 4).

Figure 4. **Recruitment process for the MAMMiS study**



3.4.1.5 Inclusion/exclusion criteria

Guidelines for PA in the postpartum period specify resumption of moderate-vigorous intensity PA should commence when it is ‘medically safe’ (Artal & O’Toole, 2003). Although there are individual variations within this, it is generally considered to be after the physiological and physical effects of pregnancy have gone (around 4-6 weeks after childbirth). As every postnatal woman in the UK is offered a 6-8 week postnatal check-up, this was chosen as the criteria for enrolment in MAMMiS. Furthermore, as the MAMMiS study was designed to increase adoption of PA in postnatal women who were insufficiently active, we adopted criteria which excluded women who self-reported already meeting PA guidelines (Haskell et al., 2007). Therefore, if participants met all criteria the first baseline appointment was set up and postnatal women were then enrolled after signing informed consent form (Figure 4).

Prior to baseline appointments an eligibility screening telephone call was conducted (usually within a week of sending out the study information) to assess whether interested women met the inclusion/exclusion criteria (Table 9). I asked a series of screening questions to assess eligibility for inclusion. I recorded date of birth, date of birth of women’s youngest child, whether they had received their postnatal check-up and whether there was a possibility that they could be pregnant or are planning to become pregnant in the next 6 months. Other inclusion criteria relating to their current PA level and medical readiness for PA was assessed as described below. No exclusions were made based on characteristics of the baby; twins or multiples; prematurity and/or admission to a special care baby unit.

Table 9. Study inclusion and exclusion criteria

Inclusion criteria

Postnatal women were eligible for inclusion if they met the following criteria:

- 18 years of age or older.
- Had given birth in the last year to a live infant
- Had received a 6-8 week postnatal check-up with a suitable health professional (GP or health visitor).
- Were insufficiently active at the level required to promote and maintain health (according to PA guidelines) as assessed via the PA Stages of Change Questionnaire (i.e. were classified as in ‘Contemplation’ or ‘Preparation’ stages of change)
- Were able to communicate verbally, and in written format, in English.

Exclusion criteria

- Had medical contradictions to PA¹
- Were pregnant, or were planning to become pregnant in the next 6 months.
- Were in ‘Action’ or ‘Maintenance’ Stages of Change

Note.

¹Unless they received GP clearance to take part in the study.

3.4.1.5.1 Assessing current physical activity levels

The PA Stages of Change Questionnaire was used (Marcus, Rakowski & Rossi, 1992) as a self-report method for assessing whether individuals would likely benefit from a PA intervention and should be included in the study. This provided a self-report assessment of current PA levels and motivational readiness for behaviour change through assigning individuals to a stage of change from the TTM. Postnatal women were asked to choose a statement that they felt best described them from one of the following options (they were advised that): “*By regular PA I mean accumulating at least 30 minutes of moderate-intensity PA on at least 5 days of the week and by moderate activity I mean activity that makes you breathe faster than usual and sweat a bit, but you can still talk, equivalent to a brisk walk.*”:

1. I am not regularly physically active and do not intend to be so in the next six months (Pre-contemplation).
2. I am not regularly physically active but am thinking about starting to in the next six months (Contemplation).
3. I do some PA but not enough to be regularly physically active (Preparation).
4. I am regularly physically active but only began in the past six months (Action).
5. I am regularly physically active and have been so for longer than six months (Maintenance).

Postnatal women choosing statements 2 and 3 (i.e. ‘Contemplation’ and ‘Preparation’ stages) were eligible for inclusion in this study as those in ‘Action’ or ‘Maintenance’ stage were likely to be already physically active. It was considered unlikely that postnatal women who were in Precontemplation stage would express an interest in joining the study and I found this during screening.

3.4.1.5.2 Assessing medical contraindications

To assess whether there were any medical contraindications to PA the eligibility screening telephone call included the PA Readiness Questionnaire (PAR-Q) (Thomas, Reading & Shephard, 1992). The PAR-Q consists of seven closed questions relating to health status, for example “*Do you feel pain in your chest when you do PA*”. The PAR-Q is designed to determine whether it is medically appropriate for adults between the ages of 15-69 to increase their activity levels. Answering “No” to all questions indicates participants are medically safe to begin gradually increasing PA levels. If the potential participant answers “Yes” to any of the questions, it is recommended that they seek medical advice before increasing their PA.

3.4.1.5.3 Feedback from screening

At the end of the telephone call women were advised of the outcome of screening. All women who were not eligible were signposted to other appropriate PA resources (e.g. the Active Stirling website). Otherwise women were advised of one of the following:

1. They were eligible to join the MAMMiS trial and the first baseline appointment was arranged.
2. They were not eligible to join the MAMMiS trial and advised of the reason for this (e.g. they were already active; they were more than 12 months postpartum).
3. They were not currently eligible but may be eligible in the future (normally due to answering “Yes” to any of the PAR-Q questions, or currently being pregnant or had not yet had their postnatal check-up). If this was the case the CI explained that they might still be eligible for inclusion following clearance from their GP or after pregnancy or their postnatal check-up. Postnatal women ineligible due to the PAR-Q assessment were provided with a letter describing the study for their GP in order to provide medical clearance. Following receipt of GP clearance participants were contacted to arrange a baseline appointment. A suitable date was arranged for the CI to contact the individual again if the reason for ineligibility was pregnancy or no postnatal check-up. This resulted in a second eligibility check for some participants (see Figure 4).

3.4.1.6 Enrolment

As shown in Figure 4, participant enrolment in the trial took place at the first baseline appointment prior to all assessments being completed. Participants signed and dated two copies of the trial consent form to confirm that they had read and understood the information sheet and were happy to take part in the study. Participants took one copy and

the CI retained the other. Participants were advised their GP would be informed that they had joined the study. Participants were informed that they might be asked to take part in further research at the end of the study and would be asked for further consent at this time.

3.4.1.7 Ethical considerations

It is important to obtain ethical approval for research conducted with human participants as there are ethical issues that arise as a result of the process of approaching and consenting postnatal women to take part in a trial such as the MAMMiS study. Furthermore, there are ethical considerations with regards to defining the study eligibility criteria, adopting the randomisation, interventions and outcomes approach and with regards to what procedures are put in place to address any possible concerns raised by participants during the trial, including experiencing physical and psychological discomfort and distress or if participants wish to withdraw from the study (British Psychological Society (BPS), 2010). As part of the development process for the MAMMiS trial ethical approval was sought from both the National Health Service (NHS) and University of Stirling Research Ethics Committees (RECs). NHS approval (from the NHS Fife and Forth Valley Research Ethics Committee) was considered important due to the recruitment process identifying postnatal women by virtue of their NHS care (i.e. as discussed above, health visitors were asked to give out advertising materials and to promote the study to postnatal women within their care). Also NHS approval was required if any recruitment was to take place on NHS-sites (e.g. at baby clinics or breastfeeding groups). As I was registered as a postgraduate student with the School of Nursing, Midwifery and Health, university procedures required approval from the School REC in addition to NHS approval. The process of approval involved a rigorous examination of the possible ethical issues involved in undertaking the research and how

these have been addressed. All MAMMiS advertising materials, study information sheets and consent forms and data collection forms, tools and procedures were checked and received ethical approval from both committees. The process of taking informed consent from participants also followed good practice guidance (BPS, 2010). Consent was taken face-to-face following a gap between postnatal women receiving the study information sheet (See Figure 4). Furthermore, information sheets were written in plain English advised postnatal women to seek advice before agreeing to take part in the study and provided contact details for a named independent person.

3.4.2 Evaluation methods

The evaluation framework for an intervention should first and foremost be able to test the research questions posed (Moher et al., 2010). Therefore, to answer the question of whether the intervention changed postnatal PA behaviour, we required a suitable measurement approach for this outcome. As discussed in detail in Chapter One, different PA options are available to researchers seeking to measure the impact of PA interventions. When choosing a measurement approach in any study researchers must carefully consider issues such as cost, availability of resources and settings, researcher and participant burden, likely compliance and suitability of the measurement. Given the findings from Chapter One regarding the advantages and disadvantages of using physiological proxy measures, self-report measures and objective measures of PA, evaluation of PA within the MAMMiS study utilised all three forms of measurement (e.g. a direct objective measure of PA behaviour using accelerometers and self-reported PA via a recall questionnaire over seven days of measurement, and cardiovascular fitness (measured via a submaximal test). PA change was measured using the Actigraph GT3X/GT3X+ accelerometers, the Seven-Day Physical Activity Recall (7-Day PAR)

questionnaire and via the Chester submaximal step-test. As discussed in Chapter One these were acceptable, reliable and valid forms of PA measurement for measuring adults' PA behaviour.

PA has health and wellbeing implications for postnatal women (Pivarnick et al., 2006). As such it can be important to measure change in these outcomes within intervention studies as part of evaluating the impact of the intervention. The secondary health and wellbeing outcomes that were measured in the MAMMiS study were chosen because they represent important indicators of morbidity and mortality in the general population and as discussed in Chapter One are commonly cited as important outcomes within studies conducted with postnatal populations due to clinical relevance in the year following childbirth. The following measures were included in the MAMMiS evaluation: weight-related anthropometric variables, psychological wellbeing and fatigue severity. These have shown to be sensitive to changes in PA participation in clinical samples (i.e. OW/OB women, women meeting criteria for PND) but it is unclear to what extent positive effects will be found in a general healthy sample of postnatal women. If implemented in real-life settings it is likely that PAC and pramwalking would be targeted at healthy low-active postnatal women so it is important to consider this.

3.4.2.1 Evaluation procedures

Figure 5 details flow through the study, with assessment timing shown in relation to recruitment, randomisation and intervention delivery. Participants were assessed at baseline, three months and six months follow-up with each measurement period taking place over a minimum of two assessment appointments, usually one week apart to allow for accelerometer data collection.

Table 10 shows the data that was collected at each appointment during each measurement period and the order used. The rationale for the ordering was psychological wellbeing and fatigue measures should precede the weight/body composition assessment and the cardiovascular fitness test, respectively. It was anticipated that postnatal women might experience a lowering of mood following weight/body composition assessment and an increase in fatigue following the fitness test. Guidelines for measuring psychological wellbeing recommend they come before other measures of health status (Chasnay et al., 2004). Accelerometers were normally provided at the end of the first appointment and returned at the beginning of the second appointment reducing participant burden.

Prior to the first appointment during each measurement period participants were mailed information confirming the date, time and location of the appointment, details about what to expect to during the appointment and instructions on pre-appointment behaviours to improve the accuracy of the measurements. The instructions were not to drink caffeine in the four hours prior to the first appointment during each measurement period and to avoid participating in any intense exercise at least 12 hours prior to the first appointment, which were in line with the specifications for conducting the cardiovascular fitness test. Participants were also asked to avoid a large meal and pass urine prior to attending the first appointment in each measurement period; also avoid taking diuretics in the seven days prior to the appointment, and to avoid alcohol in the 48 hours prior to appointment. These instructions were in line with the specifications for conducting bioelectrical impedance assessment of body fat (Tanita, technical notes).

Completion of the assessments normally took between 45 minutes to an hour (first appointment) and between 20 minutes to 30 minutes (second appointment). The first baseline appointment took longer than all other appointments due to taking informed

consent, gathering demographics details and spent time building rapport. This baseline appointment was crucial for ensuring good compliance with the study and to increase the likelihood that participants would return for all other appointments. To reduce participant burden, the first PAC was tagged onto the end of the second appointment at baseline (following randomisation) where possible. All appointments took place at the University of Stirling or in participants' homes, according to personal preference.

Table 10. Timing of data collection at baseline, three and six months

1st appointment

- Demographic details¹
- Psychological wellbeing (measured using the AGWBI questionnaire) & fatigue (measured using a VAS)
- Cardiovascular fitness (measuring using the CST)
- Height¹, weight and body composition (measured using bioelectrical impedance)
- Participants given an accelerometer

2nd appointment

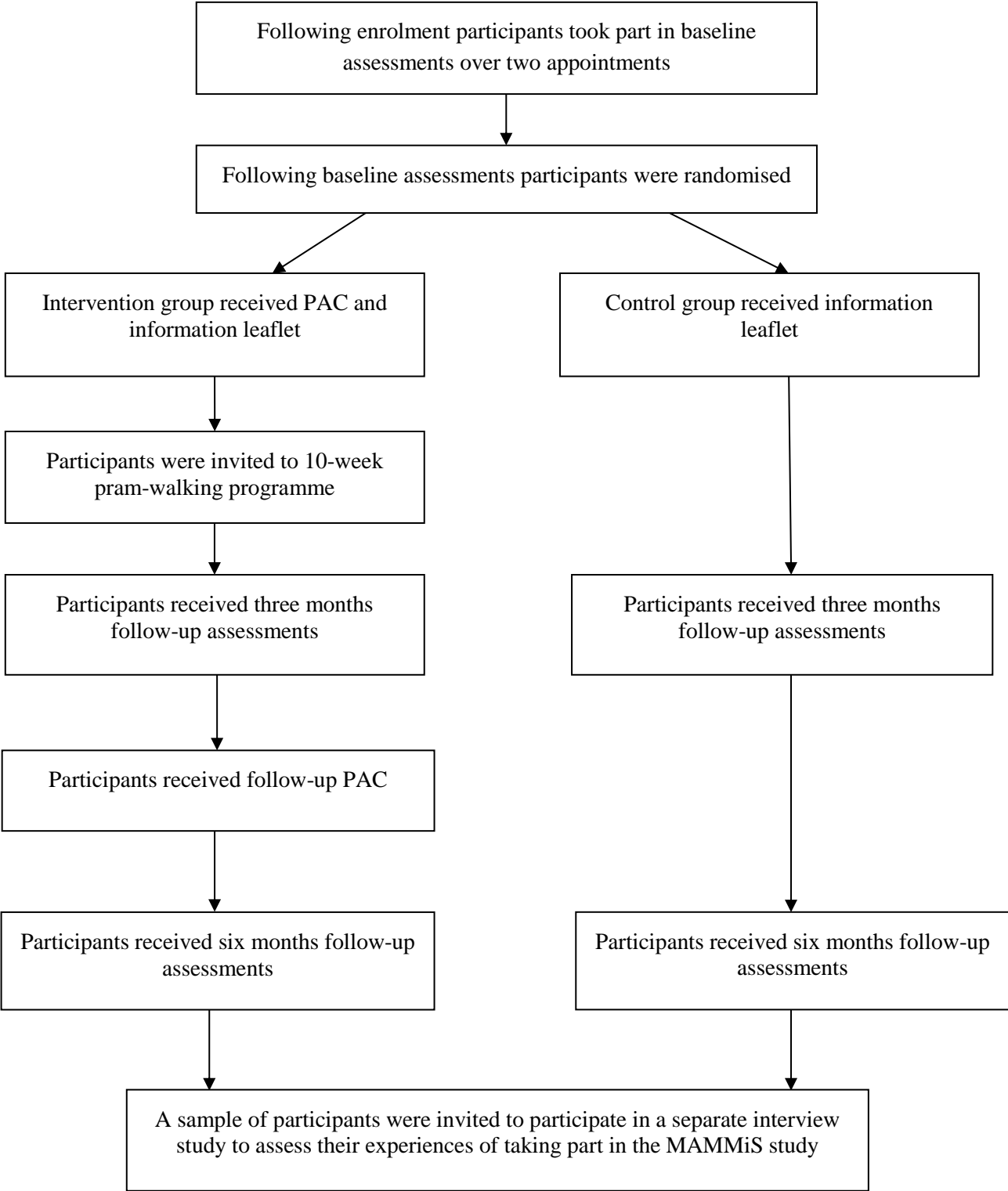
- Accelerometer returned
- Physical activity cognitions (measured via a questionnaire developed for this study)
- Self-reported time spent in moderate and vigorous PA during the previous week (measured using the 7-Day PAR)

Note.

¹Baseline measurement period only

CST, Chester Step-test, PAR, PA recall, VAS, Visual analogue scale

Figure 5. Outcome assessments and intervention process



3.4.2.1.1 Procedures for outcome assessments

3.4.2.1.1.1 Accelerometer procedures

As discussed in Chapter One a range of motion sensors are commercially available and choice of accelerometer depends on the requirements of the population under study, cost and participant burden and the reliability and validity of measurement required to answer the research questions for the study. The Actigraph range of accelerometers has been extensively studied and activity counts show good evidence of reliability and validity for measuring free-living PA (discussed in Chapter One).

As the newest version of the Actigraph accelerometers, the GT3X/GT3X+ were available from 2009, these were chosen for use in the MAMMiS study. These accelerometer models were also chosen as they provided a greater amount of battery life and memory capacity compared with earlier models. Although the GT3X/GT3X+ are triaxial accelerometers, they can be compared with data from earlier Actigraph accelerometers, when using activity counts from the single (uniaxial) axes. The specifications of the accelerometers used in the MAMMiS study are shown in Table 11. Although there are no reported differences between the two accelerometer models used in terms of their ability to reliably and accurately measure PA behavior, participants were measured using same models at baseline and follow-up.

Table 11. Specifications of the GT3X and GT3X+ accelerometers

Name	Type/Size/weight	Memory capacity/Battery life	Data provided ¹	Additional features
GT3X	Tri-axial/ 3.8cm x 3.8cm x 1.8cm/ 27 grams	4MB storage Up to 20 days	Activity counts Step counts	None
GT3X+	Tri-axial 4.6cm x 3.3cm x 1.5cm 19 grams	Up to 40 days	Activity counts Step counts	Water resistant 1 meter for up to 30 minutes
<p>Note. ¹Only the data relevant to the MAMMiS study is included here, although both monitors are capable of providing a variety of other information (i.e. sleep quality, EE).</p>				

Studies using accelerometers must carefully consider issues related to their data collection and analysis protocol including: positioning on the body, epoch length, classification of non-wear time, handling of missing data and whether to collect self-report data alongside motion sensor information. Regarding positioning on the body, the standard protocol in healthy adults is to advise that the accelerometer be worn on a belt or clip-on pouch over their right hip at the iliac crest (Troost et al., 2005). Previous research has found this protocol suitable for postnatal women when measuring free-living activity (Evenson & Terry, 2009) so this was adopted in the MAMMiS study.

It is considered good practice, when measuring free-living PA participation, that measurement is conducted over a number of days (Troost et al., 2005). This is in order to obtain a good estimate of behaviour and so that PA is not under or overestimated due to individual day-to-day fluctuations. Although there is generally high compliance with activity monitors, previous research has suggested at least three-four days of valid accelerometer data is required (Troost et al., 2005). Research with mainly working adults has suggested at least one monitored day should be at the weekend as a large proportion of adults engage in little of no moderate-vigorous PA during weekdays (Metzger et al.,

2008). However, as shown in Chapter Four, most participants in MAMMiS were not working (or working part-time hours, including weekend working) at all points during the study. Therefore, in the MAMMiS study requested participants wear the monitor during waking hours (excluding bathing and swimming) for seven consecutive days to allow for non-compliance with wearing the accelerometer². However, as discussed below I included participants' data at each measurement point, provided they included at least four days of monitoring regardless of whether this included a weekend day.

As discussed in Chapter One, to collect PA measurement in real-time accelerometers use sampling intervals (known as epochs), which are the time points at which movement is recorded. In studies using accelerometers to measure PA a variety of epoch lengths have been used, the most common being 5, 10, 15, 30 and 60 seconds (Gabriel et al., 2010). There can be a trade-off in setting the sampling interval due to the relationship between epoch length and number of activity counts across the measurement period, in particular the smaller the sampling interval, the greater number of counts, with smaller sampling intervals providing greater precision of measurement. However, across several days or weeks smaller sampling intervals require more memory for storage and greater processing power during the analysis stage. Precision is an important consideration for measuring PA and there is evidence that children and adolescents require shorter sampling intervals to account for their movements occurring in more frequent bursts than adults (Gabriel et al., 2010). However there is limited evidence for a differential effect of epoch length in studies conducted within adult populations, particularly under free-living conditions, whereby measurement is usually over at least 3-

²Since completing the data collection for MAMMiS Evenson, Herring & Wen (2012) have reported data from a cohort study of postpartum women measuring PA using the Actigraph accelerometer. The Evenson et al. (2012) study found that adopting the protocol of only including a monitoring week with at least one weekend day leads to increased numbers of postnatal women failing data validation protocols with no impact on the assessment of counts per minute or minutes per day of MVPA.

7 days, therefore requiring a greater store of the monitor's memory. The only study to have investigated the effects of epoch length in adults found small improvements in PA classification comparing 10-second epochs with 60-second epochs in a population of overweight post-menopausal females aged between 52 and 62 years (Gabriel et al, 2010); using the 60-second epoch as the sampling interval actually significantly improved agreement between the accelerometer-derived estimate of habitual PA participation and health indices such as body weight, BMI, whole body and trunk lean and fat mass. Therefore, a 60 second epoch was chosen for the MAMMiS study. Using 60 second epochs also lowered risk of the activity monitors running out of memory during each measurement period.

Prior to the first measurement appointment during each assessment period the CI ensured the accelerometer was charged and then initialised using the software provided by Actigraph (Actilife 5). This involved setting the dates over which the accelerometer should record data and assigning an identifier using the first initial, surname and measurement period (e.g. JSmith_Baseline). This ensured that there was no confusion regarding participants who were measured during the same 7-day period or across measurement periods for individual participant's data. Initialisation was also used to set the sampling intervals (epoch); as discussed above this was set at 60 seconds. The only differences in the protocol for setting epoch length were that the GT3X required the sampling interval to be assigned at initialisation, whilst the GT3X+ apportioned the sampling interval during the data download stage.

Participants were advised to wear the accelerometer during waking hours for seven consecutive days (excluding bathing and swimming) on the right hip. Although the GT3X+ was water resistant (Table 11), as some participants were measured using the

GT3X, the protocol was kept consistent, meaning contact with water was not advised. The CI provided participants with written and verbal instructions on how to wear the accelerometer (Appendix 7) and modeled appropriate positioning. This information was repeated each time the accelerometer was given out to participants. During each measurement week participants were asked to wear the monitor and to record wearing times in a diary (Appendix 7) in order to aid identification of non-wear periods. Participants were shown the example diary entries and were advised to record any time when they took the monitor off during the day or at night-time prior to going to bed. Participants were also advised to note down the time they put the monitor on, either in the morning or following a daytime non-wear period. Upon return of the accelerometer I made an initial check for monitor wear compliance by assessing self-reported wear times from the diary. Participants who recorded less than four days of wearing the monitor for at least 10 hours per day were asked to complete a second week to ensure they would have a valid dataset for that measurement period. Each participant's data was validated at each measurement period after collection of all three measurement points using a process of data cleaning and validation described in the section 'Data Analysis' below.

3.4.2.1.1.2 Self-reported physical activity

As discussed in Chapter One, there are numerous recall questionnaires available for measuring PA behaviour; during the development of MAMMiS there was no consensus on the best approach for postnatal populations. As accurately capturing PA via self-report can be difficult owing to participant recall from memory (Dishman et al., 2001), a measure which captures data from the previous week, was felt to be preferable, compared with measures that ask about a 'typical week' or participation from the previous month. As the 7-Day PAR questionnaire (Sallis et al., 1985) was the only recall questionnaire that

had been validated against an objective measure of PA behaviour (step counts measured by pedometers) in a postnatal population (Wilkinson et al., 2004), the 7-Day PAR questionnaire was used as the self-report measure in the MAMMiS study.

At the end of each measurement week, during the second appointment, the CI used the 7-Day PAR interview with all participants. Participants were asked to recall any PA conducted for *at least 10 minutes* that felt at least moderate-intensity, which was described as “*walking at a normal pace, how you would walk if you were trying to get somewhere*”. This explanation is in line with the protocol for the administration of the 7-Day PAR. Participants were asked to start with the day before the appointment and work their way backwards during the measurement week. Standardised prompts were used encourage participants to recall the duration and intensity of all activities: such as walking for transport, participation in structured exercise or any home and work-based activities that were at least moderate-intensity, but were also asked to differentiate activities that were very hard “*how you would feel if you were running*” or hard “*somewhere in between moderate and very hard: i.e. not as hard as running but harder than a normal (moderate) walking pace*”. At the end of the interview participants were also asked whether the activity levels during the previous week were “less than”, “more than” or “about the same” as the last three months and provide reasons for deviations from normal activity.

3.4.2.1.1.3 Cardiovascular fitness

Cardiovascular fitness was measured using The Chester Step Test (CST), which is a submaximal cardiovascular fitness test (Sykes, 1999). Within health interventions research there is likely to be variables levels of baseline fitness among participants. Some tests may have too strenuous protocols for unfit populations, which can lead to low-compliance with testing protocols. Alternatively, some tests show ceiling effects in fit

populations (Noonan & Dean, 2000). The CST measure was chosen as it is a validated submaximal test suitable for female untrained populations (including individuals who are sedentary and overweight) (Sykes & Roberts, 2004), therefore it was appropriate for the research population sought. The Chester step test was also chosen due to portability, which made it suitable for the research setting (i.e. in non-laboratory settings including participant's homes). As discussed in Chapter one, unlike the Harvard step test, the CST was developed and tested with untrained female participants, and unlike the CAFT the CST was available free to use.

The CST involves asking participants to repeatedly step up and down on and off a standardised step in two minute stages up to a maximum of ten minutes. The test was conducted according to the CST manual (Sykes, 1999) using a step size of (8"/20cm) as this has been recommended for participants aged 40 and under undertaking little regular exercise. Stepping rate was determined by a beep that increased in speed after each stage; this was played to participants on a portable mp3 player with internal speakers. Participants wore a heart rate HR monitor (Polar Wearlink WIND chest transmitter) and HR readings were transmitted to a wrist-watch, which the CI held at all times (Polar RS800). At the end of each two-minute stage a HR reading was taken and participants were asked to give themselves a score for the Rating of Perceived Exertion (RPE) scale (Borg, 1998). This was used to indicate participants' perception of activity intensity. The test was continued until the participants reached a heart rate that was 80% of their age-predicted maximum HR (HR_{max}) or until they reported an RPE of 14 or above (e.g. corresponding to perceiving the activity to be "hard"). Prior to commencing the first test, participants took part in a 2-minute familiarisation period. This was conducted to ensure there were no reductions in validity during the baseline measurement period as a result of

participants learning how to conduct the test. I provided standardised encouragement during the test and gave feedback on participants' cardiovascular fitness, in particular whether fitness was above or below average (or represents average) fitness for women in their age range.

3.4.2.1.1.4 Weight, body mass index and body composition

Weight and body composition (%fat mass) were measured using the Tanita portable bioelectrical impedance monitor (Tanita 300MA, Tanita Europe B.V., Amsterdam, The Netherlands) according to the measurement protocol specified in the handbook (Tanita, technical notes). Weight was measured in kilograms (to the nearest 0.1kg). Height was measured in centimetres (to the nearest cm) using a stadiometer (Leicester Portable Height Measure). Height readings were taken twice and averaged at the first baseline appointment. BMI was computed as the participant's weight in kilograms divided by their height in metres squared (kg/m^2). Participants were categorised as underweight, healthy weight, overweight or obese according to their BMI reading (according to the definitions used by the World Health Organisation (WHO), 2000 as shown in Table 12). Participants were asked whether they wished to know the results of their weight and body composition measurement at each measurement period and were advised regarding whether their BMI was in the underweight, healthy weight, overweight or obese range and whether their fat free mass was considered to be within the healthy range.

Table 12. **Body Mass Index definitions (WHO, 2000)**

Category BMI	BMI range (kg/m ²)
Underweight	<18.5
Healthy weight	18.5 – 24.9
Overweight	25 – 29.9
Obese	≥30

3.4.2.1.1.5 Psychological wellbeing and fatigue

I was interested in the impact of the intervention on improving general psychological wellbeing (a positive indicator) rather on decreasing symptoms of psychological ill-health, such as depression and/or anxiety symptomology (a negative indicator). Since the population targeted in the MAMMiS intervention were healthy low-active women not recruited on the basis of PND it was not expected that PND measures would be sensitive to change as a result of participation in the intervention. Furthermore, no previous studies had included information on the impact of PA change on fatigue severity in healthy postnatal populations; therefore a fatigue measure was included in the MAMMiS study.

Psychological wellbeing was measured using the Adapted General Wellbeing Index (AGWBI) (Hunt & McKenna, 1992). The original General Wellbeing Index was developed in the United States and was adapted for use in the UK (Hunt & McKenna, 1992). The AGWI consists of 22 items to assess positive wellbeing, self-control, anxiety and depression, vitality and general health concerns. It has been validated within a GP practice sample in the UK against several relevant criterion measures of subjective wellbeing, including global health status, reporting of ongoing psychological health problems (for example, depression), contact with health professionals, use of antidepressant medicine, tranquillizers or sleeping pills, common psychosocial worries or

difficulties and having been unemployed in the last year (Hopton, Hunt, Shiels & Smith, 1995). Each of statement was assessed using 5-point Likert response scale in relation to the past two weeks and a total wellbeing score was created by summing questions (negatively worded questions were reverse coded); therefore, total possible score range is from 22 to 110. Overall, the AGWBI was also chosen due to consistent evidence for reliability and validity and usefulness for measurement in the general population with reported norms for women (Dubois, Martin & Ware, 2004). Also the AGWBI does include evaluations of physical health status, unlike other wellbeing/quality of life measures (e.g. the SF-36). It is a short questionnaire thereby reducing participant burden (estimates are around 10 minutes or less).

Fatigue was measured using one question through a visual analogue scale (VAS). Visual analogue scales are a commonly used unidimensional method of assessing health status and are an appropriate method of measuring experience of short-term fatigue severity in general and clinical populations (Bowling, 2004). Participants were asked to place a mark on a 100mm line to indicate the extent to which they had been “affected by fatigue in the past two weeks”, where no fatigue was equal to 0 and worst possible fatigue was equal to 100 on the VAS.

3.4.2.1.1.6 Physical activity cognitions

I was interested in the impact of the intervention on cognitions targeted by the intervention techniques. The rationale for measuring targeted constructs has been discussed in detail in Chapter One. Along with the content coding approach to interventions, as shown in Chapter Two’s systematic review, measuring and reporting change in physical activity cognitions is important for the development of more

efficacious interventions. Demonstrating change in the targeted psychological constructs is one method for testing of the impact of this theoretically-based intervention.

As discussed in Chapter One previous research from within the general population and among women with young children has provided support that outcome expectancy cognitions and intentions to be active as correlates of physical activity behaviour, and for self-efficacy, and self-regulatory measures (i.e. goal-setting, planning measures and action control) as mediators of behaviour change. These constructs were specifically targeted in the MAMMiS intervention through the methods described in Table 8 and were hypothesised to change in response to the intervention. Therefore, in MAMMiS these PA cognitions were measured. Measurement was via a self-completion questionnaire developed for this study from measures used in previous studies (discussed below). The development of a new self-completion measure was required because there were no postnatal-specific validated questionnaires for measuring the PA cognitions targeted in the MAMMiS trial. The list of questions used for each construct is shown in Appendix 8.

3.4.2.1.1.6.1 Outcome expectancies, self-efficacy and intentions to be active

Outcome expectancies were measured using an adapted version of the decisional balance scale developed by Marcus et al. (1992). Six items representing three outcome expectancy domains (e.g. physical, social and self-evaluative) were used (Appendix 8), with each domain including one positively and one negatively worded statement. Statements were developed using a previous investigation of enablers to PA at three months postpartum in a US sample of 667 women (Evenson et al., 2009). These included partner, family and friends support (social), health enhancement/weight loss (physical) and feelings about oneself/energy (self-evaluative).

Self-efficacy was measured using an adapted version of the PA self-efficacy scale, which measures confidence for being regularly physically active despite experiencing barriers (Marcus et al., 1992). In the present study seven items were included based on the most frequent barriers reported by postpartum women in the study by Evenson et al. (2009). The question stem asked: “How confident are you that you can be regularly physically active during the next three months...?” This was followed by seven “...even if” statements (e.g. I’m tired, my baby is being fussy, I don’t feel like it etc.). *Intentions* to be active were operationalised using 1-item: “During the next three months do you intend to be regularly physically active?” All three constructs were assessed via a 7-point Likert scales with end points shown in Appendix 8.

3.4.2.1.1.6.2 *Action planning and coping planning*

Planning measures (both action and coping planning) were taken from Sniehotta, Schwarzer, Scholz & Schuz (2005b). *Action planning* was measured using four items following the stem: “I have made a detailed plan about being regularly physically active during the next three months...” (e.g. how/when/where/how often). A further facet (with whom) did not show good internal reliability in validation studies (Sniehotta, Scholz & Schwarzer, 2005a) so was not included in the action planning measure. *Coping planning* asked participants to rate three items, for example the extent to which they “have a detailed plan about what to do if things get in the way of them being regularly physically active during the next three months”. These planning measures have been validated in previous studies (Sniehotta et al., 2005a, 2005b). Both action and coping planning were measured using a 4-point Likert scale with definitions: completely untrue, somewhat untrue, somewhat true and completely true.

3.4.2.1.1.6.3 Self-regulatory measures (action control)

ix-items were used to measure self-regulatory effort in the present study, with questions adapted from the action control questionnaire used by Sniehotta et al. (2005b). Example statements used were: “During the last three months...I have been aware of how much PA I should be doing to meet my personal standards, I have made sure to monitor how much PA I’ve done and I have tried really hard to be physically active”. Each outcome was measured using 4-7-point Likert scales (e.g. very unlikely – very likely, completely untrue - completely true etc.).

3.4.2.1.1.7 Process data collection

As discussed above, despite the MAMMiS study not being a feasibility study, collecting appropriate process data can provide valuable information to inform the feasibility of development of future trials (Craig et al., 2008). For example, estimating the likely recruitment numbers required and practical considerations such as recruitment timeframe and geographical spread that might be required to achieve a given sample size within a larger trial.

Also as part of evaluation studies, process information is useful for assessing the generalisability and rigor with which the research was conducted (Moher et al., 2010; Oakley et al., 2006). For example, intervention fidelity (whether the intervention was delivered as intended), and loss to follow-up are important factors when considering the robustness of findings and conclusions from the study. Generalisability concerns the characteristics of participants who took part and whether they are representative of the population who might be expected to benefit from the intervention (Klesges, Estabrooks, Dzewaltowski, Bull & Glasgow, 2005). Intervention feasibility (whether the intervention could be delivered), are important considerations to ensure an implementable health

promotion programme once effectiveness has been established (Klesges et al, 2005). Intervention acceptability is also an important consideration and was addressed through the qualitative study described in detail below. The evaluation framework for a complex intervention should ideally integrate process information within the evaluation of intervention effects (Oakley et al, 2006; Craig et al., 2008; Moher et al., 2010). Therefore, within the MAMMiS study we collected process data to assess trial feasibility, generalisability and rigor, intervention fidelity and feasibility. This data collection was in line with the MRC Framework and CONSORT. Data collection included:

- The number of postnatal women who expressed an interest in joining the study, the numbers who were eligible and drop-outs at each trial stage. Recruitment source was noted to identify the most successful methods of recruitment (*trial feasibility, intervention fidelity*).
- Demographic details collected from participants at eligibility assessment using a telephone-administered questionnaire. This included age of the mother, infant's age, PA stage of change and deprivation status as measured by the Scottish Index of Multiple Deprivation (SIMD) (Scottish Government, 2012). For process data analysis, I conducted comparisons between study drop-outs and those who returned for follow-up to identify any systematic differences which might have affected the outcome results (*trial rigor*). I also compared demographics between postnatal women who were successfully recruited into the study and those who were not eligible or declined participation, in addition to comparing this data with national information regarding characteristics of postnatal women in Scotland (*generalisability*).

- Accelerometer data collection results from each measurement period, including information on wear time (e.g. average number of hours, daily common hours, numbers of participants missing wearing days etc.) and the number of the sample meeting wear time validation standards (*trial rigor, trial feasibility*)
- Attendance at each pramwalking session was logged, along with route information, walking time, distance and average walking pace. This was recorded using commercially available GPS mapping software (MapMyWalk [www.mapmywalk.com] on an iPhone 4). A supplementary study of PA intensity of the pramwalks was conducted opportunistically. A separate researcher accompanied pramwalkers from MAMMiS on five consecutive walks and measured time spent in moderate and vigorous intensities during walks using heart rate monitors (Polar RS8000X/Polar WearLink® W.I.N.D. transmitter strap) and accelerometers (Actigraph, GT3X) (*intervention feasibility and fidelity*).
- Participants' self-reported use of strategies from PA consultations (intervention group) was assessed at the three and six-month's follow-up point. Participants were reminded of each strategy that had been introduced during the PAC and asked to what extent they used this strategy in the prior three months using a 4-item response scale ('never', 'occasionally' 'often' and 'every week'). Participants were asked to provide at least one example of how they had used that strategy (unless reporting *never* using the strategy) (*intervention feasibility*).
- A random sample of PA consultations were recorded. I aimed to record 20% of all consultations (every 8th participant). Use of communication skills and adherence to the intervention content were rated by an independent person after all consultations had been delivered. The independent rater had a qualification in

Health Psychology interventions but no background in PAC. They listened to recordings and completed a form which listed each practical strategy to be rated, including a detailed description. Each item was rated as 1 (*limited skill*), 2 (*satisfactory skill*) or 3 (*very good skill*). There were six effective communication items (person-centred approach used demonstrated empathy, non-verbal communication skills, used parroting, used paraphrasing and PA knowledge). Use of non-verbal communication could not be assessed due to consultations being voice files. Each item mapped onto the intervention components shown in Table 8, with components broken down by the relevant performance objectives (i.e. targeting knowledge about PA and building positive outcome expectancies, making a behavioural resolution to change and skills development and change in environmental conditions to support adoption (1st PAC) and maintenance (2nd PAC) of PA). An example rating form is given as Appendix 9 (*intervention fidelity*).

3.4.3 Data analysis

Data analysis within RCTs can also be complex due to missing data, and data which does not meet assumptions for hypothesis testing with statistical models. Additionally, in studies using accelerometers there is a large amount of data cleaning and validation for participant wearing times prior to analysis.

3.4.3.1 Missing data imputation

Regard missing data, it is considered good practice to analyse intervention outcomes according to intention-to-treat (ITT) principles; with all participants included according to initial group allocation regardless of whether they received the allocated intervention or

control condition. This reduces bias associated with non-random cross-over and drop-out of participants within studies, which can lead to overestimation of treatment effects (e.g. Bollini, Pampallona, Tibaldi, Kupelnick & Munizza, 1999). The MAMMiS study was analysed according to intention-to-treat principles with missing data imputed to account for interim missing data, study withdrawals, equipment malfunction and non-compliance with wearing the activity monitor. The procedures for imputation of data was conducted at baseline using matched analysis methods. For each missing participant age-range (under 20, 20-39, 40+ years old) and BMI category (normal weight, overweight, obese) were calculated. Imputation followed by using median data calculated from all other participants in the sample who were matched on both characteristics. For example if a missing participant was 38 and overweight, the median data from all participants aged between 20 and 39 with a BMI between 25 and 30 was used for imputation. Missing data at three and six months was imputed by carrying forward baseline values. These procedures were discussed and agreed with an independent statistician.

3.4.3.2 Cleaning and validation of accelerometer data

Actilife 5 is a software package that provides a platform for downloading data from the Actigraph accelerometers. It also provides option for data cleaning, exporting accelerometer output and assigning activity intensity cutpoints for the accelerometer output prior to analysis using statistical software. A process of data cleaning and data validation is required for all accelerometer studies. This ensures participant's data from each measurement period met minimum standards considered appropriate for inclusion in accelerometry studies measuring free-living PA participation (Troost et al., 2005).

3.4.3.2.1 Data cleaning

The process of data cleaning involves identifying and removing accelerometer non-wear periods (i.e. the chunk of time when the accelerometer is not being worn) for each individual participant dataset at each measurement period. Non-wear periods, using accelerometer activity counts are generally considered to be portions of data that appear as strings of zero activity counts, which are long enough as to have reasonably represented a period of time when the accelerometer was removed from the body. However, there is no consensus on the ‘right’ length of zero strings (Masse et al., 2005) and previous studies in postnatal populations have used criteria for strings of zeros from ten minutes up to sixty minutes (Evenson & Terry, 2009). No study to date has conducted direct observation to validate the accuracy of accelerometer assessed non-wear-time. In the MAMMiS study we included a participant wearing time’s diary to identify whether the zero strings criteria adopted reflected participants’ accelerometer self-reported wear-time behaviour. A review of the first twenty participants’ data (collected from the baseline measurement period) suggested adoption of the 60 minute wear-time criteria proposed by Evenson and Terry (2009) was not suitable for the population in the MAMMiS study as twelve legitimate non-wear periods were recorded of between 45 and 60 minutes (e.g. due to removal of the monitor for swimming with baby, bathing etc.). Many participants also recorded removing the monitor for showering or changing, but the length of time was quite short (generally 5-30 minutes) and the impact of selecting a 20 or 30 minute zero-strings criteria would have meant a large amount of sedentary time would have been excluded from the analysis. Although the use of the diaries provided the opportunity to manually correct for incorrectly flagged non-wear time (i.e. a period of zero strings but participants had not indicated having removed the monitor), setting the

wearing time criteria at this level would have resulted in an unmanageable amount of erroneously flagged non-wear data. Therefore, a 45-minute cut-off for flagging zero strings as non-wear data was chosen for the accelerometer data cleaning.

The procedures for data validation for each participant’s dataset involved a two-step process; with step one conducted using the Actilife programme to flag strings of 45-minutes of consecutive zero counts as *likely* non-wear time. Data continued to be flagged as non-wear time until there was evidence of an activity spike (equivalent to at least one minute of non-zero counts) and provided the ‘wear-period’ that was detected if it was more than two minutes long. These details are summarised below (Table 13). To further maximise the amount of data that was available for analysis and to minimise the likelihood of the excluding sedentary wear-time, in step two, the CI also manually corrected each participant’s data, using non-wear time identified as wear-time in participant’s dairies. To assess whether the screening criteria represented a good fit for the dataset, baseline wear periods indicated by the Actilife programme were checked against participants’ wearing times dairies. This checking procedure involved manually counting the number of wear periods declared in participant’s wearing times dairies (the criterion method) and comparing this figure with number of assessed wear periods.

Table 13. **Defining accelerometer non-wear periods in the MAMMiS study**

Criteria	Definition and study choice
<i>Non-wear bouts</i>	After detecting 45 minutes of consecutive zeros (0) , ActiLife will flag data as "non-wear time". Data will be flagged as "non-wear time" until the <i>Spike Tolerance</i> is exceeded.
<i>Spike tolerance</i>	ActiLife will continue scoring a non-wear bout as non-wear until it detects more than the 1 epoch (equivalent to 1 minute) above zero.
<i>Ignore wear period</i>	>2 minutes is the minimum length of an acceptable wear period.

3.4.3.2.2 Data validation

Following data cleaning, whereby non-wear-time data was removed, each participant's dataset was then validated using a wear-time algorithm to identify firstly whether each measurement day was valid and secondly whether the whole measurement period was valid. Typically approaches to accelerometer wear-time have adopted arbitrary cut-off points, for example suggesting >10 hours of wear-time constitutes a valid day (Troiano et al., 2008). However, in this approach only complete hours can be counted towards total wear-time. Furthermore, women with infants may keep different waking hours from the general population and may take the accelerometer off and on more frequently (e.g. due to sleeping during the day), resulting in incomplete or unusual hours being recorded. Therefore, in the MAMMiS study a measurement day was considered 'valid' if non-missing data was available for at least 70% of common wear-time hours (these were the standardised hours each day where at least 70% of participants were found to be wearing the monitor). This was the approach to classifying valid wear days used in a previous longitudinal investigation of postnatal PA behaviour using accelerometers (Evenson & Terry, 2009). Incomplete hours were counted towards total wear-time (as long as >30minutes wear-time was recorded). Once each individual set of participant data from each measurement period was cleaned and shown to have been valid for use analysis of the dataset as a whole (e.g. all participants' accelerometer readings across each of the measurement periods) was conducted. The results of each stage of data cleaning and validation are reported in the results section.

3.4.3.3 Data processing prior to analysis

3.4.3.3.1 Accelerometer data processing

As the accelerometry output is a measure of activity counts these were averaged over the measurement period by dividing the total number of counts by the number of minutes of measured data to assess counts per minute (counts/minute). Counts/minute represents the accelerometer PA data and shows whether there was a change in the amount of movement (acceleration). The rationale for using counts/minute as the main measure of PA change is due to the difficulties associated with accurately calculating EE, as shown in field-based studies discussed in Chapter One. However, counts/minute is not a meaningful measure of PA behaviour. Therefore, it is important to report the amount of time participants spent in moderate-vigorous intensity PA (i.e. MVPA) across the measurement week. As discussed in Chapter Four, there is no consensus on the most appropriate cut points for assessing time spent in different activity intensity zones. As the MAMMiS study was encouraging the adoption of PA of at least a moderate-intensity (e.g. equivalent to a brisk walk), with changes to behaviour expected to occur on top of existing household and caregiving activities we adopted the cut point equation values reported by Freedson et al. (1998) to analyse the time spent in different intensity zones as recorded by accelerometer. The Freedson et al. (1998) cut points have been validated for use in field studies and this made our findings comparable to previous studies. The original power calculation (change in MVPA as a result of a 12-week intervention with female cancer survivors – Rodgers et al., 1999) was carried out using the Freedson et al. (1998) cut points. I chose not to analyse the data using the cut points proposed by (Sasaki et al., 2011) due to these not having been used previously in field-based investigations and to ensure I could make comparisons with other studies of PA participation in the general and postnatal populations. Cut points analysis included absolute amount of time spent in each intensity

thresholds per day and the relative amount of time in moderate-vigorous activity (i.e. the proportion of total wear-time spent in intensities that were at least moderate using intensity cut point thresholds). Accelerometers also provide a measure of walking behaviour change, as, like pedometers, they count the number of steps taken while wearing. In order to assess change in walking behaviour total step counts for the week were averaged by dividing the number of steps by the number of valid measurement days (steps per day). As recommended by Tudor-Locke et al. (2009) I analysed step count data with censored step counts, by removing all steps taken when activity counts were recorded as <500 counts per minute.

To summarise, accelerometer data was used in the following ways. I analysed change in the average raw activity counts (counts per minute) without imposing cut point thresholds. Secondly, I used the Freedson et al. (1998) cut points to calculate average daily minutes of MVPA and report time spent as a proportion (%) of total wear-time in MVPA. Thirdly, I analysed step count data from accelerometers, which I analysed as censored steps per valid measurement day.

3.4.3.3.2 Self-report and physiological proxy data processing

For self-reported PA I calculated total minutes of self-reported MVPA by summing moderate, hard and very hard minutes collected from the 7-Day PAR questionnaire. This data was used to assess whether individuals meet PA guidelines as data collected was from continuous bouts of at least ten minutes. For cardiovascular fitness, I predicted aerobic capacity using heart rate values obtained at each stage of the step-test. Each heart rate reading (beats per minute: BPM) at each level of the test (i.e. up to five test stages) was plotted using simple linear regression. Relative VO_2max (litres of oxygen per minute per kilogram of body weight) was then calculated using the regression equation using the

unstandardized coefficients: $\text{mlsO}_2/\text{kg}/\text{min} = \text{BPM (gradient)} \times \text{HRmax (220-participant's age)} + \text{constant (intercept)}$. Participant's fitness category was determined by comparing cardiovascular fitness predicted from the CST against standardised normative data by age group (Sykes, 2004).

3.4.3.3.3 Physical activity cognitions data processing

As the PA cognitions were measured using a series of items it was important to conduct analysis to ensure the scale has suitable internal consistency before combining individual question items. Cronbach's alpha was used to assess the questionnaire items in this study with scale items removed if acceptable alpha values (set at >0.6) were not reached (Bland & Altman, 1997).

3.4.3.4 Statistical analysis: assumptions

Statistical Package for the Social Sciences (SPSS) version 19 was used to process data, produce descriptive data and test the impact of the intervention using inferential statistics. In RCTs a number of outcomes are investigated at a number of follow-up points between in both the intervention and control group. This increases the likelihood of Type 1 error, which occurs when a statistically significant effect is wrongly concluded to represent an observed effect. This happens when sampling error alone accounts for the effect. Assuming a commonly used p-value of 0.05, Type 1 error is predicted to occur in 5% of cases (i.e. 1 in 20). Therefore, within the MAMMiS study an analysis approach was chosen to reduce the likelihood of a Type I error through minimising the number of statistical tests that were conducted to answer the questions of interest for this study. To minimise the risk of Type 1 error analysis proceeded by comparing the intervention and control group on the change in the dependent variables between baseline and three months

(the intervention effect) and between three and six months (the maintenance effect) only. This required computation of a change score by subtracting participant baseline values from the three month follow-up and the three month values from the six month follow-up results. Following discussions with an independent statistician (from the University of Strathclyde) this was considered the most appropriate approach for minimising likelihood of Type 1 error. Furthermore, as the p-value of 0.05 is an arbitrary cut-off for significance, and tells us nothing about the magnitude of the effect, I computed 95% confidence intervals (95% CI) and effect sizes (Field, 2013).

Most analyses of change in intervention trials utilise parametric statistical tests, for example independent t-tests, which analyse the difference between two groups on a dependent variable. Parametric tests make the following assumptions about the data: data is approximately normally distributed; each of the groups tested has the same variance (*homogeneity of variance*); the distance between points of scale is equal at all parts along the scale (e.g. represents interval data) and data from different participants are independent.

3.4.3.4.1 Testing assumptions with statistical testing procedures

To test the assumptions of parametric data a series of investigations are required for each of the dependent variables measured. Typically normality can be assessed by visually inspecting data using graphical means. For example, histograms and boxplots often show evidence of non-normally distributed data with positive (scores which ‘pile-up’ on the left hand side of the graph) or negative skew (scores which ‘pile-up’ on the right hand side of the graph). However, statistical testing for normality is recommended in small samples with tests such as the Kolmogorov-Smirnov (K-S) and Shapiro-Wilk test available (Field, 2013). Within the MAMMiS study prior to the analysis all variables were assessed for

normality by visually examining histograms, boxplots and using the K-S test. Parametric tests assume that that variance within each of the populations being tested is equal. Statistical tests for homogeneity are available (e.g. the Levene test). However, there is also evidence that parametric statistics are relatively robust to violation of this assumption, provided there are roughly equal sample sizes across conditions (Field, 2013), which was the case in the MAMMiS study.

Interval data refers to data that increases linearly (e.g. an individual who weighs 80 kilograms (kg) weighs exactly double an individual weighing 40kg). As discussed in Chapter One studies of accelerometer counts during lab-based studies of walking and running show evidence that counts increase linearly as treadmill speed is increased (John et al., 2010). However, the evidence for this interval relationship with EE measured by portable indirect calorimetry is less robust during lighter or more vigorous-intensity activities. This is also one rationale for not using EE as the primary PA outcome in this study, but rather analysing accelerometer counts. Regarding other outcome measures, for example the cardiovascular fitness measure and weight-related variables, both meet criteria for this assumption; they have been shown to represent validated measures with data points increasing linearly. Likert scales can be used to represent interval-level data and are generally robust to violations of this assumption (Carifio & Perla, 2007). To address the assumption of independence of data in the MAMMiS study postnatal women were recruited across a number of regions and a number of different recruitment methods were used. Also postnatal women were not recruited in groups; therefore most women taking part in the study did not know each other prior to enrolment in the study. However, there could be no guarantee that women taking part in the study who were assigned to the different study groups but did know each other did not affect each other's behaviour.

3.4.3.4.2 *Options for data that does not meet assumption*

The options to address non-normally distributed data are to conduct a transformation of the data (for example using the log or square root value). These transformations can be employed with positively skewed data, with the same transformation for negatively skewed data requiring data to be reverse scored prior to transformation. However, one of the problems with transforming data is that often in repeated measures intervention designs, some data points are skewed while others are not (e.g. baseline data follows a normal distribution but follow-up points do not). Therefore, to ensure data is comparable all data points in the same analyses must be transformed; checking the impact of transformation on all data points following transformation is crucial to ensure the process of transformation does not lead to previously normally distributed data becoming skewed. Another option for dealing with data that does not meet assumptions for parametric tests is to carry out non-parametric tests, which use the median scores and are therefore more robust, for example to violations of normality. Within-participants differences can be investigated using the Wilcoxon signed rank tests and between-participants with Mann Whitney tests.

Therefore, normally distributed data were analysed using independent and paired-samples t-tests to investigate differences between the intervention and control group on the primary outcome measure between baseline and three months (the intervention period) and between baseline and six months (follow-up period). I conducted analyses twice, firstly with all participants, using the ITT dataset and then I conducted a per protocol analysis for participants who showed high adherence to the intervention (i.e. took part in a minimum of the first PAC and five pramwalks). Log transformations were considered but did not improve distribution, therefore, analysis of medians and interquartile ranges were

used for non-normally distributed data via non-parametric tests (i.e. Mann Whitney U-test). Categorical data was analysed using chi square tests and Fisher's exact tests (FET), reported as number and proportions. Effect sizes reported are Cohen's *d* (parametric tests) and Rosenthals' *r* (non-parametric tests).

3.4.4 Post-trial interviews

Post-trials interviews with study participants were conceived of as part of the original MAMMiS trial proposal. Interviews aimed to explore the acceptability of the intervention approach among postnatal women taking part in the MAMMiS study. In particular, I was interested in gathering information about how the intervention was perceived (positive and negative experiences of taking part) and whether the methods used were responsive to the specific needs of postnatal women. Using qualitative research in this way is recommended as part of the MRC Complex Interventions Framework (Craig et al., 2008). Ethical approval for the interview study was granted as part of the original trial application.

3.4.4.1 Aims and research questions

The aim of this qualitative study was to explore postnatal women's experiences of taking part in the MAMMiS intervention. The specific research questions were:

- i) What were participants' motivations to adopt and maintain physical activity before and after the intervention?
- ii) What were participants' views and experiences of the following:
 - a) taking part in the physical activity consultations and group pram-walking programme?

- b) aspects of the intervention (if any), which supported them to adopt or maintain activity, and why do they think these helped?
- c) the length, content and delivery mode for the physical activity consultation, including the effectiveness of the interpersonal skills of the counsellor, and ease of adopting the treatment strategies (e.g. setting goals, self-monitoring)?
- d) the number, location, duration and intensity of the walking programme and the group approach?
- e) factors, if any, acted as barriers or facilitators (and may continue to do so) to adopting and maintaining physical activity behaviour change.

3.4.4.2 Study design and methods

3.4.4.2.1 Design and setting

This study was a qualitative investigation using one to one interviews. This was more suitable for this population group who had potential difficulties attending a focus group due to child care issues. Interviews took place at participants' homes (or a convenient place), depending on participant's preferences.

3.4.4.2.2 Participants and sampling

All participants who were randomised in the MAMMiS study were eligible to take part. An information sheet was given/mailed to participants at the end of the MAMMiS trial (including withdrawals). Originally, only intervention participants were sought for interview, however following feedback from the Chief Scientist's Office (CSO) reviewers, control participants were included.

We sought to interview at least half of all MAMMiS participants with recruitment targets set for the intervention (n=20) and control (n=15) groups over the 10 month study period. Early on in the study all participants who completed the trial were invited to interview and as the sample of participants became larger the researcher sought out participants with specific characteristics to ensure the study included a diverse sample. This purposive sampling approach aimed for participants with diverse socio-demographic, life situations and family circumstances. I developed a sampling matrix to record the following characteristics as participants were interviewed: whether participants had one/more than one child, whether their infant was older/younger than six months, mother's BMI (normal/overweight or obese at study onset) and trial characteristics (i.e. variable adherence to the intervention; trial completers and trial withdrawals).

3.4.4.2.3 Interviewer

Interviews and analyses were conducted by a researcher not involved in the MAMMiS study after all follow-up measures had been completed using one-to-one semi-structured interviews. This was chosen to ensure participants could talk openly about their experiences. The researcher was an experienced in-depth interviewer with PhD level qualifications in qualitative design. She was in her 40s, somewhat physically active and had two school aged children.

3.4.4.2.4 Interview schedule

A topic guide (Appendix 10) was used to guide the interviews; this was based on the research questions and amended following the first four interviews, however participants were also encouraged to raise issues important to them to accommodate unanticipated

themes. These in-depth interviews lasted 30-90 minutes. All interviews were tape-recorded and transcribed verbatim.

3.4.4.2.5 Data analysis

NVivo qualitative analysis software was used to facilitate analysis of the interviews. Once transcripts were collated in NVivo, common and diverging themes were compared and contrasted to develop theories grounded in the data. This thematic analysis involved a series of key stages, based on the approach described by Braun and Clarke (2006). In the first phase, the researcher familiarised herself with the data through reading the transcribed interviews and identifying and noticing preliminary patterns. Identification of themes followed in which an initial set of descriptive themes and sub-themes were identified throughout the text and coded appropriately. Thematic codes were continually reviewed during discussions between the researcher and two other members of the research team using a subset of interviews. A final set of themes were agreed between the researchers following iterative analysis, coding and re-coding. Finally, mapping and interpretation was used: all relevant data items were matched to codes (accounting for negative cases for each theme) and a selection of quotes were extracted for the research report to exemplify themes.

CHAPTER FOUR

4 RESULTS OF THE MAMMiS STUDY

4.1 Chapter Preface

This chapter describes the results from the MAMMiS study. I conducted all data collection, analysis and conceived of how to present the data collected in this thesis. These activities were conducted under supervision from Dr McInnes and Dr Hughes and an independent statistician from the University of Strathclyde was consulted regarding missing data handling and conducting the per protocol analysis. This chapter includes results from the screening and recruitment process, analysis of the representativeness of the sample and participant flow through the study. Baseline participant characteristics and accelerometer data wear-time results are summarised. The effect of the intervention on PA change, secondary health and wellbeing outcomes and PA cognitions are described. This chapter ends with intervention fidelity and feasibility results.

4.2 Results from the screening and recruitment process

4.2.1 Recruitment to the study and eligibility screening

Recruitment commenced in February 2011. Postnatal women were sought from two CHPs (Stirling and Falkirk) within NHS Forth Valley using nine different recruitment methods (both NHS and community-based methods). In total, expressions of interest came from 136 women with the numbers from each of the recruitment methods shown in Table 14.

Table 14. Expressions of interest by recruitment method

Recruitment method	Number (%)
Approached at baby clinic	42 (31)
Approached at community event	26 (19)
Saw poster/leaflet	18 (13)
Approached at nursery/playgroup	16 (12)
Other participant recommended study	10 (7)
Health visitor recommended study	9 (7)
Approached at breastfeeding group	6 (4)
Unknown	4 (3)
Newspaper article	3 (2)
Recommended at baby sensory class	2 (2)

Eighty-four (62%) of those who expressed an interest in joining the study came from within the Stirling CHP with 48 (35%) coming from Falkirk CHP. As ethical approval was provided by NHS Forth Valley, NHS recruitment routes were only available in these CHP areas; however, four (3%) women who lived outwith these areas also expressed interest in joining the study through other methods. These women also took part in eligibility screening. This reflects the fact that recruitment in Falkirk CHP started later (1st July 2011) than in Stirling (1st March 2011). Recruitment methods differed by CHP (Table 15), with more women from Stirling coming from community sources (e.g. mother and baby groups, breastfeeding groups etc.) or self-referral (i.e. having viewed a poster or participant recommendation etc.). In contrast, most women from Falkirk CHP came from NHS recruitment sources (e.g. via health visitors, breastfeeding groups and baby clinics). This difference in recruitment methods between the CHPs reflects the differences in allocation of recruitment resources following advice from NHS, local government and community-based contacts across the two CHP regions.

Table 15. Type of recruitment source by area

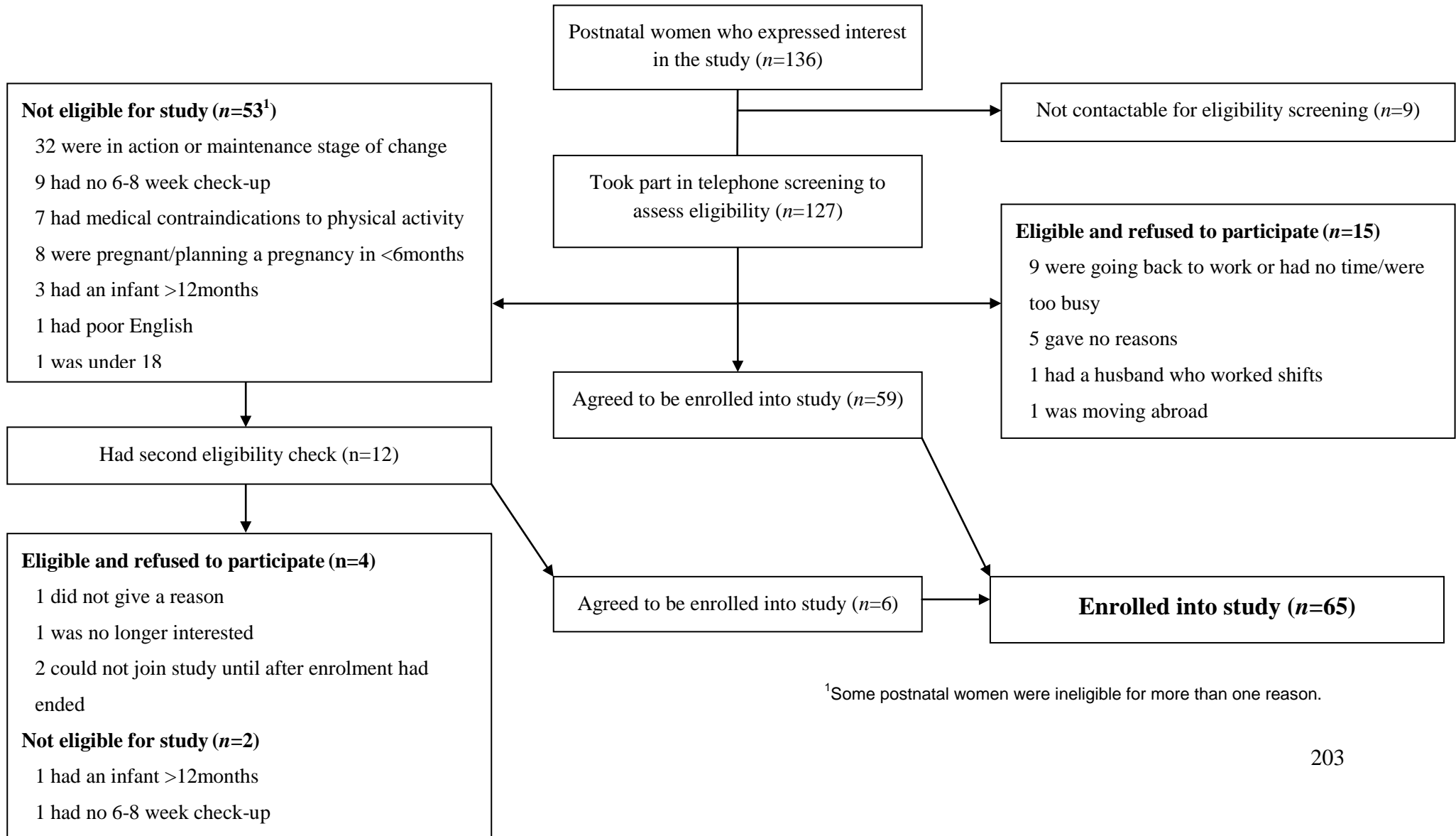
Recruitment source	Stirling CHP (%)	Falkirk CHP (%)	Other (%)
NHS (e.g. baby clinics, HV recommends)	18 (23)	37 (80)	0
Community (e.g. local groups/events, nurseries)	37 (47)	4 (9)	3 (75)
Self-referral – saw poster, leaflet, article etc.	17 (21)	3 (7)	1 (25)
Self-referral – participant recommendation HV, Health visitor	8 (10)	1 (<1)	0

4.2.2 Eligibility screening

Of those expressing an interest in joining the study, nine women could not be contacted to complete eligibility screening (Figure 6). Eligibility screening was conducted with 127 women with 53 being found to be ineligible to participate. Among ineligible women 12 were re-contacted at a later stage (with agreement from participants). A second eligibility test was only considered if women were ineligible due to a current pregnancy ($n=1$), medical contraindications to PA, whereby participation in the study was subject to approval of their general practitioner ($n=3$), or among those who had not yet had their 6-8 week postnatal check-up ($n=8$). At this second eligibility check a further 10 women were found to be eligible. Of these, six enrolled in the study. In total, 77% of those eligible to enrol in the study (65/84 participants) did enrol.

Reasons for ineligibility are shown in Figure 6, with the main reason being they were in the ‘Action’ or ‘Maintenance’ stage of change (32/43 or 74% of ineligible participants) and therefore considered too active to join the study. Reasons for refusal to participate are provided in Figure 6.

Figure 6. Flow through the eligibility screening process



4.2.3 Representativeness of women who expressed an interest in the study

Representativeness was explored using SIMD, Urban/Rural Classification (n=136) and mother's age at the time of childbirth for those who could be contacted (n=127). SIMD and Urban/Rural Classification details were available for all women through their address details, while age at childbirth was captured during the eligibility screening telephone call.

4.2.3.1 SIMD decile of women expressing an interest in the study

SIMD decile of mothers who gave birth across Scotland and the Forth Valley region were provided by the NHS Information Services Division (ISD) for the year 2010 (most recent year available). Using the postcodes of all women who expressed interest in the study, the proportion of those from each SIMD decile was calculated and compared with this proportion at the Scotland-wide level and Health Board level.

As shown in Table 16, Scotland-wide SIMD decile of women expressing interest in joining the study was largely similar to the proportions of all mothers giving birth in 2010. There were some notable deviations. Only 1% of the women expressing interest in joining this study was came from SIMD decile 1 (the most deprived), compared to 14% of all mothers in 2010. Also, almost 20% of women expressing an interest in joining the study came from SIMD decile 8, while of all mothers in 2010 9% came from SIMD 8. Only 41.5% of women expressing an interest in joining the study came from the most deprived datazones (deciles 1-5), whilst 59% came from the least deprived datazones (6-10). The Scotland-wide proportion was 57% from deciles 1-5 and 43% from deciles 6-10. Table 17 shows the Health Board level (NHS Forth Valley) SIMD decile of women expressing interest in joining the study. Among those expressing interest in joining the study there were a similar proportion from each SIMD decile as the proportion of women from NHS Forth Valley postcode regions who gave birth in 2010. In total, 43% of postnatal women expressing an interest in joining the

study came from Forth Valley NHS Board SIMD deciles 1-5 (most deprived datazones), whilst 57% came from the least deprived datazones (6-10). The corresponding figures for all NHS Forth Valley deliveries in 2010 were 54% and 46%, for the most and least deprived deciles, respectively.

Table 16. Proportion of postnatal women in the study from each SIMD decile¹ compared with Scotland-wide deliveries in 2010

SIMD Decile	Scotland-wide proportion (n=57,031)²	All interested sample, % (n=135)	Eligible sample, % (n=83)	Enrolled sample, % (n=64)
1	13.7	0.7	0	0
2	12.2	8.1	6.0	1.6
3	10.9	15.6	9.6	7.8
4	10.4	6.7	6.0	3.1
5	9.8	10.4	10.8	9.4
6	9.3	8.9	7.2	7.8
7	8.8	11.1	15.7	18.8
8	9.2	19.3	20.5	23.4
9	8.4	9.6	12.0	15.6
10	7.4	9.6	12.0	12.5

¹SIMD was not available for one participant. ²Excludes home births and births at non-NHS hospitals and excludes cases where SIMD details were unavailable.

Table 17. Proportion of postnatal women in the study from each SIMD decile^{1,2} compared with NHS Forth Valley deliveries in 2010

SIMD Decile	NHS Forth Valley proportion (n=3,268)³	All interested, % (n=133)	Eligible sample, % (n=81)	Enrolled sample, % (n=62)
1	7.8	6.8	4.9	1.6
2	9.8	8.3	3.7	0
3	15.9	10.5	8.5	7.9
4	10.5	9.0	8.5	4.8
5	10.1	8.3	8.5	9.5
6	7.5	14.3	15.9	17.5
7	11.7	10.5	12.2	14.3
8	10.6	12.8	13.4	15.9
9	10.7	8.3	11.0	14.3
10	5.4	11.3	13.4	14.3

¹SIMD was not available for one participant. ²Two participants lived outwith Forth Valley NHS Board region and were not included in this analysis. ³Excludes home births and births at non-NHS hospitals.

4.2.3.2 Urban/rural classification of women expressing an interest in the study

The Scottish Government (<http://www.scotland.gov.uk>) provides Urban/Rural classification at the datazone level for all postcodes across Scotland. Using this information the proportion of women expressing interest in joining the study from each of the six classifications (large urban area, other urban area, accessible small town, remote small town, accessible rural and remote rural) was compared with the Scottish-wide level and Forth Valley NHS Health Board level. This data was not available for mothers; data shown here includes all households living in each of the different urban/rural classifications across the NHS Forth Valley region and for the Scotland-wide level.

As shown in Table 18, women expressing interest in joining the study were largely representative of the proportion of households living in different urban/rural classifications across NHS Forth Valley. For example, most women who expressed interest in joining the study came from ‘other urban areas’ (75%), compared with 73% of households being classified across the Forth Valley NHS Board region. At the Scotland-wide level the sample who expressed interest were not representative, however this is due to the NHS Forth Valley region containing no datazones that are classified as large urban areas or remote small towns.

Table 18. Proportion of postnatal women in the study by Urban/Rural classification¹

Classification	Scotland-wide, %	Forth Valley NHS Board², %	All interested, % (n=133)³	Eligible sample, % (n=81)³	Enrolled sample, % (n=62)³
Large urban area	38.9	-	-	-	-
Other urban area	30.6	73.2	74.8	76.2	78.1
Acces. Small town	8.5	9.1	7.4	4.8	4.7
Remote small town	3.8	-	-	-	-
Acces. Rural	11.6	15.4	14.1	14.3	12.5
Remote rural	6.5	2.3	3.7	4.8	4.7

¹Urban/rural classification was not available for one participant. ²Forth Valley NHS board region figures for Urban/Rural classification differ from the Scottish-wide proportions as the region does not have large urban areas and remote small towns. ³Two participants lived outwith Forth Valley NHS Board region and were not included in this analysis.

4.2.3.3 Age of mothers at the time of childbirth among women expressing interest in the study

Age of mother at the time of childbirth among women expressing interest in the study (calculated by subtracting the youngest child's date of birth from the mother's date of birth), was compared with the Scotland-wide and NHS Forth Valley Health board region (i.e. the age of all women who gave birth in Scotland and in the Forth Valley NHS region in 2011). This information was available from the General Registrar's office (<http://www.gro-scotland.gov.uk>). The year 2011 was chosen as 69% of women who underwent eligibility screening for this study gave birth in 2011. Compared with the Scotland-wide population, the sample of women who expressed an interest in the study were more likely to be from older age bands at childbirth and less likely to be in the younger age bands (Table 19). For example, 68% were 30 years or older old at time of childbirth compared with 49% of the Scotland-wide population in 2011 and 51% for the NHS Forth Valley region.

Table 19. Age range of mothers at the time of childbirth in the MAMMiS study compared with the Scotland-wide and NHS Forth Valley live birth population in 2011

Age band (years)	Scotland-wide (%) (n=58,544)	Forth Valley NHS region (%) (n=3,154)	Expressed interest sample (%) (n=127)¹	Eligible sample (%) (n=84)	Enrolled sample (%) (n=65)
<20	5.8	6.1	2.4	1.2	0
20-24	18.1	16.8	13.4	11.9	4.6
25-29	27.1	26.3	16.5	16.7	13.8
30-34	28.8	29.2	39.4	41.7	44.6
35-39	16.2	17.6	22	22.6	29.2
40+	3.9	3.9	6.3	6.0	7.7

¹Age was not available for 9 women expressing an interest because they could not be contacted by telephone to complete the eligibility screening questionnaire.

4.2.4 Representativeness of enrolled participants compared to the eligible sample

Recruitment representativeness was explored for the eligible sample (n=83) and in the enrolled sample (n=65) using: SIMD decile classification, mother's age at childbirth, age of youngest child at the date eligibility was assessed and mother's stage of PA change.

4.2.4.1 SIMD decile comparing the eligible sample and recruited participants

Table 20 shows the proportion of women from the most and least deprived Scotland-wide SIMD deciles who were found to be eligible but did not enrol in the study with those who enrolled in the study (i.e. enrolled sample). The proportion is skewed towards those from less deprived SIMD deciles with fewer than 22% of those enrolled coming from SIMD deciles 1-5 (the most deprived). These figures were the same at the Health Board level SIMD (analysis not shown). However, as shown in Table 21, women from less deprived SIMD deciles were also more likely to be eligible to join the study. For example, among those eligible to join the study only 33% were from the most deprived SIMD deciles, whilst 68% were from the least deprived areas. These figures were the same at the Health Board level SIMD (analysis is not shown).

Table 20. Comparison of least and most deprived SIMD deciles among eligible participants by enrolment status

	Did not enrol in study,	Did enrol in study,
	n (%)	n (%)
Most deprived (SIMD deciles 1–5)	13 (68)	14 (22)
Least deprived (SIMD deciles 6–10)	6 (32)	50 (78)
<i>Total</i>	<i>19</i>	<i>64¹</i>

¹One participant did not have SIMD decile as the datazone had not existed in 2009.

Table 21. Comparison of least and most deprived SIMD deciles among all those expressing interest in joining the study by eligibility status

	Not eligible, n (%)	Eligible, n (%)
Most deprived (SIMD deciles 1–5)	29 (56)	27 (33)
Least deprived (SIMD deciles 6–10)	23 (44)	56 (68)
<i>Total</i>	52 ¹	83

¹One participant did not have SIMD decile as her datazone had not existed in 2009.

4.2.4.2 Age of women at time of childbirth: comparing the eligible sample and recruited participants

As shown in Table 19, compared with the sample of women who expressed interest in joining the study and were assessed, there appeared to be few differences with regards age of mother at time of eligibility assessment among eligible participants and those who were not eligible (i.e. 32% of all those assessed were under 30, compared with 30% who were eligible to join the study). Table 19 also shows that mother's from younger age bands were less likely to actually enrol in the study. Only 18% of those who enrolled in the study were under 30, compared with 32% who were under 30 who were assessed for eligibility to join the study.

4.2.4.3 Age of youngest child at eligibility assessment: comparing the eligible sample and recruited participants

Among the total sample that expressed interest in joining the study and were assessed for eligibility (n=127) the average age of their youngest child at eligibility assessment was 24 weeks (s.d.=14.1). Among those who were eligible to be enrolled in the study (n=84) the average age of their youngest child was=23 weeks (s.d.=13.6). Among those who did subsequently enrol (n=65) the average was 22 weeks (s.d.=13.4). There appeared to be a small difference in age of youngest child at eligibility assessment among those who were enrolled compared with those who were assessed but never enrolled (mean=26 weeks, s.d.=14.6) in the study but this was not statistically significant (t(125)=1.61, p=0.11, 95%CI -8.92, 0.92).

4.2.4.4 Stage of PA change: comparing the sample expressing interest in the study and recruited participants

Stage of PA change was identified for all women who took part in an eligibility assessment (n=127). In total 20/127 (16%) were labelled ‘Contemplators’ and 69/127 (54%) ‘Preparers’, with 8/127 (6%) and 30/127 (24%) being in the ‘Action’ or ‘Maintenance’ stage, respectively. As women who were in action or maintenance stages were deemed ineligible, the proportion of women who were eligible to enrol (i.e. excluding those in action and maintenance) but never enrolled were compared. In this case there were no differences in the proportion of women who were in either ‘Contemplation’ or ‘Preparation’ stages among those enrolling in the study 13/65 (20%) in ‘Contemplation’ and 52/65 (80%) in ‘Preparation’ stages, compared with those who were eligible to join the study but did not enrol (i.e. 3/19 (16%) in ‘Contemplation’ and 16/19 (84%) in ‘Preparation’ stages, respectively).

4.2.5 Summary of recruitment and eligibility screening results

The recruitment period for this study lasted 13 months and 136 postnatal women expressed an interest in joining the study. The most successful recruitment methods were face-to-face approaches (i.e. baby clinics, breastfeeding groups or local community groups/events). Most participants in Falkirk CHP were recruited through NHS sources; in Stirling CHP, participant recommendation and self-referral (e.g. via study leaflets, posters, newspaper articles, word-of-mouth) were the most frequently used methods. Of those expressing an interest in joining the study 93% were contactable and completed the telephone eligibility screening process, with a third of those screened being found to be ineligible. Most of the women who were ineligible were already considered too active to join the study (74%). Most of those who were found to be eligible (77%) were successfully recruited, with a total of 65 participants completing baseline assessments and being enrolled into the study.

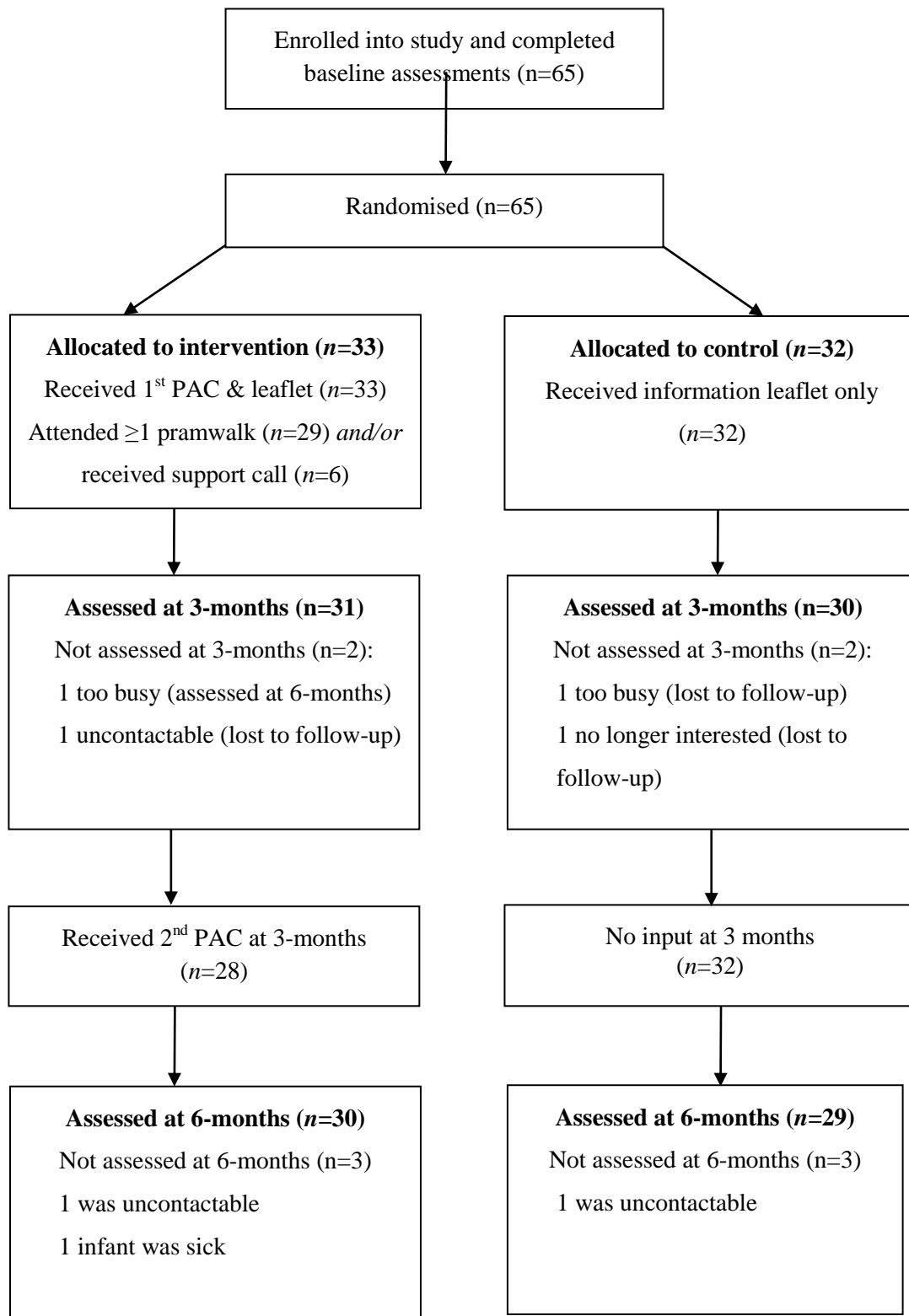
Compared to all women who gave birth in Scotland, women who expressed an interest in joining the study were from less deprived areas and older age bands. They were significantly older than women who gave birth across Forth Valley NHS Board but were similar in terms of deprivation and urban/rural classification. Women who were eligible to join the study and did enrol (i.e. enrolled sample) were not representative of the total sample expressing an interest in the study. The enrolled sample were less likely to be from more deprived postcode regions and more likely to be older. There were no differences between eligible participants who did or did not enrol in the study on age of their youngest child and stage of PA change.

4.3 Results of the study flow and baseline participant characteristics

4.3.1 Participant flow through the study

Figure 7 demonstrates the flow of participants through each stage of the study following initial enrolment. Of the 65 participants who enrolled in the study all completed baseline assessments and were randomised to the intervention or control group. 92% (60/65) of the sample completed assessments at three months, with three intervention participants not completing assessments (one participant withdrew from the study at this stage and two were subsequently assessed at six months follow-up). Two control participants withdrew from the study at three months. At six months follow-up 91% (59/65) of the sample completed assessments. Reasons for not completing three and six month assessments and reasons for withdrawing are detailed in Figure 7.

Figure 7. **Flow of participants through the MAMMiS study**



4.3.2 Baseline characteristics of the sample

Table 22 displays the baseline socio-demographic characteristics of the intervention and control group. At enrolment participants' average age was 33.1 (intervention group) and 33.8 (control group) years, with average age of their youngest child around 24 weeks or six months. SIMD was similar between groups (Table 22). Most participants were married (54/65), degree educated (54/65) and on maternity leave at enrolment (55/65). Descriptive analysis of the data suggested participants from both groups were comparable across all demographic indicators.

4.3.2.1 Clinical and health behaviour characteristics

Table 22 also shows birth-related clinical characteristics of the sample. Type of delivery (e.g. vaginal labour or Caesarean section) was similar across the groups. With regards health behaviour characteristics, at baseline, most participants in the intervention group were bottlefeeding, (exclusively or including solid food=49%) or mixed feeding (12%). In the control group a majority of participants were breastfeeding (56% either exclusively or including solids). This difference was not statistically significant between the groups ($p=0.29$, FET). For smoking status only 1/33 intervention participants and no controls smoked. Stages of PA change did not differ between groups with 73% of intervention participants and 88% of control participants being classed at contemplators and 27% (intervention) and 13% (control) being preparers, respectively.

Table 22. **Baseline socio-demographic, clinical & health behaviour characteristics**

Characteristic	Intervention (n=33)	Control (n=32)
Mean age \pm SD, y	33.1 \pm 4.1	33.8 \pm 5.4
Mean age youngest child* \pm SD, weeks	24.0 \pm 11.0	24.8 \pm 15.5
Median number of children (range)	1 (1-4)	1 (1-5)
Marital status, n (%)		
Married	27 (82)	27 (84)
Co-habiting	5 ¹ (15)	5 ¹ (16)
Single	1 (3)	0
Employment status, n (%)		
Maternity leave or housewife	31 ² (94)	24 (74)
Working (full or part-time)	2 (6) ³	5 (16)
Unemployed	0	3 (9)
Highest education level, n (%)		
Degree-level (inc. postgrad qualification)	27 (82)	27 (84)
Not degree level (e.g. HND, Highers SVQ)	6 (18)	5 (16)
Mean time spent in full-time education \pm SD, y	17.3 \pm 2.6	17.6 ^{***} \pm 3.0
Mean SIMD (Healthboard) \pm SD, y	7.1 ^{***} \pm 2.5	6.8 \pm 1.9
Method of delivery ^{**} , n (%)		
Vaginal labour	24 (73)	26 (81)
Caesarean section	8 (24)	6 (19)
Breastfeeding status, n (%)		
Breastfeeding (exclusively or inc. solids)	13 (39)	18 (56)
Bottlefeeding (exclusively or inc. solids)	16 (49)	11 (34)
Mixed feeding (can inc. solids)	4 (12)	3 (9.4)
Smoking status, n (%)		
Non-smoker	32 (97)	32 (100)
Current smoker	1 (3.0)	0
Stages of PA change, n (%)		
Contemplation	9 (27)	4 (13)
Preparation	24 (73)	28 (88)

Scottish Index of Multiple Deprivation, SIMD; Scottish Vocational Qualification, SVQ

¹Two co-habiting participants were also divorced.²One full-time intervention group participant who was on maternity leave was also working part-time.³One full-time control group participant who was working part-time was also a student. * At enrolment **Missing data from one participant from the intervention group, ***Missing data from two participants

4.3.2.2 Weight-related characteristics

Weight-related characteristics at baseline are shown in Table 23. BMI (using measured height) and self-reported pre-pregnancy weight showed participants who were randomised to the intervention group appeared more likely to report having been overweight or obese (46%) before pregnancy compared with control group (28%), At enrolment the same trend continued, with 61% of the intervention group classes in the OW/OB category compared with 44% of the controls, although this was substantial it was a non-significant difference ($p=0.33$, FET). From prepregnancy to date of enrolment participants were on average 1.7 BMI points heavier at enrolment (based on measured weight) compared with their prepregnancy self-reported weight.

Table 23. **Weight characteristics at baseline**

Characteristic	Intervention group (n=33)	Control group (n=32)
Mean self-reported prepregnancy weight \pm SD, kg	65.2 ¹ \pm 9.9	63.1 ² \pm 8.2
Mean prepregnancy BMI \pm SD, kg/m ²	25.1 \pm 4.1	23.6 \pm 3.1
Prepregnancy BMI classification*, n (%)		
Underweight (<18.5 kg/m ²)	0	1 (3)
Healthy range (18.5 -24.9 kg/m ²)	14 (54)	20 (69)
Overweight (25-29.9 kg/m ²)	10 (39)	7 (24)
Obese (\geq 30 kg/m ²)	2 (8)	1 (3)
Mean measured current weight \pm SD, kg	72.9 \pm 10.9	68.2 \pm 10.4
Mean current BMI \pm SD, kg/m ²	27. \pm 4.2	25.5. \pm 3.9
Current BMI classification, n (%)		
Underweight (<18.5 kg/m ²)	0	0
Healthy range (18.5 -24.9 kg/m ²)	13 (39)	18 (56)
Overweight (25-29.9 kg/m ²)	11 (34)	9 (28)
Obese (\geq 30 kg/m ²)	9 (27)	5 (16)

Body mass index, BMI, ¹Seven intervention group participants could not self-report their prepregnancy weight. ²Three control group participants could not self-report their prepregnancy weight.

4.3.2.3 Characteristics that changed over time: from baseline to three and six months assessment

During assessment period participants were asked about their current employment and breastfeeding status in case these changed over the study period.

4.3.2.3.1 Working status

At baseline most participants were not working; seven (11%) reporting working full or part-time. By three months 30% of the sample were working (19/63)³. Rates of return to work appeared similar between the intervention and control group. From baseline to three months 8/32 (25%) of intervention and 8/31 (26%) of control participants changed their working status. One participant from each group stopped working, while all others took up work between the two assessment periods. Between three and six months 10/31 (32%) of intervention participants and 5/29 (17%) of control participants took up full or part-time work. By the six month assessment period 33/60 (55%) of the sample (excluding five participants with missing data) were working either full or part-time.

4.3.2.3.2 Breastfeeding status

Overall 38 out of 65 (59%) of participants at baseline were breastfeeding (either as the sole method or in combination with bottlefeeding/solid foods). By three months this frequency had dropped to 30/61 (49%) and 15/60 (25%) at six months. As shown in Table 22 more control participant were breastfeeding (including with solids) at baseline compared with intervention participants. This remained true at three months as more participants from the control group reported still breastfeeding (47%) compared with the intervention group (23%).

³Two participants who returned to the study at six months self-reported their three month working status at the six month assessment.

By six months this difference narrowed and most women were no longer breastfeeding (i.e. 16% in the intervention groups and 10% in the control group).

4.3.3 Study withdrawal

I investigated systematic differences in socio-demographic and health behaviour characteristics between participants who were assessed at all study periods (i.e. n=59 completed baseline, three and six month assessments) compared with (n=6) who missed three, six months or both follow-up assessment periods. This involved a series of comparisons using independent samples t-tests for comparing means and Fisher Exact (FE) tests for categorical variables (FE tests was used due to having a small number (n<5) of participants in cells). Prior to tests all data were graphically checked via histograms and box plots to identify deviations from normal distribution. Where data was not normally distributed non-parametric tests were used in preference and medians are reported rather than means.

There were no differences between those who completed all assessment periods and those who did not on baseline PA 'stage of change' ($\chi^2 (1) = 4.61, p=0.60$). 60% (4/6) were classified as in the 'Preparation' stage among those who missed at least one follow-up assessment period, compared with those completing all assessment periods (80% or 47/59 were in Preparation). Baseline weight status was similar between participants who missed at least one assessment period (60% OW/OB=3/5) and those who did not (52% OW/OB, 31/60), $\chi^2 (1) = 1.28, p=1.00$. There were no differences between those who completed all assessment periods and those who did not on number of children at home ($\chi^2 (1) = 1.17, p=0.40$; i.e. comparing participants with 1 child or >1 child). There were also no differences on participant's SIMD (healthboard) comparing those who failed to complete one or more

assessment periods (mean=6.80, s.d.=1.64) and those who completed all assessments (mean=6.93, s.d.=2.23; $t(62)=-0.11$, $p=0.91$).

Finally, the number of participants not completing at least one assessment period was similar across the groups. Of the six participants who failed to complete all assessments, three (50%) came from both the intervention and control group. However, both participant's age (in years) and age of their youngest child (in weeks) were significantly different (or close to significance) when comparing those completing all assessment periods and those who missed at least one assessment period. Participants who failed to complete at least one assessment were younger (mean=30 years old, s.d.=4.7) and had younger infants (mean=20.9 weeks old, s.d.=12.3) compared to those who completed all assessment periods (mean age of participant=34, s.d.=4.7) and mean age of participants' younger child=32 weeks (s.d.=12.0). Independent samples t-tests for these variables were $t(63)=1.88$, $p=0.06$ (for participant's age) and $t(63)=-2.01$, $p=0.05$ (age of youngest child).

4.3.4 Summary of baseline characteristics and participant flow through the study

Postnatal women who enrolled in the MAMMiS study were on average 33 years of age with their youngest child on average 24 weeks. Most participants were primiparous, married; degree-educated and were on maternity leave. Most participants were non-smokers and were in the 'Preparation' stage (i.e. took part in some PA but not 'enough' to meet PA guidelines). Regarding clinical characteristics, most study participants had given birth vaginally. Changes in weight and BMI following pregnancy were evident; average weight gain was around 4.5 kg from pre-pregnancy (self-reported) to enrolment in the study (measured weight). There appeared to be differences in baseline weight between the two study groups, with intervention participants being heavier and more likely to be OW/OB, although this difference was not significant. Control participants were more likely to be breastfeeding at baseline, but this

difference was also not statistically significant. There were no other differences between intervention and control participants in terms of baseline socio-demographic, health behaviour and clinical characteristics. Although many participants returned to either full or part-time work during the six month study period, the rate of return to work was similar across the groups. Considering breastfeeding, at three months control participants were still more likely to be breastfeeding compared with the intervention group but this was not the case by six months follow-up.

Over 90% of participants who were enrolled in the study remained in the study and completed assessments at three and six month follow-up. Comparing participants who missed at least one assessment period with those who did not, there was no evidence that most of the clinical or health behaviour characteristics differed. However, younger participants and those with younger infants were more likely to miss at least one assessment period (either the three or six month follow-up). Two participants became pregnant at the six month follow-up; results are included as both were around 9-10 weeks gestation at the time of the measurement appointment and one came from each of the intervention and control group, therefore would be unexpected to bias trial results. As described in Chapter Two PA outcome data were analysed according to intention-to-treat principles with missing data imputed.

4.4 Results of the accelerometer data cleaning and validation

4.4.1 Data cleaning results

Data cleaning was conducted for each participant's accelerometer data at each measurement period by identifying and removing non-wear periods, using the two-step process described in the methodology section. The results of Step 1 are shown in Table 24 for n=61 participants at baseline. Four participants were not included due accelerometer malfunction (n=1), low-

compliance (i.e. failure to wear the monitor on at least four days during the measurement week) (n=1), incomplete diary (n=1) and data file corruption (n=1). As shown in Table 24 there was good agreement between the accelerometer-assessed number of wear periods (i.e. as discussed in Chapter Three these are the chunks of time that met the screening criteria, suggesting the monitor was being worn by the participant) and the declared number of wear periods throughout the week (i.e. self-reported from participants' wearing times diaries). This suggests the 45-minute wear-time criteria with associated spike tolerance of one minute and ignoring wear periods under three minutes had good fit with the data. Twenty-four participants had a negative discrepancy (i.e. reported fewer wear time periods than the accelerometer assessed, probably caused by periods of inactivity >45mins which were assessed as non-wear periods by the accelerometer screening algorithm). These incorrectly flagged "non-wear bouts" were corrected manually during Step 2 of data cleaning. The remaining 37 participants had a positive discrepancy (i.e. reported non-wear periods of <45mins, which were assessed by the accelerometer screening algorithm as wear periods). Zero (i.e. no discrepancies between the declared and accelerometer assessed wear periods) were recorded in 10 (16%) participants, 1/-1 discrepancies were recorded in 10 (16%) participants, 2/-2 discrepancies were recorded in 17 (28%) of participants, 4/-4 discrepancies were recorded in 10 (16%) participants and 5/-5 discrepancies (4; 7% of participant). In five (8%) cases participants recorded a positive discrepancy of 6 wear periods between declared and assessed figures.

Table 24. Comparison between assessed and declared accelerometer wear-periods¹ for n=61 participants at baseline

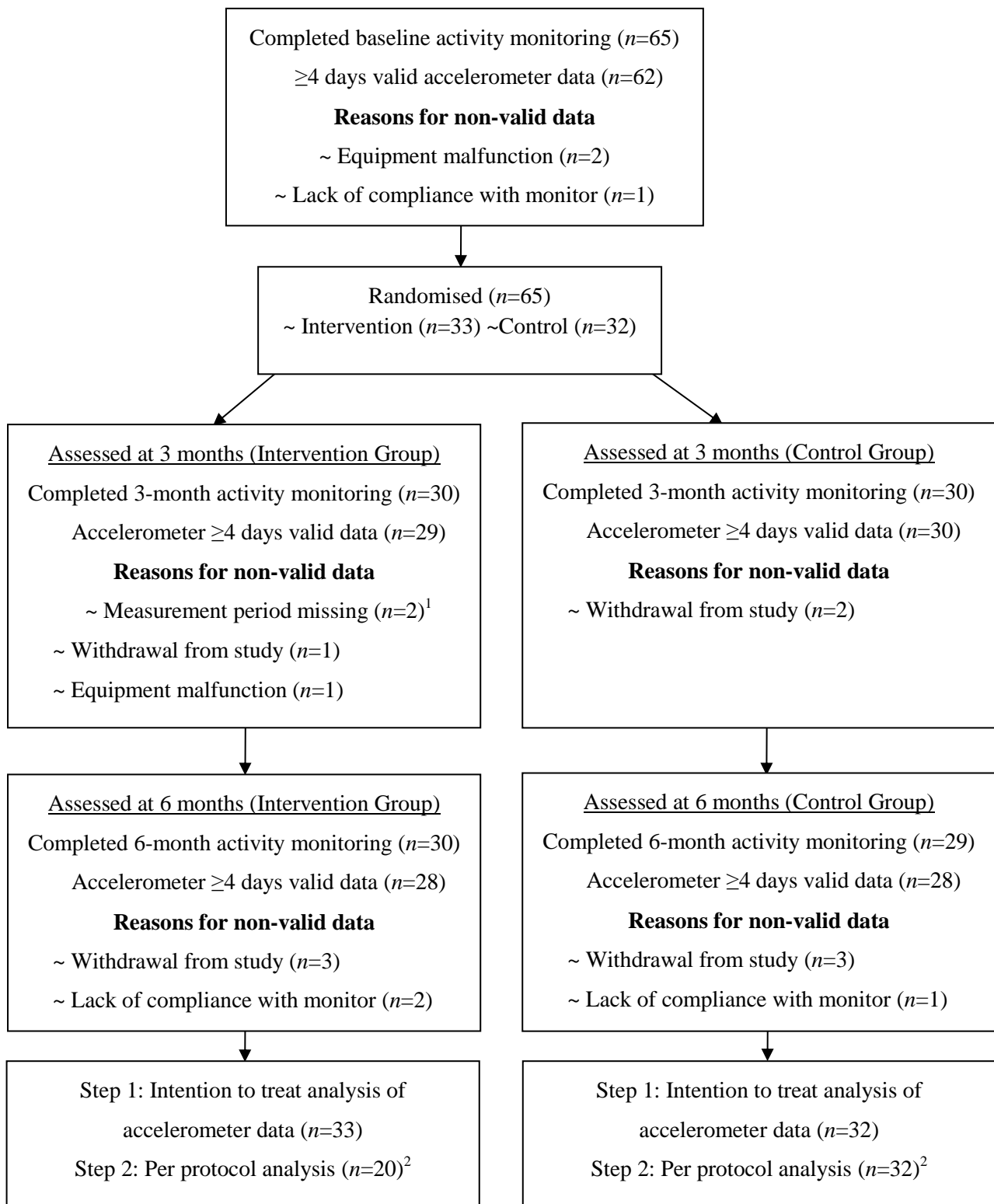
	Median (IQ Range)
Assessed wear periods (Actilife with screening criteria applied)	9 (8, 11)
Declared wear periods (Self-report diaries)	9 (7, 13)
Difference between declared and assessed wear periods	0 (-2, 2)

¹Median number of wear periods throughout the whole measurement week.

4.4.2 Data validation results

After non-wear periods were screened and manually corrected, accelerometer data from each participant at each measurement period was assessed against the wear-time criteria (WTC) algorithm developed for this study, which was discussed in Chapter Three. The number of participants with valid accelerometer data is summarised in Figure 8, along with reasons why the data was not valid. As discussed, imputation of missing accelerometry data was used to enable the ITT analysis to be conducted (full dataset and per protocol sample). At baseline, imputation was used for three participants due to non-valid accelerometer data. At three months this figure was six participants (four from the intervention group and two from the control group), and at six months' nine participants' accelerometer data was imputed (five from the intervention group and four from the control group).

Figure 8. **Results of the accelerometer data cleaning and validation**



¹Participants did not complete assessments at three months but returned for measurement at the six months follow-up.

²The per protocol analysis included imputed accelerometer data for both groups; only including participants from the intervention group who met minimum adherence standards (e.g. 1 PAC and ≥5 walks).

4.4.2.1 Baseline data validation results

Table 25 shows wear-time information at baseline for participants. Average wear-time across the sample was 13 hours for weekdays and weekends. During weekdays almost all participants (e.g. 91-95%) wore the accelerometer for at least 70% of common wear-time hours and on Saturday and Sunday these figures were 86% and 84%, respectively. Complete non-wear days (i.e. the monitor was not worn by participants) were most likely on weekends or on Monday (Table 25). Sixty-two participants provided valid data at baseline (at least four valid days of data monitoring, which met WTC). One of the three participants who did not provide valid data was non-compliant and the other two were due to equipment malfunction (during measurement/download), which were not identified until after randomisation (Figure 8). Forty-five participants (69%) wore the accelerometer for all seven consecutive days. 5% wore the accelerometer for four days, 11% of participants wore the accelerometer for five days, and 12% wore the accelerometer for six days during the baseline measurement week.

Table 25. **Wear-time information for the baseline dataset (n=65)**

Day	Average wear-time, hrs (s.d) ¹	>70% of sample WT hours ¹	No. (%) sample >70% of WT hrs	No. (%) sample <70% of WT hrs	No. (%) with 0 WT hrs
Monday	13 (2.1)	9am-10pm	59 (91)	1 (2)	5 ² (8)
Tuesday	14 (1.7)	9am-10pm	62 (95)	2 (3)	1 ² (2)
Wednesday	14 (2.1)	9am-10pm	62 (95)	2 (3)	1 ² (2)
Thursday	13 (2.3)	8am-10pm	60 (92)	4 (6)	1 ² (2)
Friday ³	13 (2.6)	10am-10pm	59 (92)	4 (6)	1 (3)
Saturday ³	13 (3.9)	10am-10pm	55 (86)	5 (9)	4 (6)
Sunday ³	13 (3.2)	10am-9pm	54 (84)	2 (3)	8 (13)

¹Data for calculation was only included if participants wore the accelerometer for at least one hour on that day.

²One participant had 0 wear time hours on these days due to accelerometer malfunction, which was not identified and no second measurement week was conducted.

³One participant is not included in this analysis as she was on night-shift for three days of the measurement week. This participant's accelerometer data was included where each day met traditional wear time criteria (i.e. >10 hours of wearing the accelerometer, used in Tudor-Locke et al, 2008).

4.4.2.2 Follow-up validation results (three and six months)

WT data from at three and six months are shown in Tables 26 and 27 for participants who returned for assessment during each follow-up. At three months average wear-time hours for each day were 13 hours during weekdays and 12 hours during weekends. During weekdays over 92-93% of the sample wore the accelerometer for at least 70% of common wear-time hours. On weekends these figures were lower with 86% (Saturday) and 83% (Sunday) wearing the accelerometer for common wear-time hours. Participants were more likely to have a non-wear day on a Saturday or Sunday; and these days were also associated with shorter wear-time hours (e.g. 11am – 9pm) compared with weekdays. Accelerometer WT data at three months was similar to baseline. The six months dataset showed average wear time was similar to baseline and three months (i.e. averaging 13 hours Monday-Thursday and 12 hours Friday, Saturday and Sunday). However, the proportion of the sample reaching the >70% common wear-time hours cut-off was lower at six months (83 and 90%), and the number of participants recording complete non-wear days was greater. Common wear-time hours were largely similar to those at baseline and three months.

4.4.2.3 Number of valid days at three and six months

By the three month follow-up 59 of the 60 (98%) participants who returned for measurement provided valid data. One intervention participant had an equipment malfunction (see Figure 8). Of those five who were unable to return for three month follow-up assessment, three did not complete their accelerometer measurement week due to dropping out of the study completely, while two participants could not complete the measurement week due to life circumstances (work commitments and one participant's baby was unwell). Both of those who dropped out at three months for these reasons returned at six months for a full accelerometer measurement week.

Of the 59 participants who provided a valid dataset at three months, 36 (61%) wore the accelerometer for all seven consecutive days, three (5%) for four days) and 10 participants (17%) for five and six days, respectively. At six months 56 of the 59 (95%) participants returning for six month follow-up had valid data, with those not meeting WTC being due to poor compliance with wearing the monitor. Those participants recorded two (n=3) and three (n=1) days valid wear-time, respectively. The remaining six participants were those who dropped out at the three months follow-up and who did not return at the six month follow-up point (n=3) and a further three participants who dropped out at six months. Among those participants with valid data 30 (54%) wore the accelerometer for seven days, while five (9%) wore the accelerometer for four days, seven (13%) for five days and 14 (25%) for six days.

Table 26 Wear-time information for the three months dataset (n=60)

Day	Average wear-time, hrs (s.d) ¹	>70% of sample WT hours ¹	No. (%) sample >70% of WT hrs ¹	No. (%) sample <70% of WT hrs ¹	No. (%) of participants with 0 WT hrs ²
Monday ³	14 (2.6)	10am-10pm	54 (92)	2 (3)	3 ⁴ (5)
Tuesday	13 (2.4)	9am-10pm	56 (93)	1 (2)	3 ⁴ (5)
Wednesday	13 (2.3)	9am-9pm	55 (92)	1 (2)	4 ⁴ (7)
Thursday	13 (2.7)	9am-9pm	55 (92)	3 (5)	2 (3)
Friday ³	13 (3.3)	9am-9pm	54 (92)	4 (7)	1 (2)
Saturday ³	12 (2.5)	11am-9pm	51 (86)	3 (5)	5 (9)
Sunday ³	12 (3.1)	11am-9pm	49 (83)	4 (7)	6 (10)

¹Data for calculation was only included if participants wore the accelerometer for at least one hour on that day.

²Excludes five participants who did not return for analysis at three months.

³One participant is not included in this analysis as she was on night-shift for four days of the measurement week. This participant's accelerometer data was included where each day met traditional wear time criteria (i.e. >10 hours of wearing the accelerometer used in Tudor-Locke et al, 2008).

⁴One participant had 0 wear time hours on these days due to accelerometer malfunction, which was not identified and no second measurement week was conducted.

Table 27. **Wear-time information for the six months dataset (n=59)**

Day	Average wear-time, hrs (s.d) ¹	>70% of sample WT hours ¹	No. (%) sample >70% of WT hrs ¹	No. (%) sample <70% of WT hrs ¹	No. (%) of participants with 0 WT hrs ²
Monday	13 (2.8)	8am-9pm ^S	52 (88)	6 (10)	1 (2)
Tuesday	13 (3.1)	9am-9pm	53 (90)	3 (5)	3 (5)
Wednesday	13 (2.9)	9am-9pm	52 (88)	4 (7)	4 (7)
Thursday	13 (2.4)	9am-9pm	53 (88)	4 (7)	3 (5)
Friday	12 (3.5)	10am-9pm	52 (88)	7 (12)	0 (-)
Saturday	12 (3.8)	10am-10pm	49 (83)	6 (10)	4 (7)
Sunday	12 (3.3)	11am-9pm	49 (83)	2 (3)	8 (14)

¹Data for calculation was only included if participants wore the accelerometer for at least one hour on that day.

²This excludes six participants who did not return for analysis at six months.

4.4.3 Summary of the data cleaning and validation results

The wearing time algorithm showed good fit with self-reported data from wearing times diaries. Postnatal women in the MAMMiS study showed good compliance with wearing the accelerometer. On average participants wore the monitor for 13 hours per day. During all measurement almost all participants (i.e. over 95% (baseline), 98% (three) and 95% (six months) met wear-time criteria for inclusion in that measurement period (i.e. had at least four valid days of wearing the monitor). A majority of participants at each assessment period (>50%) recorded seven consecutive days of accelerometer measurement. A small number of participants showed poor compliance with the monitor or had equipment malfunctions during the measurement week. Compliance was better during the week compared with weekends.

4.5 Results from the primary outcome: effect on physical activity

4.5.1 Normality checking for accelerometer measured physical activity

Using the Kolmogorov-Smirnov (K-S) test and visual inspection of boxplots and histograms there were deviations from normality at three months for counts/minute ($D(65)=0.17$, $p=0.03$), at all measurement periods for combined minutes/day spent in MVPA per day

(absolute time) and proportion of time spent in MVPA (relative time compared to total accelerometer wear time). Steps/day was non-normally distributed at baseline ($D(65) = 0.11$, $p = 0.05$) but not at three or six months. Therefore, we report means, medians and interquartile range for all variables. Graphs show median and 95% confidence intervals.

Considering the full sample change in counts/day from baseline to three months ($D(65) = 0.81$, $p = 0.20$) and three to six months ($D(65) = 0.10$, $p = 0.08$) were normally distributed so analysis proceeded with t-tests. Change in MVPA minutes/day and MVPA proportion between baseline to three (Absolute MVPA: $D(65) = 0.13$, $p < 0.01$; Relative MVPA: $D(65) = 0.11$, $p = 0.06$) and three to six months (Absolute MVPA: $D(65) = 0.15$, $p < 0.01$; Relative MVPA: $D(65) = 0.13$, $p < 0.01$) were skewed, therefore Mann Whitney U-tests were used. Change in steps/day between baseline to three months was not normally distributed based on visual inspection and testing using the K-S tests ($D(65) = 0.11$, $p = 0.05$), change between three and six months was normally distributed ($D(65) = 0.13$, $p < 0.01$). Mann Whitney U-tests were used to analyse change in steps/day.

4.5.2 Accelerometer measured physical activity

Descriptive statistics for accelerometer data at baseline, three and six months follow-up are shown in Table 28 for the full dataset ($n = 65$) and Table 29 for the per protocol sample ($n = 52$).

Table 28. Accelerometry results for intervention and control participants at baseline, three and six months follow-up using the full dataset

	Intervention group (n=33)									Control group (n=32)								
	Baseline			3-months			6-months			Baseline			3-months			6-months		
	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR
Counts per minute	343	330	281-390	352	334	272-412	360	346	290-393	315	297	253-389	340	340	276-416	348	323	256-449
Absolute time (minutes/day):																		
Sedentary*	475	458	427-516	437	452	359-497	447	450	400-502	469	474	399-526	442	448	389-497	447	452	380-515
Light	311	293	271-348	307	299	264-346	313	319	268-357	304	300	249-360	320	326	266-361	327	318	285-375
Moderate	30	28	14-39	29	27	17-38	27	23	17-35	26	23	16-32	29	27	16-35	26	24	14-35
Vigorous**	2	0	0-2	<1	0	0-2	3	<1	0-6	<1	0	0-1	<1	0	0-1	<1	0	0-1

	Intervention group (n=33)									Control group (n=32)								
	Baseline			3-months			6-months			Baseline			3-months			6-months		
	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR
Relative time (% of total wear time):																		
Sedentary*	58	58	55-62	56	56	51-62	57	56	51-62	59	60	53-66	56	57	51-60	57	55	50-63
Light	38	37	37-41	40	40	35-44	40	40	33-46	38	36	31-45	40	40	35-45	41	41	34-46
Moderate	4	4	2-5	4	4	2-5	3	3	2-4	3	3	2-4	4	4	2-5	3	3	2-4
Vigorous**	<1	0	0-0.5	<1	<1	0-0.5	<1	<1	0-1	0	0	0-0	<1	0	0-0	<1	0	0-1
Steps per day ***	7540	7266	5584-8710	7431	7162	5808-8451	7477	7653	5737-8828	7150	6962	5934-8103	7451	7409	5909-8937	7361	7530	5662-9393

IQR, interquartile range; \bar{x} , mean; M, median, mpd, minutes per day

Note: Percentage values may not add to 100% due to rounding.

*Count <100 were considered sedentary using both cut points as per Matthews et al (2008)

**Values below 0.1 were treated as 0 for reporting purposes.

***Steps taken <500 counts were removed from analysis

Table 29. Accelerometry results for intervention and control participants at baseline, three and six months follow-up using the per protocol dataset

	Intervention group (n=20)									Control group (n=32)								
	Baseline			3-months			6-months			Baseline			3-months			6-months		
	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR
Counts per minute	335	329	238-391	334	322	252-399	355	366	278-392	315	297	253-389	340	340	276-416	348	323	256-449
Absolute time (minutes/day):																		
Sedentary*	485	466	433-542	439	451	362-204	446	455	410-525	469	474	399-526	442	448	389-497	447	452	380-515
Light	297	281	269-319	293	297	256-327	302	312	240-358	304	300	249-360	320	326	266-361	327	318	285-375
Moderate	30	28	14-38	27	26	17-36	27	23	13-36	26	23	16-32	29	27	16-35	26	24	14-35
Vigorous**	2	0	0-2	1	0	0-2	4	<1	0-7	<1	0	0-1	<1	0	0-1	<1	0	0-1

	Intervention group (n=20)									Control group (n=32)								
	Baseline			3-months			6-months			Baseline			3-months			6-months		
	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR	\bar{x}	M	IQR
Relative time (% of total wear time):																		
Sedentary*	59	60	56-63	58	58	51-62	57	57	51-65	59	60	53-66	56	57	51-60	57	55	50-63
Light	36	36	34-38	39	38	35-44	39	40	32-46	38	36	31-45	40	40	35-45	41	41	34-46
Moderate	4	4	2-5	4	3	2-5	3	3	2-5	3	3	2-4	4	4	2-5	3	3	2-4
Vigorous**	<1	0	0-0.5	<1	<1	0-0.5	<1	<1	0-1	0	0	0-0	<1	0	0-0	<1	0	0-1
Steps per day ***	7506	7232	5015-8737	7050	6888	5642-8294	7602	7654	5278-9023	7150	6962	5934-8103	7451	7409	5909-8937	7361	7530	5662-9393

IQR, interquartile range; \bar{x} , mean; M, median, mpd, minutes per day

Note: Percentage values may not add to 100% due to rounding.

*Count <100 were considered sedentary using both cut points as per Matthews et al (2008)

**Values below 0.1 were treated as 0 for reporting purposes.

***Steps taken <500 counts were removed from analysis

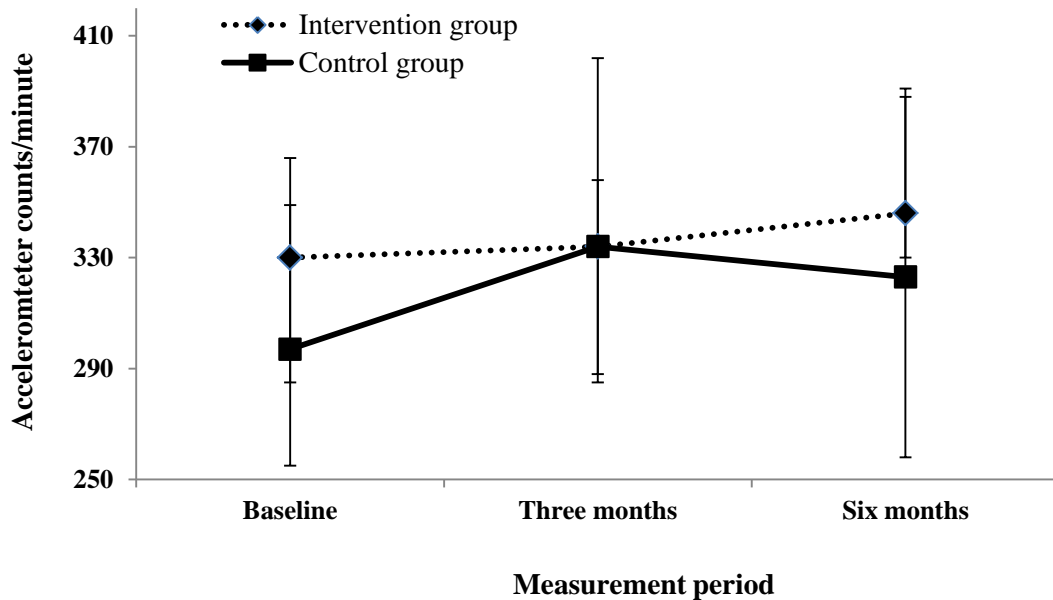
4.5.2.1 Baseline physical activity measured by accelerometer

At baseline average counts/minute were 343 (s.d. 118.31) for the intervention group and 315 (s.d. 89.38) for the control group. This difference between the groups was not significant $t(63) = 1.07$, $p = 0.29$; 95% CI -24.11, 80.08, $d = 0.13$). Descriptive data (i.e. median and 95% CI) for minutes/day (absolute time) and proportion (%) of time participants spent in combined MVPA (relative to total accelerometer wear time) during each measurement period are shown in Figure 10 and 11, respectively. Figure 11 shows the intervention groups' MVPA minutes/day were higher at baseline compared with controls although the error bars suggest this difference was not significant. This was confirmed using Mann Whitney U-tests at baseline ($U(65) = 462$, $p = 0.39$; $r = 0.12$).

4.5.2.2 Change in counts per minute from baseline to three and six months

Change in mean count/minute from baseline to three months were not significantly different between the groups, although there was evidence for a small effect size: $t(63) = -0.95$, $p = 0.35$ (95% CI -73.50, 26.17), $d = 0.22$ (Figure 9). Mean count/minute from baseline to three months increased in the intervention group by 9.33 (s.d. =92.47) and the control group by 32.99 (s.d. =108.20). From three to six months the intervention group showed an increase in counts/minute of 7.60 (s.d. =105.45); in the control groups average counts/minute decreased by -8.26 (s.d. =117.59). The difference between the groups on change in mean counts/minute from three to six months was not significant ($t(63) = 0.57$, $p = 0.57$ (95% CI -39.46, 71.18), $d = 0.13$). As with the analysis of the full dataset, per protocol analysis showed that there was no significant change in counts/minute from baseline to three months ($t(50) = -1.14$, $p = 0.26$ (95% CI -93.85, 25.82) or three to six months between the groups: $t(50) = 0.95$, $p = 0.35$ (95% CI -33.40, 93.15).

Figure 9. Accelerometer counts per minute at baseline, three and six months in the intervention and control group*

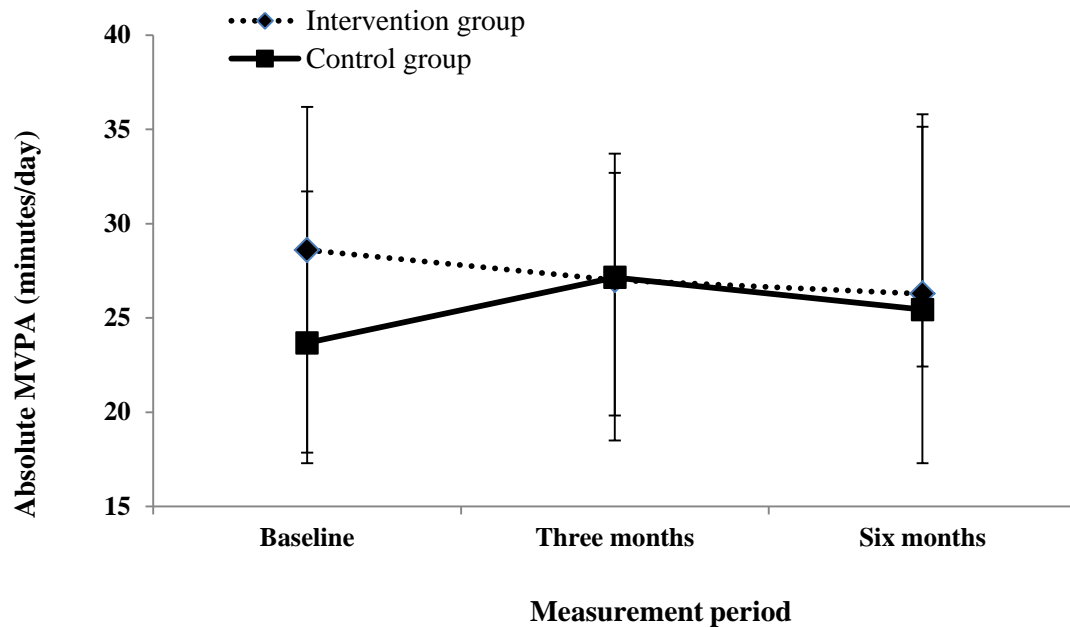


*Data shown in Figure 9 shows median counts/minute from the full dataset; error bars show 95% confidence intervals.

4.5.2.3 Change in absolute time spent in moderate-vigorous physical activity

From baseline to three months there was little change in MVPA minutes/day in the intervention group (median=-0.70, IQR -9.86, 8.36) or the control group (median=1.65, IQR -4.79, 8.21), see Figure 10; with no statistically significant between-groups differences from baseline and three months found ($U(65)=585$, $p=0.43$; $r=0.10$) using the full dataset or the per protocol analysis ($U(52)=383.50$, $p=0.23$). From three to six months there was no change MVPA minutes/day in the intervention groups (median=0, IQR -1.13, 1.10) or among controls (median=0, IQR -9.86, 8.23). There was also no differences between the groups using the full dataset ($U(65)=504$, $p=0.75$, $r=0.09$) or the per protocol analysis ($U(52)=302$, $p=0.74$).

Figure 10. **Absolute MVPA (minutes per day) at baseline, three and six months in the intervention and control group***

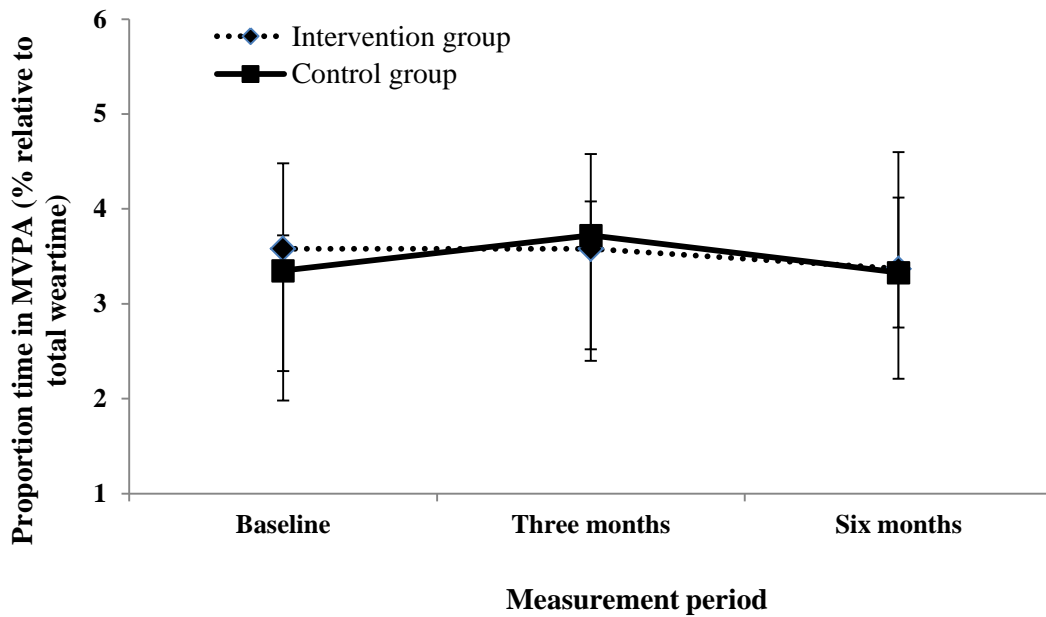


*Data shown in Figure 10 shows median counts/minute from the full dataset; error bars show 95% confidence intervals. Analysis of MVPA using the Freedson et al (1998) cut points (i.e. Light intensity = 100-1951counts, Moderate-intensity counts = 1952-5724; Vigorous/Hard intensity counts = ≥ 5725 .)

4.4.2.4 Change in proportion (%) of time in moderate-vigorous physical activity

There was no increase in median % of time in MVPA among the intervention group (0, IQR -1.13, 1.10) or control group (0.12, IQR -0.82, 1.58) from baseline to three months and no between-groups difference using the full dataset ($U(65)=562$, $p=0.66$, $r=0.08$) or per protocol analysis ($U(52)=366.50$, $p=0.38$), see Figure 11. From three to six months the median change in % time in MVPA among the intervention group was 0 (IQR -2.20, 1.29) and among the control group was -0.09 (IQR -1.45, 1.02). There were no differences between the groups from three to six months using the full dataset ($U(65)=512$, $p=0.83$, $r=0.03$) or per protocol dataset ($U(52)=305.50$, $p=0.79$).

Figure 11. Proportion (%) of time spent in MVPA (relative to total wear time) at baseline, three and six months in the intervention and control group*



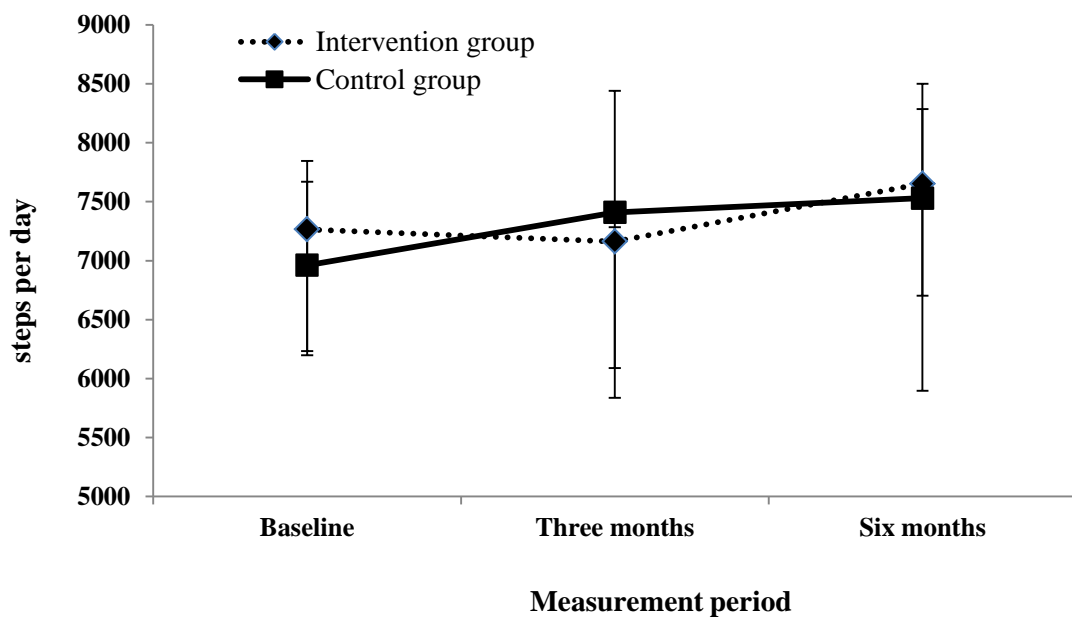
*Data shown in Figure 11 shows median counts/minute from the full dataset; error bars show 95% confidence intervals. Analysis of MVPA using the Freedson et al (1998) cut points (i.e. Light intensity = 100-1951counts, Moderate-intensity counts = 1952-5724; Vigorous/Hard intensity counts = ≥ 5725 .)

4.4.2.5 Change in steps per day

Median step per day (step/day) and 95% Confidence intervals for each group at each measurement period are shown in Figure 12. Among the intervention group there was no change in median steps/day (0, IQR -1619.44, 1047.94) from baseline to three months but there was evidence that steps/day increased among controls (195.95, IQR -1519.55, 1691.03). The large confidence intervals shown in Figure 12 suggest this change in control step/day is not statistically significant. There was no significant differences between the groups from baseline to three months using the full dataset ($U(65) = 596, p=0.37, r=0.18$) or the per protocol dataset ($U(52) = 398, p=0.14$). Between three to six months the intervention group showed an increase in steps/day (549.74, IQR -1057.48, 1738.54), but controls did not change (0, IQR -1147.50, 1303.52). Again the confidence intervals suggest the increase in the

intervention groups was not significant. Between three and six months change in steps/day was not significantly different between the groups ($U(65) = 456, p = 0.35, r = 0.16$). Analysis using the per protocol dataset showed similar findings ($U(52) = 251, p = 0.19$).

Figure 12. Median steps per day at baseline, three and six months in the intervention and control group*



*Data shown in Figure 12 shows median step/day from the full dataset; error bars show 95% confidence intervals. Steps taken <500 counts were removed from analysis.

4.5.3 Change in self-reported moderate-vigorous physical activity

Weekly minutes of self-reported MVPA (mean, median and IQ range) at baseline, three and six months are shown in Table 30. Figure 13 shows median minutes graphically, 95% CIs shown as error bars. Only bouts of ten minutes or more of MVPA were included. Data was non-normally distributed during all measurement periods, as were the change in weekly self-reported MVPA from baseline to three months ($D(65) = 0.13, p = 0.01$) and three to six months ($D(65) = 0.11, p = 0.04$) based on visual inspection of boxplots and histograms and K-S tests.

As shown in Figure 13, baseline self-reported MVPA was significantly higher among the intervention group compared with controls ($U(65) = 361.5, p = 0.03, r = 0.27$). From baseline to three months there was a median decrease in weekly self-reported MVPA of 15 minutes (IQ range -111, 15) in the intervention group and an increase of 30 minutes (IQ range -68, 75) among the control group. Analysis of the difference between the groups from baseline to three months found this was non-significant but was associated with a small effect size ($U(65) = 665, p = 0.71, r = 0.22$). During the period from three to six months there was no change in median weekly self-reported MVPA minutes (i.e. 0, IQ range -26, 71) in the intervention group. The control group showed a median decrease of 53 minutes (IQ range -41, -101). This difference from three to six months (explained by the decrease among the control group) was significant between the groups and associated with a small effect size ($U(65) = 371, p = 0.04, r = 0.26$).

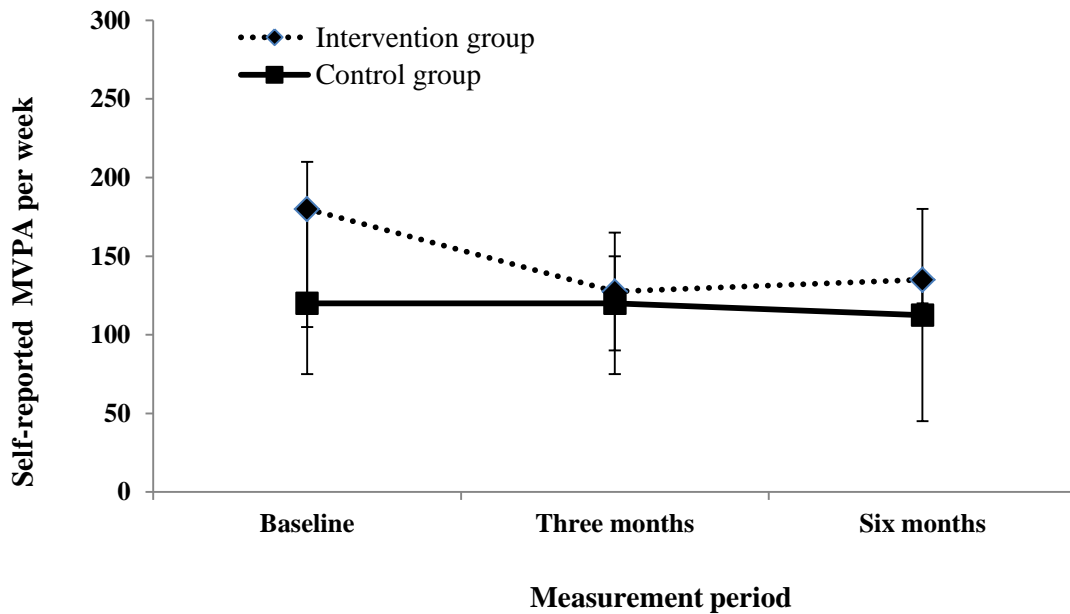
Table 30. Self-reported total weekly minutes of moderate-vigorous physical activity*

Measurement period	Intervention group		Control group	
	Mean	Median (IQ range)	Mean	Median (IQ range)
Baseline	199	180 (98, 180)	132	120 (60, 191)
Three months	162	128 (86, 128)	158	120 (75, 221)
Six months**	169	135 (105, 199)	110	113 (34, 165)

*Only includes moderate-vigorous activity performed in ten minute bouts

**Between groups difference in change from previous follow-up point significant ($p < 0.05$).

Figure 13. Self-reported total weekly minutes of moderate-vigorous physical activity*

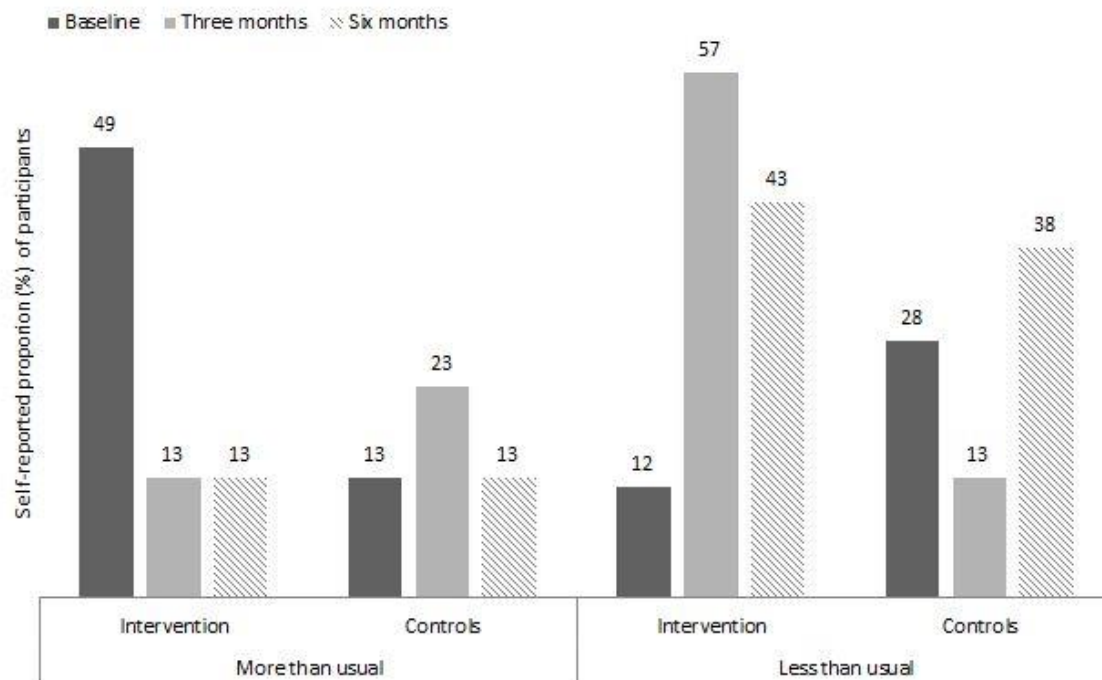


*Data shown in Figure 13 shows median self-reported MVPA from the full dataset only including bouts of ten minutes or more; error bars show 95% confidence intervals.

4.5.3.1 Representativeness of the measurement week

Participants reported whether their previous week's PA was more, less or about the same as their usual activity levels during the previous three months. The proportion of participants reporting representativeness of activity levels during each measurement week is shown in Figure 14. Compared with usual activity levels, 49% (intervention) and 13% (controls) reported more PA during the baseline measurement period, while 12% (intervention) and 28% (controls) reported less than usual activity during the baseline measurement week. By three months this trend reversed with more control participants reporting greater activity than usual (23%), compared to intervention participations (13%) and more intervention participants reporting less activity than usual (57%) compared with controls (13%). At six months the proportion reporting more activity than usual was equal (13%) in both groups, and less activity than usual was also similar (43% intervention, 38% controls).

Figure 14. **Proportion of participants reporting how their physical activity levels differed from usual habits during each measurement period**



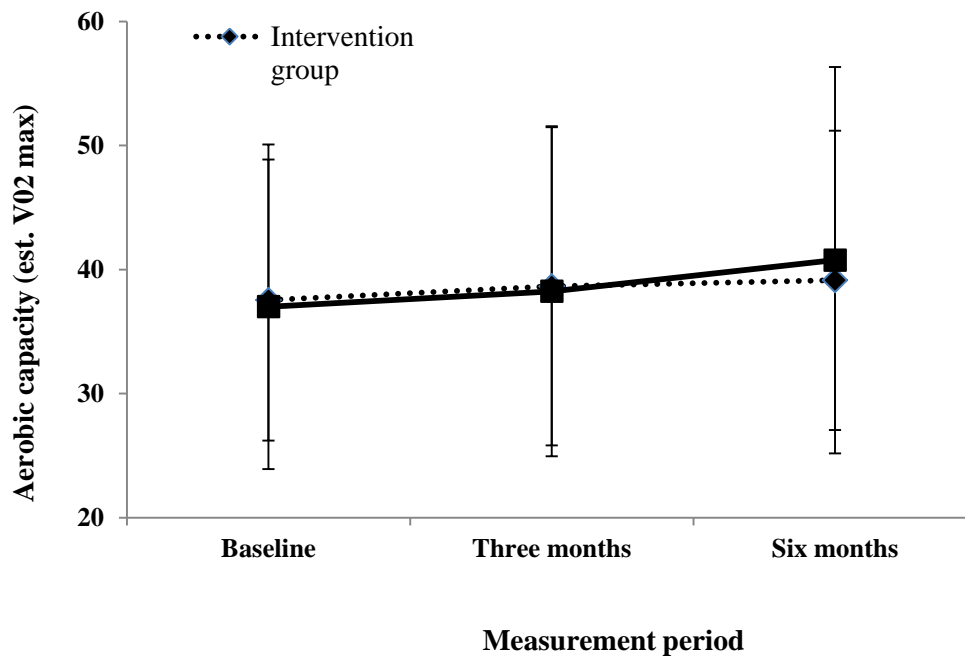
4.5.4 Cardiovascular fitness change

Using the K-S test, along with visual inspection of the data showed cardiovascular fitness, measured via estimated aerobic capacity was normally distributed. The means and standard deviations are shown in Table 31 and Figure 15 shows cardiovascular fitness at each measurement period with the 95% CI error bars for the distribution around the mean. As shown in Table 31/Figure 15 there was no difference between the groups at baseline. No significant differences were found between groups for the change in aerobic capacity from baseline to three months ($t(63) = -0.06, p=0.95$ (95% CI -2.82, 2.66) or from three to six months ($t(63) = -1.31, p=0.20$ (95% CI -4.82, 1.01). There appeared to be no difference in aerobic capacity from baseline to three and from three to six months in either group.

Table 31. Mean aerobic capacity reported as estimated VO₂ max (mlsO₂/kg/min) at baseline, three and six months

Measurement period	Intervention group Mean (s.d.)	Control group Mean (s.d.)
Baseline	37 (5.78)	37 (6.68)
Three months	38 (6.54)	38 (6.79)
Six months	39 (6.16)	41 (7.95)

Figure 15. Mean aerobic capacity (estimated VO₂ max) at baseline, three and six months in the intervention and control group



*Error bars show 95% confidence intervals for the mean (standard error).

4.5.4.1 Proportion of participants in each fitness category

The proportion of participants in each fitness category across the sample at baseline, three and six months are shown in Table 32 (intervention group) and Table 33 (control group). At baseline most participants from both groups were in the average or good category when considering their aerobic capacity against established age-adjusted normative data. From baseline to three months 15/33 (45%) participants from the intervention group and 12/32

(38%) participants from the control group changed fitness category. Of those changing fitness category 8/15 intervention participants increased one (6, 18%) or two (2, 6%) categories, six (18%) intervention participants dropped their fitness category by one category. One participant dropped two levels. Similar results were found among controls with 8/12 (25%) and 1/12 (3%) of participants showing an increase of one or two fitness categories, respectively from baseline to three months follow-up. Two participants (6%) dropped a fitness category (one level) and one participants showed dropped two levels. From three to six months 17/33 or 52% (intervention) and 14/32 or 44% (control) participants showed a change in fitness category. Of those, 10 intervention participants (30%) increased by one category level (e.g. from average to good etc.) and seven participants (21%) dropped by one category. Among control participants six (19%) and two (6%) increased their category for fitness by one or two levels, respectively; six control participants (19%) dropped a category.

Table 32. Participants in each fitness category at baseline, three and six months (intervention)

Measurement period	Poor (%)	Below Average (%)	Average (%)	Good (%)	Excellent (%)
Baseline	-	2 (6)	12 (36)	17 (52)	2 (6)
Three months	-	5 (15)	7 (21)	16 (49)	5 (15)
Six months	-	2 (6)	9 (27)	18 (55)	4 (12)

Table 33. Participants in each fitness category at baseline, three and six months (control)

Measurement period	Poor (%)	Below Average (%)	Average (%)	Good (%)	Excellent (%)
Baseline	1 (3)	1 (3)	14 (44)	13 (41)	3 (9)
Three months	1 (3)	1 (3)	10 (28)	15 (47)	5(16)
Six months	-	2 (6)	9 (28)	14 (43)	8 (22)

4.5.5 Summary of physical activity outcomes

At baseline intervention participants' counts/minute and minute/day of accelerometer-measured MVPA were higher than controls but these differences were not statistically significant. There were no significant differences between the intervention and control group for the change in the main PA outcomes as measured by accelerometer from baseline to three months follow-up. The intervention group maintained counts/minute at three months showing a small increase at six months. Among the control group there was a small increase in counts/minute at three months followed by a decrease at six months, which did not return to baseline levels but was lower compared with the intervention group at six months. There was a small non-significant effect size for the between-groups difference on counts/minute from baseline to three months follow-up ($d=0.22$). There were no significant differences in the proportion of time spent in MVPA or absolute minutes/day of MVPA between groups or across the measurement periods and analysis of the confidence intervals suggested minimal change occurred in both groups from baseline to three to six months follow-up. Considering steps/day the increase among control groups from baseline to three months was small (<200 steps/day) and the intervention groups' steps/day did not change. From three to six months the control group maintained similar steps/day while the intervention group showed an increase of around 550 step/day. These differences between the groups were non-significant although were associated with small effect sizes ($d=0.16$ to 0.18). Baseline values for self-reported MVPA was significantly greater compared with controls (i.e. 180 minute/week compared with 120 minute/week). Considering self-reported weekly minutes of MVPA from baseline to three months there was a small decrease among the intervention group (15 minutes) with the control group increasing their self-reported weekly minutes of MVPA by 30 minutes. This effect was small favouring the control group ($r=0.22$), but was not statistically significant. From three to six months the intervention group showed no change

while the control group self-reported a large decrease in weekly minutes MVPA (53 minutes), this difference was significant between the groups with a small effect size ($r=0.26$). Considering representativeness of the PA measurement week, at baseline a large proportion of intervention participants self-reporting being more active than usual (compared with the previous three months). By three and six months this was reversed with a high percentage of intervention participants reporting less PA than usual during their measurement week. There were no significant between group differences in estimated aerobic capacity from baseline to three and three to six months with no evidence for an increase in either group.

4.6 Secondary outcomes: effects on physical and psychological health

4.6.1 Anthropometric measures and body composition

4.6.1.1 Weight and body mass index

Weight at three (D (60) =0.13, $p=0.01$) and six months (D (59) =0.14, $p=0.01$) were positively skewed and BMI was non-normally distributed (positive skew) at six months D (59) =0.16, $p<0.01$. Table 34 shows the mean, median and interquartile range for weight and BMI at all measurement points. Change in weight and BMI from baseline to three months follow-up and from three to six months were non-normally distributed. Therefore, Mann Whitney U-tests were used to analyse change in weight and BMI over the study period. There was evidence for a trend in both groups of a small decrease in weight and BMI from baseline to three months and from three to six months, however as shown in Figures 16 and Figure 17 there were large confidence intervals surrounding the median weight loss and BMI change suggesting these changes were not significant. The intervention groups' median weight and BMI remained higher than controls at all measurement points. There was no between groups

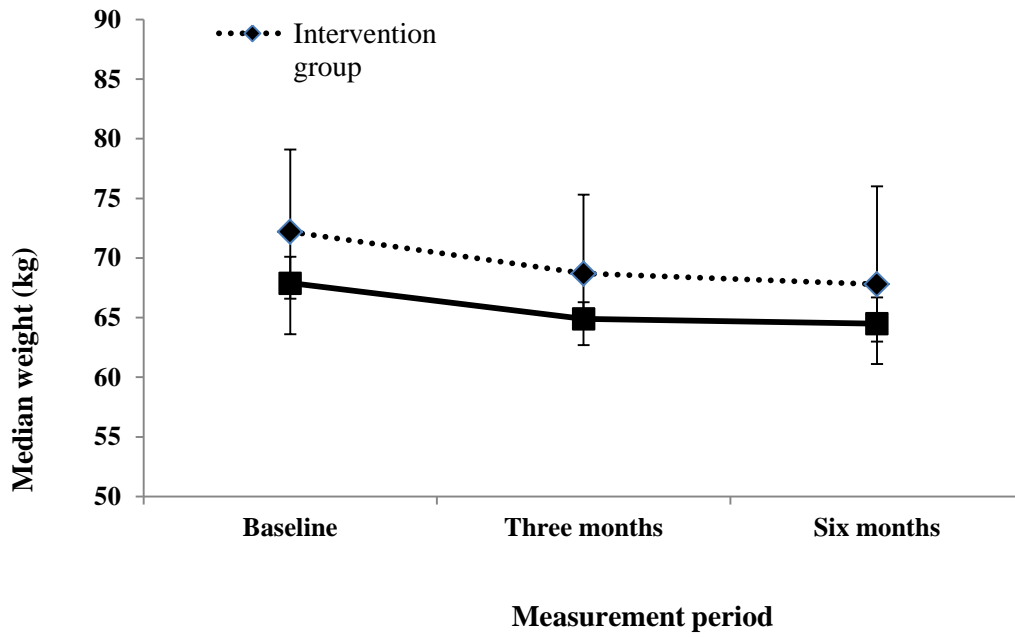
difference for the change in weight from baseline to three months (U (60) =468.00, p=0.80) or from three to six months U (58) =433.50, p=0.84). There were no differences in change in BMI between the groups from baseline to three (U (60) =467.50, p=0.80) and from three to six months (U (58) =456.50, p=0.58).

Table 34. **Anthropometric results at baseline, three and six months follow-up**

Measurement period	Intervention group		Control group	
	\bar{x}	Median (IQ Range)	\bar{x}	Median (IQ Range)
Weight (kg)				
Baseline	73	72 (65, 80) ¹	68	68 (62, 72) ⁴
Three months	71	69 (63, 79) ²	67	65 (62, 72) ²
Six months	71	68 (61, 79) ²	66	65 (61, 71) ³
BMI (kg/m²)				
Baseline	27	27 (24, 30) ¹	25	25 (22, 27) ⁴
Three months	26	26 (23, 29) ²	25	24 (22, 27) ²
Six months	26	25 (23, 29) ²	25	24 (22, 27) ³
Fat mass (kg)				
Baseline	26	26 (20, 33) ¹	23	22 (18, 26) ⁵
Three months	26	25 (20, 32) ²	22	20 (17, 26) ²
Six months	25	25 (18, 34) ³	22	19 (17, 25) ³
% Fat mass				
Baseline	36	35 (32, 41) ¹	33	32 (30, 36) ⁵
Three months	34	35 (35, 40) ²	32	31 (29, 35) ²
Six months	34	34 (29, 41) ³	31	30 (27, 35) ³

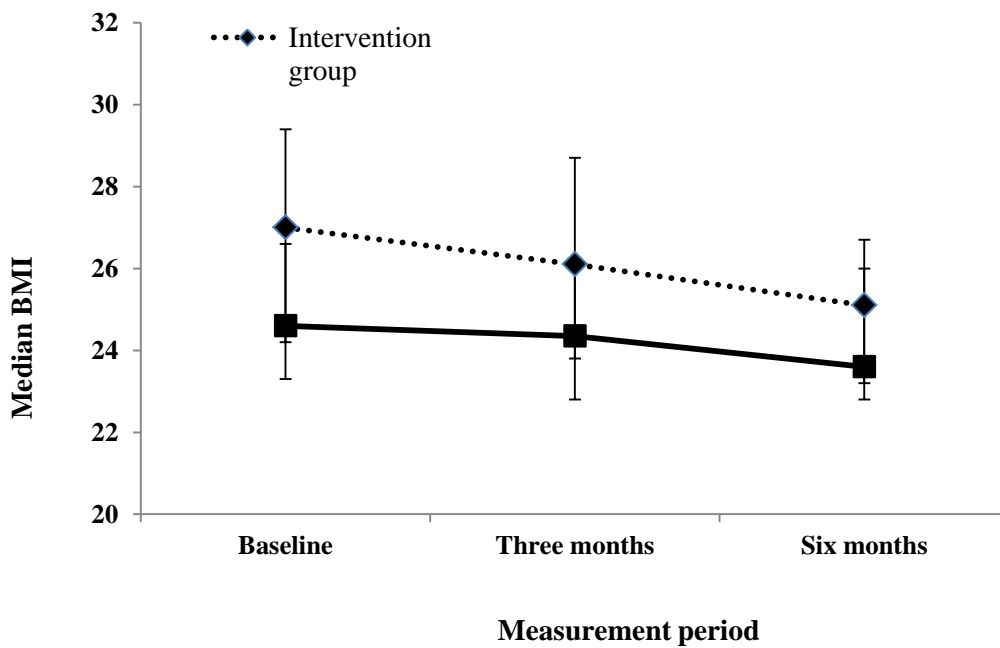
BMI, Body mass index; IQR, interquartile range; \bar{x} , mean.
 Numbers in analysis: ¹n=33, ²n=30, ³n=29, ⁴n=32, ⁵n=31.

Figure 16. Median weight (kg) at baseline, three and six months



*Error bars show 95% confidence intervals for the median.

Figure 17. Median Body Mass Index at baseline, three and six months

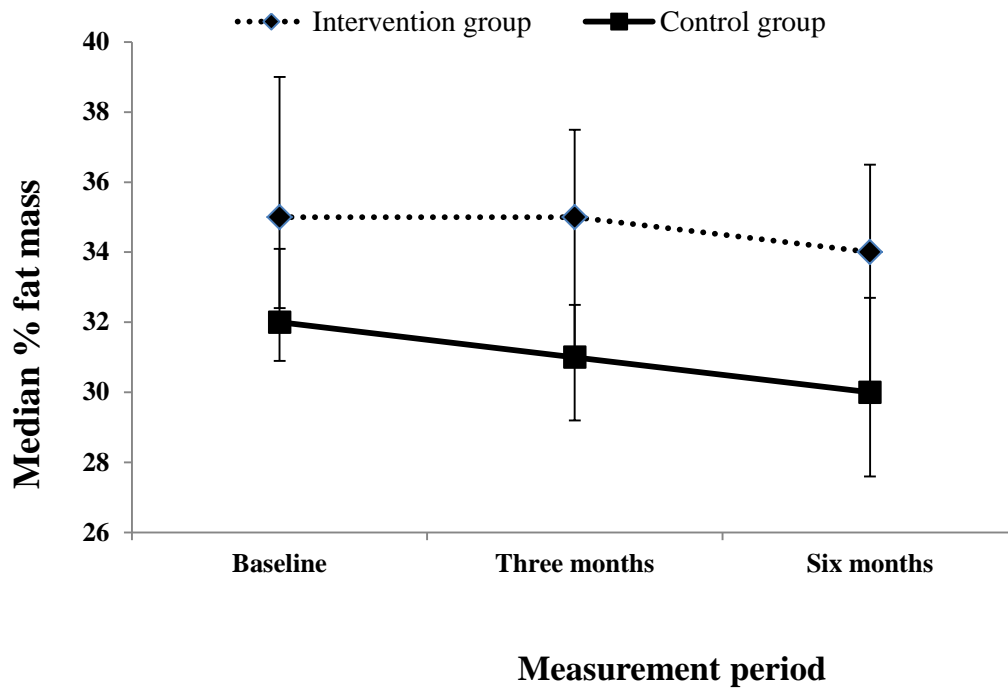


*Error bars show 95% confidence intervals for the median.

4.6.1.2 Body composition

Fat mass (kg) at baseline followed normal distribution, however, at three and six months K-S tests showed the data was positively skewed (three months: $D(56)=0.14$, $p=0.01$ and six months: $D(56)=0.15$, $p=0.01$); change in fat mass was non-normally distributed from three to six months follow-up ($D(56)=0.20$, $p<0.01$). Change in %fat mass was also non-normally distributed from three to six months ($D(56)=0.09$, $p<0.01$). Table 34 gives the mean, median and interquartile range for fat mass and % fat mass at baseline, three and six months for both groups. Analysis proceeded with Mann Whitney U-tests. Figure 18 shows median %fat mass and 95% confidence intervals at each measurement point. As shown a small decrease in %fat mass was found across both groups with the intervention groups' %fat mass remaining higher at all measurement periods but the large confidence intervals around the median suggest this is a non-significant trend. As expected, there were no significant differences between the groups from baseline to three ($U(59)=396.00$, $p=0.55$) and three to six months ($U(58)=434.00$, $p=0.66$) for change in fat mass. There were no significant between groups differences for change in %fat mass from baseline to three months ($U(58)=419.50$, $p=0.81$) and from three to six months ($U(58)=423.50$, $p=0.78$).

Figure 18. Median % fat mass in at baseline, three and six months



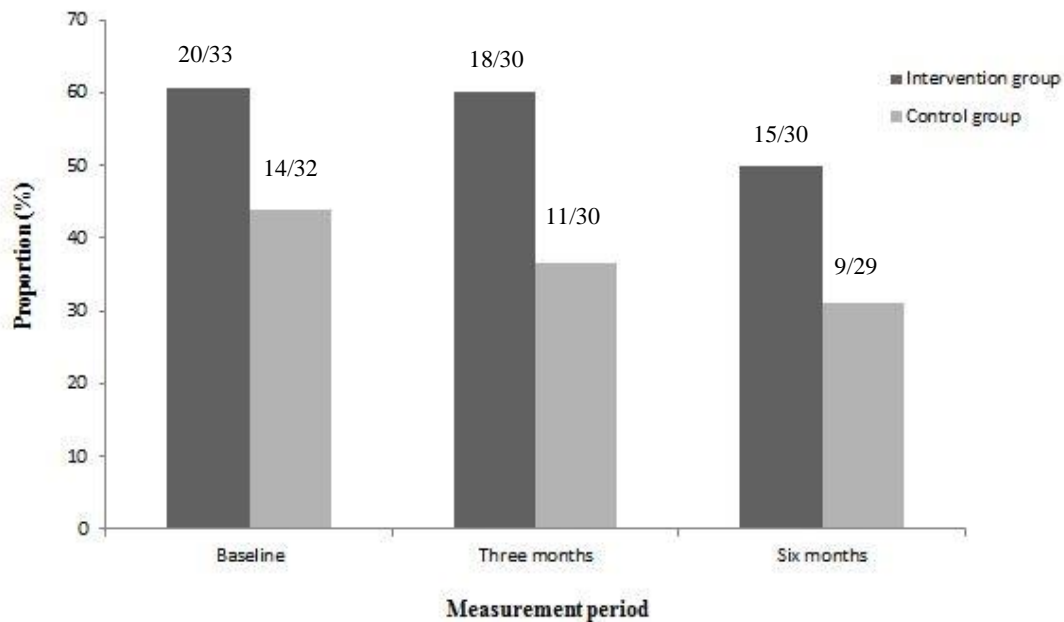
*Error bars show 95% confidence intervals for the median.

4.6.1.3 Proportion of overweight and obese participants

The proportion of overweight and obese participants across the sample at baseline, three and six months is shown in Figure 19. Overall from baseline to three months 7/61 (12%) of participants showed a positive change in their BMI classification (i.e. went from overweight at baseline to normal weight (four participants) or obese to overweight (three participants)); these changes occurred in two participants from the intervention group and five from the control group. From three months to six months an additional three intervention participants and two control participants showed a positive change in their BMI classification (five participants in total). Of those five one changed from being in the obese category to being overweight and four changed from overweight to normal weight. No participants showed a

negative change in their BMI classification (i.e. moved from the normal to overweight or the overweight to obese category).

Figure 19. **Proportion of overweight and obese participants at baseline, three and six months between the intervention and control group**



*Overweight: BMI>25kg/m², Obese: (BMI>30kg/m²)

4.6.2 Psychological wellbeing and fatigue

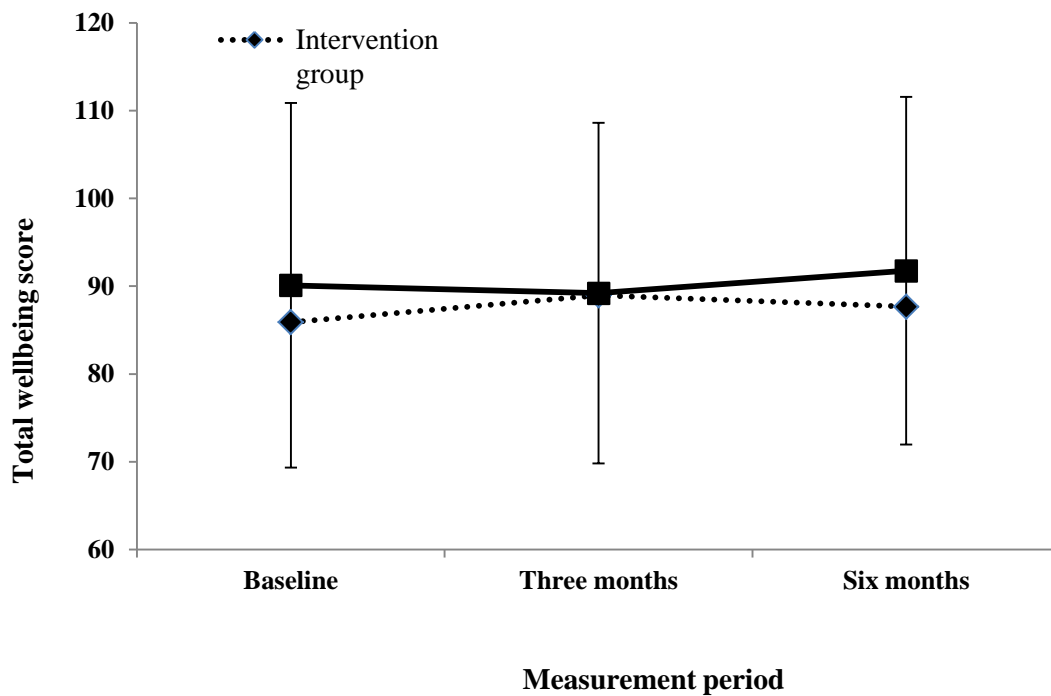
Total psychological wellbeing on the AGWBI was normally distributed at all measurement periods based on visual inspection and analysis with the K-S test. Independent samples t-tests were used to test the effect of the intervention on change in psychological wellbeing. The means and standard deviations are shown in Table 35 and Figure 20. Over the study period there was little evidence for a change across either group and no significant between groups' differences from baseline to three ($t(59)=1.74$, $p=0.09$; 95% CI -0.77, 10.95) and three to six months follow-up ($t(57)=-1.32$, $p=0.19$; 95% CI -9.68, 1.97).

Table 35. Psychological wellbeing at baseline, three and six months

Measurement period	Intervention group	Control group
	mean (s.d.)	mean (s.d.)
Baseline	86 (10.6)	90 (8.1)
Three months	89 (9.9)	89 (8.2)
Six months	88 (10.1)	92 (7.5)

Intervention group: n=30, control group: n=29. Note. The AGWI Likert scale range is 22-110.

Figure 20. Mean psychological wellbeing at baseline, three and six months



*Error bars show 95% confidence intervals (standard error) for the mean.

4.6.2.1 Fatigue

Fatigue was non-normally distributed (positive skew) at all measurement periods based on visual inspection and analysis with the K-S test. Median scores at baseline, three and six months are shown in Table 36. Change in fatigue from baseline to three months and three to six months were normally distributed and analysis with independent t-tests showed the

fatigue decreased among intervention group between baseline and three months follow-up, while among control group participants fatigue increased; this difference between the groups was significant ($t(58)=-3.34$, $p<0.01$ (95% CI -36.49, -9.14)). This pattern was reversed from three to six months, with fatigue increased among intervention participants and decreasing among controls ($t(55)=2.71$, $p<0.01$ (95% CI 5.20, 34.86)).

Table 36. Fatigue score at baseline, three and six months by group

Measurement period	Intervention group median (IQ Range)	Control group median (IQ Range)
Baseline ¹	44 (31, 66)	28 (20, 49)
Three months ²	26 (15, 58)	49 (26, 61)
Six months ³	49 (16, 62)	27 (17, 46)

N in the intervention (I) and control (C) groups: ¹I=33, C=32, ²I=31, C=29, ³I=31, C=28

4.6.3 Summary of health and wellbeing outcomes

There were no differences between the intervention and control group on change in anthropometric variables from baseline to three months follow-up and from three to six months. Descriptive data showed a trend for weight, BMI and fat mass proportion to have reduced in both groups from baseline to three and from three to six month follow-up. The proportion of participants who were overweight or obese also reduced over time. However, there was not sufficient evidence that these changes were significant and the intervention group remained higher on all anthropometric variables across the measurement periods. There were also no significant difference between the groups on change in psychological wellbeing and scores remained relatively stable throughout the measurement periods with no evidence for group differences at baseline, three of six months. However, fatigue scores significantly improved in the intervention group (as shown by the reduction in score compared to the controls group) from baseline to three months follow-up. There was a

significant between groups difference with controls at this stage, however this pattern reversed at six months follow-up and intervention participants reported significantly greater fatigue relative to controls.

4.7 Effect of the intervention on physical activity cognitions

4.7.1 Internal consistency and distribution

Prior to analysis of PA cognition, Cronbach's alphas were computed for all variables. There was evidence that all constructs met criteria for internal consistency (with the exception of outcome expectancies); Figures at baseline were: outcome expectancies ($\alpha=0.38$), self-efficacy ($\alpha=0.78$), action planning ($\alpha=0.94$), coping planning ($\alpha=0.94$) and action control ($\alpha=0.75$). Analysis of the outcome expectancies construct suggested internal reliability would improve to $\alpha=0.60$ if the item "if I were regularly physically active my family and friends would get to spend less time with me" was deleted. As $\alpha=0.60$ is considered an acceptable alpha score for combining questionnaire items, this item was removed. Therefore, the outcome expectancies scale was the total score of the five other items, with items four ("I would have less energy") and six ("it would make no difference to my weight") reverse-coded as these were negatively worded. Self-efficacy, action planning, coping planning and action control were totalled with no items deleted.

The results of K-S test for all psychological variables at baseline, three and six months are shown in Table 37 below. Significant values indicate deviations from normality, which were confirmed via visual inspection of plots. Change scores were also non-normally distributed; therefore analysis preceded using non-parametric tests for all variables. Given the number of PA cognition variables being tested I considered a value of ≤ 0.05 indicative of a

significant difference and values of ≤ 0.01 to be significant differences and reported effect sizes throughout to aid interpretation of results.

Table 37. Normality testing for psychological variables

Theoretical variable	Baseline	Three months	Six months
Outcomes expectancies	0.10	0.12*	0.12*
Self-efficacy	0.06	0.11	0.07
Intentions	0.23**	0.19**	0.21**
Action planning	0.18**	0.18**	0.17**
Coping planning	0.25**	0.25**	0.18**
Action control	0.12*	0.09	0.12*

Results shown are Kolmogorov-Smirnov (K-S) test of normality, $df=65$, * $p<0.05$, ** $p<0.01$

4.7.2 Change in physical activity cognitions as a response to the intervention

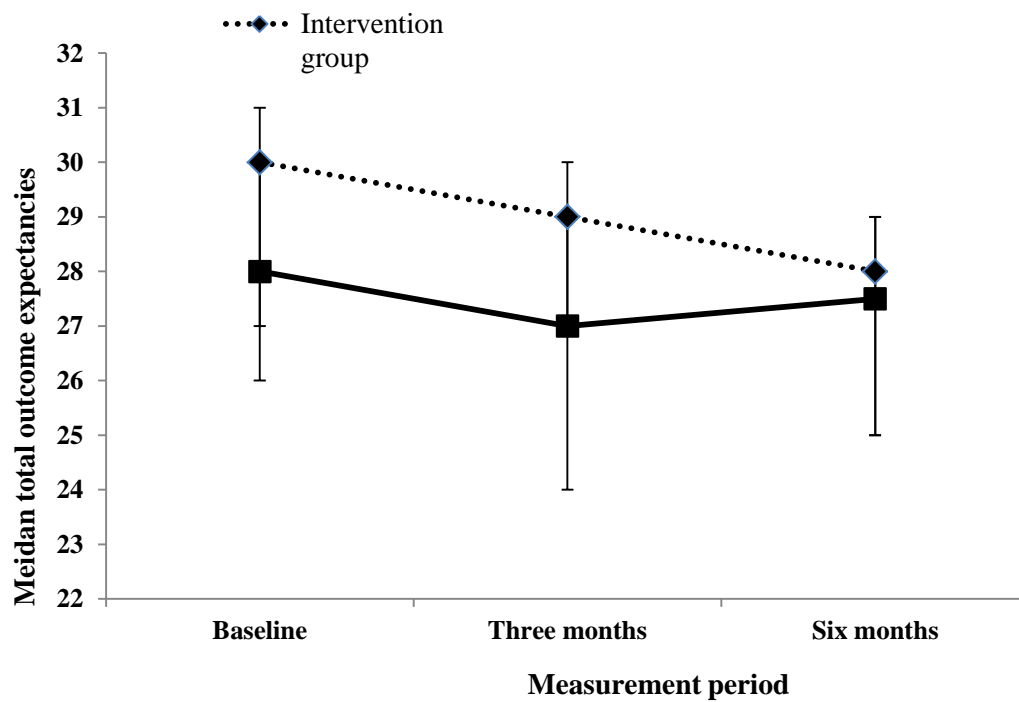
Table 38 shows the mean, median and interquartile range scores for all psychological variables.

4.7.2.1 Outcome expectancies and intentions

Figure 21 shows a decrease in the median outcome expectancies score from baseline to three months follow-up in both groups. As expected there were no significant between-groups difference in change in outcome expectancies with a Mann Whitney test ($U(65)=474.00$, $p=0.48$, $r=-0.09$). However, there was a further decrease in outcome expectancies between three and six months in the intervention group and a small increase among controls. This between groups difference was indicative of a significant trend and was associated with a small effect size ($U(65)=688.50$, $p=0.03$, $r=0.26$) suggesting the intervention group's outcome expectancies became more negative during the period from three to six months. Intentions were high at baseline in both groups (Table 38). There was no significant difference in intentions to be active between

groups from baseline to three months ($U(65)=389.00$, $p=0.06$, $r=-0.24$), although the small effect size reflects the small drop in intentions to be active that was found among the control group (Table 38). From three to six months follow-up ($U(65)=551.00$, $p=0.74$, $r=0.04$) there was no between-groups difference in scores. The control group's intentions remained lower compared to the intervention group at six months.

Figure 21. Median outcome expectancies score at baseline, three and six months*



*Error bars show 95% confidence intervals for the median.

Table 38. Physical activity cognitions at baseline, three and six month's follow-up

Measurement period	Intervention group (n=33)		Control group (n=32)	
	\bar{x}	Median (IQ Range)	\bar{x}	Median (IQ Range)
Outcome Expectancies¹				
Baseline	29	30 (26, 32)	28	28 (25, 31)
Three months*	29	29 (27, 32)	27	27 (23, 29)
Six months	27	28 (25, 31)	28	28 (24, 29)
Self-efficacy²				
Baseline	24	23 (18, 30)	25	25 (20, 30)
Three months*	27	27 (24, 31)	23	24 (17, 27)
Six months	27	27 (23, 33)	24	22 (17, 28)
Intentions³				
Baseline	6	6 (5, 7)	6	6 (5, 7)
Three months*	6	6 (5, 7)	5	6 (5, 6)
Six months	6	6 (5, 7)	5	5 (5, 7)
Action planning⁴				
Baseline	10	10 (8, 12)	11	11 (7, 12)
Three months*	12	12 (11, 13)	10	10 (7, 12)
Six months**	12	12 (10, 13)	12	12 (8, 14)
Coping planning⁵				
Baseline	6	6 (3, 6)	4	4 (3, 8)
Three months*	7	7 (6, 9)	5	6 (3, 6)
Six months**	8	8 (7, 9)	6	6 (3, 8)
Action control⁶				
Baseline	13	13 (11, 16)	13	13 (11, 15)
Three months*	19	18 (16, 22)	15	15 (11, 18)
Six months	18	19 (15, 20)	14	14 (12, 19)

IQR, interquartile range; \bar{x} , mean. Note: A higher score indicates greater endorsement of the construct (e.g. higher self-efficacy, greater coping planning etc.) with the following Likert score ranges=¹5-35, ²7-49, ³1-7, ⁴4-16, ⁵3-12, ⁶6-24

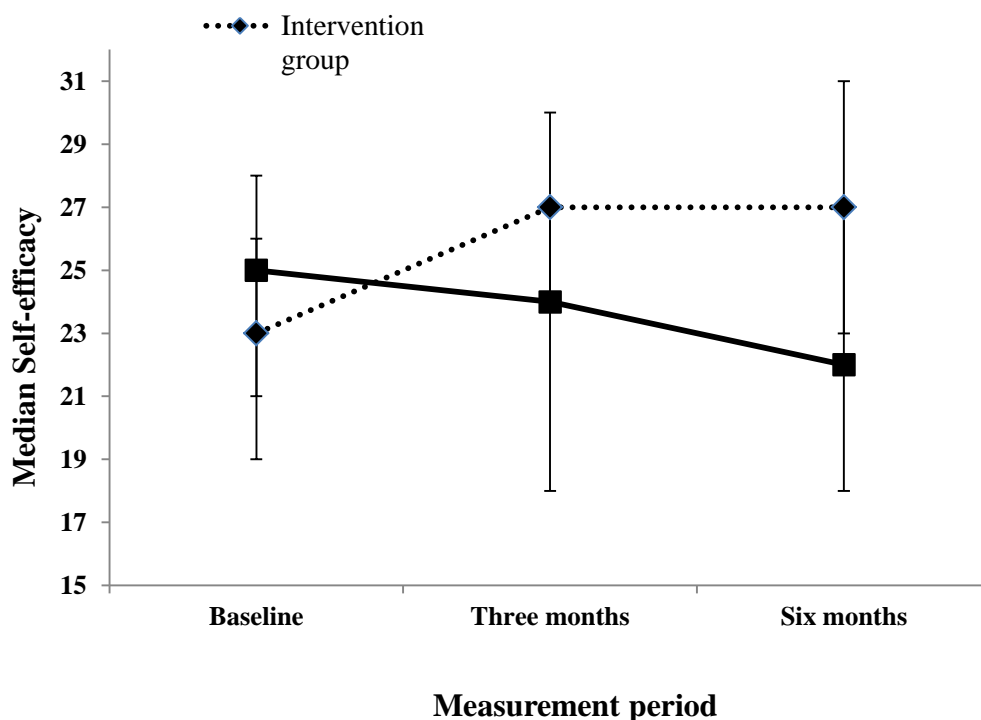
*Difference in change between groups from baseline p<0.05

**Difference in change between groups from three months p<0.01.

4.7.2.2 Self-efficacy, planning measures and action control

Table 38 and Figure 22 show there was an increase in self-efficacy from baseline to three months in the intervention group and a small decrease among controls. The error bars suggest the mean self-efficacy scores were similar at baseline in the two groups and analysis showed this difference in change in self-efficacy was indicative of a significant trend ($U(65)=357.50$, $p=0.03$, $r=-0.27$) with a small effect size noted. From three to six months the intervention group's improved self-efficacy score was maintained but the control groups self-efficacy dropped further. This between groups difference in self-efficacy from the three to six months follow-up was not significant ($U(65)=537.00$, $p=0.91$, $r=0.01$) but scores in the intervention group remained higher (Figure 22).

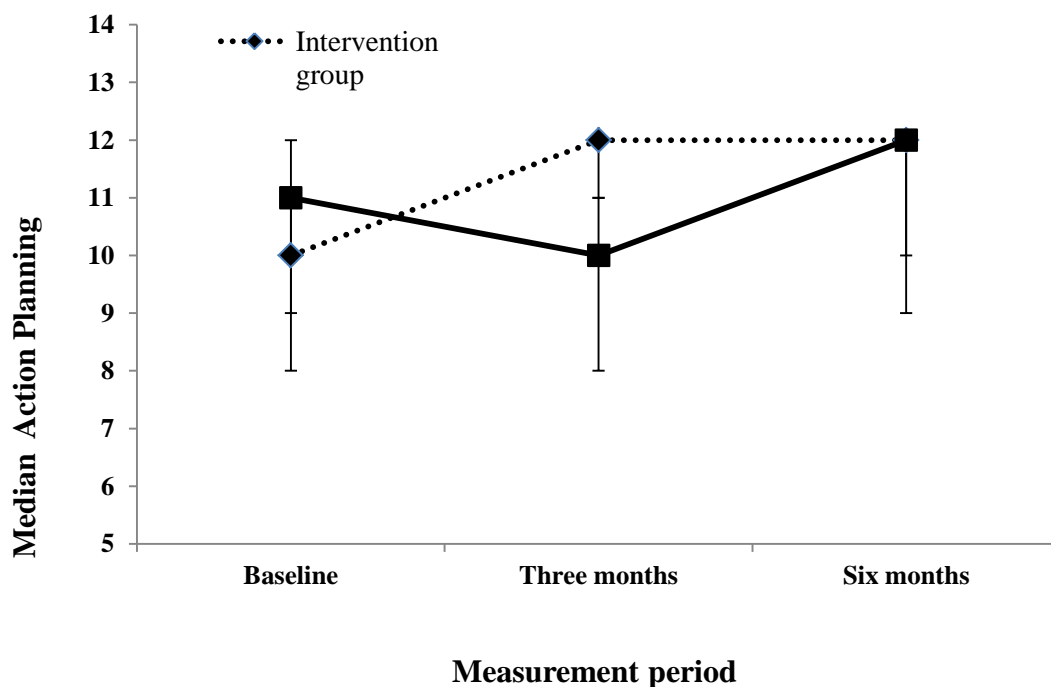
Figure 22. Median self-efficacy score at baseline, three and six months*



*Error bars show 95% confidence intervals for the median.

Table 38 and Figure 23 shows both groups started with similar action planning scores at baseline. The intervention groups' median action planning score increased, while the control groups' decreased from baseline to three months. This increase was maintained in the intervention group from three to six months, however and control groups showed an increase in action planning during this period, which brought their score in line with the intervention groups' score (Figure 23). There were significant between group difference in change in action planning between baseline and three months ($U(65)=320.50$, $p<0.01$, $r=-0.34$) favouring the intervention group. Between three and six months follow-up the significant between-groups difference ($U(65)=793.50$, $p<0.01$, $r=0.39$) favoured the control group.

Figure 23. **Median action planning score at baseline, three and six months***



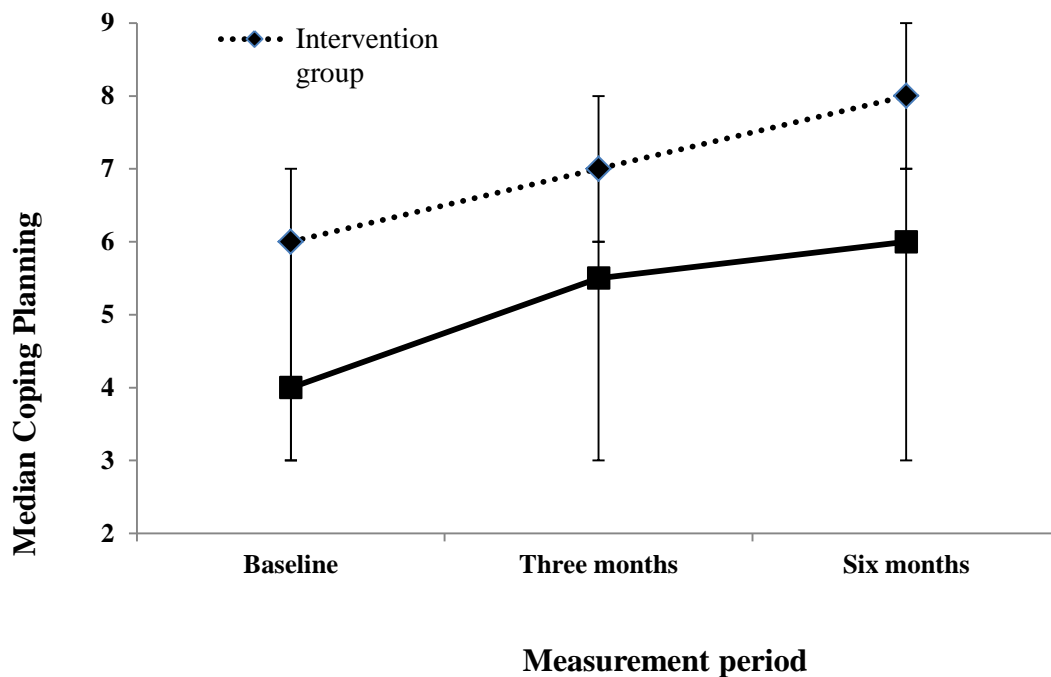
*Error bars show 95% confidence intervals for the median.

Coping planning scores were greater in the intervention compared to controls at baseline.

Considering the change in scores from baseline to three months both groups showed an

increase in their total median score (Table 38, Figure 24) but there was a between groups difference in coping planning change from baseline to three month ($U(65)=798.50$, $p<0.01$, $r=0.44$) and from three to six months ($U(65)=813.00$, $p<0.01$, $r=0.41$), which were due to a significantly greater improvements in coping planning the intervention group. These differences were associated with small-moderate effect sizes.

Figure 24. Median coping planning score at baseline, three and six months*

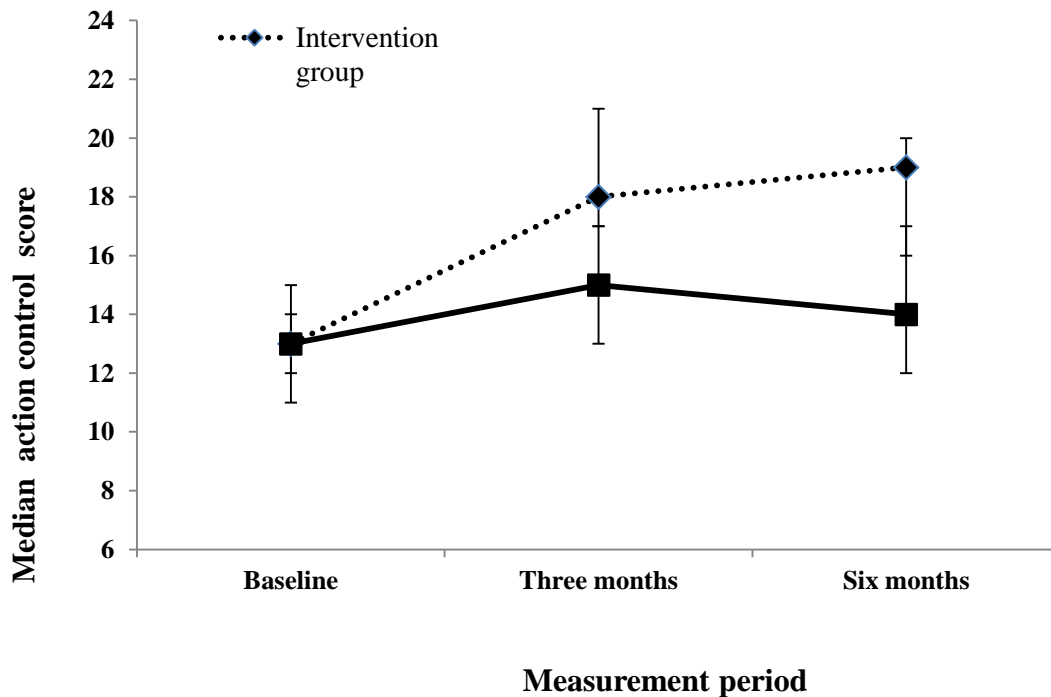


*Error bars show 95% confidence intervals for the median.

Total action control score was similar at baseline between the groups (Table 38 and Figure 25). Action control increased slightly in the control group from baseline to three months, while in the intervention group there was a large increase (Table 38). This between-groups difference was significant with a small-moderate effect size ($U(65)=265.50$, $p<0.01$, $r=0.43$). The intervention groups' action control score at six months increased again slightly relative to three months, while the controls' score decreased slightly, but did not return to baseline

levels. This between-groups difference for the change in action control score did not reach significance from three to six months ($U(65)=622.00$, $p=0.22$, $r=0.15$).

Figure 25. Median action control score at baseline, three and six months*



*Error bars show 95% confidence intervals for the median.

4.7.3 Summary: change in physical activity cognitions

Significant changes in PA cognitions in response to the intervention were found. Intentions to be active remained high in both groups over the study period and the intervention group showed a small decrease in their total outcome expectancies score relative to controls between three and six months. The decrease (i.e. worsening) outcome expectancies score did not reach significance using the more conservative p-value. From baseline to three months the intervention group showed an increase in self-efficacy, action planning, coping planning and action control scores relative to controls (who showed a decline in action planning and self-efficacy score). These differences represented small-moderate effect sizes, although the

between-groups difference in self-efficacy was not significant using the more conservative p-value; the other PA cognitions were significantly increased relative to controls from baseline to three months follow-up. From three to six months follow-up self-efficacy, action planning and action control scores were maintained in the intervention group and coping planning further increased; this demonstrated a moderate effect size compared with the control group. During this period the control group's action and coping planning score also increased, with action planning brought up to the levels shown by intervention participants. Self-efficacy and action control among controls did not change and their scores remained lower than the intervention groups at follow-up with no evidence for a between-groups difference in the change in self-efficacy or action control from three to six months.

4.8 Intervention feasibility and fidelity

All of the participants randomised to the intervention group received their first PAC and associated workbook to guide them through the process of planning and monitoring their PA over the next three months. As planned all participants received a pedometer during the initial consultation and also received the information leaflet described in Chapter Three. All control participants received the information leaflet. Four participants in the intervention group did not receive a follow-up consultation. The reasons for this were: two people who withdrew from the study at the three month assessment point, one person returned to work and did not have time and one person who was not available during their appointments and could not be contacted to reschedule. As discussed in Chapter Three four participants who did not attend any pramwalks received a support call (three advised in advance that they would not attend any walks due to having both an infant and a toddler). Two participants who attended one pramwalk (after the first two weeks from their PAC) also received support calls. Support

calls lasted approximately ten minutes and participants were asked about progress towards their goals set during the first PAC and were encouraged to problem solve any barriers they had encountered while trying to achieve activity goals.

4.8.1 Fidelity checking for physical activity consultations

A total of six 1st consultations and three 2nd consultations were successfully recorded. Due to problems with retrieving information from the recording equipment, independent ratings were available for seven consultations (five 1st and two 2nd consultations) from five participants (15% of the total intervention sample). As discussed in Chapter Three, each communication or PAC technique item was rated from 1 (limited skill), 2 (satisfactory skill) or 3 (very good skill). Communication techniques were person-centred, empathy used, parroting, paraphrasing and PA knowledge. In all consultations, for all communication skills, the rating given was 3 (very good skill). For each of the PAC techniques the score in each consultation are given in Table 39. The average score for information about PA guidelines was 2.8 (s.d. 0.45) and for decisional balance 3. For setting short and medium term PA goals, identifying opportunities for PA, problem solving barriers and assessing and developing self-efficacy the rating score was 2.8 (s.d. 0.45). For developing a PA action plan and encouraging social support the score was 3. As shown in Table 37 for the two 2nd consultations that were recorded the scores for feedback on change and setting of long-term goals were 2.5 (s.d. 0.70) and for relapse prevention the score was 3.

Table 39. **Independent skill ratings for recorded consultations**

Participant	A	B	C	D	E
<i>Knowledge: benefits of PA</i>					
- Information about PA guideline	3	3	3	3	2
- Decisional Balance	3	3	3	3	3
<i>Make a behavioural resolution to change</i>					
- Set short and medium-term PA goals	3	3	2	3	3
<i>Knowledge, skills and environment support adoption of PA</i>					
- Develop a PA action plan	3	3	3	3	3
- Identify opportunities for PA	3	2	3	3	3
- Identify and problem solve barriers	3	3	3	3	2
- Assessed and developed self-efficacy	3	3	2	3	3
- Encourage social support	3	3	3	3	3
<i>Knowledge, skills and environment support maintenance of PA*</i>					
- Feedback on change in PA	2	3	-	-	-
- Set long-term PA goals	3	2			
- Relapse prevention	3	3			

Rating of 1=limited skills, 2=satisfactory skill and 3= very good skill. *Only two participants also had second consultations recorded. Note. A 6th participant's consultation could not be rated due to problems during download.

4.8.2 Participants' use of self-management strategies

Participants' use of self-management strategies between baseline and three months are reported in Table 40 and between three and six months in Table 41. Appendix 9 provides more detail, highlighting specific examples (e.g. for monitoring their PA behaviour Appendix 9 breaks this down into the numbers reporting use of a pedometer, written logs etc.). Between baseline and three months follow-up participants reported that the most used self-management strategies were: monitoring their PA behaviour, thinking about benefits of PA, and making a detailed PA plan (see Table 40). The proportion of participants self-reporting using these strategies between the three and six months follow-up point dropped slightly (see

Table 41) but these were still the most frequently used (either every week or most weeks). Of those who monitored their PA between baseline and three months, 66% said they used a pedometer to do so; 59% wrote down their PA in a diary (many participants did both) and 21% of participants were “mentally conscious” of how active they were. From three to six months follow-up the numbers of participants using a pedometer and/or writing down their activity had dropped to 26%, whilst 59% of participants reported being “mentally conscious”.

Participants thought about the benefits of PA every week or most weeks over the 6 month study period. A number of benefits (>20 themes) were reported/experienced or thought about (Appendix 9). The most common benefits were related to weight loss/maintenance and increased cardiovascular fitness (28% of participants at three; 33% at six months). Although increased energy (10%) and improved mood (17%) were not as reported as often at the three month follow-up point, by six months these were more frequently reported by participants, 19% and 26%, respectively. Planning techniques most likely to be reported by participants included writing down weekly plans (e.g. where, what and when) in their diaries and maintaining the same weekly slots for walking/PA classes etc. (for further details see Appendix 9). Between baseline and three months and three and six months around a quarter of participants utilised social support for PA every week with a further 30-40% using some form of social support most weeks. The most common sources of and purpose of support were childcare from husband/partner or family members (>60% at three months and >40% at six months), although a large number of participants also got support (>50% at three months and >35% at six months), by being active with people, this included their husband/partner, family member and friends (see Appendix 9 for details).

The least used strategies between baseline and three months were changing PA gradually, planning for overcoming barriers and changing their environment to make PA easier (Table 40). Of those participants who did use the strategy planning to

overcome barriers, these included having back-up options readily available (e.g. home exercise DVDs), having flexible/adaptable exercise plans and planning for long-term barriers (such as developing childcare options, setting long-term goals and borrowing equipment to enable PA) (see Appendix 9). Between three and six months few participants reported using the strategies: substituting inactive options, knowledge of local opportunities for PA, planning to overcome barriers and changing their environment to make PA easier (Table 41). Regarding the first two strategies, discussions indicated these strategies were not required as much in the three to six month period as they had been used successfully in the baseline to three month period.

Table 40. Use of self-management strategies from the consultation during the period between baseline and three months follow-up (n=29)

	Never used (%)	Occasionally used (%)	Used most weeks (%)	Used every week (%)
Monitoring PA	1 (3)	4 (12)	8 (24)	16 (55)
Thought about the benefits of PA	-	2 (21)	9 (31)	14 (48)
Set PA goals	4 (14)	11 (38)	6 (21)	8 (28)
Made a detailed PA plan	2 (7)	3 (10)	14 (49)	10 (35)
Changing PA gradually	15 (52)	8 (27)	4 (14)	2 (7)
Knowledge of local PA opportunities	6 (21)	20 (69)	3 (10)	-
Sought support for PA	4 (14)	6 (21)	11 (38)	8 (28)
Prompted myself to be active	13 (45)	9 (31)	2 (7)	5 (17)
Changed my environment	7 (24)	12 (41)	6 (21)	4 (14)
Substituted inactive options	4 (14)	8 (28)	8 (28)	9 (31)
Planned how to overcome barrier to PA	9 (31)	14 (48)	5 (17)	1 (3)

Table 41. Use of self-management strategies from the consultation during the period between three and six months follow-up (n=27)

	Never used (%)	Occasionally used (%)	Used most weeks (%)	Used every week (%)
Monitoring PA	4 (15)	6 (22)	7 (26)	10 (37)
Thought about the benefits of PA	1 (4)	7 (26)	6 (22)	13 (48)
Set PA goals	6 (22)	7 (26)	8 (30)	6 (22)
Made a detailed PA plan	4 (15)	5 (19)	10 (37)	8 (30)
Changing PA gradually	17 (63)	8 (30)	1 (4)	1 (4)
Knowledge of local PA opportunities	8 (30)	19 (58)	-	-
Sought support for PA	6 (22)	6 (22)	8 (30)	7 (26)
Prompted myself to be active	11 (41)	5 (19)	6 (22)	5 (19)
Changed my environment	5 (19)	16 (60)	-	6 (22)
Substituted inactive options	13 (48)	10 (37)	2 (7)	2 (7)
Planned how to overcome barrier to PA	9 (33)	9 (33)	6 (22)	3 (11)

4.8.3 Attendance at pramwalking groups

Over the period March 2011 - March 2012 a total of 85 out of 95 (89%) planned walks were conducted as part of the MAMMiS study. Four of the ten scheduled walks that did not go ahead were due to no walkers being present; six out of ten were cancelled due to adverse weather. Median attendance at walks was two participants (range 1-4). 29 participants attended at least one walk, with the average number of walks attended being five (s.d.=3.13) out of a possible ten walks. 61% of participants attended five or more walks, with 39% attending less than five walks (including four participants who did not attend any walks).

Analysis of the number of walks participants attended in each of the four locations showed participants from the Stirling (rural) group attended a greater number of walks

(mean=8, s.d.=1.5) compared with the other groups. Participants attending the Stirling (town) walks averaged 5 walks (s.d.=2.8). In Grangemouth and Larbert these figures were 6 (s.d.=3.5) and 6 (s.d.=1.5) walks, respectively.

4.8.3.1 Seasonal effect

There was no evidence of a seasonal effect on attendance at pramwalking groups. Attendance among participants recruited from February 2011-August 2011 averaged 5 walks (s.d.=3.70), which was similar to attendance among participants recruited from September 2011-February 2012 (4.9 walks, s.d.=2.81).

4.8.3.2 Intensity, distance and duration of walks

Of 85 walks, 78 were recorded (seven walks could not be recorded due to phone battery failures or poor GPS signals). Mean walk distance was 2.44 miles (s.d.=0.46) and walk length averaged 46.37 minutes (s.d.=7.81). Pace in miles per hour across all walks averaged 3.16 (s.d.=0.27). Walking routes generally lasted for the advertised 35 minutes to an hour.

Five walks were objectively monitored using HR monitors and Actigraph accelerometers (11 intervention participants were monitored in total). There was evidence from both heart-rate and accelerometer readings that the majority of walks were conducted at least moderate-intensity (Table 42). For accelerometer readings intensity was calculated from the raw accelerometer counts using the Freedson cut points (Freedson et al, 1998) and for HR monitors intensity was calculated in relation to the percentage of each participants' age-predicted maximum heart-rate value (HRmax), using the criteria <50% = low intensity, 50%-70% = moderate and >70% vigorous intensity (McArdle, Katch and Katch, 2007). Although there were no significant differences between the heart-rate and accelerometer intensity

readings overall (95% CI): -57.4, 3.8; p=0.07), heart-rates did find a greater proportion of time was spent at vigorous intensities during walks (95% CI: 1.3 – 60.8; p=0.05).

Table 42. Time/proportion of time spent in low, moderate and vigorous intensities during pramwalking

Objective monitoring method	Low Intensity	Moderate Intensity	Vigorous Intensity
HRM (% time)	0 (0–1)	74 (15–94)	24 (6– 85)
Accelerometer (% time)	4 (2–4)	93 (80–96)	2 (0– 18)
HRM (mins)	2 (1–2)	44 (40–50)	1 (0– 9)
Accelerometer (mins)	0 (0–1)	34 (8–47)	11 (3– 42)

Note. Values shown are median and IQ Range; HRM, heart-rate monitor; Mins, Minutes

4.7.4 Summary of intervention feasibility and fidelity

Intervention fidelity was good in the MAMMiS study. All intervention participants received the initial PAC, most attended at least one walk (61% of participants attended five or more walks) and all non-pramwalkers received a telephone support call. Independent ratings of the recorded consultations suggested the intervention was delivered as planned and the consultant displayed effective communication skills.

Participants adopted pedometers for self-monitoring their walking behaviour and found the planning/diary sheets in the workbook useful for weekly planning and monitoring. For example, a large proportion (66%) self-reported wearing the pedometer and viewing daily step counts and/or writing down activity participation (including steps counts) between three months and six months. Between three and six months however, fewer participants did this (26%), with more participants reporting monitoring their activity levels through being “mentally conscious” (59%). Participants also regularly thought about the benefits of PA but the content of these thoughts differed somewhat. Between three and six months a greater number of participants endorsed distal (e.g. weight loss/improve cardiovascular fitness)

benefits, while at six months more proximal outcome expectancies (e.g. improved mood/energy) were more frequently endorsed. Having specific goals and developing weekly action plans was seen as important to successful adoption of PA. Social support from partners and family was also readily used by intervention participants, in particular for childcare; support from partners, family and friends for being active together was used, although the frequency of use of these types of social support declined from three to six months. Participants did not use other strategies as readily between baseline and three or three to six months, these included problem solving barriers to being active and changing their environment to make PA easier.

Feasibility of the pramwalking was good with 89% of walks going ahead as planned even over the winter months. Participants recruited during colder months (i.e. autumn/winter) attended just as many pramwalks relative to participants recruited during spring/summer. The rurally based groups were the most well attended. Walks were broadly conducted as planned, with most walks lasting between 35 minutes and 1 hour and on average being conducted at a brisk (>3 miles per hour) pace. Regarding intensity, there was evidence from heart-rate and accelerometer readings that the walks were conducted at at least a moderate-intensity throughout.

4.9 Results of the post-trial interviews

4.9.1 Participants

Thirty-five participants were interviewed (C n=15; I n=20). Tables X (intervention group) and X (control group) below shows the participants who took part had a range of different socio-demographics life situations and family circumstances. In particular, a wide age range (21-45 years) informed the results of this study. Interview participants were largely

representative of those participants in the MAMMiS trial. For example, 46% of participants in post-trial interviews had more than one child, compared with 40% in the main trial. For postnatal stage (i.e. greater than six months postpartum at onset) the figures were 40% (interview study) and 38% (trial), overweight or obese participants were 57% (interview study) and 52% (trial) and for study drop-outs 9% (interview study) and 8% (trial),

Table 43: Sampling matrix for intervention group interviews (up to $n=20$)

Characteristic	More than one child (yes/no)	>6months postnatal at study onset (yes/no)	BMI at study onset (normal/overweight or obese)
Study follow-ups ¹	$n=9$ yes $n=10$ no	$n=7$ yes $n=12$ no	$n=5$ normal $n=14$ ow/obese
Study drop-outs ²	$n=1$ no	$n=1$ no	$n=1$ normal

¹Study follow-ups: participants who attended both follow-up appointments

²Study dropouts: participants who did not attend one or both follow-up appointments

Table 44: Sampling matrix for control group interviews ($n=15$)

Characteristic	More than one child (yes/no)	>6months postnatal at study onset (yes/no)	BMI at study onset (normal/overweight or obese)
Study follow-ups ¹	$n=7$ yes $n=6$ no	$n=6$ yes $n=7$ no	$n=8$ normal $n=5$ ow/obese
Study drop-outs ²	$n=2$ no	$n=1$ yes $n=1$ no	$n=1$ normal $n=1$ ow/obese

¹Study follow-ups: participants who attended both follow-up appointments

²Study dropouts: participants who did not attend one or both follow-up appointments

4.9.2 Main themes

The following themes were thematically extracted from the post-trial interviews with participants from the MAMMiS trial, shown here with quotes from participants:

i) Physical activity prepregnancy and the value of being physically active

Many participants joining the MAMMiS trial had pre-existing positive beliefs or previous physical activity habits, which had stimulated them to join the study. This included enjoying and valuing being physically active:

“I like to exercise...I think it’s important for them, as well, to set a good example so that they grow up wanting to be fit and active” (control participant)

Motivations also included weight loss, health and mood benefits.

“The long-term reason is that I think it benefits your health. And I think it increases, in terms of, it improves your mood” (intervention participant)

There was evidence some participants were previously active before pregnancy, and/or felt they required limited support to regain these habits:

“It just felt a natural progression in a way because I was still going to get back to exercise regardless of whether I was going to be in the study.”(intervention participant)

Furthermore, some participants demonstrated perceptions that they were less physically active or less fit than they ‘should’ or wanted to be. This might have motivated them to join the study despite being outwith the ideal target audience for the trial (i.e. low-active postnatal women):

“I did the step thing and she goes, “Well, you are actually quite healthy”, I managed the step thing quite well. But that’s what I’m saying. I might be quite healthy, but I’m not healthy enough for me.”(intervention participant)

ii) Factors influencing adoption and maintenance of physical activity postnatally

Participants in the interview study talked about factors influencing adopting and maintaining physical activity during the postnatal period. Some of the specific barriers and facilitators mentioned by participants were reported, for example, time, the weather and motivation:

“The weather doesn’t put me off at all, I don’t mind walking in the rain, or the cold, or anything, it’s just the time” (intervention participant)

Factors such as having a good routine, having a work place or commute that allowed for physical activity and having a supportive and encouraging partner were all viewed as facilitating factors:

“The other week I was going to go to the zumba class and I was just really exhausted and he was like oh just go, just go, the kids will be fine and I sort of thought oh he is, you know, I should go, he by saying that made me think no I should go rather than just lazing on the sofa.” (control participant)

However, participants did not just provide a list of barriers and facilitating factors, but rather discussed the inherent complexity in which they lived their lives as the mother of at least one small child, and the potential guilt and conflicting priorities that ensue:

“I still feel torn between being a mum and going and doing that ...you feel torn between the two...yes it’s like I know if I go to an aerobics class for an hour I will feel better that night and I’ll sleep better that night...I do feel it is important to be here with her if she’s upset” (intervention participant)

Furthermore, many participants believed their activity levels had improved during the trial but described their PA fluctuating according to the varying demands of life. Again

participant's stories reflected the complexity of trying to prioritise being physically active while caring for young children, and alongside other roles, such as work. The quote below also demonstrates the measurement difficulties encountered when trying to capture a 'typical' week:

"I think it just showed me how inactive I can be for weeks, but I think overall, in between, I actually had improved, but it just maybe didn't reflect entirely that week because I think the second time I got measured, was not long after I started back to work, so I was feeling the effects of that, and I was feeling quite tired." (intervention participant)

iii) Changes to knowledge, intentions and behaviour as a result of the trial

Participants from both groups reported increased motivation and behaviour change for PA.

"I think it was and I would say that being in the study for me personally was more benefit than any access to like a health visitor or anything like that because it was a bit challenging, but it was like...I'm doing this and yes this is really important" (control participant)

"I mapped out walks and everything on my phone as well and I found that helpful, because it was telling me to do it I think well, I'd better go and do something rather than just sit."

(intervention participant)

For some intervention participants though, the effect of changing intentions and behaviour toward being more active was transformational, having an impact on their personal, social and work and home-life. Noticing these wider impacts was a sense of renewed motivation:

"I've said to you the main issue, to begin with, was the weight. So, I lost a stone from doing it... well, in that time period. Just being able to exercise. I did a wee bit of running."

That's motivated me, doing this and just being able to keep going, and say, I'm going to run to the next lamppost, and keep going" (intervention participant)

"I think it was mainly not having enough time. And that's what my husband and I have really focussed on is... at the end of the day an hour out of the whole day is not very much in terms of going to a class. It's just...again going back to the kind of organisation of what we're both doing and booking it in, because I think time was a big factor. We felt we didn't have enough time but actually we do have enough time." (intervention participant)

iv) Usefulness of the approach and strategies used in the physical activity consultation
(note. all intervention participants)

Participants viewed the positive and supportive relationship provided by the PA consultant as important:

"I didn't feel like she was saying, "Oh, you know, you're fat, you need to go on an exercise bike". It never felt like that, it was always supportive and always thought it helpful"

In addition, specific motivational and self-regulatory strategies were singled out as particularly useful: *"I think it is good to think about your barriers because, you know, like for me having to go out and exercise is sometimes a barrier. So one...was to bring the exercise in here [gym equipment in to home] and that was good."*

"I think if you write it down and then don't meet the targets that's really better, though, because you're looking at it going, "Oh right, okay, well I haven't done that and I haven't done that," and it makes you confront it a bit more than if it's just in your head, you know like, just forget about it." (intervention participant)

Despite the perceived usefulness of the strategies introduced as part of the PAC some participants still described significant challenges or barriers which were perhaps more nuanced, or difficult to overcome, particularly those relating to their children's safety, security and wellbeing. For example:

"I know, obviously there was discussion about what barriers there were, but it's almost like well every barrier can be overcome. Actually I don't think it can be overcome"

"This is no criticism of [consultant], it's a reflection of the fact that she doesn't have any children, that sometimes it just doesn't happen [PA] and you just can't do it and all the planning you put in place, it doesn't matter, if you can't leave your child at the time you're going it just doesn't happen. Maybe that is important, maybe a really important thing"

"...so where do you put them then, you can't go, you know, so I suppose, having crèches would help people, because you wouldn't feel guilty if the child was doing something, that they're in the crèche having fun, and yet you'd still know they're safe"

v) Experiences of the pramwalking groups: acceptability and feasibility (note. all intervention participants)

Views about the pramwalking group were generally positive. The walks were viewed as providing instruction/modelling for a brisk pace and introducing new routes:

"It was good because she [the consultant] would set the pace. She would, obviously, pick up the pace a bit. It was good her being there and doing that because it let you see how brisk you needed to walk."

The walks/routes being prearranged was important to some:

“I quite enjoyed the walks, I think having something organised made me go and do it, otherwise, you would get up and think, oh, it’s not very nice today I’m not going to do it, which is exactly what I’ve said today, I’m not going out, because it is not nice”

The exception to these positive views were comments about the difficulty getting times that suited everyone *“I did find at the time, she’s probably better now, but at the age she was at the time, the times were a bit of a hit or a miss, whether she’d be asleep, happy, not happy”* and the ten week programme coming to an end *“I was quite sad when I had to stop”*

vi) Participation in the trial stimulating thinking about behaviour change

The majority of participants in the interviews felt that participating in this study, whether as intervention or control, encouraged them to think about issues around increasing physical activity they might otherwise not have done and in new ways:

“It’s really changed my complete belief that pregnancy can affect your physical activity and you should try and maintain some physical activity and then definitely try and regain it while there’s a chance, the sooner the better. With the sort of lifestyle people lead now we have to be more aware of that” (control participant)

Some participants felt this change in mindset (though not behaviour) during the trial might lead to changes at a later stage:

“For something, in my mind, to be effective, it doesn’t necessarily mean that it might be translated, at that moment in time, to being more active, yet just having that thought, or actually, when I get the chance, or when work-wise, whenever, then I might be able...” (intervention participant)

4.10 Summary of Chapter Four

Over 13 months 65 postnatal women were successfully recruited to the MAMMiS study. Recruitment was achieved mainly through face-to-face approaches utilising NHS sites or community settings (e.g. playgroups, community fairs etc.). The majority of ineligible postnatal women were too active to participate. Of those who were eligible, enrolment into the study was high; however, compared to all women expressing interest in the study the women who were recruited were older and less deprived. In addition, participants who enrolled in the study were not representative of postnatal women across Scotland in terms of age and deprivation (i.e. MAMMiS participants were older and less deprived). At baseline there was evidence that more participants randomised to the intervention group were overweight or obese and more participants in the control group were breastfeeding, although these differences were non-significant. Other socio-demographic and clinical characteristics were similar between the two groups. There was a high retention rate in the trial (90%), although younger participants and women with younger infants were less likely to return for three or six months follow-up.

There was good compliance with the activity monitors with almost all participants wearing the accelerometer for a minimum of four days during each measurement period. A majority of participants had a full seven days of activity monitoring data at each follow-up period. Descriptive data suggested baseline counts/minute, absolute MVPA expressed as minutes/day and self-reported weekly minutes of MVPA were higher among participants from the intervention group at baseline; the latter was confirmed with significance testing. Also a greater proportion of intervention participants reported doing more PA during the baseline measurement week compared with usual habits over the previous three months.

The intervention did not significantly change objectively measured PA behaviour from baseline to three months relative to the control group; results were similar considering the per protocol sample and self-reported MVPA. From three to six months there was a significant difference between the groups considering self-reported MVPA due to a decline in participation from three months in the control group, this represented a small effect size.

A more detailed analysis of the PA change results suggests counts/minute and step/day among the control group increased at three months bringing them into line with the intervention groups results (although the effect sizes were small and non-significant). From three to six months there was a small increase in counts/minute and steps/day among the intervention group (changes at three months among the control group were largely maintained), with non-significant between groups differences. Considering minutes/day of MVPA and relative time (i.e. proportion of MVPA time relative to total wear time) there was no evidence for change over time in either group. Cardiovascular fitness, a physiological proxy measure of change in PA behaviour, did not change from baseline to three or three to six months as a result of the intervention; there was no evidence that either group increased their aerobic capacity.

There was no effect of the intervention on change in anthropometric variables or psychological wellbeing relative to controls; both groups showed trends indicative of a reduction in weight, BMI and percentage fat mass over time. Fatigue scores reduced significantly among the intervention group from baseline to three months, but then reversed to baseline levels at six months.

PA cognitions changed in the intervention group with three months scores on planning measures and action control significantly increased from baseline relative to controls. An increase in self-efficacy from baseline to three months among the intervention group was associated with a small effect size relative to the control group, although this

difference was not significant using a more conservative p-value. Increased self-efficacy, action planning and action control were maintained among the intervention group between three and six months follow-up with increases in action and coping planning, but not self-efficacy and action control seen among control participants. Intervention participants also reported increased coping planning from three to six months, which was significantly greater than the increase among the control group. From three to six months there was evidence for a decline in outcome expectancies in the intervention group relative to the control group, which was associated with a small effect size, although non-significant, using a more conservative p-value.

Overall, the PAC and pramwalking groups were conducted as planned. Both approaches appeared feasible for the sample of postnatal women who were recruited to MAMMiS study (although some participants were unable to commit to pramwalking groups and attendance was variable). Process data revealed participants liked and used the process of setting goals, creating specific plans and self-monitoring their PA behaviour using the workbook and pedometer. Participants seemed to be less likely to problem-solve barriers to PA or make changes to their environment to enable PA, although many used social support regularly.

Participants taking part in post-trial interviews provided a rich and varied account of the complexities of adopting and maintaining physical activity while caring for a young child/children. However, elements of participating in the trial stimulated intentions, motivations and behavioural change, this was true for both intervention and control participants, many of whom already had positive views about being active. Strategies introduced during the PAC (e.g. particularly those associated with self-regulatory actions such as goals, planning and feedback) were commented upon as influencing behavioural

change, although in some cases fluctuating habits meant some women felt this was not adequately picked up by the measurement approach.

CHAPTER FIVE

5. DISCUSSION OF THE RESULTS OF THE MAMMiS STUDY

5.1 Chapter Preface

This chapter discusses the results of the MAMMiS trial in light of previous research, methodological considerations and the results from the post-trial interviews. I consider the strengths, limitations and implications of the study with concluding comments and suggestions for future research. The discussion is all my own work, although previous drafts were reviewed by Dr Hughes and Dr McInnes.

5.2

5.3 Effects of the intervention on physical activity behaviour

MAMMiS was the first study to test the impact of a theoretically-based intervention consisting of PAC and postnatal pramwalking group on PA behaviour change measured by an objective measure among postnatal women. The main finding was that postnatal PA measured by accelerometers and self-report did not significantly change in response to the intervention from baseline to three months follow-up relative to the control group. No changes were found in either group from baseline to three months on accelerometer-measures of MVPA, considering either absolute minutes per day or relative time spent in MVPA as a proportion of weekly activity. From baseline to three months follow-up there was a small increase in accelerometer counts per minute in the control group with the intervention group showing no change. Although non-significant, the between groups difference from baseline to three months was associated with a small effect size favouring the control group (i.e. $d=0.22$). Furthermore, in post-hoc subgroup analysis (results not shown) there was further evidence that there was no significant effect of the intervention relative to controls. By

breaking down the effect of the intervention (from baseline to three months) between those showing an increase of 60 minutes or more MVPA, those showing a decrease of 60 minutes or more MVPA and those showing a less than 60 minutes change (in either direction); results showed most participants (51.5%) showed no or limited change in MVPA participation in response to the intervention. Of those intervention participants showing a change in behaviour, 24.2% increased MVPA and 24.2% decreased MVPA. Results were similar in the control group, with their response to being part of the trial being no/limited change in MVPA (59.4%), increase MVPA by 60 minutes or more (21.9%) and decreased MVPA by 60 minutes or more (18.8%).

Regarding steps per day, there were small non-significant between group differences from baseline to three months also favouring the control group ($r=0.18$). Steps per week increased in the control group by around an extra 1400 steps per week with no change in the intervention group. Research has suggested this increase in step count would amount to around 10-15 minutes extra weekly walking (Tudor-Locke & Bassett, 2004), which would not be considered clinically significant (Baker et al., 2008). Self-reported MVPA increased by 30 minutes/week from baseline to three months in the control group, with a small decline of 15 minute/week in MVPA in the intervention group; although this between group difference was non-significant it was associated with a small effect size (i.e. $d=0.22$).

Participants in MAMMiS also took part in a six months follow-up period (three months after intervention contact ended) with no evidence that the intervention was effective at changing PA behaviour relative to the control group from three to six months. However, from three to six months the intervention group did show an increase in steps/day of around 550 (equivalent to an additional 3800 steps per week) with no change in the control group. This difference was not statistically significant but did represent a small effect size ($r=0.18$) favouring the intervention group, although again would not be considered clinically

significant considering healthy or at-risk populations (Baker et al., 2008; Ogilvie et al., 2007). There were no changes in either the intervention or control group on counts/minute or accelerometer-measured MVPA minutes/day. There was a significant difference between the groups from three to six months follow-up on self-reported MVPA; explained by declining participation in MVPA in the control group (by approximately 50 minutes/week) and no change in the intervention group. There was no difference in the results considering the per protocol analysis (only including intervention participant who attended at least one PAC and five or more walks).

Findings from the process measures taken during the MAMMiS trial suggest the intervention was delivered as intended with good attendance and engagement with the intervention techniques delivered during the PAC and the pramwalking group. The intervention intensity was in line with previous PAC interventions in the general and clinical populations, which have demonstrated change in PA behaviour measured by accelerometry at three months follow-up (Hughes et al., 2007; Kirk et al., 2004a; Baker et al., 2008); it seems unlikely that intervention intensity explains the lack of effect (Eden et al., 2002). Possible explanations for the nil effects found on change in PA behaviour in MAMMiS are discussed below with reference to findings from other PA interventions conducted among postnatal women and the post-trial interviews.

5.3.1 Changes in physical activity in the context of a reasonably active sample

The intervention may have been ineffective at changing PA levels among intervention participants as MAMMiS seemed to attract a reasonably active sample of postnatal women and the intervention group reported more PA at baseline than controls. Average weekly self-reported MVPA at baseline was 180 minutes/week in the intervention group and 120 minutes/week in the control group at baseline. Findings from the qualitative study suggest

many participants had been active pre-pregnancy and/or believed PA to be important, which may have skewed their perceptions of how active they were post-pregnancy (i.e. considered themselves less physically active than they actually were). This may have motivated them to join the study. Also, participants reporting being “more active than usual” at baseline were more likely to be randomised to the intervention group. As baseline results were conducted prior to randomisation this cannot be attributed to participant or researcher knowledge of group assignment. Also, there were better correlations between accelerometer measured absolute MVPA and self-reported MVPA in the intervention group using the Kendall’ tau rank correlation coefficient (i.e. at baseline among the intervention group $r_t = .58$, $p < 0.01$ compared to the control group $r_t = .32$, $p = 0.16$). Previous research in the general population has shown structured or planned PA (e.g. walking for exercise, structured exercise or LTPA) are more accurately self-reported compared with non-structured PA (Chasan-Taber et al., 2002) suggesting the higher levels of self-reported MVPA found in the intervention group may have truly reflected greater planned PA participation in this group during baseline assessments. Analysis of steps at baseline (measured by the accelerometer) also suggests high PA at baseline as median censored steps were approximately 7300 among the intervention group and 7000 among controls. Tudor-Locke, Leonardi, Johnson, Katzmarzyk and Church (2011) have recently shown that achieving this step count (i.e. an average of 7000 steps per day over a week) is a good proxy for obtaining 150 minutes of weekly MVPA among women. Furthermore, Tudor-Locke et al. (2009) have found that a step count of over 7,500 represents a reasonably active PA profile. In MAMMiS 16/33 (49%) of women in the intervention group and 11/32 (34%) of the control group were reasonably physically active at baseline. Overall the baseline PA results underlie the differences between the groups and that PA among some participants (particularly in the intervention group) was higher than would be expected given the target group for the study.

Attracting reasonably active participants is problematic because MAMMiS was designed to target healthy low-active postnatal women to increase participation in MVPA. Although the PA guidelines indicate additional health and fitness benefits can be achieved by increasing PA above the minimum standards (i.e. 150 minutes per week of moderate-intensity PA) (Oja et al., 2010), women with young children face barriers to being active, which may preclude increasing existing MVPA by a considerable amount (Evenson et al., 2009; Bennet et al., 2013). Barriers were mentioned by participants in the post-trial interviews. Participation in the pramwalking group promoted moderate-intensity PA. Given the evidence that participants spent little time in vigorous-intensity PA, there may have been opportunities to significantly increase this, however this would have required participation in leisure-time/structured activities (i.e. jogging, exercise class etc.), which may be more challenging or unsuitable for some postnatal women. There are also implications for the sample size calculation which was based on recruiting a low-active sample and increasing their MVPA participation by 60 minutes, which may have been unachievable in this sample. Also considering the baseline PA results there was more variability in accelerometer-measured MVPA in the sample than originally assumed, which meant the sample was underpowered to detect an effect of the intervention. I originally calculated 31 participants would be required per group assuming an intervention effect of an increase in 60 minutes of weekly MVPA measured by accelerometer. This was based on a standard deviation of 75 minutes of weekly MVPA measured by accelerometers from a previous study (Rogers et al., 2009). As shown in Appendix 10 the MAMMiS sample had a higher standard deviation at baseline (i.e. 131 minutes of weekly MVPA). Had this figure been used to calculate the sample size at least 59 participants per group would have been required to detect a between group difference based on an increase of 60 minutes of weekly MVPA.

There was also no effect of the intervention on change in cardiovascular fitness from baseline to three months or three to six months relative to the control group in MAMMiS. Given the lack of change in PA among participants it isn't surprising that fitness did not improve. Other studies have demonstrated a significant improvement in aerobic capacity after a 12-week intervention comprising of pramwalking groups 2-3 times per week (Armstrong & Edwards, 2003; 2004). However, these studies were conducted with populations of postnatal women meeting criteria for PND and most participants were assessed as being in the low/average fitness category, therefore an increase in brisk walking would be sufficient to increase/improve aerobic capacity (Manson et al., 1999). As a number of participants in MAMMiS demonstrated good or excellent aerobic capacity at baseline, it is likely they would need to have participated in vigorous-intensity PA to improve fitness (Haskell et al., 2007).

5.3.2 Previous findings in postnatal populations

The finding from the MAMMiS study adds to a somewhat mixed picture reported in previous postnatal PA intervention trials as reported in our systematic review from Chapter 2. As discussed, Lewis et al. (2011) and Albright et al. (2009) found large and statistically significant increases in self-reported MVPA from baseline to eight and 12-weeks follow-up among participants through the use of face-to-face or telephone PAC interventions, although neither included a control group. In another two postnatal PA intervention studies (Cramp & Brawley, 2006; Fjeldsoe et al., 2010), self-reported MVPA increased from baseline to eight and 13-week follow-up in both the intervention and control group although the increases were significantly larger in the intervention groups. In Cramp and Brawley (2006) the difference in total weekly MVPA was greater among the intervention group compared with a control group who received four weeks of structured PA sessions. Fjeldsoe et al. (2010) found an increase in self-reported frequency of MVPA participation (but not total weekly

MVPA) after a face-to-face PAC and SMS-text messaging intervention compared with a control group who received an information leaflet (Fjeldsoe et al., 2010). In the only study to be conducted in the UK to date, Daley et al. (2007) did not show a significant change in self-reported MVPA frequency following two PACs sessions over 12-weeks with support calls relative to a control group.

There are several differences between the above studies and the MAMMiS study, which may help explain why these studies found significant effects and MAMMiS did not. Firstly, the method for excluding participants based on their self-reported PA levels was different. In MAMMiS the stage of change questionnaire was used to exclude participants in the ‘Action’ or ‘Maintenance’ stage. I found 80% of those who enrolled in the study reported doing some PA but not enough to meet guidelines at baseline (i.e. were in the ‘Preparation’ stage). As participants in the ‘Preparation’ stage might still be taking part in up to 150 minutes of MVPA, this may explain why MAMMiS baseline MVPA results were relatively high. Other studies have excluded postnatal women participating in >30, >60 minutes and >90 minutes of MVPA week (Albright et al., 2009; Cramp & Brawley, 2006; Daley et al., 2007; Lewis et al., 2011). All studies (except Fjeldsoe et al., 2010) reported low (or lower) self-reported MVPA at baseline compared with MAMMiS. In Lewis et al. (2011), Cramp and Brawley (2006) and Albright et al. (2005) for example, participants self-reported 70, 125 and three minutes/week, respectively⁴. Daley et al. (2007) recruited postnatal women on the basis of having clinical diagnosis or clinical cut-off score for PND so may not be comparable to the population of healthy postnatal women recruited in MAMMiS.

5.3.2.1 Physical activity measurement and blinding in intervention trials

⁴Daley et al. (2007) did not report total volume of MVPA but did report low frequency of PA participation at baseline (i.e. participation in 1.8 and 0.3 times per week moderate and vigorous intensity among the intervention group and 0.8 and 0.6 times per week moderate and vigorous intensity among the usual care group).

The studies discussed above all used subjective methods of PA (i.e. via self-report questionnaire/interviews) and non-blinded outcome assessors. Self-report methods may be more susceptible to exaggerated effect size estimates among the intervention group due to social desirability effects, which may also be affected by lack of blinding (Adams et al., 2005; Prince et al., 2008). In MAMMiS the use of an objective measure of PA behaviour change (i.e. accelerometers) was more robust as this measure is not affected by social desirability. Objective monitoring may act similarly to blinding as participants who know they are being monitored may be less likely to show social desirability effects when self-reporting PA behaviour from that same week (Wood et al., 2008). The lack of intervention effect found in MAMMiS study is somewhat consistent with three other postpartum studies, which have used blinded outcome assessors or accelerometers to measure change in PA behaviour post-intervention (Bertz et al., 2012; Craigie et al., 2011; Ostbye et al., 2009). Ostbye et al. (2009), for example, found no effect on weekly frequency or total weekly self-reported MVPA at ten months follow-up following a weight management intervention, which included group behavioural counselling for PA change. Two other similar studies (i.e. PA change components were introduced as part of weight management interventions) did not find significant effects of interventions on change in minutes of MVPA or steps per day among at 12 weeks follow-up (Bertz et al., 2012; Craigie et al., 2011) when participants were assessed using accelerometers. However, as discussed in Chapter Two there was a general lack of effect on PA change among postnatal weight management trials, perhaps due to the intervention including dietary components as well and/or most studies limiting their inclusion criteria to OW/OB participants.

Finally, the effects of taking part in a PA trial and being measured at regular intervals plus receiving a PA leaflet might be enough to elicit small increases in counts/minute and steps/day found in the control group. Mere measurement and/or minimal intervention effects

have been found on self-report and objective measures of PA in previous intervention studies in non-postnatal populations (Kinmonth et al., 2008; Spence, Burgess, Rodgers & Murray, 2009; van Sluijs, van Poppel, Twisk & van Mechelen, 2006). This is somewhat supported by the qualitative study (discussed below) with participants from both groups reporting increased motivation and behaviour change for PA. This may have had an impact on the ability to show intervention effects, although as discussed there were minimal changes in both groups from baseline to three and three to six months considering accelerometer-measured MVPA.

5.3.3 Perceived impacts of participating in the trial on physical activity

Many participants in the qualitative study reported that participation in the trial stimulated change in their thinking about how to fit PA into their everyday lives and changed their PA behaviour. This was mentioned by both control and intervention participants. However, considering accelerometer-measured PA outcomes there was limited evidence for a change in either group over time. This difference between perception of participants and the objective measure of PA behaviour change could be due to using the accelerometer to measure PA in this population. One consideration is that accelerometers are not worn during swimming, however the numbers of participants reporting any moderate-vigorous swimming at any measurement period was small (i.e. 1-4 participants in each group). This seemed to be because swimming was usually conducted with their babies, which often precluded using this time for exercise. Another possibility is that the small increase in step count (in the control group from baseline to three months and the intervention group from three to six months) were not conducted at a moderate intensity or were not picked up by the accelerometer as moderate-intensity. As discussed in Chapter One activity counts recorded by the accelerometer (and used to assign intensity based on cut point equations) do not change

during uphill walking or when pushing or carrying, despite associated additional EE costs (Hendelman et al., 2000; Mendelson & Freedson, 1995; Nichols et al., 1999). Research using indirect calorimetry found that among mothers with children under five walking whilst pushing a pram was performed at a moderate-intensity (Brown, Ringuet, Trost & Jenkins, 2001). However, participants in the Brown study did not walk at a self-selected pace, but rather a brisk pace chosen by experimenters (approximately 5km/hour) on a flat surface. Of note, this walking pace was similar to the walking pace used in MAMMiS pramwalking sessions. Furthermore, some of the MAMMiS walking sessions were monitored using HR monitors and accelerometers, which showed that walks were conducted at at least moderate-intensity (see Chapter Four). This finding is in keeping with studies from the general population which have found “brisk walking” in the field was conducted at at least moderate-intensity PA (Murtagh, Boreham & Murphy, 2002). It is possible that among participants whose walking increased outwith the MAMMiS pramwalking sessions, the pace was slower speed than would meet moderate-intensity thresholds (Norton et al., 2010). This might explain the increase in steps in the intervention group from three to six months with no associated increase in self-reported or accelerometer-measured MVPA. One reason might be due to the increased age of the infants at the latter follow-up point, with most women in the study now having an ambulatory child. Young children when walking independently would walk at a much slower rate than an adults moderate-intensity speed. The qualitative study picked up on the issue of competing priorities among some participants who mentioned a tension between being active for their own health and wellbeing and encouraging their children being safety, secure, happy and active themselves. This tension was not discussed with participants in the PACs and participants may not have identified this as a potential barrier to problem solve around for the future.

5.3.3.1 Changes in lifestyle activities and cut points used for measuring activity intensity

One possible explanation for the difference in perceived PA change and accelerometer-measured MVPA might be as a result of participants in MAMMiS reducing sedentary behaviour and possibly increasing their time spent in household or caregiving tasks; the latter would probably not have been picked up as MVPA by the accelerometer cut points used in MAMMiS (as discussed below it is not clear whether household and caregiving tasks in general should be considered at moderate intensity). A recent cohort study, which used accelerometers and a detailed PA questionnaire to measure PA behaviour among women at three and 12 months postpartum, supports this (Evenson, Herring & Wen, 2012). They found self-reported PA from work, recreational, outdoor household, child care and transportation activities did not change among a cohort of participants assessed at both three and 12 months postpartum. However, participants reported an increase in self-reported indoor household activities, which they perceived as meeting moderate-intensity cutoffs; notably Evenson et al. (2012) also found an increase in accelerometer measured MVPA, but using different cut points from those used in MAMMiS (i.e. the Swartz et al. (2000) cut points⁵). Analysis using the Freedson cut points showed MVPA did not change from three to 12 months postpartum (Evenson et al., 2012).

In the MAMMiS trial, sedentary time decreased in both groups (i.e. from 7.9 to 7.3 hours/day among the intervention group and 7.8 to 7.4 hours/day in the control group; representing declines of around 36 and 27 minutes per day in sedentary behaviour, respectively). Detailed information on the domain of PA from the self-report measure was not available so it is not possible to differentiate structured PA, transportation and lifestyle activities. Given the 7 Day PAR measure only includes PA performed in ten minute bouts it

⁵As discussed in Chapter One the Swartz et al. (2000) cutpoints classify counts/minute above 573 as moderate-intensity and these correlate better with lifestyle activities but at the cost of poorer correlations with walking and running activities.

might be less likely to pick up on PA performed as part of lifestyle and caregiving activities, which are likely to be more sporadic in nature. Theoretically, if caregiving and household activities were performed at moderate-intensity these could contribute to achieving participation in line with recommendations from PA guidelines. However, studies from the general population have found that despite making up a large proportion of self-reported moderate physical activity for women, participation in domestic activities negatively correlates with health indices, such as leanness and cardiovascular disease (Murphy, Donnelly, Breslin, Shibli & Nevill, 2013; Stamatakis et al., 2009). Regarding the intensity of caregiving and household activities, this is not well researched in postnatal populations. Brown and colleagues (2001) have found certain activities (i.e. washing windows and vacuuming) but not others (i.e. doing dishes, laundry etc.), met moderate-intensity thresholds when measured using indirect calorimetry.

5.3.3.2 Fluctuating physical activity among postnatal women

Furthermore, many participants in the post-trial qualitative study mentioned that they experienced fluctuating habitual PA levels, which may have affected the results of the trial. For some participants fluctuating PA habits were seen as an unavoidable consequence of having young children at home, while others seemed to feel the measurement week was unrepresentative of changes they had made, perhaps due to other factors occurring (for example a return to work). This was exemplified by the large number of participants reporting PA was either 'more or 'less than usual' during each measurement period. Considering return to work, the qualitative study found this had different impacts for different women: for some participants the return to work period contributed to a decline in PA as they prioritised time spent at work or with children over PA or found structured PA, such as exercise classes, more challenging. However, for other participants return to work opened up

possibilities for PA, perhaps in the form of active travel, preparing their infant for being separate from their mother or because time away from their children to participate in PA was more ‘legitimised’. This chimes with evidence from focus groups conducted by Jones and colleagues (2010), who found that some mothers of young children considered time for PA was potentially viewed by others as “*selfish*” or an “*indulgence*” (p. 94), with household and caregiving activities in particular taking precedence over PA performed during leisure-time or for exercise purposes. This was also found in post-trial interviews with MAMMiS participants, which suggests the extent to which PA, particularly LTPA is prioritised by postnatal women is a complex issue perhaps not adequately addressed in the PAC intervention when considering barriers to change.

5.4 Changes in physical activity cognitions following the intervention

Changes in PA behaviour were not found in MAMMiS following participation in the intervention. However, there were changes to PA cognitions, which were targeted through the intervention approach. These changes are discussed in relation to previous research in postnatal and non-postnatal populations and with reference to theoretical models underpinning health behaviour change approaches.

5.4.1 Effects of the intervention on outcome expectancies and intentions

There was limited impact of the intervention on change in PA outcome expectancies from baseline to three months and then a decline was observed among intervention participants compared to the control group from three to six months follow-up. The decline was not significant at the more conservative p-value, although was associated with a small effect size. No significant changes were shown in relation to intentions to be PA in either group from

baseline to three and six months follow-up. Outcome expectancies and intentions were positive at baseline in both groups, possibly due to most participants enrolling in a trial to become more active, and being in 'Preparation' stage at baseline. In this context perhaps the lack of effect of the intervention on PA outcomes at three months is unsurprising. The findings that outcome expectancies declined among the intervention group from three to six months in MAMMiS was unexpected but somewhat consistent with a recent postnatal PA study showing a decline in outcome expectancy constructs following an SCT-informed intervention consisting of PAC and SMS-text messaging support (Fjeldsoe, Miller & Marshall, 2012). In Fjeldsoe et al. (2012) the decline in average outcome expectancies was as a result of a decline in participants endorsing the importance of PA for weight loss and improved fitness. Process questions about the use of self-management strategies during the MAMMiS trial suggested a decrease in the number of postnatal women from the intervention group who thought about the benefits from being active in terms of weight loss/maintenance between three and six months follow-up compared with baseline and three months. As PA cognitions were defined in relation to taking part in MVPA for at least 30 minutes on most days of the week, this did not separate participants beliefs about moderate and vigorous PA, the former might be more likely to be associated with positive proximal health, social and evaluative consequences, while the latter might be associated with more distal outcomes related to weight, fitness and general health. If this is the case then we might expect to see a change in outcome expectancies in line with participants' experience of outcomes of change. This may underlie participants in the study increasingly recognising the benefits of moderate-intensity PA postnatally for non-weight loss reasons over time and becoming more realistic in terms of their beliefs about the outcomes from being active. Previous research in postnatal populations has suggested that endorsing more immediate or proximal outcome expectancies, (i.e. the immediate outcomes we experience following PA participation such as "feel energized, better

overall mood, enjoyment and sense of accomplishment” (Cramp & Brawley, 2009, p. 599) is related to being more active compared to more distal outcome expectancies (e.g. weight loss, fitness change). It is not clear from the outcome expectancy construct whether this was the case as questions included a range of beliefs about PA and I did not separate out weight and health-related beliefs from other social/personal evaluative beliefs, nor did I explicitly ask about weight loss/maintenance or physical fitness; instead an existing questionnaire was adapted by including items related to the top most frequently cited benefits among postnatal women. In hindsight, the outcome expectancy questionnaire might have been more comprehensive if it had been developed from formative research with the population and separated proximal/distal outcomes, and outcomes related to moderate and vigorous PA.

The value of changing outcome expectancies relates to the predicted importance of increasing awareness of the benefits of PA. In the MAMMiS intervention this was done during the decisional balance strategy/technique in the first PAC. The TTM model, which underlies much of the content of the PAC intervention predicts participants in later stages of change will report more benefits and less barriers than participants in earlier stages of change. Correlations between outcome expectancies and PA behaviour have been shown in postnatal populations (Cramp & Brawley, 2009; Fjeldsoe et al., 2012; Roozbahani, Ghofranipour, Ardabili & Hajizadeh, 2013), however, other models (e.g. the TPB and HAPA) suggest changing outcome expectancies would only be predicted to affect intentions to change behaviour, with a resulting effect on behaviour mediated through other constructs (e.g. perceived behavioural control/self-efficacy, action and coping planning). Therefore, in the context of a group with high intentions to be active, perhaps that the targeting of outcome expectancies is of little value to enacting PA change. This is supported by postnatal PA intervention research which has failed to find evidence that changes in outcome expectancies mediate PA behaviour change (Cramp & Brawley, 2009; Fjeldsoe et al., 2012).

In contrast, Rothman (2000) suggests individuals' beliefs that there have been noticeable improvements to important outcomes since changing behaviour (e.g. satisfaction with outcomes of becoming more physically active) are crucial to continued effort/sustaining behavioural change. This may be more relevant in a group that has already begun to change PA behaviour. Recent research has demonstrated some support for this, for example in relation to maintenance of attendance at walking groups over six months (Kassavou, Turner, Hamborg & French, 2013). In the second PAC I asked for feedback from participants about any changes they noticed during the process of changing their PA behaviour; however as I did not measure satisfaction with those outcomes it is not clear to what extent this affected participants' PA behaviour.

5.3.2 Effects on self-efficacy, planning and action control

Previous studies of PAC interventions in non-postnatal and postnatal populations have shown increased self-efficacy for overcoming barriers to change (Fjeldsoe et al., 2012; Sharma et al., 2005; Miller et al., 2002). This is consistent with the findings in MAMMiS which found that barrier self-efficacy increased among the intervention group from baseline to three months and declined among the control group, this increase was associated with a small effect size and was maintained at six months. This is positive given negotiating barriers to PA may be more challenging for postnatal women, particularly as their child ages and circumstances change (i.e. a return to work, their child starts to walk etc.). The decline in self-efficacy found among control participants, perhaps suggest this. Despite the positive change in self-efficacy, PA behaviour did not change in response to the intervention, which is in contrast to previous interventions and predictions from the health behaviour change models discussed in Chapter One. One consideration, however, is that self-efficacy may have increased among intervention participants, not as a result of postnatal women becoming more confident that

they could overcome barriers and be physically active during their leisure-time, but rather due to the change in their perception about what constitutes regular PA (perhaps as a result of attending the pramwalking group and/or increasing walking on their own to meet step count goals) and therefore their ability to meet these standards despite barriers. The PA cognitions questionnaire did not differentiate between LTPA and walking (with or without a pram). Participants in the qualitative study discussed that participation in the trial led to increased efforts to be physically active and some changed their beliefs about walking as a form of acceptable exercise. This may underlie why increased stepcounts (but not MVPA or self-reported MVPA) was found among intervention group participants from three to six months. In support of this Fjeldsoe et al. (2012) has recently found that improvements in barrier self-efficacy significantly mediated changes in self-reported MVPA participation at 13 weeks follow-up, but not walking behaviour in response to a postnatal PA intervention. Their questionnaire asked postnatal women to self-report change in frequency of “exercise” and asked about self-efficacy for overcoming barriers to “exercise”, which is different to the MAMMiS study, which asked about self-efficacy for overcoming barriers to regular PA.

Changes to self-regulatory facets of behaviour may also be particularly important for changing behaviour in postnatal populations. In the qualitative study intervention participants suggested that the aspects of the PAC designed to promote goal-setting, specific action planning and coping planning and self-monitoring were regarded as particularly useful and important. I found all planning measures and action control constructs increased significantly from baseline to three months among the intervention group relative to the controls, which suggest the techniques introduced as part of the PAC (i.e. asking postnatal women to make specific weekly plans for where, when and how long they would be active, encouraging self-monitoring using diaries/pedometers and developing if-then plans to manage potential obstacles) can change these constructs postnatally. Although these did not lead to changes in

PA behaviour in MAMMiS, Fjeldsoe et al. (2012) recently found that changes to goal-setting skills (which encompassed action, coping planning and action control components) mediated both MVPA and walking behaviour change in response to a postnatal intervention.

There is also a likely reciprocal relationship between self-efficacy and self-regulatory strategies (i.e. increased self-efficacy affects adoption of self-regulatory skills which in turn increases self-efficacy). Indeed, this underlies Bandura's concept of mastery experience and is a central feature within the HAPA (Bandura, 1997; Schwarzer, 1992). Studies in the general population have shown that planning strategies only mediated PA behaviour change if participants held sufficient self-efficacy (Lippke et al., 2009). In the MAMMiS study both self-efficacy and action planning increased in the intervention group and declined in the control group from baseline to three months (although action planning scores recovered from three to six months in controls), therefore it is possible that asking participants to engage in action planning is important for both increasing and preserving self-efficacy during the postnatal period. A review of behaviour change techniques in PA interventions in the general population found use of action planning was associated with an increase in both self-efficacy for PA and PA behaviour change (Williams & French, 2011).

The largest change in PA cognitions in MAMMiS was found in coping planning, with an increase from baseline to three months and then a further increase from three to six months among the intervention group relative to controls, which was associated with a small-moderate effect size. Previous studies have found coping planning to be particularly helpful for young adult women in adopting PA behaviour change (Scholz, Sniehotta, Burkert & Schwarzer, 2007; Molloy, Dixon, Hamer & Sniehotta, 2010). In the context this increase in coping planning the finding that there was no change in PA behaviour was interesting. In addition to some of the possible explanations discussed above for nil effects on PA behaviour, one finding from the post-trial qualitative study was that some women appeared

doubtful about the extent to which the inherent unpredictability of caring for a young child could be overcome through problem solving approaches. Perhaps, a different approach might be to ask participants to consider controllable and uncontrollable barriers and encourage different strategies depending on the context. This is often used as part of stress or chronic illness self-management as participants are likely to experience barriers that cannot be overcome through problem solving approaches alone (Kirby, Williams, Hocking, Lane & Williams, 2006).

Furthermore, despite the changes to coping planning PA cognitions, there was evidence from participants self-reports of strategy use (reported in Chapter Four) that planning to overcome barriers to being active was used relatively infrequently. The thematic analysis (shown in Appendix 10) also suggests coping plans produced by many participants were non-specific (i.e. a quarter of respondent said they “adapted plans in response to changes/unforeseen problems” without specifying the usefulness or precise content of plans). One explanation for this discrepancy is that the technique used to teach coping planning skills in MAMMiS (i.e. the development of two implementation intentions or if-then plans) may have taught participants in the intervention group the importance of coping planning but did not enhance their coping planning skills. The implementation intentions technique was also designed to create a mental link between the occurrence of the barrier to activity and the back-up plan (Gollwitzer, 1999), however often discussions during the second PAC illustrated the barriers participants expected to experience had not materialised and different unexpected issues had got in the way of their PA plans. In this case the coping plans produced during the PAC would not be expected to enact behaviour change and in the absence of participants feeling confident and skilled to develop new plans, would not necessarily support continued PA participation. This hypothesis is supported by the findings from Cramp and Brawley (2009) that self-regulatory efficacy (i.e. the confidence that one can

successfully develop realistic plans and back-up plans for PA) mediated PA behaviour change among postnatal women in their intervention, although this was only found for self-reported PA.

Given the theoretically-informed design of the MAMMiS intervention and the inclusion of physical activity cognition measures in the MAMMiS trial, the intention was to conduct a similar mediation analysis to those reported by Cramp and Brawley (2006) and Fjeldsoe et al (2013). This could have strengthened the results of the study by revealing possible mechanisms for change and go some way to understanding intervention effectiveness. However, as the results of the study were non-significant, mediation analysis was not conducted. As there was no intervention effect to be mediated the analysis failed at the first step using the hypothesis testing method established by Baron and Kenny (1981). Even the more robust Sobel method of mediation analysis requires an initial relationship between independent variable (in the case of MAMMiS, participation in the intervention) and the dependent variable (change in behaviour) to be established prior to testing the null hypothesis that there is no difference between the total effect path and the mediated effects path (Field, 2013). Despite the null results of the intervention (with possible reasons discussed extensively above) and the fact that mediation analysis was not possible, the changes shown in physical activity cognitions as a result of participation in the intervention, suggests the potential for physical activity behaviour change via individual-level intervention targeting postnatal women's' physical activity cognitions.

5.5 Effect of the intervention on secondary measures

5.5.1 Change in weight, BMI and fat mass

There was no significant difference between the groups on change in anthropometric measures. There was a trend for a small reduction in weight, BMI and %fat mass across both groups over time. Some participants did show a clinically significant change in BMI status over the six month study period. For example, 25% (n=5) of the 20 participants who were overweight or obese at baseline in the intervention group showed a positive change in their BMI (i.e. went from obese to overweight or overweight to normal weight) and 50% (n=7) of the 14 participants in the control group who were overweight or obese at baseline showed a similar positive change.

It seems likely that the changes seen in anthropometric and body composition measures were as a result of postnatal women showing a natural reduction in pregnancy-related weight gain. Upon entry to the study participants self-reported their prepregnancy weight, which when compared with measured weight at baseline, suggested both groups were around 5-6kg heavier postpartum. Prepregnancy weight may have been underestimated as it was self-reported (Shin, Chung, Weatherspoon & Song, 2013). Research has suggested it can take up to 18 months after childbirth to fully lose pregnancy-related weight gain and that long-term weight retention is less likely in affluent, married postpartum women, who were overly represented in the MAMMiS study (McCrary, 2002; Gore et al., 2003; Oken et al., 2007; Gunderson et al., 2008; Olson et al., 2003). Given the average time of recruitment (six months after childbirth), average differences in weight compared with prepregnancy and the lack of change in PA the small decline seen in weight and BMI seem to most likely represent a natural decline over time.

Another possible explanation is that participants adopted dietary control strategies during the course of the study. Advice about diet or behaviour change strategies related to dietary intake were not part of the MAMMiS intervention, although feedback from participants suggested that up to a third of participants in each group at each follow-up point

were seeking to manage their weight through dietary control strategies (e.g. adopting a calorie controlled diet, using weight loss products and/or using a commercial weight loss programme). I did not collect validated information on dietary behaviours or eating habits, therefore it is unclear to what extent participants across the study made changes to their diet, which would be expected to lead to weight loss. As discussed in Chapter One previous postpartum weight management interventions have not generally found significant effects on PA behaviour (using both objective and subjective measures), although significant weight change has occurred alongside reported improvements in diet (Bertz et al., 2012; Craigie et al., 2011; Ostbye et al., 2009). Findings from the general population suggests women are more likely than men to adopt dietary control strategies rather than PA to manage weight (McElhone, Kearney, Giachetti, Zunft, & Martinez, 1999). Dietary restriction is sufficient for weight-loss following childbirth (Amorim et al., 2013; Nascimento, Pudwell, Surita, Adamo & Smith, 2013), therefore participants might have preferred to change eating habits rather than become more physically active if motivated by weight loss. However, with dietary restriction in isolation there is more likely to be an increase in %fat mass as a result of a loss of muscle and lean tissue (Bertz et al, 2012), which was not seen in MAMMiS. However, the evidence for PA preserving body composition (in the context of weight loss) to date has been restricted to OW/OB postpartum samples (Amorim et al., 2007; Bertz et al., 2012), which is different to the sample who enrolled in MAMMiS.

5.5.2 Effects on psychological wellbeing and fatigue

MAMMiS was the first study to consider the impact of a PAC and group pramwalking intervention on general psychological wellbeing in a sample of healthy of postnatal women recruited up to 12 months after childbirth. Psychological wellbeing remained stable in both groups with no evidence for an impact of the intervention. MAMMiS participants showed

relatively high psychological wellbeing at baseline; mean scores were slightly higher (i.e. 86, s.d.=10.6 among the intervention group and 90, s.d.=8.1. among controls) compared to the scores reported among females aged 16-44 from a UK primary care sample who were randomly selected (82, s.d.=14.1) but slightly lower than a subsample of those participants (both genders) who reported being in “excellent health” and without any longstanding physical or psychological illness (94, s.d.=10.9) (Hopton et al., 1995). Previous research has demonstrated short-term (at 12 weeks follow-up) reductions in EPDS score among nonclinical postpartum women (2 months after childbirth) following 8-weeks of group onsite exercise classes alongside educational topics (Norman et al., 2010) or 12-weeks group pramwalking 2-3 times per week (Armstrong & Edwards, 2003; 2004). It is unclear whether change shown in Norman et al. (2010) was attributable to changes in PA, which is an ongoing issue in the postnatal PA literature as positive effects on psychological wellbeing may be somewhat attributable to the addition of social support provided via group exercise (Daley et al., 2009). A further pilot study among women with PND was underpowered to detect a change in PND score and did not demonstrate change in PA behaviour at follow-up (Daley et al., 2007). Given the population differences in Armstrong & Edwards (2003; 2004) and in Daley et al. (2007) these studies are not readily comparable with the MAMMiS intervention. Overall, there may be limited benefit of PAC and group pramwalking to general psychological wellbeing among women already experiencing good psychological health.

Fatigue severity significantly improved in the intervention group (with the control groups' showing a worsening of fatigue) from baseline to three months, however this was shown in the absence of a change in PA and fitness so is likely to be unrelated in the present study. Fatigue severity during the postpartum period is likely to be affected by a number of factors (e.g. sleep quality, feeding choice, child wakefulness, bedsharing, depression etc.) perhaps it would be difficult to demonstrate improvement in this measure in the context of

increasing PA only or these factors would need to be assessed and added to the model as covariates. Previous research has found improvements in unadjusted general and physical fatigue severity following a 12-week home-based exercise prescription intervention delivered postpartum, however this was among women with PND (Drista et al., 2009). Also mental fatigue only improved in response to the exercise intervention when adjusting for baseline fatigue, cardiovascular fitness and depression score and improvements in physical and mental fatigue were greater among individuals adhering to the programme (Drista et al., 2009).

5.6 Strengths, limitations and implications from the MAMMiS study

5.6.1 Strengths of the study

The main strengths of the MAMMiS study were the use of a randomised controlled design, inclusion of an objective measure of PA and a three-month post-intervention follow-up; these methods had not been previously been used in PA promotion trials among postnatal women. Despite the lack of blinding at follow-up, the accelerometer may have also reduced social desirability bias associated with self-report PA measures. Many previous studies (both in postnatal and non-postnatal samples) have not explicitly described the content of their intervention and how the interventions were informed by behaviour change research and theory. Several interventions to date have been atheoretical. Therefore, a further strength of the MAMMiS study is the use of a theoretically and empirically-based intervention, that has been shown to be effective in other groups that and that the precise content of the intervention is replicable. Inclusion of PA cognition measures and process data have provided evidence that the PAC intervention and pramwalking group programme was feasible, well adhered to and liked by postnatal women and enacted change in targeted constructs from health behaviour theory. These aspects of the study design have also provided information about the parts of the intervention that could be improved to be more effective (discussed below), this

information is useful for researchers and practitioners. Further strengths include the low drop-out rate (8%) compared to previous trials, which was achieved through developing a good rapport with participants, sending out reminder letters/phone contacts and being flexible about when and where assessment and intervention appointments were conducted; these factors have been previously shown to facilitate retention to lifestyle interventions among mothers and are particularly important within postnatal populations (Chang, Brown & Nitzke, 2009, MacLeod, Craigie, Barton, Treweek & Anderson, 2013).

5.6.2 Limitations of the study

The main limitation of the study was the recruitment of a sample that was potentially unrepresentative of postnatal women in Scotland in terms of socio-demographics and PA participation. MAMMiS recruited more postnatal women who were older and more affluent compared with the postnatal women generally. Most participants were married, highly educated and on maternity leave at baseline. This has implications for the generalisability of the findings from the study. Recruitment methods used in MAMMiS may have contributed to this, for example 50% of the women who expressed an interest were self-selected (i.e. proactively contacted the researcher following seeing the study advertised or word-of-mouth). The remaining 50% were approached at baby clinics and community events, with the former done explicitly to attempt to recruit women from disadvantaged areas but this did not translate into the sample who enrolled in the study; participants were demonstrably older and less likely to be living in more deprived areas compared with women who did not take part in the study. In particular, there was a poor rate of recruitment from health visiting staff, despite this being an ideal method of recruitment due to their regular contact with postnatal women. Efforts were made to engage health visitors through a series of presentations and personalised recruitment packs, however only 7% of interested participants came via health visitor referral.

This is similar to the results from Daley et al. (2009), who received 8% of referrals to a physical activity intervention study from health visitors. Possible reasons for a lack of engagement include low management support, in addition to the time pressures facing health visitors in the current NHS climate. Other research has shown health visitors own knowledge and beliefs, for example about the amount of physical activity recommended and the likelihood of participants' willingness to change, affects their likelihood of promoting physical activity opportunities to their patients (Douglas et al., 2006). Given this, future research may require a theory-based intervention targeting health visitors' behaviours as well. For example, Penseau et al. (2014) plan to target individual primary care practitioners to improve diabetes health promotion behaviours, through increasing professionals' self-efficacy, outcome expectancies, intentions, plans and addressing the priority given to their goals, goal conflict and methods for goal facilitation. Behaviour change methods for this are likely to include information provision, goal-setting, action and coping planning, and through using prompts/cues in the workplace as reminders. A similar intervention could be tested with health visiting staff to improve referral rates.

The limited recruitment of women from more disadvantaged backgrounds has been shown across research; educated affluent women are overly represented in studies as they are easier to recruit (Yancey et al., 2006; Foster et al., 2011). The method of screening of participants for inclusion in the study (i.e. based on their perceptions of their current PA levels) was potentially problematic. The stage of change questionnaire may have led to MAMMiS recruiting a relatively active group. Due to the large variability in baseline PA and activity levels of the sample the study was potentially underpowered with implications for definitely assessing the impact of the intervention. Also despite being randomised there was evidence that groups were uneven at baseline, considering their weight, breastfeeding status and PA behaviour. In particular, the finding that the intervention group was more physically

active at baseline compared with the control group was a potential limitation; this may have been due to OW/OB women (who were overly represented in the intervention group) experiencing a heightened sense of salience regarding the need to be physically active to manage their weight (French & Sutton, 2010; Criagie et al., 2011). This may have led to more intervention participants increasing PA during the baseline measurement week (i.e. after being weighed), whilst wearing the accelerometer. Alternatively, higher breastfeeding rates in the control group at baseline may explain this finding, with evidence from previous research that breastfeeding may impact on PA through contributing to lower energy levels (Tulman & Fawcett, 1988 cited in Mottola, 2002), a perceived inability to leave infants with others in order to take part in structured PA and possible discomfort during physical activity (Evenson et al., 2009).

Another potential limitation of the study was the potential for control group contamination affecting the results. There was evidence for this as the control groups' physical objectively and subjectively measured physical activity increased from baseline to three months follow-up. There were instances recorded of intervention participants and control participants from the same area and being aware of each other and their group assignment. This occurred partially due to recruitment methods, for example, attracting many participants from the same baby clinic or playgroup; however the nature of the target group (postnatal women) and the small geographic area involved in recruitment were also factors. Furthermore, the introduction of equipment for measurement of physical activity and the heightened awareness about physical activity (mentioned by participants from both groups during the post-trial interviews) may have encouraged control group participants to purchase and use their own self-monitoring equipment, which was a key flank of the intervention approach.

Finally, one potential limitation is that the intervention approach and PA cognitions measures may not have include all the factors which may influence PA behaviour change postnatally. For example, past PA behaviour (prepregnancy) was not considered despite evidence that this affects intentions and self-efficacy for postnatal PA (Godin et al., 1989; McIntyre et al., 2009; Bauer, Pivarnik, Feltz, Paneth & Womack, 2013). Furthermore, beliefs about social norms and social support were not measured, although the later was discussed as part of the PAC. McIntyre & Rhodes (2009) has shown the normative belief “my friends would approve of me being regularly physically active” (p. 71) correlated with frequency of weekly PA among women with young children. For this reason, perhaps setting up pramwalking groups among individuals who do not know each other is not particularly effective for encouraging postnatal PA and instead group-based PA change should concentrate on taking advantage of existing peer networks; indeed Cleland, Granados, Crawford, Winzeberg & Ball (2012) have recently found group-based delivery of PA behaviour change to be particularly effective among women from more disadvantaged groups. Furthermore, being active with children (i.e. through pramwalking) though feasible and potentially practical for postnatal women may not normalise the importance of PA that is conducted at a vigorous intensity (i.e. likely during time away from infants). This is important as given the reasonably active profile of the MAMMiS sample; change in vigorous PA would likely be required to engender health and wellbeing benefits. Considering social support, I did ask intervention participants to report how often and what types of social support they used to enable them to be active, with evidence for a decline in self-reported use of social support from three to six months. Despite previous research showing social support directly mediates behaviour change among women with young children (Miller et al, 2002), recent analysis within postnatal populations has found increased social support did not mediate either MVPA or walking behaviour among postnatal women in a PA intervention

(Fjeldsoe et al., 2012). Molloy and colleagues (2010) have recently shown that the impact of social support for PA in female students was mediated by perceived behavioural control (similar to self-efficacy) and coping planning, therefore the importance of social support may be due to the impact it has on confidence and self-regulatory behaviours, which did change in the MAMMiS study.

5.6.3 Implications of the study

There are implications from the MAMMiS trial which should be considered when developing and conducting future research and interventions in postnatal populations.

5.6.3.1 Implications for physical activity intervention approaches with postnatal women

Future postnatal PA interventions may wish to differentiate whether the change target behaviour is walking as part of lifestyle activities and/or structured LTPA (i.e. exercise, including walking for exercise). Although walking participation appears to be an important way for postnatal women to accumulate MVPA, at later postpartum stages or among mother with other young children, walking may not be the preferred method of PA or be at a sufficient intensity to confer health benefit (e.g. due to children being ambulatory and/or mothers return to work). Given research has continued to identify declines in LTPA-related activity following pregnancy and childbirth (Bennet et al., 2013) interventions should seek to facilitate postnatal women to participate in structured PA in the likely context of fluctuating PA habits, differing priorities and expectations of postnatal women over time, variable social support and due to the unpredictability of caring for a small infant.

Findings from the MAMMiS study and previous research perhaps suggest the following: given the decline in outcome expectancies, among postnatal women who have an existing intention to be active through moderate-intensity PA (i.e. brisk walking etc.), or who

have limited opportunities to increase vigorous-intensity PA, health professionals should be careful to avoid making more salient unrealistic outcome expectancies related to fitness gain and weight loss, which in the long term may lead to failure to adopt and sustain regular PA. Rather a focus on satisfaction from more proximal outcomes (e.g. improved stress management, enhanced wellbeing) and/or intrinsic enjoyment is perhaps more likely to engender sustained behavioural change in this population (Lewis & Ridge, 2005).

To better improve self-efficacy future interventions could consider encouraging postnatal women to identify circumstances under which they feel confident they can be active, rather than placing too much emphasis on barriers to change. Considering social support, PA promoters may find it is unrealistic for behaviour change interventions targeting individuals to effectively facilitate this in all cases. Therefore, interventions may need to both enhance perceptions of social support for PA (in order to increase self-efficacy) and also help participants to develop and seek out strategies to be physically active in the absence of a high level of support from family and friends. However, since the latter may conflict with postnatal women's goals to increase LTPA future research is needed to identify how best to accomplish this.

Coping planning techniques appear particularly useful for postnatal women, the MAMMiS results suggest these should be used in conjunction with action planning and self-monitoring techniques (Caudroit, Bioche & Stephan, 2014). Participants developing action plans for PA where there are potential obstacles to behaviour change should be encouraged to develop several coping plans updating these as they experience new barriers and monitoring the success of the strategies they adopt to meet PA goals. One possible approach is through further follow-ups after the PAC these could be facilitated through telephone, SMS-texts, online discussions. Although, pramwalking groups were used for this purpose in MAMMiS not all participants could attend these and individual attention was dependent on other factors

(such as group composition and personalities). Promotion efforts should perhaps explicitly differentiate controllable and uncontrollable barriers and help postnatal women to identify how to overcome the former and manage their own expectations regarding the latter to avoid feelings of failure or demotivation. It is predicted this would further enhanced self-efficacy for being physically active and lead to improved adherence to PA goals although this should be tested in a postnatal sample.

5.6.3.2 Implications for trial design and measurement

The lack of intervention effect relative to the control group highlights the importance of appropriately targeting PA promotion and using an appropriately designed objective measurement approach to assess postnatal PA behaviour and behaviour change. Furthermore, the findings from MAMMiS underlie the importance of including a control group and having detailed information on PA domains and intensity, in order to identify whether changes in different domains/intensities occur naturally over time or in response to measurement/minimal intervention and how this impacts on the ability to show significant change in postnatal PA behaviour in behaviour change interventions.

In future research it may be more appropriate to use accelerometers that offer multisensing capabilities, for example the Actihart or the Sensewear Pro (Strath et al., 2013). Although more expensive than the Actigraph used in MAMMiS, costs have declined, making them feasible for use in larger-scale studies (Strath et al., 2013). This would allow researchers more sophistication in identifying the potential additional energy costs associated with pushing, carrying or walking uphill, which is relevant to postnatal women. Furthermore, it may be worth considering an extension of accelerometer wear time in postnatal studies (i.e. beyond the typical seven days), or discarding wear days, which deviated markedly from usual activity (for example due to mother or baby illness, return to work issues etc.). This may help

alleviate concerns over fluctuating PA which is not representative of usual activity. Avoiding the return to work period in future postnatal PA studies and using a PA self-report measure that enquires about typical PA or PA from the last four weeks may also be warranted. However, postnatal-specific validation studies should also be conducted for self-report measures and there is a need for carefully controlled field studies of postnatal women's lifestyle activities in order to provide advice about which activities contribute to health benefit.

One possible implications arising from the findings from MAMMiS is whether healthy postnatal women should in general be targeted for PA promotion. However, as the MAMMiS study did not randomly select participants from the postnatal population in Scotland it is not possible to draw conclusions about the PA behaviours of the group as a whole and therefore their suitability for PA promotion efforts. However, this is important for public health programme planners to consider in terms of investment in services. Therefore, future research should seek to identify characteristics of postnatal women in Scotland who would most benefit from a PA promotion intervention. The MAMMiS trial did demonstrate large variability in baseline PA among postnatal women who were recruited; this has potential implications for future intervention trials measuring PA change. Studies may need a greater number of postnatal women to be sufficiently powered when using objective measures, seek to avoid control group contamination through adopting a cluster-randomised design, and/or may need to target interventions towards increased time spent in vigorous PA postnatally to show significant PA change and impacts on health and wellbeing outcomes.

5.6.3.2.1 Identifying and recruiting low-active postnatal women to physical activity trials

Some of the variability in PA behaviour might be reduced if different strategies are used for identifying and recruiting low-active postnatal women. Perhaps more sophisticated strategies are needed. The question of how best to attract and enrol an appropriate postnatal sample is important for future research and practice. Findings from MAMMiS suggest the stage of change questionnaire should not be used as a screening tool in healthy samples when trying to recruit low-active postnatal women. Baseline results from an ongoing trial of a PA intervention have indicated that excluding postnatal women self-reporting >30 minutes of MVPA resulted in a recruited sample in which 14% meet guidelines at baseline, compared with 51% in MAMMiS (Albright et al., 2012), therefore low thresholds (based on self-reported PA behaviour) may be more appropriate.

Also due to the potential attraction of pramwalking and most women self-selecting to join the study, researchers should be aware this could result in a more active and less socio-demographically and socio-economically diverse group being enrolled. MacLeod et al. (2013) and Daley et al. (2006) have shown that personalised contact letters sent through primary care were effective methods for recruiting overweight women from deprived communities and women with PND, this may be a more promising approach, although the extent this would apply to healthy postnatal populations is unclear.

Another option is to target groups that may be at-risk of insufficient PA due to clinical indicators (i.e. obese postnatal women, diagnosis of GDM or PND). These postnatal groups might be expected to show a more homogenous and low-active PA profile and would perhaps benefit to a greater extent from increasing participation in PA than a general healthy postnatal population; although evidence is still inconclusive and to date this has not been tested using objective measures of PA (Daley et al., 2012; Bennet et al., 2013). Also there is limited evidence for the efficacy of PA interventions in clinical postpartum populations to date when

considering PA change and many studies report poor compliance/retention (Craigie et al., 2011; Cheung et al., 2011; Daley et al., 2007; Ferrara et al., 2011).

5.7 Conclusions

The MAMMiS study set out to test the efficacy of a theoretically and empirically-based intervention, consisting of PAC plus group pramwalking, for changing postnatal PA behaviour among healthy low-active postnatal women. The study also sought to evaluate the impact of the intervention on secondary health and wellbeing outcomes, targeted PA cognitions, and identify the potential feasibility and acceptability of this approach. The main findings from the MAMMiS study was there was no evidence for a significant impact of the intervention on PA behaviour, either objectively or subjectively or measured of by physiological proxy (i.e. reviewing change in cardiovascular fitness). Despite this, many participants reported that participation in the trial stimulated change in their thinking about how to fit PA into their everyday lives, changed their perceptions of how they could be physically active while caring for a young infant, and changed their PA behaviour. Thirdly, the MAMMiS study has shown it was feasible to use relatively straightforward behaviour change techniques during a PAC (e.g. setting goals, action planning, self-monitoring and developing coping plans) and these led to changes in theoretical constructs, which have been empirically demonstrated to mediate postnatal PA behaviour change. These techniques could be implemented by trained health professionals and/or lay people in a variety of contexts. The intervention was largely acceptable and appeared feasible for most postnatal women, however as the sample was not generalisable it is not clear whether this would extend to healthy postnatal women in general.

Despite attempting to attract a diverse sample of healthy postnatal women and to screen out already reasonably active participants, MAMMiS attracted and enrolled a

relatively affluent, older and educated sample, of whom many were relatively physically active already. Due to variability in PA at baseline the trial was insufficiently powered, there was also evidence for fluctuating PA habits among postnatal women; these findings have implications for measurement of postnatal PA in future studies. Finally, there was no significant impact of taking part in PAC and a group pramwalking intervention on secondary health and wellbeing outcomes. It is unclear if this is due to targeting healthy postnatal women or due to the lack of change in PA at a sufficient dose.

Overall, results suggest that a healthy postnatal women taking part in PAC and pramwalking experienced positive changes in PA cognitions; however this was not translated into measurable PA behavioural change at three or six months follow-up. Future research is needed to identify which groups of postnatal women to target for PA promotion and how best to identify and recruit low-active postnatal women.

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Appendix 1. PRISMA checklist for the systematic review

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	1
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	1
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	1-3
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	4-5
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	N/A
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	4-5
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	4
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	Additional file 1
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	Figure 1
Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	5-6

Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	5-8, additional file 2, additional file 3, additional file 4
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	5-6, additional file 2
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	7
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	6-8
Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	7, Figure 3a-3b, additional file 2
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	6-8
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	Figure 1
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	Table 1
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	Additional file 4
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	9-12, Figures 2a-2c
Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	Figures 2a-2c,

			12-13
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	Additional file 5
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	N/A
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	14-17
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	17-18
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	14-20
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	20

Appendix 2. Review search terms

Search strategy for all databases on EBSCO host

S1 post partum
S2 postpartum
S3 post natal
S4 postnatal
S5 preg*
S6 childbirth
S7 birth
S8 (post OR after OR following)
S9 S8 AND S5
S10 S8 AND S6
S11 S8 AND S7
S12 S1 OR S2 OR S3 OR S4 OR S9 OR S10 OR S11
S13 physicl*
S14 activ* and S13
S15 exerci*
S16 aerobic
S17 walk*
S18 leisure
S19 S18 OR S17 OR S15 OR S14
S20 S19 AND S12
S21 intervention
S22 trial
S23 study
S24 promotion
S25 s24 OR S23 OR S22 OR S21
S26 S25 AND S20

Appendix 3. Table of physical activity and walking outcome measures from systematic review and meta-analysis

Reference (1st author)	Data collection methods	Measurement instrument	Physical activity: domains^a (D), intensity^b (I), measurement unit(s)^c (MU) and reference period^d (RP)	Walking behaviour: domains^a (D), intensity^b (I), measurement unit(s)^c (MU) and reference period^d (RP)	Outcomes included in meta-analysis (MA)
Albright, 2005	Self-report questionnaire on site	Godin LTEQ	<i>D:</i> Leisure-time activity <i>I:</i> Strenuous activity ‘makes heart beat quickly, makes you sweat’ and moderate activity ‘doesn’t make you tired, makes you sweat a bit’ <i>MU:</i> minutes/week (volume) only including bouts lasting at least 15 minutes <i>RP:</i> Typical 7 days	Not separately assessed	N/A as no control group
Bertz, 2012	Doubly labeled water* and activity monitor	SenseWear Pro2 Armband (for walking behaviour only)	<i>D:</i> N/A <i>I:</i> N/A <i>MU:</i> Total energy expenditure (TEE) in kcal/day <i>RP:</i> Previous 15 days	<i>D:</i> Walking <i>I:</i> N/A <i>MU:</i> steps p/day (volume) <i>RP:</i> measurement over 5 consecutive days	Volume of walking (separately for exercise only and diet and exercise intervention)
Craigie, 2011	Activity monitor	SenseWear (Bodymedia Inc. Pittsburgh)	<i>D:</i> N/A <i>I:</i> Moderate and vigorous physical activities <i>MU:</i> minutes/week (volume) <i>RP:</i> 7 days prior to assessment (>4 days valid wear-time required)	Not separately assessed	Volume of physical activity
Cramp, 2006	Self-report via face-to-face interview	7-Day PAR	<i>D:</i> Unclear if non leisure-time activity <i>I:</i> Moderate and vigorous activity <i>MU:</i> minutes/week (volume), times/week (frequency) <i>RP:</i> Typical week from last 4	Not separately assessed	Frequency and volume of physical activity as separate outcomes

Daley, 2007	Self-report questionnaire via post	Godin LTEQ	<p><i>D</i>: Leisure-time activity</p> <p><i>I</i>: Mild, moderate and vigorous physical activities^f</p> <p><i>MU</i>: times/week (frequency) only including bouts^e lasting ≥ 15 minutes</p> <p><i>RP</i>: Typical week</p>	Not separately assessed	Frequency of physical activity (combined moderate-vigorous only)
deRosset, 2013	Self-report via questionnaire on site (interviewer assisted due to language issues)	Health Promoting Lifestyles Profile II (exercise sub-scale)	<p><i>D</i>: Exercise (e.g. brisk walking, aerobic dancing), sustained walking, stretching activities, leisure-time activities (e.g. dancing, swimming, bicycling) and daily activities (e.g. using stairs)</p> <p><i>I</i>: Light-moderate (at least 30-40mins) and vigorous activities (≥ 20mins)</p> <p><i>MU</i>: Total combined score from 8 items relating to frequency of performance of various exercise behaviours measured on a 4-point scale from “never-routinely”</p> <p><i>RP</i>: N/A</p>	Not separately assessed	Frequency of physical activity
Fjeldsoe, 2010	Self-report via face-to-face interview	AWHS + single-item frequency question	<p><i>D</i>: Exercise, planned activity and transportation (inc. brisk walking). “Domestic, childcare and employment” domains were excluded</p> <p><i>I</i>: Moderate and vigorous activity</p> <p><i>MU</i>: minutes/week (volume), times/week with bouts lasting at least 30 mins (frequency)</p> <p><i>RP</i>: Unclear</p>	<p><i>D</i>: Walking for exercise</p> <p><i>I</i>: not specified</p> <p><i>MU</i>: minutes/week (volume), times/week (frequency)</p> <p><i>RP</i>: Unclear</p>	Frequency and volume of physical activity and total volume of walking all as separate outcomes
Montgomery, 2010	Pedometer (Self-report via activity log)	Yamax Digiwalker SW-200	Not separately assessed	<p><i>D</i>: Walking</p> <p><i>I</i>: N/A</p> <p><i>MU</i>: steps/day (volume)</p> <p><i>RP</i>: Pedometer worn for at least 3 days each measurement week</p>	N/A as no control group

Lioret, 2012	Self-report questionnaire on site	Active Australia Survey	<p><i>D</i>: Walking continuously for 10 minutes and unspecified "physical activity"</p> <p><i>I</i>: vigorous and moderate</p> <p><i>MU</i>: Total minutes/week (volume) weighting time spent in vigorous intensities by a factor of 2.</p> <p><i>RP</i>: Previous week</p>	Not separately assessed	Weighted volume of physical activity
Maturi, 2011	Self-report questionnaire (both groups) and pedometer (Intervention group only via a self-reported activity log)	Short form IPAQ and Omron, HJ-152K-E, China	<p><i>D</i>: Leisure-time, domestic, work and transport (inc. walking)</p> <p><i>I</i>: All intensities included</p> <p><i>MU</i>: Participants were assigned categories (light, moderate or vigorous) by weighting time spent in activity intensities according to METmins (only where bouts lasted at least 10 minutes)</p> <p><i>RP</i>: Previous week</p>	<p><i>D</i>: Walking</p> <p><i>I</i>: N/A</p> <p><i>MU</i>: steps/day (volume)</p> <p><i>RP</i>: Pedometer was worn for at least 5 days during each measurement week</p>	N/A as the main physical activity measure was categorical and walking behaviour was only assessed in the intervention group
Norman, 2010	Self-report via questionnaire	Non-standard questionnaire used	<p><i>D</i>: Aerobic activity and strength training</p> <p><i>I</i>: Not specified</p> <p><i>MU</i>: minutes/week (volume)</p> <p><i>RP</i>: Unclear</p>	Not separately assessed	Volume of physical activity
Ostbye, 2009	Self-report via telephone interview	7-Day PAR	<p><i>D</i>: Unclear if non-leisure activities included</p> <p><i>I</i>: Moderate: 'similar to how you feel when you're walking at a normal pace', very hard: 'similar to how you feel when you're running' and hard: 'falls just in between' activity^e</p> <p><i>MU</i>: minutes/week (volume), times/week with bouts lasting at least 10 mins (frequency)</p> <p><i>RP</i>: Previous week</p>	Not separately assessed	Frequency and volume of physical activity as separate outcomes

O'Toole, 2003	Self-report via face-to-face interview	YPAS	<p><i>D</i>: 'Work, care-giving, recreational activities and exercise'</p> <p><i>I</i>: All intensities, with separate estimates of vigorous and 'exercise' intensities</p> <p><i>MU</i>: Estimated kcal/week from exercise (energy expenditure)</p> <p><i>RP</i>: Typical week from past month</p>	Not separately assessed	Volume of exercise ^g
Reinhardt, 2012 ^f	Self-report questionnaire on site	IPAQ-long version	<p><i>D</i>: Physical activity related to work, transport and in leisure-time (housework and yard-work excluded)</p> <p><i>I</i>: Moderate and vigorous activities</p> <p><i>MU</i>: Total mins/day (not weighted) and METmins/day (weighted), both measures of volume of physical activity</p> <p><i>RP</i>: Previous seven days</p>	Not separately assessed	Total volume of physical activity (both METmins and non-weighted mins) ^h
Walker, 2012	Self-report questionnaire on site	13-item SCI (3 PA items)	<p><i>D</i>: Exercise (e.g. running, swimming), brisk walking, muscle toning activities (e.g. yoga, weight training) and in leisure-time activities (e.g. bowling, golf, housework and gardening) – lasting 15-30 mins,</p> <p><i>I</i>: Moderate 'some form of physical work out' and vigorous activities</p> <p><i>MU</i>: Total score frequency participation in various physical activity behaviours combined from 3-items (0-3 scale) from 'rarely-very often' (reverse coded)</p> <p><i>RP</i>: N/A</p>	Not separately assessed	Frequency of physical activity (separate analysis for three ethnic groups)

Watson, 2005	Self-report via questionnaire. Non-returners via telephone interview.	Adapted from National Physical Activity Survey (1999)	<i>D</i> : Exercise, transportation activity (e.g. cycling) and “gardening or heavy yardwork” <i>I</i> : Moderate and vigorous physical activities <i>MU</i> : minutes/week (volume), times/week (frequency) <i>RP</i> : Previous week	<i>D</i> : Walking for exercise, transportation or recreation <i>I</i> : Not specified <i>MU</i> : minutes/week (volume), times/week (frequency) only where bouts lasted at least 10 minutes <i>RP</i> : Previous week	N/A as insufficient information Provided to include in MA
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7-Day PAR: Seven-day Physical Activity Recall, AWAS: Australian Women’s Health Survey, Godin LTEQ: Godin Leisure-time Exercise Questionnaire, IPAQ: International Physical Activity Questionnaire, Mins: Minutes, MV: Moderate-vigorous, Paffenbarger PAQ: Paffenbarger Physical Activity Questionnaire, SCI, Self-Care Inventory; YPAS: Yale Physical Activity Survey

*The DLW technique measured total energy expenditure, which does not partial out energy expenditure from non-physical activity sources, this outcome was not included in the review.

^aActivity domains refers to the nature of the physical activity that was measured such as leisure-time, exercise, transport, lifestyle (e.g. housework and gardening) etc.

^bIntensity refers to the amount of effort the physical activity entailed such as mild, moderate and vigorous intensity etc.

^cMeasurement unit(s) refers to raw data used to capture physical activity participation such as number of minutes per day, k/cal expended or number of steps etc.

^dReference period refers to the period of time used for measuring physical activity participation such as over a typical week, the seven days prior to assessment or three days of activity monitor wear time etc.

^eAuthors provided combined data as moderate and vigorous intensity results were provided separately in the article.

^fDesign/protocol paper was consulted (e.g. Campbell et al., 2008)

^gAs the total physical activity estimate included light intensity activities, the estimated volume of exercise activity was the chosen outcome for the meta-analysis.

^hFor inclusion in the meta-analysis we used both weighted and unweighted volume of physical activity behaviour as both were reported in the paper, however the sample size was halved to ensure appropriate weighting for the pooled effect size.

Appendix 4. Risk assessment form for pramwalks

Walk location/Name:

Length of walk/Approximate time:

Date completed:

Full assessment or pramwalking risk only?

HAZARD	WHO MIGHT BE HARMED?	HOW IS THE RISK CONTROLLED?	WHAT FURTHER ACTION IS NECESSARY TO CONTROL RISK?
Path issues: Slippery? Icy etc.?			
Terrain: Incline? Steps? Pothole etc			
Risk of minor injury?			
Weather: Conditions differ across seasons?			
Risk of major injury? Road-crossings? Path used by others e.g. horses/cyclists?			
Other concerns: Parking/transport facilities? Baby change/toilets? Food/drinks availability? Benches?			

Appendix 5. MAMMiS study leaflet



What is More Active MuMs in Stirling?

MAMMiS is a study for women who have given birth in the last year. It is being carried out by researchers at the University of Stirling.

We are recruiting women from the Stirlingshire area to see if we can help them be more active.

If you have given birth in the last year and you are thinking about getting more active you can contact us now to get more information about this study.

You can call, email or return in a freepost envelope the attached card with your details on it.

We will send you out an information pack and telephone you to find out if you are eligible to take part and answer any questions you might have.



Why are you doing this study?

There are health benefits from being more active. We know that more active women are fitter, less likely to be overweight or obese and have greater feelings of well-being. Women are sometimes less active than they would like after having a baby so we are hoping to help them to be more active.

What will this study involve?

Taking part in this study will mean meeting with a researcher several times over a 6 month period. We would like to know if the study helps women with infants to be more active, so we will measure your activity levels. We will also be measuring your fitness levels, weight and asking you questions about your well-being.

Some women taking part in this study will take part in two physical activity consultations. These are one-to-one meetings with a trained counsellor to discuss how to build activity into your daily life. We will be organising a 10-week group pram-walking programme to go along with this so you'll meet other mums interested in being more active in your area.

www.mammis.weebly.com

Not all women who take part in this study will get this though. Half of the women will instead receive a leaflet about being more active. These women will still meet up with the same researcher to measure their activity levels, fitness levels, weight and well-being over the next 6 months.

Can I get more information?

You can find out more by getting in touch with the Chief Investigator - Alyssa Gilinsky using the contact details below.

She will be happy to answer any of your questions and can tell you if you are eligible to join this study.



University of Stirling

School of Sport
University of Stirling
Stirling, FK9 4LA
Office: 01786 467345
Mobile: 07974321789
Email: a.s.gilinsky@stir.ac.uk



Study Information Sheet

More Active MuMs in Stirling

A physical activity intervention for postnatal women: A randomised controlled trial

You are being invited to take part in a research study. Before you decide it is important for you to know why the research is being done and what is involved. Take time to read this information carefully. Discuss it with friends and relatives, your health visitor or GP. You can ask us if anything is not clear.

What is the purpose of the study?

We want to find out whether receiving a leaflet or physical activity consultations, and attending a 10-week group pramwalking programme, helps mums to be more active, and improves their fitness, weight management and wellbeing.

Why have I been chosen?

You have been invited to take part because you have given birth to a baby in the last year and because you contacted us for more information about this study.

Who is carrying out this research?

This research is being carried out by a PhD student at the University of Stirling. The student [Alyssa Gilinsky] is supervised by lecturers from the School of Nursing, Midwifery and Health and the School of Sport. Alyssa Gilinsky is a trained physical activity counsellor and walk-leader.

Do I have to take part in this study?

No, taking part is voluntary. You decide whether or not to take part. If you decide to take part you will sign a consent form and get a copy to keep. You are still free to leave at any time. If you decide not to take part you do not have to give a reason, and the care you receive will not be affected.

What will I be asked to do if I take part?

You will be invited to attend a meeting with Alyssa Gilinsky where she will ask you questions about your wellbeing, test your fitness and measure your height, weight and body fat. This will take up to 1 hour. You will also get an accelerometer and a pedometer. These are worn on your hip to measure how active you are and count the steps you take. A week later you will have a second visit where you will hand these back and discuss activities you took part in.

After this second visit you will be randomly allocated to attend one of two groups. In one group you will receive two physical activity consultations and a 10-week pramwalking programme. You can choose not to come to the pramwalking group. In the other group you will receive normal care and a leaflet about being active after pregnancy. You have an equal chance of being in either group.

What happens if I'm allocated to the leaflet only group?

You will be given a leaflet after the second visit and will be contacted 3 and 6 months later to complete the same measurements as the earlier meetings.

What happens if I'm allocated to the consultation and pramwalking group?

Your first physical activity consultation will be at the end of the second visit and will last around 30-40 minutes. We might ask your permission to record this session and your later session. You will also be invited to attend a pramwalking group for up to 1 hour each week for the next 10 weeks. It is up to you whether to attend this group or not. You'll have another consultation at the end of the programme. After this you will complete the same assessments as you did in the earlier meetings. You will be contacted 3 months later to complete these again.

Is there anything else I should know?

We will conduct assessments and consultations in your home or at the University of Stirling. If you have to come to the university we will pay reasonable travel costs. If you received the consultation and pramwalking group we might ask you to take part in a short individual or group interview to find out about your experiences of taking part. You will be asked at the end of the last set of assessments if you want to take part. You don't have to take part if you don't want to.

If I take part what will be expected of me?

We will ask you to take part in the assessments and activities involved in this study. You can let us know if you have any problems or feel uncomfortable at any time. To improve accuracy of the measurements we will ask you to try not to drink alcohol 48 hours before visits, avoid very hard exercise 12 hours beforehand and try not to eat or drink anything 4 hours before being weighed.

If you are taking part in pramwalking you should make sure you and your baby are dressed appropriately, as we won't cancel the group if it rains. You are responsible for your baby's safety. We will try and ensure good public transport links to the meeting point for the group but we ask that you make arrangements for getting there. Please let us know if you think you might have difficulties.

What are the possible benefits in taking part?

We cannot guarantee benefits from taking part. The information we get from this study may help us to understand how to help mums to be more active.

What are the possible disadvantages and risks of taking part?

There is a small possibility of injury and pain - we will help you minimise risk by encouraging you to gradually take part in moderate activities, like brisk walking.

During this study we will ask you about wellbeing. If we are concerned that you might be feeling distressed we will give you information about services that are available to you and ask you to speak to your health visitor or your GP. If you are concerned about being asked about this you should consider talking to someone you trust about this before agreeing to take part.

If you think you may have a health condition that prevents you from being active you can speak to your GP before agreeing to take part in this study. We will ask you questions about your general health before letting you know whether you are eligible for this study. If you are concerned about anything during the study, you can speak to Alyssa. If she can't help, or if you need specialist advice, she will ask you to speak to your health visitor or GP.

What happens when the study is finished?

The results from this study will be used as part of a doctoral thesis, submitted to the University of Stirling. The results will be presented at conferences and written up for publication in academic journals. This information will be published online for you to see at: www.sports.stir.ac.uk.

Is the information I give kept confidential?

Yes, information you provide will be kept private. All data will be anonymous in the final report. Your name will not be disclosed outside the research study. With your permission, your GP will be informed you are taking part. We will only ever break confidentiality if we have reason to believe that you or someone you have told us about is at immediate risk.

How will you ensure my information is kept secure?

All information collected as part of this study will be held in a locked cabinet in the offices of the School of Sport, University of Stirling. All information will be entered onto a secure password protected computer. Any personal information you provide will be coded to protect your identity. If you are allocated to the consultation and pramwalking group and we record these sessions we will code a copy of the recordings and destroy the original. After the study has ended we will keep your research results for 10 years in accordance with data protection principles. The information we keep will be anonymous.

Who has approved this study?

The Fife & Forth Valley Research Ethics Committee, which has responsibility for scrutinising proposals for medical research on human, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant medical records, be made available for scrutiny by monitors from the University of Stirling and NHS Forth Valley, whose role it is to check that research is properly conducted and the interests of those taking part are adequately protected.

What do I do now?

Thanks for considering taking part in this research. Alyssa Gilinsky will contact you in a few days to find out if you are eligible for this study. You can ask her to let her know if you would like to consider taking part. If you have any questions please contact the Chief Investigator: Alyssa Gilinsky on: 01786 467345 or email: a.s.gilinsky@stir.ac.uk.

If you would like to speak to someone else who is not involved in the project to get further information and advice, please contact Billy Lauder, Head of the School of Nursing, Midwifery and Health, University of Stirling on: 01786 466345 or email: william.lauder@stir.ac.uk.

What do I do if I want to complain?

If you are concerned about any aspect of this research you can speak to the Chief Investigator in the first instance to raise your concerns. If you need further assistance or wish to speak to someone else who is not involved in the project to complain you can contact Bill Lauder, Head of the School of Nursing, Midwifery and Health using the information above.

Professional indemnity cover for this research is underwritten by March Ltd. For more information about this please contact Deborah Miller, Business Development Manager, Research & Development Offices, University of Stirling, on: 01786 466444 or email: deborah.miller@stir.ac.uk

How to wear your accelerometer

Thank you for taking part in the MAMMiS Study. Here is information about the accelerometer we have asked you to wear in order to measure your physical activity levels.

What does the accelerometer do?

- The accelerometer will record all of your **movements** over the next 7 days.

How do I know the accelerometer is working?

- Alyssa will advise you of when you should start wearing the accelerometer. This will usually be the day after your 1st meeting with Alyssa.
- The accelerometer will continue recording up to 24 hours each day for the next 7 days.
- It will reset each day.

When should I wear the accelerometer?

- You should try and wear the accelerometer **at all times** during the next 7 days, **except** when bathing or swimming.
- Ideally you should try and put it on first thing in the morning when you get up and take it off last thing at night.
- Use the diary on **page 2** to write-down each day when you wear the accelerometer.
- If you forget to attach the accelerometer, if possible, attach it as soon as you remember. We may still be able to use the data from that day.

How should I wear the accelerometer?

- Alyssa will show you how to wear the accelerometer correctly.
- The accelerometer has an adjustable strap; it can be clipped on like a belt. It should sit snug against your body so as not to fall off.
- You should attach it onto your **right hip** – next to where your hip bone is. It can be worn inside **or** outside clothing.

Accelerometer wearing times diary

Instructions

- On the first day you wear the accelerometer fill in the **first column** (labelled 1) with that day *e.g. Monday* and write down the time you put your accelerometer on *e.g. (8am)*. Ideally this should be when you get up.
- If you take off your accelerometer that same day (e.g. for bathing or swimming) then please write down the time you **take it off** and then write down when you put it back on.
- The last record for time off should ideally be last thing at night before going to bed *e.g. 11pm*.
- Please complete the diary for each of the **7 days** you are wearing the accelerometer and pedometer. If you forget to put them on – please write – “**not worn**” in the space for that day.
- Don't forget to bring your accelerometer and this diary along to your 2nd meeting with Alyssa.

Day	<i>Ex - Monday</i>	1	2	3	4	5	6	7
time on	<i>8am</i>							
time off	<i>9am</i>							
time on	<i>9.30am</i>							
time off	<i>11pm</i>							
time on								
time off								

Any questions call Alyssa on 07974321789 or email a.s.gilinsky@stir.ac.uk.

Appendix 8. Physical activity cognition measures

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY

Here are some questions about your beliefs about changing the amount of physical activity you take part in and about things you might have already done to help you become more active. Please answer these questions as honestly as you can.

In this questionnaire when we mention being **regularly physically active** what we mean is taking part in **moderate-vigorous** activities for at least 30 minutes on most days of the week.

Moderate activities are those that take moderate physical effort. They make you breathe a bit harder than normal (*e.g. brisk walking, light swimming or cycling*).

Vigorous activities are those that take hard physical effort. They make you breathe a lot harder than normal (*e.g. running, fast swimming or aerobic classes*).

1. If I was **regularly physically active** during the next 3 months...

	Very Unlikely						Very Likely
...I would be healthier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...my family and friends would get to spend less time with me	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...my partner would respect me more	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...I would have less energy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...I would feel better about myself	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...It would make no difference to my weight	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

2. During the next 3 months do you intend to be **regularly physically active**?

	Completely Disagree					Completely Agree	
I intend to...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

3. I have made a detailed plan about being **regularly physically active** during the next 3 months. I have planned...

	Completely Untrue	Somewhat Untrue	Somewhat True	Completely True
...how to do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...when to do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...where to do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...how often to do it.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Certain things can make it harder to be **regularly physically active**.

How confident are you that you can be **regularly physically active** during the next 3 months...

	Not at all Confident					Very Confident	
...even if I'm tired?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...even if the weather is bad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...even if I don't have the time?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...even if I feel unwell?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...even if my baby is being fussy?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

...even if I can't get childcare?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...even I don't feel like it?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. I have a detailed plan about what to do if things get in the way of me being **regularly physically active** during the next 3 months. I have planned...

	Completely Untrue	Somewhat Untrue	Somewhat True	Completely True
...what to do if something interferes with my plan	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...what to do in difficult situations in order to stick to my intentions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...how to cope with possible setbacks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6. During the last 3 months I have...

	Completely Untrue	Somewhat Untrue	Somewhat True	Completely True
...I have paid attention to amount of physical activity that is recommended.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...I have been aware of how much physical activity I should be doing to meet my personal standards.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...I have carefully watched whether I was physically active enough.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...I have made sure to monitor how much physical activity I've done.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...I have tried really hard to be physically active.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
...I have made an effort to be more active than before.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Appendix 9. Physical activity consultation rating form

First Consultation	Date:			Consultation Length: ___ mins ___ secs	Participant no:
COMPONENTS USED	Limited skill 1	Satisfactory Skill 2	Very Good Skill 3	Description	
Targeting knowledge of the benefits of increasing activity to recommended standards (outcome expectancies)					
Assess activity levels	NOT ABLE TO ASSESS AS NOT RECORDED				
Provision of information about PA guidelines				Explained light, moderate and vigorous intensity activity and the different modes of activity in relation to outcomes (e.g. what activity recommended for fitness, health benefits, weight loss etc.). This should include discussing discrepancy between guidelines and their self-reported and/or pedometer-assessed current activity levels.	
Completed decisional balance				Encouraged client to explore pros and cons of change. If appropriate, consultant provided information on benefits of physical activity, including postnatal specific benefits. Client elicited own pros and cons for change, consultant provided suggestions if appropriate.	
Makes a behavioural resolution to change behaviour to meet personal PA goals (Intentions/Goals)					
Set short (week one) and longer-term (3 months) goals				Followed the SMARTER principles (i.e. set in terms of how much physical activity/step counts were to be achieved, ensuring goals were realistic), goals set by client with guidance by consultant.	
Has knowledge, skills and environmental conditions in place to change behaviour to meet personal PA goals (sociostructural factors, self-efficacy, action and coping planning, action control)					
Developed an action plan.				For at least one week of activity behaviour (specify the activity, location, frequency and duration i.e. where, when, what?). This was sensitive to the client's likes and dislikes of activities they have done recently and in the past and encouraged adoption of active alternative (e.g. walking to the shops rather than taking the car).	
Identified opportunities for activity				Took into account client's likes and dislikes of past and present activities, barriers to activity, current lifestyle and needs. If required gave information on opportunities for activity locally. Encouraged active alternatives for previously inactive situations (e.g. walking instead of taking the car).	

Identified and problem solved barriers jointly				Client was prompted to identify barriers and discussed ways to overcome these, client provided own suggestions, consultant provided suggestions if appropriate. Implementation intention format (if-then) used to solidify plans to cope with anticipated barriers.
Encouraged self-monitoring of activity				Encouraged participant to self-monitor either through writing down in a diary format or pedometer or both.
Assessed and developed self-efficacy				Self-efficacy was considered throughout the consultation process for example through encouraging a gradual build-up of activities towards goals, encouraging clients to choose activities that they would enjoy and feel confident they could do, ensuring goals followed SMARTER principles, assessing confidence for goals etc.
Established support				Helped client to identify what support they need and how to receive this.
Second Consultation		Date:		Consultation Length:
COMPONENTS USED	Limited skill 1	Satisfactory Skill 2	Very Good Skill 3	Description
Has knowledge, skills and environmental conditions in place to maintain personal PA goals (Relapse prevention, action control)				
Provided feedback in light of previously set goals.				This should include discussing discrepancy between previously set goals and their self-reported and/or pedometer assessed activity levels. Participant is asked to discuss what positive changes they have noticed since becoming active.
Set longer-term (6 months) goals				Followed the SMARTER principles with goals set by client with guidance by consultant.
Relapse prevention				Encouraged client to identify high risk situations for relapse (e.g. going back to work, baby walking etc.) and develop ways to avoid or cope with these situations, including reminding client about helpful strategies they have reported.

OBSERVER CHECKLIST - PHYSICAL ACTIVITY CONSULTATION

EFFECTIVE COMMUNICATION SKILLS

Core Skills	Limited skill 1	Satisfactory Skill 2	Very Good Skill 3	Description
Person-centred approach used				guiding style used (client elicited reasons for change and developed goals for change), consultant avoided being confrontational, directing or providing information only, avoided persuasion and providing solutions. Suggestions offered but watched for resistance
Non-verbal communication	NOT ABLE TO ASSESS AS VOICEFILES			Used SOLER principles (sit in a position that avoids barriers, open posture, lean towards not away, appropriate eye contact, relaxed)
Empathy used				Respected and understood client's world, goals and needs (e.g. when developing activity plan and goals), used examples of other clients' experiences to express empathy.
Parrotting				Repeated key words and phrases to convey that you have listened and encouraged the client to talk
Paraphrasing				Summarised (reflecting) in own words what the client had said and checking for accuracy to convey that you have listened and that you understand them and their position.
Physical Activity Knowledge				Used appropriate physical activity knowledge

For all participants in the study

1. Motivations to join/Benefits of PA

What prompted you to find out about the study?

What were your reasons for deciding to join? Was it important to you to be more active or were there other reason(s)?

Could you tell me about your motivations to be active now? How important is PA as part of your day-to-day life?

In what ways do you think your motivations changed (if at all) from taking part?

Prompts if required

- Improve personal health? – probe areas concerned about (e.g. weight, fitness, wellbeing, fatigue etc.)
- Meet other mums?
- Lack of other options for activity locally? – impact particularly on more rural participants.
- Take part in research – interesting, worthwhile, experts etc.?
- Recommendations? – probe who from (e.g. family, friends, health visitor, GP) and what they thought about being recommended?
- Research highlighted certain reasons to be active - what were these reasons and what was the affect on you? – how highlighted (e.g. taking part in outcome assessments, the study leaflet or other?)

2. Facilitators/barriers to being active

How active did they feel during the study? And what was it that helped or hindered them to be as active as they would like?

What specific problems did they face being active over the study period and how did they overcome these (if applicable)?

What did they learn about being active and the best ways for them to adopt or maintain activity in line with their personal goals or the recommended amount?

Are they aware of the recommended amount of PA for health and wellbeing? Is this something they strive for, if not – more or less?

How realistic do they think the guidelines/their personal goals are a) for them, b) more generally for women with infants?

Do they think there times when the guidelines/their personal goals are more or less achievable for them (e.g. weather related, having other children, maternity/being back at work).

3. Personal outcomes

What impacts (if any) did they see on their own health and wellbeing over last 6 months during the study?

If no personal outcomes why do they think that is?

Prompts if required

- Weight, Fitness change, improved mood/fatigue?
- Noticed self less/more active, outdoors more, time with baby/time away from baby?
- More knowledgeable about PA?
- More/less time with family/friends, greater/less feelings of being supported, new friends?

Control group only

4. Control group effects (leaflet intervention, contamination and retention)

Did they know others taking part in the study? If so, what were their views and did they discuss what was involved?

Did they feel any benefit from the feedback they received on fitness, weight etc. Would they like more or less information about the outcomes, how might this affect their behaviour?

What were their thoughts about the leaflet – helpful, interesting, and relevant or not?

Were they disappointed to receive the leaflet only and if so how did this impact on them taking part in the study further.

Would they/did they recommend the study to others?

Intervention group only

5. Taking part in the intervention

Prompts if required

- Did they enjoy it?
- Did this increase their knowledge?
Encourage or motivate them

- Did they enjoy it?
- Did this increase their knowledge?

- Encourage or motivate them?
- Did they feel supported (who - e.g. the counsellor, other women in the pramwalking group, family and friends)?
- What did it change (if anything)?

6. What do they think about the PA consultations

Prompts if required

- Perception of the PA counsellor (e.g. approach, empathy, listen etc.)?
- Length of consultation - too long, too short or just about right?
- Thoughts on delivery method (e.g. face-to-face versus telephone, email etc.)?
- Which techniques/strategies from the PA consultation did they find most useful?
 - o Things that worked well?
 - o Things that worked less well?
 - o Things they will continue to use?

7. What did they think of the group pramwalking programme?

Prompts if required

- Preference for group setting or an individual programme
- Thought on walking-routes (e.g. length, intensity, duration of sessions, travel arrangements, hazards, amenities, etc.)?
- Walk-leader style (e.g. clear communicator, gave detailed instructions, did not listen to feedback, etc.)?
- Did/would they continue pramwalking on their own/in another group?

Appendix 11. Participants use of self-management techniques (themes)

	N, 3-months follow-up (%)	N, 6-months follow-up (%)
<i>Monitoring activities</i>		
Used pedometer	19 (65.5)	7 (25.9)
Wrote down PA levels in book/diary	6 (58.6)	7 (25.9)
Mentally conscious of activity levels	17 (20.7)	15 (55.6)
<i>Benefits of activity</i>		
Improved general health and wellbeing	5 (17.2)	2 (7.4)
Noticed increased energy	3 (10.3),	5 (18.5)
Increased aerobic capacity/cardiovascular fitness	8 (27.6)	9 (33.3)
Improved bodily shape/muscular tone,	5 (17.2)	4 (14.8)
Helped with weight-loss/maintenance of weight loss	15 (51.7)	13 (48.2)
Improved overall mood	5 (17.2)	7 (25.9)
Increased motivation in life	1 (3.4)	-
“Feel better”	2 (6.9)	4 (14.8)
Noticed improved sleep pattern	1 (3.4)	-
Feelings of self-esteem/improved body image	5 (17.2)	4 (14.8)
Mum/baby got outside in sunshine/fresh air	2 (6.9)	2 (7.4)
Mum/ baby had time away from each other	2 (6.9)	-
Mum/baby got out of the house more,	3 (10.3)	-
Feel more able to do things I want/need to do	4 (13.8)	2 (7.4)
General stress relief	-	2 (7.4)
Have increased socialising opportunities	1 (3.4),	-
Less fatigued	-	2 (7.4)
Will prevent excessive weight gain in pregnancy	-	1 (3.7)
Has prevented using asthma inhaler	-	1 (3.7)
Noticed nicer skin	-	1 (3.7)
Given a clear head to deal with problems at work	-	1 (3.7)
<i>Goals</i>		
Described having specific weekly PA/walking goals	13 (44.8),	15 (55.6)
Wrote down weekly PA/walking goals	1 (3.4),	-
Mentally conscious of weekly PA/walking goals	4 (13.8)	3 (11.1)
General goal “do more”	3 (10.3)	1 (3.7),

Long-term PA goal mentioned	2 (6.9)	4 (14.8),
Maintaining goals achieved at three months point	-	1 (3.7)
Has a good PA routine so no need for goals		1 (3.7)
<i>Plans</i>		
Write down weekly plan in diary (where, when, what)	17 (58.6)	10 (37.0)
Have regularly booked PA/walks timetabled	3 (10.3)	4 (14.8)
Mentally conscious when can be active	2 (6.9)	2 (7.4)
Plan PA daily to account for flexible routine	3 (10.3)	1 (3.7),
In a regular routine so weekly planning not required	-	4 (14.8)
<i>Changing activity levels gradually</i>		
Increased intensity of PA (e.g. jogging instead of running)	7 (24.1)	5 (18.5)
Increased duration or distance of PA (e.g. longer walks)	6 (20.7)	3 (11.1)
Increased frequency of PA (e.g. more active days)	3 (10.3)	1 (3.7),
PA fluctuated naturally	1 (3.4)	-
<i>Knowledge of local opportunities</i>		
Identified new classes in area (e.g. Zumba, Pilates)	14 (44.8)	14 (51.9)
Identified new walking/running/cycle routes	4 (13.8)	2 (7.4)
Identified local PA/walking groups	3 (10.3)	2 (7.4)
Enquired about memberships (e.g. gym)	2 (6.9)	1 (3.7)
Looked for PA events to sign up to	1 (3.4)	-
<i>Social support seeking</i>		
Childcare support (e.g. from husband/partner, family)	18 (62.1)	12 (44.4)
People to be active with (e.g. husband/partner, mum, friends)	15 (51.7)	10 (37.0)
Verbal encouragement	6 (20.7)	6 (22.2)
Reminder about my PA plan	1 (3.4)	2 (7.4)
Support to plan activities around routine/time management	1 (3.4)	-
Noticed role model for active lifestyle	-	1 (3.7)
<i>Prompts for activity</i>		
Visual prompt (e.g. timetable on fridge, gym kit)	8 (27.6)	10 (37.0)

out)		
Auditory prompt (e.g. alarm goes off, friend mentions)	1 (3.4),	3 (11.1)
Social prompt (e.g. having arranged to meet friends)	3 (10.3)	-
Motivational prompt (e.g. checking daily step count)	1 (3.4)	2 (7.4)
<i>Environmental changes</i>		
Went more places to be active/could get to in an active way	8 (27.6)	3 (11.1)
Got off train/bus earlier/parked care further away	4 (13.8)	1 (3.7)
Hired/bought equipment (e.g. cross-trainer, torch, jacket)	3 (10.3)	7 (25.9)
Arranged childcare to enable activity	2 (6.9)	1 (3.7)
Left car at home more often	2 (6.9)	2 (7.4)
Adjusted mum/baby routine	1 (3.4)	1 (3.7)
Moved equipment to a more/less accessible spot	1 (3.4)	2 (7.4)
Joined a gym/club	1 (3.4)	3 (11.1)
<i>Substituted inactive options</i>		
Walked places would have previously driven/taken bus	21 (72.4)	9 (33.3)
Leisure time more active (e.g. gardening instead of baking)	2 (6.9)	2 (7.4)
Adapted inactive activities to be more active (e.g. increased intensity of family walks)	2 (6.9)	3 (11.1)
<i>Solutions to overcoming barriers</i>		
Adapted plans in response to changes/unforeseen problems	7 (24.1),	7 (25.9)
Had back up option (e.g. home exercise DVDs)	2 (6.9)	3 (11.1)
Sought novel childcare options (e.g. crèche at gym)	3 (10.3)	5 (18.5)
Borrowed required equipment (e.g. raincoat)	4 (13.8)	1 (3.7)
Made long-term plans to quell low motivation (e.g. signed up for 10k)	1 (3.9)	5 (18.5)

Three months $n=29$, Six months $n=29$, Note: Totals do not add together as multiple themes were often endorsed by the same participant

Appendix 12. Graph showing spread of minutes of weekly MVPA in the MAMMiS study and Rogers study

