



Programme Grants for Applied Research

Volume 12 • Issue 9 • November 2024

ISSN 2050-4330

Midwifery-led antenatal pelvic floor muscle exercise intervention to reduce postnatal urinary incontinence: APPEAL research programme including a feasibility and pilot cluster RCT

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Published November 2024

DOI: 10.3310/TJDH7946

This report should be referenced as follows:

MacArthur C, Bick D, Salmon V, Jones E, Hay-Smith J, Bishop J, *et al.* Midwifery-led antenatal pelvic floor muscle exercise intervention to reduce postnatal urinary incontinence: APPEAL research programme including a feasibility and pilot cluster RCT. *Programme Grants Appl Res* 2024;12(9). <https://doi.org/10.3310/TJDH7946>

Programme Grants for Applied Research

ISSN 2050-4330 (Online)

A list of Journals Library editors can be found on the [NIHR Journals Library website](#)

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This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This article

The research reported in this issue of the journal was funded by PGfAR as award number RP-PG-0514-20002. The contractual start date was in March 2016. The draft manuscript began editorial review in December 2022 and was accepted for publication in May 2024. As the funder, the PGfAR programme agreed the research questions and study designs in advance with the investigators. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The PGfAR editors and production house have tried to ensure the accuracy of the authors' manuscript and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

This article presents independent research funded by the National Institute for Health and Care Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, CCF, PGfAR or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, the PGfAR programme or the Department of Health and Social Care.

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Abstract

Midwifery-led antenatal pelvic floor muscle exercise intervention to reduce postnatal urinary incontinence: APPEAL research programme including a feasibility and pilot cluster RCT

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Background: Antenatal pelvic floor muscle exercises are effective in reducing postnatal urinary incontinence. Midwives, however, lack training and confidence to promote these exercises and often do not provide information or support to women to do the exercises.

Objectives: Objectives were to: (1) investigate current antenatal care in relation to pelvic floor muscle exercise support from midwives for women; (2) develop an intervention to increase the likelihood of midwives supporting women to do pelvic floor muscle exercises during pregnancy; and (3) test the intervention in a feasibility and pilot cluster randomised controlled trial with numerous trial and process evaluation outcomes.

Design: Study designs included critical interpretive synthesis, ethnography and other methods (interviews, focus groups, behaviour change theory mapping, stakeholder and patient/public involvement activities) and piloting questionnaires to develop an intervention to test in a feasibility and pilot cluster randomised controlled trial. Clusters were community midwife teams.

Setting: Main setting: two National Health Service hospital trusts providing maternity care in Birmingham.

Participants: Participants included pregnant women and midwives. Pilot trial participants included women who gave birth during a prespecified month in study maternity units. Midwives participated in trial process evaluation.

Interventions: Midwives in teams randomised to the intervention were trained how to teach pelvic floor muscle exercises to women and support them in undertaking these exercises throughout pregnancy. Midwife teams allocated to control provided standard antenatal care.

Main outcome measures: Early-phase outcomes were whether current antenatal midwife care supported women to undertake pelvic floor muscle exercises, and a midwife pelvic floor muscle exercise training intervention. Main feasibility and pilot trial outcomes included return rates and associated intraclass correlation coefficient; whether midwives provided pelvic floor muscle exercise support to women during antenatal care; women's adherence to undertaking pelvic floor muscle exercises antenatally; and prevalence estimates of urinary incontinence at 10–12 weeks post partum. Other process outcomes included intervention midwives' confidence in pelvic floor muscle exercise knowledge and views on intervention delivery; women's views on pelvic floor muscle exercise support received; and control midwives' views on pelvic floor muscle exercises in standard care.

Results: The critical interpretive literature synthesis showed that current antenatal pelvic floor muscle support was constrained by numerous factors including women's and healthcare professionals' capacity to implement pelvic floor muscle exercises. Reform of healthcare policy and service delivery was recommended to provide opportunity to genuinely support women and healthcare professionals.

Main findings of early-phase qualitative research showed that women and midwives 'know' that pelvic floor muscle exercises are important, but that midwives infrequently communicate to women the large 'gains' available from undertaking these exercises. There was lack of confidence among women and midwives on when and how to initiate discussion on pelvic floor muscle exercises and urinary incontinence.

A systematic review of diagnostic tests for midwives to use to support women's practice of pelvic floor muscle exercises identified no available studies.

Qualitative research with women and midwives, mapping to behaviour change theory, and stakeholder and patient/public involvement activities followed by a practice training event showed that the intervention should consist of five steps: raising the topic of incontinence and pelvic floor muscle exercises; screening for symptoms; teaching the exercises; reminding and supporting women to do the exercises; and knowing when and how to refer.

Midwife training evaluation findings showed median positive change following training of 1 point (0–5 scale) for each of eight questions related to confidence about pelvic floor muscle exercise knowledge and teaching the exercises.

In the cluster trial, 17 clusters were randomised and 95 midwives in intervention clusters were trained. Of 998 women included in the trial, 175 returned a questionnaire: 15.8% in intervention and 16.4% in control clusters. Based on women's responses to the post-partum postal questionnaire, 65% of those in intervention clusters said their midwife explained how to do pelvic floor muscle exercises compared to 38% of those in control clusters. Among women in intervention clusters, 50% undertook the exercises in a manner likely to improve symptoms compared to 38% of women in control clusters, and 44% of women in intervention clusters reported urinary incontinence compared to 54% in control clusters.

Interviews with midwives and women generally supported trial findings and emphasised the importance of service change for ensuring time to implement the Antenatal Preventative Pelvic floor Exercises And Localisation intervention into antenatal appointments.

Limitations: There was a low questionnaire return rate. A definitive trial, which would have provided evidence of effectiveness not possible from a pilot trial, could not be undertaken because of changes to standard midwife antenatal care due to National Health Service England's new perinatal pelvic health service.

Conclusions: Training midwives to appropriately support women to undertake pelvic floor muscle exercises in pregnancy is feasible, acceptable and could improve exercise adherence and reduce post-partum urinary incontinence.

Future work: Implementation work with National Health Service England has begun.

Study registration: This study is registered as ISRCTN10833250.

Funding: This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research Programme (NIHR award ref: RP-PG-0514-20002) and is published in full in *Programme Grants for Applied Research*; Vol. 12, No. 9. See the NIHR Funding and Awards website for further award information.

Contents

List of tables	xi
List of figures	xiii
List of supplementary material	xv
List of abbreviations	xvii
Plain language summary	xix
Scientific summary	xxi
Synopsis	1
Summary of alterations to the programme's original aims/design	1
<i>Cluster randomised controlled trial changed to pilot and feasibility cluster randomised controlled trial</i>	1
<i>COVID-19 pandemic</i>	2
<i>Implications for full trial</i>	2
Work package 1 particular context awareness: identifying barriers and enablers of change	2
<i>Work package 1.1: critical interpretive synthesis</i>	2
<i>Work package 1.2: focused ethnographic observation of clinical practice</i>	3
Work package 2: performance measurement: determining relevant measures of performance	4
<i>Work package 2.1: diagnostic accuracy systematic review and data synthesis to identify the accuracy of tests for assessment of pelvic floor muscle localisation and contraction in women</i>	4
<i>Work package 2.2: constructing a health economic decision-analytic model</i>	6
Work package 3: plans for change: developing the constituents and means of delivery of the Antenatal Preventative Pelvic floor Exercises and Localisation intervention	8
<i>Aims</i>	9
<i>Methods</i>	9
<i>Key findings</i>	9
<i>Limitations</i>	12
<i>Inter-relationship with other parts of the programme</i>	12
Work package 4: piloting the intervention	13
<i>Work package 4.1: what is the response rate for the trial questionnaire and the intraclass correlation coefficient?</i>	13
<i>Work package 4.2: feasibility and pilot cluster randomised controlled trial of an antenatal preventative pelvic floor muscle exercise intervention led by midwives to reduce postnatal urinary incontinence (Antenatal Preventative Pelvic floor Exercises and Localisation Programme)</i>	14
<i>Work package 4.3: process evaluation</i>	23
Account of involvement of patients and the public	27
Reflections on what was and was not successful in the programme	28
<i>What was successful?</i>	28
<i>What was not successful?</i>	29
Reflections on issues relating to equality, diversity and inclusion	29
<i>Participant representation</i>	29
<i>Research team</i>	29

CONTENTS

Limitations relating to the method or execution of the research	30
Conclusions from the whole programme	30
Recommendations for future research	31
Implications for practice	31
Additional information	33
References	39
Appendix 1 Work package 3 phase 1 focus groups: quotes from four themes arising from the focus groups with women and midwives	43
Appendix 2 Logic model illustrating theory of change for APPEAL training intervention	47
Appendix 3 Full report of work package 4.1	49
Appendix 4 Additional work package 4.2 tables	57
Appendix 5 Data collection and analysis methods (work package 4.3)	67
Appendix 6 Summary of training evaluation	79
Appendix 7 Champion monitoring data (including interview data)	81
Appendix 8 Implementation questionnaire results	85
Appendix 9 Interviews with intervention midwives during implementation	87
Appendix 10 Interviews with intervention and control midwives at the end of the APPEAL study	93
Appendix 11 Findings from postnatal interviews with women in the APPEAL feasibility and pilot trial	99
Appendix 12 APPEAL refinements and recommendations for future development	105

List of tables

TABLE 1 Women's questionnaire return rate overall	19
TABLE 2 Women who leaked urine at the start of their pregnancy	20
TABLE 3 Women's reports of midwife support for PFME in pregnancy, women's PFME practice and UI prevalence	20
TABLE 4 Midwives' characteristics	22
TABLE 5 Birth baseline characteristics of women: long questionnaire and short questionnaire	52
TABLE 6 Results of ICIQ-UI SF questionnaire for UI	53
TABLE 7 Results of RFIS questionnaire for FI	54
TABLE 8 Pelvic floor muscle exercises during the pregnancy and post partum	55
TABLE 9 General information on sending/receiving women's questionnaire	57
TABLE 10 Information on sending/receiving women's questionnaire by group	58
TABLE 11 Details on women's exclusion	58
TABLE 12 Minimisation variables used in the randomisation by group and overall	59
TABLE 13 Other baseline characteristics by group and overall	59
TABLE 14 Prevalence of UI at 10–12 weeks using ICIQ-UI SF, EARS and PFMESES	62
TABLE 15 Prevalence of FI at 10–12 weeks using RFIS	64
TABLE 16 Process evaluation reporting framework: processes involving clusters	68
TABLE 17 Process evaluation reporting framework: processes involving target population	70
TABLE 18 Identifying fidelity to PFME intervention – interpretation of responses to women's questionnaire section 3	77
TABLE 19 Contact questionnaire results: midwives' reported PFME experience	79
TABLE 20 Descriptive summary of midwives' post-training evaluation questionnaire	79
TABLE 21 Change in midwives' confidence ratings	79
TABLE 22 Time spent on champion role and number of queries and referrals reported to champions	81

TABLE 23 Activities reported by champions	81
TABLE 24 Acceptability of champion role (from qualitative interviews)	82
TABLE 25 Challenges and solutions reported and/or discussed by champions in team meetings	83
TABLE 26 Summary of implementation questionnaire response scores from midwives in the APPEAL intervention trial arm	85
TABLE 27 Summary of implementation questionnaire numerical and related free-text responses from midwives in the APPEAL intervention arm	85
TABLE 28 Experience of midwives interviewed during implementation	87
TABLE 29 Themes developed from interviews with midwives during implementation	87
TABLE 30 Concurrent acceptability of implementing PFME following APPEAL training	88
TABLE 31 What are the challenges, concerns and opportunities for midwives implementing PFME following training?	91
TABLE 32 Experience of midwives interviewed at the end of the APPEAL pilot and feasibility RCT	93
TABLE 33 Summary themes from interviews with midwives at the end of the APPEAL pilot and feasibility RCT	94
TABLE 34 Postnatal interviews with women in the APPEAL intervention and control arms: participant characteristics	99
TABLE 35 Illustrative quotes arising from postnatal interviews with women relating to the degree of fidelity of delivery of PFME during antenatal care	100
TABLE 36 Themes and illustrative quotes arising from postnatal interviews with women relating to the barriers and enablers of doing PFME	101
TABLE 37 Changes to APPEAL following training and factors facilitating implementation of APPEAL	105
TABLE 38 Recommendations from midwives for ongoing improvement to APPEAL	105
TABLE 39 Recommendations from postnatal women to improve support and resources for PFME during pregnancy	106

List of figures

FIGURE 1	Research pathway diagram	5
FIGURE 2	PRISMA flow chart of included studies	7
FIGURE 3	Work package 4.2 CONSORT flow diagram	18
FIGURE 4	Logic model illustrating theory of change for APPEAL training intervention	48
FIGURE 5	Work package 4.1 CONSORT flow diagram	51

List of supplementary material

Report Supplementary Material 1 World package 3 mapping of behaviour change wheel, theoretical domains framework and behaviour change techniques to inform intervention development

Report Supplementary Material 2 Women's questionnaire

Report Supplementary Material 3 Champion manual and role description

Supplementary material can be found on the NIHR Journals Library report page (<https://doi.org/10.3310/TJDH7946>).

Supplementary material has been provided by the authors to support the report and any files provided at submission will have been seen by peer reviewers, but not extensively reviewed. Any supplementary material provided at a later stage in the process may not have been peer reviewed.

List of abbreviations

APPEAL	Antenatal Preventative Pelvic floor Exercises and Localisation programme	NHSE	National Health Service England
BCT	behaviour change technique	NICE	National Institute for Health and Care Excellence
BCTU	Birmingham Clinical Trials Unit	NIHR	National Institute for Health and Care Research
BCW	behaviour change wheel	PFM	pelvic floor muscle
DAM	decision-analytic model	PFME	pelvic floor muscle exercises
EARS	Exercise Adherence Rating Scale	PFMESES	Pelvic Floor Muscle Exercises Self-Efficacy Scale
FI	faecal incontinence	PPIE	patient and public involvement and engagement
GDPR	General Data Protection Regulation	QALY	quality-adjusted life-year
GP	general practitioner	QoL	quality of life
HCP	healthcare professional	RCT	randomised controlled trial
ICC	intraclass correlation coefficient	RFIS	Revised Faecal Incontinence Scale
ICIQ-UI SF	International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form	SF-12	Short Form questionnaire-12 items
IRAS	Integrated Research Application System	UI	urinary incontinence
LMNS	local maternity and neonatal system	URL	uniform resource locator
MSW	maternity support worker	VTC	variation to contract
		WP	work package

Plain language summary

After having a baby, it is very common to leak urine. We know that pelvic floor muscle exercises, when done correctly during pregnancy, can help. The problem is that midwives lack confidence to teach, or do not always explain how to do pelvic floor muscle exercises very well. Even when they do, women may not do them as it is unclear why they should.

By talking to many women, midwives and researchers, we developed a way of training midwives to teach and support women during pregnancy to do these exercises. After their training, we found that midwives knew more about pelvic floor muscle exercises and were more confident to teach and support women.

To test how well the training worked, we did a pilot trial where midwife teams were randomly selected to be given this training or continue with usual antenatal care. We sent a questionnaire to women when their baby was 3 months old. This asked what advice and support their midwife had given them about pelvic floor muscle exercises during pregnancy, whether they did the exercises, and whether they leaked urine over the last 4 weeks.

We found that more women who had antenatal care from a midwife who had been trained were told why and how to do pelvic floor muscle exercises, more of these women did these exercises, and not as many leaked urine. These consistent outcomes are promising, but it was only a pilot trial and not many women returned their questionnaire, so we cannot be certain of these results.

We interviewed some women: most were pleased about getting help with pelvic floor muscle exercises and all wanted this help. We interviewed some of the trained midwives. They were keen to help women but said lack of time meant it could be difficult to fit teaching these exercises into antenatal appointments.

We could not progress to doing a definitive trial because a new National Health Service perinatal pelvic health service is being set up. However, we have provided the training developed in this programme to many of the lead staff who are setting up the new services.

Scientific summary

Background

A Cochrane Review published when planning this programme showed that antenatal pelvic floor muscle exercises (PFME) in women without urinary incontinence (UI) were effective in reducing postnatal UI. Most interventions in the trials were undertaken by specialist healthcare professionals (HCPs), specifically physiotherapists. It is important to consider whether midwives who provide antenatal care for women could incorporate a suitable PFME intervention into their routine antenatal care since in the UK all women are seen throughout pregnancy by a midwife. Work by the team prior to starting the programme showed that many midwives do not advise women on how to undertake PFME, often due to lack of confidence in how to support women to perform PFME. We also found that women often do not do these exercises in a manner likely to improve their UI symptoms.

Objectives

To improve the implementation of antenatal PFME and thus reduce the likelihood of UI following childbirth. This was addressed by the following research questions and work packages (WPs):

- **WP1 Particular context awareness: identifying barriers and enablers**

Why, in the context of organisational practices and cultural norms, do HCPs and women behave the way they do in relation to PFME?

- **WP2 Performance measurement: determining relevant and acceptable measures**

What is the most accurate and acceptable objective test for pelvic floor muscle (PFM) localisation in pregnancy, and the most appropriate way to capture health economic impact of an intervention?

- **WP3 Plans for change: developing constituents and means of delivery of the intervention**

What are the suitable means for delivering PFME training to midwives so they can teach and support women during routine antenatal contacts to undertake PFME? What are the most appropriate constituents of a training intervention to enhance PFME implementation, and how should training delivery be optimised?

- **WP4 Piloting the intervention**

What is the return rate for women's questionnaires and what is the intraclass correlation coefficient (ICC)? Is it feasible to undertake a full cluster randomised controlled trial (RCT) to assess antenatal midwife PFME implementation, women's PFME adherence and prevalence of postnatal UI? What do process outcomes show us about intervention implementation and effects?

Methods

Design

- **WP1.1** Systematic review using critical interpretive synthesis of individual, professional and organisational issues that enable or hinder implementation of PFME training during childbearing years.

- **WP1.2** Qualitative research using ethnographic methods including interviews with pregnant women, some followed postnatally; interviews with midwives and other HCPs and observations of midwives and HCPs in antenatal care.
- **WP2.1** Systematic review of diagnostic accuracy tests to assess PFM localisation.
- **WP2.2** Preliminary decision-analytic model to compare alternative diagnostic and treatment pathways for antenatal prevention of UI.
- **WP3** Intervention development using a range of qualitative methods including focus groups, mapping data to behaviour change theory, and stakeholder and patient and public involvement and engagement (PPIE) activities.
- **WP4.1** Pilot study to test women's post-partum questionnaires, including individual RCT of long versus short questionnaire.
- **WP4.2** Feasibility and pilot cluster RCT to test the intervention on midwives' and women's behaviour in relation to PFME.
- **WP4.3** Process evaluation of RCT using qualitative and quantitative methods.

Data sources, study selection, data extraction and data synthesis

- **WP1.1** Sources for review inclusion were identified through databases and purposive searches. Titles and abstracts were screened and appraised using a mixed-methods appraisal tool by two independent reviewers. Findings of included studies were coded using a framework based on initial research questions; patterns and themes were identified; and new constructs were linked to theory developed to explain overall findings.
- **WP1.2** Interview data from pregnant and post-partum women, midwives and HCPs and antenatal care observations were obtained. Analysis included reflexivity, with initial coding to develop a coding framework and to identify emerging themes to guide theme development. The analysis was inductive and deductive in addressing the Antenatal Preventative Pelvic floor Exercises and Localisation (APPEAL) programme objectives.
- **WP2.1** A search strategy was developed in consultation with an international PFME expert and databases, ongoing trials registers and abstracts/conference proceedings were searched from inception to October 2016. All study designs were considered for inclusion except diagnostic case-control studies which are known to overestimate test accuracy. Titles, abstracts and full articles were screened by two independent reviewers, with disagreements resolved by a third. A data extraction proforma and quality assessment tool, based on the QUALity of Diagnostic Accuracy Studies tool, were prepared.
- **WP2.2** To identify model parameters, a search strategy was developed. Databases were searched to identify formal economic evaluation and cost analysis studies which were screened for inclusion using a two-stage categorisation process. Data on resource use and costs were extracted from included studies. To identify effectiveness and health-related quality-of-life data, targeted literature searches were conducted. Collated evidence informed the preliminary decision-analytic model used.
- **WP3** This comprised four iterative phases:
 - *Phase 1* Separate focus groups with pregnant/postnatal women and midwives were conducted in various sites. Data were analysed using thematic analysis.
 - *Phase 2* Intervention development used data from WP1 and WP3 phase 1. Comprehensive mapping used the behaviour change wheel (BCW), the theoretical domains framework and the behaviour change technique (BCT) taxonomy. PPIE activity included advisory group meetings and 'citizens' jury' assessment of relevant mobile phone apps; and a national stakeholder event was held which considered midwifery training needs and antenatal service provision.
 - *Phase 3* A practice training event was held with midwives in a different region to the future trial. A questionnaire designed to assess midwives' confidence was completed before and after training. Focus groups after training obtained feedback on intervention format, content, and delivery methods. Researchers facilitated these and recorded discussions and recommendations.
 - *Phase 4* Intervention refinement used phase 3 findings and PPIE events to refine the format and content of the package. Additional refinements were subsequently made in response to COVID-19.

- **WP4.1** Piloting of the data collection postal questionnaire was completed by women at 10–12 weeks post partum, comparing return rates from long versus short questionnaires.
- **WP4.2.** A feasibility and pilot cluster RCT randomised community midwife teams to intervention and control; intervention teams received PFME training, which was evaluated, and then gave advice and support to all women in their care. Women who gave birth during a predefined 1-month period, chosen so that all their antenatal care occurred during the trial, were sent postal questionnaires (refined from WP4.1) at 10–12 weeks post partum. These were linked to baseline data obtained (with consent) from their hospital records.
- **WP4.3** Process measures included questionnaires (Likert scale response options and free-text space) and audio-recorded interviews with midwives and women, observations of training (using checklists) and meeting notes. Some process outcomes were collected in the 10–12-week women's questionnaires. Quantitative data were summarised, and qualitative data were analysed with content analysis (free-text data) or thematic analysis (transcribed interview data).

Results

- **WP1.1** Fifty quantitative and qualitative sources were found. The concept of agency (ability to effect change through interaction with other people, processes, and systems) provided an overarching explanation of how PFME can be implemented during childbearing years. Women and HCPs, maternity services, and policy-makers all have agency, although their capacity to implement PFME is enhanced or diminished by the professional, organisational, and policy environment.

Numerous factors constrained women's and HCPs' capacity to implement PFME. The implementation of evidence-based PFME requires policy-makers, organisations, HCPs, and women to value prevention of UI by using low-risk, low-cost and proven strategies.

- **WP1.2** From three maternity units in different parts of England, 23 midwives and 15 pregnant women were interviewed; 12 of the women were followed up postnatally. Interviews were carried out with physiotherapists ($n = 4$), a link worker/translator ($n = 1$) and obstetricians ($n = 2$). Seventeen antenatal clinic observations took place.

Key findings were that women and midwives knew that PFME training is important, but often midwives did not communicate to women the gains available from PFME. There was a widespread lack of confidence among women and midwives to initiate conversation about PFME and UI, exacerbated by misunderstandings and assumptions and lack of clear guidelines and policy.

- **WP2.1** A total of 9678 unique titles and abstracts were screened, and 1429 full-text articles were retrieved. No studies met the review inclusion criteria due to an absence of an index test in parallel with the reference standard of digital vaginal palpation. In studies where an index test was conducted in parallel with the reference test, the paper did not provide information from which to derive an estimate of accuracy.
- **WP2.2** Initial results from pre-trial economic analysis suggested some potentially helpful information for trial design and proposed data collection. An example was that the time spent by midwives providing the intervention was not likely to be a key driver in the results and allowed the trial team to be non-prescriptive about midwives recording the time spent with women, an initial concern. The planned health economic analysis was discontinued when the decision was made to change from full to feasibility and pilot cluster trial.
- **WP3** In phase 1, four themes emerged from six focus groups (12 women, 14 midwives) regarding designing the intervention: 'knowing', 'doing', 'remembering' and 'supporting' antenatal PFME. Suggestions for maximising implementation included: 'train the trainer' model; having a midwife PFME champion within each team; and including knowledge about local referral pathways.

Phase 2 mapped findings onto the BCW; elements were coded using the BCT taxonomy. Mapping incorporated comments from PPIE advisers (nine meetings with six mothers) and national stakeholders (20 delegates from 18 relevant maternity service organisations). This resulted in the first iteration of the intervention materials: a five-step midwife training programme and resources for midwives to support PFME implementation, and a resource package for women given by midwives during the antenatal booking appointment. The five steps were: (1) raise the topic of PFME; (2) screen for UI; (3) teach PFME; (4) remind women about how to perform PFME and (5) refresh women's understanding about PFME and refer to specialist services if required. PPIE advisers helped co-develop resources for women.

The phase 3 practice training event showed positive evaluation for content and delivery which participating midwives ($n = 18$) had found useful. Free-text responses acknowledged the importance of midwives leading regarding PFME, but lack of time, confidence, and skills to raise the issue presented challenges for PFME implementation. Midwives showed increased total PFME confidence from 2.70 (range 1.18–3.50 on a 0–4 scale) before training to 3.68 (range 3.37–4.00) after training.

Phase 4 resulted in final modifications to the intervention materials, for example: refresher on muscle exercise physiology training principles; resources for women in a cloth bag the size of a clean nappy. Extensive speaker notes were included to facilitate 'train the trainer' plans for future implementation, the training session was shortened from a half-day to 2 hours, and extra resources were developed to support PFME champions. Further modifications, due to COVID-19, enabled remote training delivery by trial staff and enabled midwives to deliver intervention elements to women via telephone appointments. The final WP output was the logic model for the feasibility and pilot trial.

- **WP4.1** In piloting the data collection instruments, 777 women were randomised to being sent a long or short questionnaire. Overall response rate was 31.3% (243/777), with 30.8% (119/387) and 31.8% (124/390) responding in the long and short questionnaire arms, respectively [absolute difference in return rate –1.05%, 95% confidence interval (CI) –7.6% to 5.5%]. While not statistically significant, these results rule out any large differences according to questionnaire length. The ICC of response rate was 0.007 (95% CI 0.0005 to 0.094). Of the total responders, 49% (119/243) reported UI and 64.2% (156/243) reported receiving some advice to perform PFME in pregnancy from their midwife. There were 42.4% (103/243) of women who reported doing PFME often enough (a few times a week or more) to possibly reduce post-partum UI. All responses were similar between the long and short questionnaire trial arms. It was realised that a question about explanation of how to do PFME was important for inclusion in the WP4.2 questionnaire.
- **WP4.2** There were 17 midwifery team clusters randomised, comprising 186 midwives and 1304 women. After exclusions, 998 women were sent a post-partum postal questionnaire and 175 (17.5%) were returned from 88/531 (16.6%) women in intervention clusters and 87/467 (18.6%) in control clusters. Baseline characteristics of the women, including maternal, obstetric and infant characteristics, were similar across trial arms. There was some suggestion of differences between those who did and did not return questionnaires in the proportions of women from ethnic minority groups and having second or subsequent babies, but other baseline characteristics were similar.

Based on women's responses to the questionnaire, 65% (95% CI 56.9% to 72.4%) of those in intervention clusters said their midwife explained how to do PFME, compared to 38% (95% CI 24.6% to 51.2%) in control clusters; 50% (95% CI 24.1% to 77.1%) of women in intervention clusters compared to 38% (95% CI 12.4% to 67.1%) in control clusters undertook PFME in a manner likely to reduce symptoms; 44% (95% CI 32.0% to 56.1%) of women in intervention clusters reported UI compared to 54% (95% CI 42.2% to 65.8%) in control clusters; and 18% (95% CI 6.6% to 28.9%) of women reported faecal incontinence in the intervention clusters compared to 13% (95% CI 4.8% to 21.2%) in control clusters.

- **WP4.3** Training was delivered as intended with acceptable fidelity compared to the training protocol checklist (mean score 86.4%, standard deviation 9.2%), with successful training uptake: all 95 intervention cluster midwives received training. Each team appointed a midwife champion.

Most midwives reported acceptability for most training aspects although some would have preferred in-person training. Midwives' confidence about PFME increased following training (median increase at least 1 point on 0–4 scale for each of eight questions). Implementation questionnaire respondents ($n = 59$) reported raising the topic (89%), giving the resource bag (68%), teaching a PFME contraction (68%), and practising a contraction in antenatal clinic (45%) with most or all of the women. The most frequently reported barriers were lack of time (26%); forgetting (19%); language (17%); other priorities (15%) and not on the maternity records system (12%) to act as prompt.

Intervention midwife interviews ($n = 13$) indicated positive responses ('I'm enthusiastic about it'), but there was some ambivalence about the burden of implementation mainly due to workload, limited appointment time, remembering everything and opportunity costs ('so many other priorities'). Minimal evidence of between-group contamination was found in post-trial interviews with midwives ($n = 12$ control, $n = 6$ intervention) and women ($n = 16$ control, $n = 13$ intervention). Opportunities for improving implementation included: longer appointments; prompts on records; training update; greater women's resources accessibility (e.g. online leaflets); and more understanding of referral processes and physiotherapy consultations' content to aid communication.

Conclusions

This programme has produced consistent data to demonstrate that training and resourcing antenatal care midwives appropriately to teach and support women to undertake PFME in pregnancy is feasible, could improve women's PFME adherence and might reduce post-partum UI. A definitive trial would have provided best effectiveness evidence, but this was not possible because of changes to standard antenatal midwife care as a result of NHS England's new perinatal pelvic health service. So, although there were limitations in this programme of research, it probably represents the best available evidence on whether it is feasible to embed a PFME intervention in standard antenatal care in England and how this can be done.

Study registration

This study is registered as ISRCTN10833250.

Funding

This award was funded by the National Institute for Health and Care Research (NIHR) Programme Grants for Applied Research Programme (NIHR award ref: RP-PG-0514-20002) and is published in full in *Programme Grants for Applied Research*; Vol. 12, No. 9. See the NIHR Funding and Awards website for further award information.

Synopsis

Summary of alterations to the programme's original aims/design

Cluster randomised controlled trial changed to pilot and feasibility cluster randomised controlled trial

The major change within this programme was a change from a full cluster randomised controlled trial (RCT) to a pilot and feasibility RCT – details of this change and the reasons for it are described below.

The original Antenatal Preventative Pelvic floor Exercises and Localisation (APPEAL) programme was of 5 years' duration and included four work packages (WPs) with the ultimate aim of developing and testing an intervention to train midwives to advise and support women during antenatal care in undertaking pelvic floor muscle exercises (PFME) to reduce post-partum urinary incontinence (UI). There is high-quality Cochrane evidence¹ that antenatal interventions to increase PFME substantially reduce the proportion of women who experience post-partum UI. However, many midwives do not offer advice and support to women, and many pregnant women do not undertake these exercises. Thus, it was considered important to develop an intervention to integrate this advice and support into routine midwifery antenatal care and investigate its effectiveness.

The programme was planned to develop an intervention in the earlier WPs and to undertake a definitive cluster RCT within WP4. The aim was to assess whether women in community midwife teams (clusters) allocated to receive intervention care reported less UI at 10–12 weeks post partum than women in clusters allocated to receive standard care. Approximately 40 community midwife teams were to be recruited and randomised in 8–10 NHS Trusts across England.

Piloting the trial data collection instruments was the first phase of WP4 (4.1) but it was in the first stage of the programme (stage 1 being assessed to progress to stage 2) and a low rate of return of women's questionnaires was found, at 31%. Shortly after commencing the programme, the team examined recent surveys in similar populations and realised that the proposed estimate in the grant application of 60% of women returning a postal questionnaire in the pilot study and 80% in the full trial (after developing additional online methods) was substantially over-estimated: recent return rates were around 30–35%.^{2,3} The team considered what might maximise return rate. A Cochrane Review ('Methods to increase response to postal and electronic questionnaires') showed that giving incentives, and ones not dependent on returning the questionnaire, both increased response rates.⁴ As a consequence, it was decided to send women a £10 voucher with the first questionnaire rather than on questionnaire receipt. The Cochrane Review also found a higher response from shorter questionnaires. The questionnaire developed for the pilot study was only four pages, but given that women who have recently given birth are busy, it was decided to pilot whether an even shorter questionnaire just including main outcomes might elicit a higher return rate. Thus, the WP4.1 pilot study was designed as a RCT to test a longer versus a shorter questionnaire. Women who had antenatal care from 15 community midwife teams in two NHS Trusts were randomly allocated to either long or short questionnaires. Those who returned the short questionnaire were then sent the remainder of the questions in another questionnaire. No difference in return rate was found between those randomised to the long or short questionnaire.

Possibly it was this pilot trial, of a long versus a short questionnaire, that led to a misunderstanding by National Institute for Health and Care Research (NIHR) stage 1 assessors that the pilot study had been a pilot trial assessing the proposed intervention, and that there was no difference across trial arms in the proportion of women doing PFME often enough (a few times a week or more) to possibly reduce post-partum UI. There had been no PFME intervention, but the misunderstanding was that there had been but with a lack of difference in PFME adherence. This, together with the low return rate, meant that the

assessors considered that there was too much of a risk for a full trial to go ahead in WP4.2. Following the pilot trial of a long versus a short questionnaire, it was decided, in consultation with NIHR stage 1 assessors, that a full trial was a risk because, in addition to the low return rate, it may be burdensome to staff. The midwifery staffing levels and workload difficulties occurring subsequent to the programme being funded may have meant that additional midwifery tasks may be more problematic.

The APPEAL team therefore proposed a pilot and feasibility trial to collect additional process outcomes to determine whether a full trial could be feasible. A variation to contract (VTC) was submitted and NIHR agreed to this proposed change. This reduced second stage also included dropping the health economic analysis.

Work package 2 was discontinued following funding review

COVID-19 pandemic

The intervention developed in the early WPs of the programme was a training package for community midwife teams to enable them to advise and support pregnant women in undertaking PFME. The first face-to-face training session was delivered to six midwives in the week before lockdown (March 2020).

The APPEAL trial was then paused, along with all non-COVID trials, until January 2021. Following restart, it was likely that routine maternity care would continue to be affected by the pandemic, so during the trial pause it was necessary to take steps to ensure that the training intervention was 'COVID-proof'. This meant amending the intervention so it could be delivered to midwives online and organising for women to be provided with resources in ways that reflected some routine maternity care contacts not being face to face. This was approved in a VTC, and some additional funding was given, which together with use of underspend, allowed the programme to be completed.

Implications for full trial

Members of the APPEAL team had been liaising with the Maternity and Women's Health Policy Team at NHS England (NHSE) since 2018. As part of the NHSE Ten-Year Long Term Plan there was an intention to set up new perinatal pelvic health services across England, and NHSE were aware of our work and its relevance to the planned roll-out of this service. A significant component of the new pelvic health service is to ensure that midwives are trained in how to advise and support women to achieve better pelvic health, a central part of which includes women undertaking PFME in pregnancy and post partum. Had it not been for the pandemic, this service would not have been set up until the results from the APPEAL programme had been available. The APPEAL team are pleased that this new service is going ahead, members having previously undertaken research providing findings to show its need. It does mean, however, that a full RCT is no longer possible since many elements of the intervention will become part of standard maternity care.

The APPEAL team have continued to work with the NHSE Maternity and Women's Health Policy Team in the early phases of the new NHS services being introduced. In July 2021 14 'early adopter' local maternity and neonatal systems (LMNSs) were funded to develop a service, and 9 more 'fast follower' LMNSs were funded in July 2022. The aim is that by March 2024 all LMNSs will be required to set up a new perinatal pelvic health service. The APPEAL team are already working with numerous of these LMNSs, and more details are given later in the report.

Work package 1 particular context awareness: identifying barriers and enablers of change

Work package 1.1: critical interpretive synthesis

See also protocol Salmon *et al.*⁵ (<https://doi.org/10.1186/s13643-017-0420-z>) and full paper Salmon *et al.*⁶ (<https://doi.org/10.1002/nau.24256>).

Aims

The aim of WP1.1 was to undertake a systematic review using critical interpretive synthesis of what is known about the complex individual, professional, and organisational issues that enable or hinder the implementation of PFME training during women's childbearing years.

Methods

Sources for inclusion were identified through structured database searches supplemented by purposive searches. Titles and abstracts were screened for eligibility and critically appraised using the Mixed Methods Appraisal Tool⁷ by two independent reviewers. Following data extraction using a structured template, the findings of included studies were coded using a framework based on the initial research questions. Patterns and themes were identified. New (synthetic) constructs were generated and linked to broader theory to explain the overall findings.

Key findings

Fifty quantitative and qualitative sources were included. The concept of agency (people's ability to effect change through their interaction with other people, processes and systems) provided an overarching explanation of how PFME can be implemented during childbearing years. Women and healthcare professionals (HCPs) (individually or in groups), maternity services and organisations, funders, and policy-makers all have agency, although their capacity to implement PFME is enhanced or diminished by the professional, organisational, and policy environment.

Numerous factors constrained women's and HCPs' capacity to implement PFME. It is unrealistic to expect women and HCPs to implement PFME without reforming policy and service delivery to genuinely support women and HCPs in this endeavour. The implementation of evidence-based PFME requires policy-makers, organisations, HCPs, and women to value the prevention of incontinence by using low-risk, low-cost and proven strategies as part of women's reproductive health care across the lifespan.

Limitations

For the reviewed quantitative studies, limitations included small sample size and lack of reporting of any sample size calculation; too few details regarding reasons for declining participation; lack of details regarding calibre of survey tools/outcome measures; and variable response rates. For the reviewed qualitative studies, many did not consider impact or relevance of contextual factors or did not demonstrate reflexivity.

Work package 1.2: focused ethnographic observation of clinical practice

See also Terry *et al.*⁸ (<https://doi.org/10.1016/j.midw.2020.102647>).

Aims

The main aim of WP1.2 was to explore individual, HCP and organisational barriers and enablers to implementation of PFME and assessment in current UK practice. Further aims related to understanding how individual, professional and organisational factors interact to enhance or reduce effective PFME implementation in the UK context with a view to informing subsequent WPs in the APPEAL programme.

Methods

Designed with input from patient and public involvement and engagement (PPIE) activities, a variety of methods were planned: interviews from three differing sites with antenatal women and, for a subset of women, postnatal follow-up interviews; interviews with midwives and other HCPs; and observations in antenatal clinics. Additional data sources included field notes, photographs, websites, leaflets, clinic documents and antenatal service policies, all obtained from visits to the study sites.

Analysis used reflexivity and reflexive accounting (key aspects of ethnographic research^{9,10}), with initial coding to develop a coding framework and then identify emerging themes (following principles of thematic analysis¹¹) and adopted a process similar to the 'constant comparative method'¹² to guide

theme development. Analysis was inductive (data driven) but also deductive in terms of addressing the specific objectives of the APPEAL research programme.

Extensive discussions about emerging findings took place among the research team, including with Jean-Hay Smith and Helena Frawley (our international specialist academic physiotherapy collaborators from New Zealand and Australia, respectively). These were ongoing remote and in-person meetings during June 2018.

Key findings

Data were collected at three sites (large city, small city, coastal town). A total of 23 midwives and 15 pregnant women were interviewed, with 12 also interviewed postnatally. Interviews were carried out with physiotherapists ($n = 4$), a link worker/translator ($n = 1$) and obstetricians ($n = 2$). Seventeen antenatal clinic observations took place.

Key findings based on all data, including clinic observation notes and interviews, were that women and midwives know that PFME training is important, but that midwives may not communicate fully to women the relatively large 'gains' available from engaging with PFME. There was widespread lack of confidence among women and midwives to initiate a discourse about PFME and UI. This was exacerbated by both misunderstandings and assumptions and by a lack of clear guidelines and policy, further impacting on communication between women and midwives.

Ethics

Ethical approval was obtained for the ethnography {HRA approval 15 December 2016 [Integrated Research Application System (IRAS) project ID 215180]}.

Limitations

A criticism of ethnographic research is that the presence of a researcher will impact the behaviour of those observed, creating an observer effect bias.¹³ The midwives were fully informed of the purpose of this study, so it is possible that this bias occurred. It is argued, however, that even if this happens, ethnographies can still expose honest accounts about the topic under investigation.¹⁴ Ethnographies do provide a detailed account and thus findings cannot be generalised to other women or HCPs; furthermore, we were not able to carry out interviews with women who did not speak English.

Inter-relationship of work package 1 with other parts of the programme

Both studies from WP1, one evidence synthesis and one empirical, were combined to create a platform of research to inform WP3 activities for the development of the APPEAL intervention, which would then be tested in the feasibility and pilot trial in WP4. *Figure 1* shows diagrammatically how the whole programme fits together.

Work package 2: performance measurement: determining relevant measures of performance

Work package 2.1: diagnostic accuracy systematic review and data synthesis to identify the accuracy of tests for assessment of pelvic floor muscle localisation and contraction in women

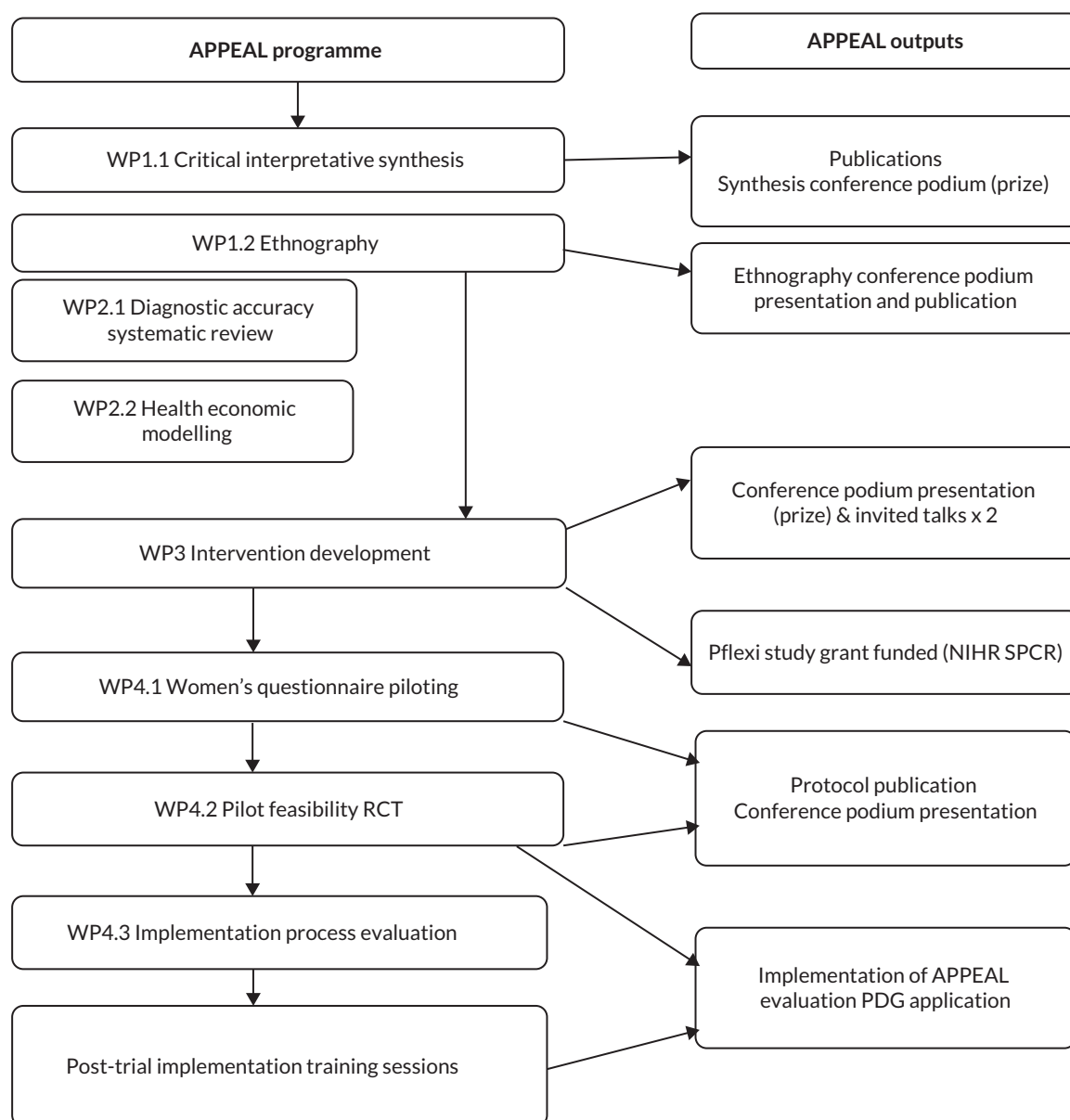
Aims

The main aim of this study was to determine whether there were any tests for assessment of pelvic floor muscle (PFM) localisation that might be used to assist in the trial intervention.

Methods

A diagnostic test accuracy systematic review was undertaken to compare the accuracy of tests for assessment of PFM localisation and contraction in women. The population was not restricted to

SYNOPSIS



WP2 discontinued following funding review.

FIGURE 1 Research pathway diagram. PDG, Programme Development Grant.

pregnant women to maximise data available; however, pregnancy was considered as a potential source of heterogeneity.

The secondary objectives of the review were to investigate other sources of heterogeneity; that is, factors which may affect test accuracy. Potential sources of heterogeneity included population characteristics (e.g. presence or absence of UI, obesity, menopausal status, parity, current pregnancy); index test characteristics (e.g. index test technology, expertise of test operator); and reference standard characteristics: whether digital vaginal palpation was conducted by a specialist [e.g. physiotherapists, obstetricians, gynaecologists, general practitioners (GPs) with accreditation/specialist interest in women's health, specialist midwife or health visitor] or a non-specialist HCP. A further objective was to combine findings from WP1 to identify which of the most accurate tests are likely to be most acceptable to pregnant women. A comprehensive search strategy was developed in consultation with

an international PFME expert. The following databases were searched: MEDLINE (Ovid), MEDLINE In Process (Ovid), EMBASE (Ovid), PsycINFO (Ovid), Cochrane Library (Wiley) CDSR, DARE, HTA, NHS EED and CENTRAL; CINAHL (EBSCO); SCI Web of Science SSCI. Ongoing trials registers (CT.gov and the World Health Organization's International Clinical Trials Registry Platform register) were searched and abstracts and conference proceedings sought using Conference Proceedings Citation Index (CPCI) – Science and CPCI – Social Science and Humanities (Web of Science). Electronic searches were supplemented by citation searching and searching references of included studies and relevant systematic reviews. Databases were searched from inception to October 2016. No language limits were applied. In anticipation of a paucity of studies with a primary objective of estimating test accuracy, all study design types were considered for inclusion, except for diagnostic case-control studies as these are known to overestimate test accuracy. Test accuracy study design filters were avoided as these have been shown to miss studies. Titles and abstracts and full-text articles were screened for eligibility by two independent reviewers, with disagreements resolved by a third. A data extraction proforma and a quality assessment tool based on the QUALity of Diagnostic Accuracy Studies tool¹⁵ tailored to the topic were prepared a priori.

Key findings

A total of 9678 unique title and abstracts were screened, and 1429 full-text articles subsequently retrieved. No studies met the review inclusion criteria. Most commonly, this was because of the absence of an index test (one or more of: methods for observation, palpation, pressure measurement, measurement of electrical activity by muscles, imaging with ultrasound) in parallel with the reference standard of digital vaginal palpation. In studies where an index test was conducted in parallel with the reference test, the paper did not provide information from which to derive a 2 × 2 diagnostic table and therefore an estimate of accuracy. This was because, except for one test accuracy study (that did not use an acceptable reference standard), all other studies identified used either an index test or the reference standard to measure the outcome of an intervention to improve PFM function. Furthermore, in the majority of these studies women were educated how to contract the pelvic floor musculature correctly so that any improvement in strength and endurance following an intervention could be measured. These studies therefore only had women who were able to contract their pelvic floor; thus, the ability of index tests to identify women unable to localise and contract their PFM could not be estimated ([Figure 2](#)).

Limitations

The lack of any available studies to assist in assessment of PFM localisation that might be used in the trial intervention was a major limitation.

Inter-relationship with other parts of the programme

The intention of this WP was to provide a diagnostic test to use in the intervention for midwives to check whether women were able to locate their PFM.

Work package 2.2: constructing a health economic decision-analytic model

Aims

The aim of this study was to collate relevant evidence to inform and develop a preliminary decision-analytic model (DAM) which would compare a range of alternative tests and treatment pathways for reducing UI among pregnant women. The overall objective of the preliminary model-based evaluation was to identify gaps in the evidence that required specific focus in the full definitive trial.

Methods

Systematic review

A pragmatic search of identified literature from WP2.1 showed insufficient evidence for the proposed model, and a scoping search did not find any economics studies on PFME among pregnant women. Hence a systematic review was conducted with the broader purpose of identifying evidence for economic evaluations of interventions to prevent and treat UI in general, not just in pregnancy, to inform a preliminary model.

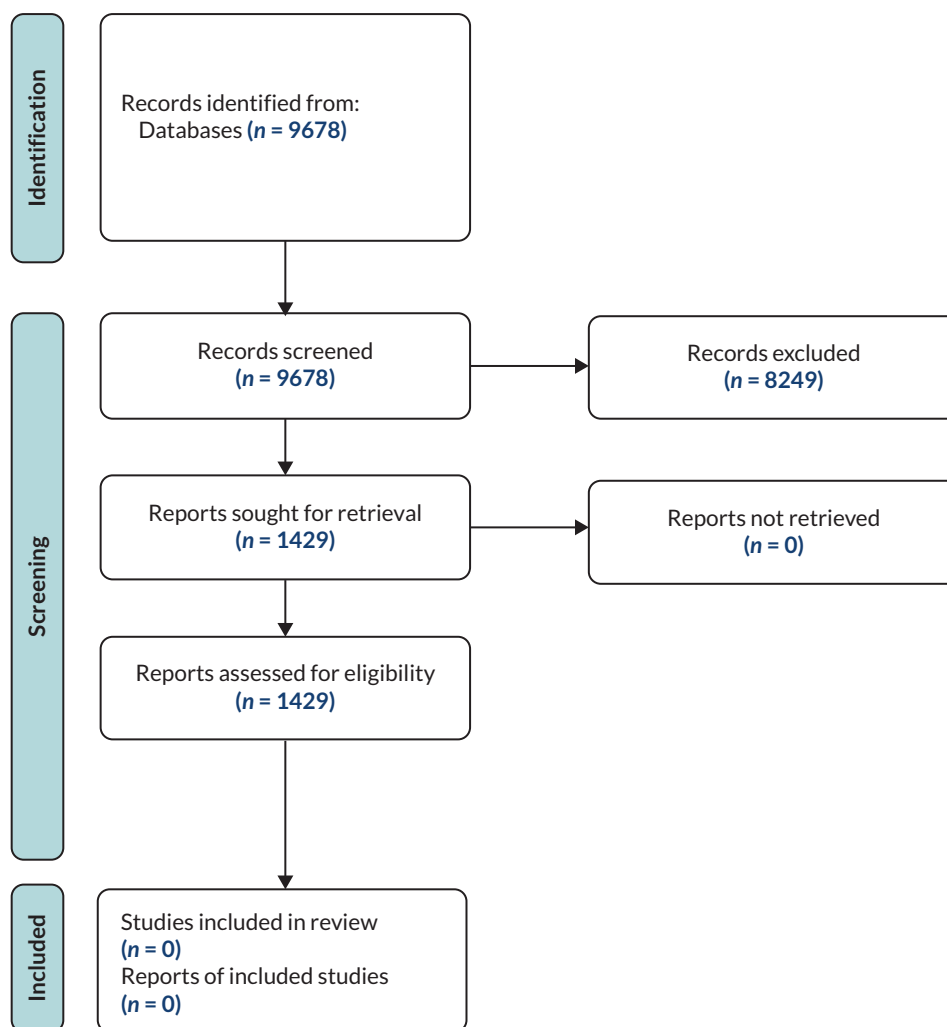


FIGURE 2 PRISMA flow chart of included studies.

The systematic review was conducted according to the guidelines of the UK's Centre for Reviews and Dissemination.¹⁶ A search strategy was developed using the population, intervention, comparison and outcomes framework.¹⁷ Five electronic databases – MEDLINE, EMBASE, Web of Science, NHS Economic Evaluation database and CINAHL – were searched.

Formal economic evaluation and cost analysis studies were included if *participants* were females suffering from UI; the *intervention* was PFME to prevent or treat UI; the *comparison* was any alternative test and/or treatment strategy to prevent UI in women; and the main *outcome* was cost per quality-adjusted life-year (QALY). A two-stage categorisation process was used to screen studies for inclusion using published methods.^{18,19} A quality appraisal was not undertaken because the review's objectives required a description of all economic evidence.

Information on resource use and associated costs were extracted from reviewed studies. In addition, effectiveness data and health-related quality-of-life (QoL) data were sought from the published Cochrane Review¹ and pragmatic literature searches. The collated evidence was used to estimate a baseline DAM which explored potential issues and/or gaps relating to either the intervention or QoL.

Preliminary model

We constructed a model in TreeAge (TreeAge Software, Inc., Williamstown, MA, USA) to compare the APPEAL intervention with usual care, based on a series of potential pathways to represent the wide range of viable pathways that women could follow. The pathways included scenarios in the

intervention arm where pregnant women were referred to physiotherapists when they had UI or had problems locating their pelvic floor. Group and individual physiotherapy sessions were included in the modelled scenarios.

Effectiveness data were obtained from a Cochrane Review¹ identified from a pragmatic literature search and an alternative study²⁰ identified through hand searching. Similarly, utility values were obtained from a pragmatic search.^{21,22} Cost and resource-use data used in the model were based on published sources.²³ Assumptions were made about all model parameters to form a complete set of values for the analysis, and these parameters were varied in sensitivity analyses to see the effect on the results.

Key findings

Systematic review

The search identified 10 studies^{22,24-32} out of a possible 1163. Overall, all the studies evaluated the cost/cost-effectiveness of PFME as treatment rather than as prevention for UI. The delivery of PFME differed between the studies with variations in the number, duration and frequency of physiotherapy sessions.

The studies were mostly formal economic evaluations ($n = 8$), with only two cost analyses. The majority ($n = 6$) of the economic evaluations were cost-utility analyses (with outcomes presented in terms of cost per QALY). There were variations, however, in the instruments used to measure QoL. Three of the studies (two cost-utility analyses and one cost-effectiveness analysis) were model-based. All studies included direct medical costs, and six studies included some form of direct non-medical costs (e.g. the cost of incontinence pads). Only three studies included indirect non-medical costs such as time forgone by not working and time for extra laundry loads. All but one study recommended PFME as a cost-effective intervention for treating UI.

Economic analysis

Initial results from the pre-trial economic analysis suggested some potentially helpful information for the trial design and proposed data collection. An example of such information was that the time spent by midwives providing the intervention was not likely to be a key driver in the results; this allowed the trial team to be non-prescriptive about midwives recording the time spent with women, which was initially a cause for concern. However, the preliminary results were extremely sensitive to both the effectiveness of the intervention and the QoL data inputted into the model.

Limitations

The systematic review and additional reviews provided some evidence for the pre-trial model. There were insufficient data, however, to carry out a complete economic evaluation without some fundamental assumptions. Many of the data used were proxy values from other studies of related (but not the same) populations.

Inter-relationships with other parts of the programme

The purpose of the pre-trial model was to identify gaps in the literature and areas worthy of particular focus, such as data collection, in the definitive trial. When the second stage of the programme was changed to be a feasibility and pilot RCT rather than a full definitive trial, however, the health economic analysis was discontinued.

Work package 3: plans for change: developing the constituents and means of delivery of the Antenatal Preventative Pelvic floor Exercises and Localisation intervention

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provided the original work is properly cited. See: <https://creativecommons.org/licenses/by/4.0/>. The text below includes minor additions and formatting changes to the original text.

Aims

Work undertaken in WP3 aimed to develop a training package and resources for midwives to give them the confidence to teach and support women to do PFME within routine antenatal care. The aim also included developing resources for midwives to give to women, providing further support for women to do PFME during pregnancy. The developed intervention was planned to operate at two levels: to change midwives' behaviour (to teach and support women to do PFME) and to change women's behaviour (to do PFME during pregnancy). The training package and resources would then be evaluated in the pilot and feasibility cluster RCT described in WP4.2 and WP4.3.

Methods

Development followed the Medical Research Council guidance for complex interventions³⁴ and was guided by the Consolidated Framework for Implementation Research.³⁵ Designed over four iterative phases, the intervention development included a stakeholder event and multiple PPIE activities.

Ethics approval was obtained for WP3 phases 1 and 3 (University of Exeter Medical School Research Ethics Committee 18/06/169; HRA approval: IRAS project ID 238874).

Phase 1: focus groups

Two participant groups were planned: pregnant women or those who had given birth within the previous 12 months, and midwives providing antenatal care. They were invited to take part in separate focus groups in a range of sites in England. Data were analysed using thematic analysis.¹¹

Phase 2: development of a training programme including intervention mapping

The intervention was developed using data from WP3 phase 1 and WP1. A comprehensive mapping exercise was undertaken using the behaviour change wheel (BCW), theoretical domains framework³⁶ and behaviour change technique (BCT) taxonomy (v1).³⁷ PPIE activity included APPEAL advisory group meetings and a wider group of advisers undertaking a citizens' jury style assessment of mobile phone apps to determine which might be recommended as part of the women's resources to support PFME.³⁸ A national stakeholder event was arranged to consider midwife training needs and antenatal service provision.

Phase 3: practice training event

An in-person practice training event was carried out with a cohort of midwives located in a different region to the future trial. A 5-point (scoring 0–4) Likert scale eight-item questionnaire was designed to assess midwives' confidence before and after training regarding pelvic floor knowledge and teaching PFME. Focus group style discussions took place after the training session to obtain feedback on intervention format, content, and methods of delivery. An anonymous evaluation questionnaire with options to rate the training and provide free-text comments was also prepared. Researchers facilitated these activities and made field notes to record discussions and recommendations.

Phase 4: intervention refinement

Findings from WP3 phase 3 and further PPIE were used to refine the format and content of the intervention package. Additional refinements were made in response to COVID-19.

Key findings

In WP3 phase 1, 12 women (age 20–44 years; education range: secondary education to postgraduate degree) and 14 midwives (age 25–59 years; midwifery experience: 3–32 years) took part in six focus groups.

The practice training in WP3 phase 3 was attended by a different cohort of 18 midwives (age 25–60 years; midwifery experience: 2–20 years). Of the 32 midwife participants in WP3 phases 1 and

3 of the study, 13 (41%) reported no previous PFME training (formal or informal), 2 (6%) had attended specific pelvic floor rehabilitation courses, 9 (28%) reported varying amounts of training and 8 (25%) did not provide data on this.

The PPIE advisory group included six mothers with young children, with nine meetings held. The citizens' jury included 10 women who had given birth within the previous 5 years, with two meetings held.

The stakeholders were 20 delegates representing 18 organisations across the UK with an interest in maternity services (see [Acknowledgements](#)).

Phase 1

Four themes emerged from the six focus groups. These were: 'knowing', 'doing', 'remembering' and 'supporting' antenatal PFME. Illustrative quotes for each theme are available in [Appendix 1](#).

Knowing about pelvic floor muscle exercises and urinary incontinence

Analysis showed a lack of information and promotion of antenatal PFME meaning that women were unaware of the importance of PFME, and a lack of training and guidance for midwives. Midwives needed more knowledge on anatomy and muscle training physiology, and women needed to know why PFME were important and the consequences on UI of not doing them. Both groups agreed that midwives needed the confidence to raise the topic and make sure all women understood about PFME and their relationship to UI. For midwives, knowing the importance of PFME included wider implications, such as economic implications.

Doing pelvic floor muscle exercises

Midwives and women wanted guidance on how and when to teach and perform PFME; analysis made it clear that this should be done early in antenatal care and followed up at every subsequent appointment. Midwives and women were ambivalent about doing vaginal examination for checking the correct muscle contraction was happening. This was not regarded as something universally needed but could be offered if required.

Remembering pelvic floor muscle exercises

Prompts were seen as critical to support women to do PFME and to support midwives to implement PFME teaching. Both wanted consistent and regular reminders to help women put PFME into a daily routine. Women emphasised the need for meaningful dialogue to support them, not just simply asking whether they are doing their exercises. Women suggested signposting to smartphone apps, and midwives suggested a variety of cues, such as key chains, lanyards, and visual prompt cards.

Supporting implementation and delivery of pelvic floor muscle exercises

Women wanted multimedia options for delivery of PFME information, including online and written resources. Although debated by women and midwives, there was overall agreement that a paper leaflet, given at the booking appointment, would be acceptable provided it was accompanied by detailed verbal instruction at a subsequent appointment, hence acting as a reminder.

Midwives wanted PFME training to be delivered face to face, with demonstrations from experts on how to teach effective PFME. E-learning was not regarded as acceptable for initial training but could be an option for refresher training, as it was likely to improve accessibility. Finding time to fit in PFME training was clearly going to be challenging, and many midwives believed it should be mandatory. Implementation of training would require local organisational support to enable midwives to attend.

Further suggestions for maximising implementation included using a 'train the trainer' model and having a midwife PFME champion within each midwife team. Midwives also wanted to know more about local referral options and strengthening of referral pathways to physiotherapy services for women they identified as needing further support. Both midwives and women felt the need to raise awareness and strengthen support for antenatal PFME at a wider societal level, and suggested a national campaign.

Midwives were also asked to consider methods for assessing fidelity to the proposed intervention in the future trial; they suggested a PFME tick box on antenatal appointment checklists, audit of antenatal notes, and observations of midwifery practice. They did not consider audio or video recording of appointments acceptable.

Phase 2

In this phase, data from WP3 phase 1 and the earlier APPEAL research^{6,8} were mapped onto the BCW. This helps identify intervention functions (the broad categories of things that can be done to change behaviour) and intervention content and BCTs and these were all discussed by the research team.

One example relates to the theoretical domain of knowledge (awareness of the existence of something), which is a psychological capability component of the capability–opportunity–motivation–behaviour (COM-B) model.³⁶ For this to be implemented, women need to develop understanding of PFME and their relationship with pelvic health and UI, and understand the principles of how PFME might reduce UI. Similarly, midwives need to develop knowledge and understanding of the rationale for antenatal PFME for promoting PFM health during pregnancy and childbirth.

The proposed intervention functions (in this example the methods by which these knowledge gains can be achieved) through education, with the policy category (vehicle) being service provision and guidelines, and marketing-style communications. Thus, the ideas for intervention content (application) were designed to follow these principles at the two levels. At the level of women, the intervention needed to ensure that midwives could provide information and facts relating to what the pelvic floor is, its role relating to UI, what happens in pregnancy, what PFME are, why they are important, how to do them, and what the benefits are, including information on their effectiveness for preventing UI as well as other benefits of PFME. At the level of midwives, the intervention needed to cover a review of anatomy, physiology and function of PFMs, presentation, and discussion of evidence for prevalence of UI during/after pregnancy, including effectiveness of antenatal PFME for reducing UI. Furthermore, the intervention needed to impart new knowledge and understanding to midwives about the impact of UI on physical and mental health, giving examples of women's stories (e.g. social isolation, shame, embarrassment) as well as including information on other benefits of PFME (e.g. sex, reducing time of second-stage labour).

These knowledge elements of the intervention were then coded to the BCT taxonomy, namely: shaping knowledge (instruction on how to perform a behaviour, BCT 4.1) and informing about natural consequences (information about health consequences, BCT 5.1; salience of consequences, BCT 5.2; and information about social and environmental consequences, BCT 5.3).

Finally, comments or issues arising from PPIE advisers and stakeholders were added to the map. In this example they commented that 'knowledge is power' for both midwives and women, but also had wider importance within society, as it would help raise the profile, and thus result in a clearer understanding of why PFME is important.

The full mapping exercise is included in [Report Supplementary Material 1](#). Once mapping was completed, the first iteration of the intervention was prepared. Intervention materials included a midwife training programme and resources for midwives to support PFME implementation, and a resource package for women to be given by midwives during the antenatal booking appointment.

The training programme for midwives included five steps for putting PFME into antenatal clinical practice: (1) raise the topic of PFME; (2) screen for UI; (3) teach PFME; (4) prompt/remind women about how to perform PFME; and (5) refresh women's understanding about PFME and refer to specialist services if required. A manual containing training session slides, summary leaflets and additional resources about PFME and UI was prepared for midwives.

The PPIE advisers helped co-develop the resources for women. In addition, the citizens' jury work considered smartphone apps from a list provided by the app review undertaken by APPEAL's

collaborators in New Zealand.³⁸ Jury members tried out various apps and the three most highly rated were added to an app decision card with QR codes supplied to ensure ease of access. Other resources were a leaflet with information about PFME and how to perform a correct PFM contraction, and stickers to use as prompts/reminders for PFME. These, with the app decision card, were placed in a small bag to be given by midwives to women at their antenatal booking appointment.

Phase 3

Following the practice training event, evaluation scores were positive for content and delivery, and participating midwives ($n = 18$) found it useful. Free-text responses indicated that midwives acknowledged the importance of taking the lead regarding PFME, but lack of time, confidence, and skills to raise the issue presented challenges for implementing PFME in practice. However, these midwives reported an increase in total confidence relating to PFME from 2.70 (range 1.18–3.50) before training to 3.68 (range 3.37–4.00) after training, suggesting that with additional refinements the training had potential to address some of these challenges. The midwives raised additional considerations for implementation of PFME, time constraints of antenatal appointments, not wanting to overload women with too much information early in maternity care, and whether insufficient continuity of care would impact on their ability to develop rapport with women to teach and support PFME throughout pregnancy. The midwives also highlighted the importance of establishing PFME champions within midwifery teams and the need for buy-in from senior midwives/clinical managers to support implementation.

Phase 4

Intervention materials and content were modified and refined by the research team and PPIE advisory group in response to feedback from the practice training event. Examples were more detail for the anatomy refresher and for the physiology to cover muscle exercise training principles; and to package resources for women in a cloth bag big enough to hold a clean nappy (not a box, which would take too much space for midwives). A second version of the midwives' manual was prepared as the trainer's manual, with extensive speaker notes, to facilitate the plan for using a 'train the trainer' model in future implementation. The training session was shortened from half a day to 2 hours. Additional training and resources were developed to support a PFME champion midwife role. Further modifications were made at the onset of the COVID-19 pandemic to enable training delivery via the Zoom online platform (Zoom Video Communications, San Jose, CA, USA), and to support midwives to deliver intervention elements via telephone appointments. The final output of WP3 phase 4 was the development of the logic model for the pilot feasibility trial in WP4 (see [Appendix 2, Figure 4](#)).

Limitations

The challenges identified by midwives regarding wider system pressures,⁶ past difficulty accessing training, and appointment time constraints did limit intervention range and complexity. Despite these constraints, midwives and women believed that implementing PFME in antenatal care would be beneficial for large numbers of women.

At this stage, evaluation of the APPEAL intervention has used observational, before–after or qualitative data; findings from the pilot feasibility RCT in WP4.2 and 4.3 add to this evaluation.

Inter-relationship with other parts of the programme

We benefitted from continuing to work closely with PPIE advisers and drew upon known BCTs throughout the four phases to develop a comprehensive understanding of the needs of midwives, women, and stakeholders within current organisational contexts. Findings from WP1, and behaviour change theory helped us bring WP3 activities together into a training package for midwives and resources for supporting women to address these needs, to be used in WP4.

Work package 3 aimed to ensure that whatever the APPEAL intervention asked of women and midwives for implementing PFME was evidence-based, with sound theoretical underpinnings and consensus

acceptance from experts and lay members of the public. Our extensive PPIE, plus national stakeholder involvement, added credibility to intervention development, which has been piloted, refined, and adapted for remote delivery.

Work package 4: piloting the intervention

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Work package 4.1: what is the response rate for the trial questionnaire and the intraclass correlation coefficient?

See also [Appendix 3](#) for full report of WP4.1 and [Tables 5–8](#).

Aims

The main aim of WP4.1 was to test the data collection instruments in the questionnaire to be sent to women at 10–12 weeks post partum and, in so doing, to test what the return rate might be in a full trial. We also wanted to estimate the intraclass correlation coefficient (ICC) for a full trial. This study was completed in the first stage of the programme before there was a change to a feasibility and pilot trial for the second stage.

Recent studies in similar populations^{2,3} showed that response rates had been dropping, so it was decided to also assess whether a long or shorter questionnaire might give a higher response.

Methods

This study was an individually RCT undertaken in the two NHS Trusts which would be part of the subsequent pilot cluster trial. Eligible women (all except those under 16 years or with no live baby on hospital discharge) cared for in 15 community midwife teams who gave birth in two Trusts during the study period were included.

A sample size of 800 women with an anticipated response rate of between 30% and 60% would allow a return of between 240 and 480 questionnaires. With a sample size of 800, with 400 allocated to each trial arm, at 80% power and 5% significance, the study would be able to detect a 10% absolute difference in the percentage response rate between the shorter and longer questionnaires.

The first 54 consecutive women to give birth during July 2018 from each of the 15 midwifery teams were informed by their midwife at their first postnatal home visit that they would receive a postal questionnaire at 10–12 weeks post partum about incontinence and PFME.

The questionnaires comprised several validated measures to assess: UI [International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF⁴⁰)]; faecal incontinence (FI) [Revised Faecal Incontinence Scale (RFIS⁴¹)] (FI was included in APPEAL as PFME are generally considered to be a help but RCT evidence to show that antenatal PFME can reduce post-partum FI is not of high quality, hence not a major focus of APPEAL); confidence in PFME [Pelvic Floor Muscle Exercises Self-Efficacy Scale (PFMESES⁴²) and Exercise Adherence Rating Scale (EARS⁴³)]; and general health [Short Form questionnaire-12 items (SF-12⁴⁴)]; as well as questions about advice that women may have received on PFME in pregnancy and their PFME practice. The long questionnaire comprised two double-sided pages with all the above measures. The short questionnaire comprised one double-sided page and did not include PFMESES, EARS or SF-12. For women who returned this questionnaire a second questionnaire, which included PFMESES, EARS and SF-12, was then sent.

Individual randomisation to the long or the short questionnaire was undertaken using a computer programme at the Birmingham Clinical Trials Unit (BCTU), stratified by community midwifery team to account for potential variation between different sociodemographic areas.

Local Trust research midwives sent the questionnaires with a cover letter, a £10 voucher, and a stamped return envelope, then sent a reminder questionnaire to women who had not responded by 2 weeks.

Permission was obtained from the Proportionate Review Subcommittee of the London – Brighton & Sussex Research Ethics Committee (18/LO/0934).

Key findings

A total of 777 women were randomised to receive a long ($n = 387$) or short ($n = 390$) questionnaire. Overall response rate was 31.3% (243/777). Response rate in the long questionnaire arm was 30.8% (119/387) and 31.8% (124/390) in the short questionnaire arm [absolute difference in return rate -1.05% , 95% confidence interval (CI) -7.6% to 5.5%]. While not statistically significant, this finding rules out large differences between response rates. The ICC of response rate was 0.007 (95% CI 0.0005 to 0.094). The baseline characteristics of the women who returned a long questionnaire were similar to those who returned the shorter version.

Of total responders, 49% (119/243) reported some leaking of urine based on responses to the ICIQ-UI SF.⁴⁰ A total of 64.2% (156/243) of women reported receiving advice to perform PFME during pregnancy from their midwife. There were 42.4% (103/243) of women who reported doing PFME often enough (a few times a day, once a day, a few times a week) to possibly reduce post-partum UI. All these responses were similar between the long and short trial arms.

The questionnaire in general was well completed by the women, with low rates of missing values, but the response was low, despite having incorporated Cochrane Review⁴ recommendations to increase responses to postal questionnaires.

The estimated ICC for the return rate was 0.007 (95% CI 0.0005 to 0.094) The upper limit of the 95% CI was taken as a conservative estimate of the 'true' return rate ICC and was used to inform the sample size calculation for the pilot trial in WP4.2.

Limitations

The main limitation in this study was the low return rate of questionnaires from the women.

Inter-relationship with other parts of the programme

This WP was planned to test the data collection instruments and procedures ready to undertake a full trial. The low rate of questionnaire return, however, increased the risk of proceeding to a full trial (see [Summary of alterations to the programme's original aims/design](#)). The data obtained from WP4.1 were used to inform the feasibility and pilot trial described in the next section.

Work package 4.2: feasibility and pilot cluster randomised controlled trial of an antenatal preventative pelvic floor muscle exercise intervention led by midwives to reduce postnatal urinary incontinence (Antenatal Preventative Pelvic floor Exercises and Localisation Programme)

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Aims

The aim of WP4.2 was to assess the feasibility of undertaking a future trial of a midwife-led antenatal intervention to support women to perform PFME in pregnancy to reduce post-partum UI.

Other aims were to assess intervention acceptability to midwives and the women they supported. Objectives were:

- Provide training for community midwife teams randomised to the intervention arm to encourage incorporation of a PFME care package into their usual antenatal care (outcomes related to these objectives reported in WP4.3).
- Assess whether training, intervention implementation and trial processes were acceptable to midwives (outcomes related to these objectives reported in WP4.3).
- Assess whether midwife characteristics (e.g. years qualified) were similar across trial arms.
- Assess questionnaire return rates from women at 10–12 weeks post partum overall and in both trial arms to assess feasibility and allow sample size estimation for a full-scale RCT.
- Assess characteristics of women overall and within trial arms who returned questionnaires compared with all those who gave birth in the same midwife teams over the same study period but did not respond, using anonymised routine data.
- Assess whether baseline characteristics collected following birth (self-reported UI at pregnancy commencement, maternal and obstetric characteristics collated from maternity records) were similar across trial arms.
- Assess midwife support for PFME in both trial groups using women's questionnaire data and qualitative interviews with midwives and women.
- Assess women's practice of PFME during and after pregnancy (outcomes related to qualitative interviews reported in WP4.3) using women's postnatal questionnaire and interview data.
- Assess prevalence of UI and FI at 10–12 weeks post partum using women's questionnaire data to inform the sample size calculation for a full RCT (FI was included in APPEAL as PFME is generally considered to be a help but RCT evidence to show that antenatal PFME can reduce post-partum FI is not of high quality, hence not a major focus of APPEAL).
- Undertake any necessary revisions to the APPEAL training package and following this, recommend roll-out by midwives to all pregnant women as part of the NHS Long Term Plan (outcomes related to this objective reported in the section on practice implications).

Methods

The study design was a feasibility and pilot cluster RCT, with community midwife teams forming the clusters. This design was chosen as randomisation of individual women would likely lead to contamination because midwives would have to provide two forms of care; and randomisation of individual midwives was not possible because midwives provide care on a team basis.

Midwife teams (clusters) were randomised in a 1:1 ratio to standard care only or standard care plus intervention. A minimisation algorithm ensured approximate balance over the variables:

- midwife team size, defined by number of monthly births
- NHS Trust.

Blinding of midwives providing care was not possible. Women receiving antenatal care were not explicitly blinded but the PFME support they experienced was the usual care provided by their midwives. Due to the nature of recorded data, those responsible for conducting trial analysis could not be blind to allocation.

Ethics approval

Protocol version 4.2, dated 21 November 2021, approved by West Midlands – Edgbaston Research Ethics Committee (19/WM/0368, approval date 10 January 2022). Study sponsor is Birmingham Women's and Children's Hospital NHS Foundation Trust.

Intervention

Two research midwives led and facilitated online training sessions developed from earlier WPs which lasted approximately 2 hours. Midwives in intervention teams were asked to introduce the topic of

pelvic floor health at antenatal 'booking' appointments or as early as possible after this to all women. All women were given an APPEAL resource pack, including an APPEAL leaflet with PFME information, a link to APPEAL developed videos, recommended apps to support PFME, and APPEAL logo stickers to use as reminders. Women were to be asked by the midwife at all subsequent antenatal appointments about PFME progress and any problems with PFME or incontinence symptoms. In teams where a high proportion of women were non-English-speaking, the maternity support workers (MSWs) who provided translation were also trained. Midwives and MSWs had 2–3 months to practise implementing the PFME intervention into their routine care.

Midwife 'champions' in each intervention team received additional training on how to support and manage women with more severe UI symptoms, referred to them by team colleagues, and recommend appropriate specialist referral; and provide reminders and advice for their team to implement the intervention.

Feasibility and pilot outcomes

Feasibility of undertaking a definitive future trial was assessed by:

- questionnaire return rates from women who gave birth over a preselected 1-month period, at 10–12 weeks post partum overall and across trial arms
- prevalence of UI at 10–12 weeks using the ICIQ-UI SF,⁴⁰ and FI at 10–12 weeks using the RFIS⁴¹
- women's practice of PFME, their adherence (predefined as PFME a few times a week or more) and PFME confidence using the PFMESES,⁴² and EARS⁴³ (as data on QoL were not relevant for a feasibility trial, the SF-12⁴⁴ scale was not included in the questionnaire used in WP4.2). During data entry, it was noted that responses to four items from the 17-item PFMESES were missing. An error occurred when the questionnaire was downloaded from FORMAP (online tool for designing case report forms for clinical trials), which omitted these four items. However, when viewing the FORMAP version online, all four items were visible. The missing items were raised with the trial statisticians and the Trial Management Group decided to send out a corrected questionnaire containing the full set of questions to women who had not returned the first questionnaire. As this was a feasibility trial, when reporting summary data for the PFMESES questionnaire, no distinction was made between missing responses from women and missing responses due to women being sent incomplete questionnaires. Sites were asked to stop sending reminder copies of the questionnaires until a corrected version was available.

Process outcomes included whether the intervention could be implemented within routine antenatal care; whether midwives provided support for PFME in both trial arms; and women's and midwives' experiences in both trial arms of advice and support to perform PFME during pregnancy.

For the original aim of a full trial to go ahead, the following progression criteria had to be met:

- Questionnaire return rate from women across trial arms did not result in substantial bias, indicated by either a high overall return rate and/or that women who returned questionnaires in both trial arms had similar baseline characteristics.
- Women's self-reported adherence to performing PFME was higher among women in intervention clusters than in controls.
- Midwife support for PFME was reported as greater among women in intervention clusters than in controls.

Sample size

Sample size was based on the number and size of clusters needed to estimate the return rate of questionnaires (across trial arms) to an acceptable level of precision. In WP4.1 the estimated ICC for return rate was 0.007 (95% CI 0.0005 to 0.094). Assuming a conservative ICC of 0.1, the width of the 95% CI for different rates (e.g. return rate of questionnaires) was estimated based on a *t*-distribution.⁴⁶ To set a conservative upper bound on the required sample size, we determined the widest 95% CI for a given sample size which will occur for a rate of 50%.

To reflect changes from WP4.1 in the number of midwife teams and women cared for by the teams, the overall sample size target was around 1400 (17 clusters of average size 82) to estimate the 95% CI for return rate to a maximum width of 17.2%.

Data collection and analysis

Analyses were based on the intention-to-treat principle. Data analysis was descriptive, mainly focused on CI estimation, with no hypothesis testing. Analysis methods included:

- Continuous end points summarised using means and standard deviations (SDs), by arm.
- Categorical (dichotomous) end points (e.g. return rates of questionnaires, adherence to PFME). The number of participants and percentages experiencing the event were summarised by arm.

For all total scores and dichotomous feasibility outcomes, summary measures and 95% CIs per trial arm were estimated using a cluster-level analysis based on *t*-distributions with $K - 1$ degrees of freedom (K denotes the number of clusters in each group) and appropriate transformation where necessary (and weighting if there was variation in cluster sizes). Quantitative data were summarised using descriptive statistics.

Women's questionnaires

Trust research midwives were asked to exclude women who had a stillbirth or neonatal death, those whose infants were taken into care, and women who had severe mental health problems, providing these data were available in maternity records. All women were to be told by their midwives at their first postnatal home contact that they would receive a questionnaire at 10–12 weeks postnatally enquiring about any incontinence they may have experienced and their PFME performance during and after pregnancy. If more than 2 weeks had elapsed since the initial questionnaire was sent but not returned, another copy was posted to the woman. A £10 voucher was offered to women who returned their questionnaire (questionnaire shown in [Report Supplementary Material 2](#)).

Trust research midwives were also asked to identify women who did not speak English as a first language from their maternity record. If the woman's first language was Urdu, Polish, Romanian or Arabic (main non-English languages in the areas), a shortened version of the questionnaire and a cover letter translated into the relevant language were sent. As only the ICIQ-UI⁴⁰ SF is translated in these languages, questionnaires sent to women who required a translated version did not include the RFIS,⁴¹ the PFMESES,⁴² or the EARS.⁴³

Responses from completed questionnaires were entered by a research midwife at the NHS Trust sites, who provided a list of the hospital/NHS numbers of women who consented for their maternity records to be accessed, to obtain information on:

1. woman's age, ethnicity, parity, onset of labour (spontaneous/induced), mode of birth (spontaneous vaginal, instrumental, caesarean section), anaesthetic/analgesia used, perineal trauma, episiotomy, duration of active second stage
2. baby's gestation at birth, birthweight and head circumference.

Key findings

As this was a feasibility trial, no statistical tests were used for comparisons between groups for any outcomes with only group-specific point estimates and 95% CIs used.

Women's questionnaire return rate

[Appendix 4, Tables 9 and 10](#) present information on sending/receiving women's questionnaire by group and the total number of women who gave birth at both study sites during the 1-month birth period.

[Appendix 4, Table 11](#) presents women excluded from receiving a copy of the questionnaire by study site.

After exclusions, a total of 998 women who received antenatal care from 1 of the 17 study clusters randomised to the trial and who met inclusion criteria were sent a questionnaire; 175 (17.5%) women returned a questionnaire. Of 531 questionnaires sent to women in intervention clusters, 88 (16.6%) were returned and of 467 in the control clusters, 87 (18.6%) were returned (Figure 3). Ninety women were sent a translated questionnaire, and eight women (five in intervention clusters and three in control) returned this.

Table 1 presents the estimation of the return rate of women’s questionnaires pooled across both arms. As the return rate was low, an overall estimation provides more representative information than separate estimates by trial arm.

A summary of the minimisation variables by treatment arm and those not returning a questionnaire is shown in Appendix 4, Table 12.

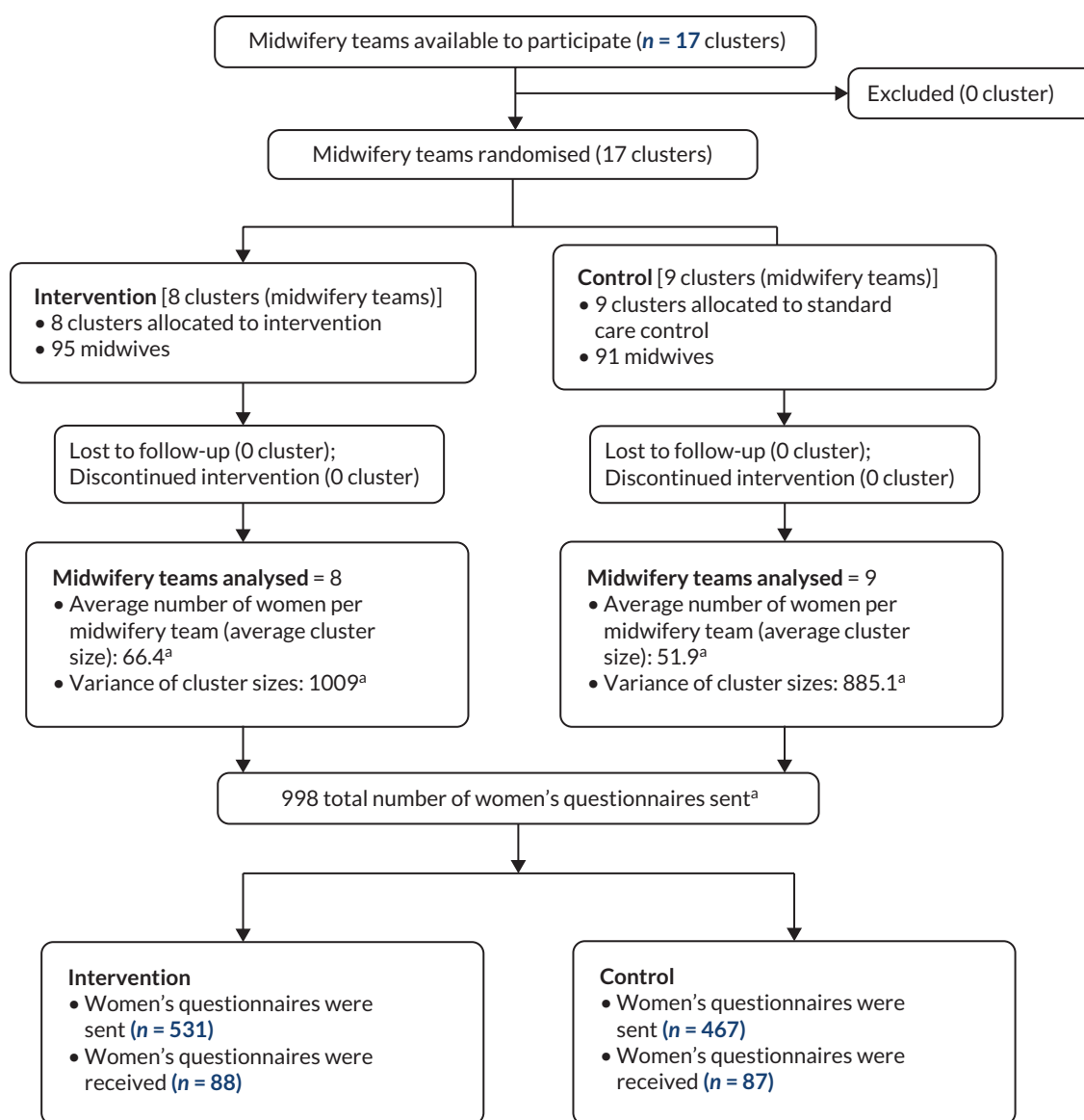


FIGURE 3 Work package 4.2 CONSORT flow diagram. a, Figures based on the total number of women who received antenatal care and gave birth across both study sites during the 1-month sample birth period.

TABLE 1 Women's questionnaire return rate overall

	Intervention: 8 clusters (n = 531)	Control: 9 clusters (n = 467)	Overall: 17 clusters (N = 998)
	% return rate estimation ^a	% return rate estimation ^b	% return rate estimation (95% CI) ^c
Percentage returning women's questionnaire	15.8	16.4	16.0 (11.6 to 21.4)

Each analysis assumed a *t* distribution based on:

a 7.

b 8.

c 16 degrees of freedom.

Note

All return rates and 95% CIs are estimated using cluster-level analyses, weighted by the cluster size, after natural log transformations of the data.

Characteristics of women who did not return a questionnaire (see [Appendix 4, Table 13](#))

Characteristics of women who gave birth in the study sample month but did not return a questionnaire were obtained and, using anonymised routine obstetric data, were compared with those who did return a questionnaire. Around one-third of women who did not return a questionnaire were of White British ethnicity (371/34.9%), which is a lower proportion than in the group who did return a questionnaire, and 205 (19.3%) women were of Pakistani origin, which is a higher proportion than among those who did return a questionnaire. Ethnicity data were unavailable for 205 women (19.3%) who did not return a questionnaire. Of the women who did not return a questionnaire, a higher proportion were having a second or higher birth order baby than those who did return a questionnaire. Obstetric and infant characteristics were similar among women who did and did not return a questionnaire.

Women's baseline characteristics (see [Appendix 4, Table 13](#))

The overall mean age of women who returned a questionnaire was 31.8 years (SD 5.2 years). Of these women, 77 (50%) were recorded as White British, 10 (6.5%) Pakistani, 7 (4.6%) Black African or Black Caribbean, and the remainder as 'other' ethnic minority groups. Data on ethnicity were not available for 21 women (12%). Overall, 62 women had given birth for the first time (41%), 61 (40.4%) for the second time, 28 (18.6%) had two or more previous births. Data on parity were missing for 24 (13.7%) women.

Women's obstetric outcomes were similar across trial arms except for induction of labour: 23 (29.5%) women had induction in control clusters and 12 (15.8%) in intervention clusters. Data on mode of birth were missing for 22 women. Infant outcomes including gestation, birthweight and head circumference were similar across trial arms.

When asked in the questionnaire about their symptoms of UI at pregnancy commencement, 24 women in intervention and 24 women in control clusters reported some degree of UI, although in most cases this was infrequent ([Table 2](#)).

Midwife support for performing pelvic floor muscle exercises in pregnancy

Women were asked in the questionnaire about midwife support for PFME in pregnancy. Overall, 73 (83%) women in the intervention and 54 (62.1%) in the control arms reported that their midwives had advised them to perform PFME. The critical information, however, and the main prespecified assessment of midwife support, was 'did your midwife explain how to perform PFME when pregnant?' and 57 (64.8%) of women in the intervention and 33 (37.9%) in the control arms reported that they had ([Table 3](#)). Thirteen (14.8%) women in the intervention arms reported that a midwife never talked to them about PFME; this figure was 30 (34.5%) women in the control arms. Other aspects of midwife support are shown in [Table 3](#).

TABLE 2 Women who leaked urine at the start of their pregnancy

How often did you leak urine at the start of your pregnancy?	Intervention (n = 88)	Control (n = 87)
Never	60 (68.1%)	61 (70.0%)
About once a week or less often	13 (14.7%)	12 (13.8%)
Two or three times a week	4 (4.6%)	6 (6.9%)
About once a day	3 (3.4%)	4 (4.6%)
Several times a day	4 (4.6%)	1 (1.2%)
All of the time	0 (0%)	1 (1.2%)
Can't remember	4 (4.6%)	2 (2.3%)

TABLE 3 Women's reports of midwife support for PFME in pregnancy, women's PFME practice and UI prevalence

Outcomes from questionnaire	Response	Intervention (n = 88)	Control (n = 87)
Key pilot outcomes			
Did your midwife explain how to perform pelvic floor muscle exercises when you were pregnant?	Yes	57 (64.8%)	33 (37.9%)
	95% CI	56.9 to 72.4 ^a	24.6 to 51.2 ^b
Women's predefined adherence in performing PFME in pregnancy ^c	Yes	43 (50.0%)	33 (38.4%)
	Missing	2	1
	95% CI	24.1% to 77.1% ^d	12.4% to 67.1% ^e
Prevalence of UI ^f	Yes	39 (44.3%)	47 (54.0%)
	95% CI	32.0% to 56.1% ^g	42.2% to 65.8% ^h
Further outcomes			
Did your midwife advise you to perform pelvic floor muscle exercises when you were pregnant?	Yes	73 (83.0%)	54 (62.1%)
Did your midwife give you a pack of information on pelvic floor muscle exercises when you were pregnant?	Yes	49 (57.7%)	17 (19.8%)
	Missing	3	1
When did your midwife give you the pack of information on pelvic floor muscle exercises?	Never given	35 (42.7%)	65 (77.4%)
	At first (booking) appointment	15 (18.3%)	10 (11.9%)
	At second antenatal appointment	15 (18.3%)	3 (3.6%)
	At later antenatal appointment	17 (20.7%)	6 (7.1%)
	Missing	6	3
How often did your midwife talk to you about pelvic floor muscle exercises when you were pregnant?	Never	13 (14.8%)	30 (34.5%)
	Only at booking appointment	20 (22.7%)	15 (17.2%)

TABLE 3 Women's reports of midwife support for PFME in pregnancy, women's PFME practice and UI prevalence (*continued*)

Outcomes from questionnaire	Response	Intervention (n = 88)	Control (n = 87)
	Occasionally	33 (37.5%)	22 (25.3%)
	Every antenatal appointment	18 (20.5%)	10 (11.5%)
	Can't remember	4 (4.5%)	10 (11.5%)
Did your midwife ever ask you if you had any difficulties with performing pelvic floor muscle exercises?	Yes	27 (31.0%)	8 (9.3%)
	Missing	1	1
Before you were pregnant, have you ever been taught or learned how to perform pelvic floor muscle exercises?	Yes	36 (41.4%)	39 (45.4%)
	Missing	1	1
How often did you perform pelvic floor muscle exercises when you were pregnant?	Never – not advised to	9 (10.2%)	18 (20.7%)
	Never – other reasons	9 (10.2%)	4 (4.6%)
	Few times a month	19 (21.7%)	27 (31.0%)
	Once a week	6 (6.8%)	4 (4.6%)
	Few times a week	23 (26.1%)	17 (19.5%)
	Once a day	11 (12.5%)	5 (5.8%)
	Few times a day	9 (10.2%)	11 (12.6%)
	Can't remember	2 (2.3%)	1 (1.2%)
Do you currently perform pelvic floor muscle exercises?	Yes	46 (66.7%)	45 (64.3%)
	Missing	19	17
How often did you do pelvic floor muscle exercises over the last month?	Never – not advised to	9 (10.2%)	12 (13.8%)
	Never – other reasons	10 (11.4%)	13 (14.9%)
	Few times a month	25 (28.4%)	23 (26.4%)
	Once a week	5 (5.7%)	4 (4.6%)
	Few times a week	24 (27.3%)	17 (19.5%)
	Once a day	6 (6.8%)	9 (10.4%)
	Few times a day	9 (10.2%)	9 (10.4%)

- a The 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 7 degrees of freedom.
- b The 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 6 degrees of freedom.
- c Women's self-reported adherence in performing antenatal PFME was assessed by response to the question: 'How often did you perform pelvic floor muscle exercises when you were pregnant?' and a binary outcome defined as 'yes' if the answer was 'few times a week' or 'once a day' or 'few times a day', and 'no' if the answer was: 'never, was never advised to', or 'never, other reasons', or 'few times a month', or 'once a week'. If the answer was 'can't remember' or was missing, then binary outcome was missing.
- d The 95% CI around the proportion who responded 'yes' was estimated after natural log transforming the data using cluster-level analysis, *t*-distribution with 7 degrees of freedom, and weighted by the cluster size.
- e The 95% CI around the proportion who responded 'yes' was estimated after natural log transforming the data using cluster-level analysis, *t*-distribution with 6 degrees of freedom, and weighted by the cluster size.
- f UI prevalence was determined by the question: How often do you leak urine? and defined as 'no' if the answer was 'never' and 'yes' if any other response.
- g 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 7 degrees of freedom.
- h 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 6 degrees of freedom.

Women's reporting of pelvic floor muscle exercise practice in pregnancy

The main prespecified assessment of undertaking PFME was the women's responses to the question 'How often did you perform pelvic floor muscle exercises when you were pregnant?', with PFME adherence in a manner likely to improve symptoms predefined as a few times a week or more (see [Table 3](#)). There were 43 women (50%) in intervention clusters who reported this level of adherence and 33 women (38.4%) in control clusters.

[Table 3](#) also shows whether they currently were performing PFME and how often they had done so in the last month: 39 (44.3%) women in intervention clusters reported performing PFME a few times a week or more during the month prior to completing the questionnaire and 35 (40.2%) in control clusters.

Women's confidence in performing PFME, assessed using PFMESES⁴², is shown in [Appendix 4, Table 14](#). Women's exercise adherence was further assessed using EARS⁴³ with adherence score a little higher among women in the intervention arm. As described earlier four items from the PFMESES were omitted rendering the full score invalid.

Prevalence of urinary incontinence and faecal incontinence

Based on women's completion of the ICIQ-UI SF⁴⁰ in the 10–12 weeks questionnaire, UI prevalence was categorised into a binary 'yes'/'no' outcome, and 39 (44.3%) intervention women and 47 (54%) control women reported they did leak urine (see [Table 3](#)). The full ICIQ-UI SF data are shown in [Appendix 4, Table 14](#).

Based on the RFIS,⁴¹ completed in the 10–12-week questionnaire, 15 women in intervention (18.1%) and 11 in control clusters (13.3%) reported FI. The full RFIS data are shown in [Appendix 4, Table 15](#).

Midwives' characteristics

Data relating to midwives' experience in the intervention and control clusters are shown in [Table 4](#). The number of years working as a midwife and as a community midwife were similar in intervention and control groups, and most midwives in both groups were band 6 level.

Limitations

Despite several initiatives, including a short questionnaire, translated versions, £10 voucher on questionnaire return and their midwife telling them that a questionnaire would arrive, the proportion of

TABLE 4 Midwives' characteristics

		Intervention (n = 73)	Control (n = 31)
Current midwifery band	5	3 (4.4%)	0 (0%)
	6	62 (91.2%)	26 (92.9%)
	7	3 (4.4%)	2 (7.1%)
	Missing	5	3
Number of years working as a midwife	n	68	28
	Mean (SD)	11.3 (9.2)	13.0 (9.5)
	Missing	5	3
Number of years working as a community midwife	n	68	28
	Mean (SD)	6.2 (6.4)	8.8 (7.7)
	Missing	5	3

women who returned a questionnaire was low. This proportion, however, was similarly low in both trial arms, and the characteristics of women in both trial arms were similar. The proportion of women who reported UI was higher than is generally found in studies, so it may be that more women who returned a questionnaire did so because they experienced UI.

Although the intention was, and trial protocol stated, that women may be 'offered other options of completing the questionnaire, including online or mobile-friendly versions', when online versions were explored with BCTU, their decision was that this was not possible without women's prior consent because University of Birmingham would then hold the woman's internet provider address (potentially identifiable data) and hence would not meet General Data Protection Regulations (GDPRs) requirements.

Not all the midwives completed questionnaires, and fewer did so in the control clusters. This may have been because of the lengthy (six-page) participant information leaflet and consent form that were necessary before coming to the questionnaire because of BCTU's requirements, which intervention midwives were familiar with. In addition, in both groups some midwives had technical difficulties accessing the questionnaire.

Another limitation was that the BCTU omitted to print four of the questions in the questionnaire from the PFMESES,⁴² which assessed women's confidence in their practice of performing PFME, so this scale was invalid.

The pilot and feasibility trial had been set up to assess whether a future definitive trial would be possible. However, as described in [Summary of alterations to the programme's original aims/design](#), a future definitive trial would not be possible due to changes introduced as part of the NHSE Long Term Plan to improve women's pelvic health. This meant that we were not able to go on to undertake a study to obtain the best evidence of effectiveness.

Inter-relationship with other parts of the programme

Work package 4.2 piloted the intervention developed in earlier WPs (WP1, 3 and 4.1) and ran in parallel with the trial process evaluation (WP4.3).

Work package 4.3: process evaluation

Aims

This WP explored the feasibility and acceptability of APPEAL training and implementation. Aims included identification of facilitators and concerns or challenges to implementation during the trial, and recommendations for refinement to the training in any subsequent practice implementation (see [Implications for practice](#) and [Appendix 12](#)). Four objectives listed in WP4.2 relevant to this WP are repeated here with additional details to reflect the theory of change presented in the logic model (see [Appendix 2, Figure 4](#)) plus a fifth objective. Objectives were to:

1. Provide training for community midwife teams randomised to the intervention arm to encourage incorporation of a PFME care package into their usual antenatal care.
2. Assess whether training, intervention implementation and trial processes were acceptable to midwives by identifying and investigating factors impacting on:
 - I. fidelity of training delivery to midwives by trainers
 - II. uptake of training by midwives
 - III. effectiveness of the training intervention for improving implementation of PFME by midwives in antenatal care
 - IV. fidelity of PFME intervention delivery to women by midwives.

3. Assess women's practice of PFME during and after pregnancy using women's postnatal questionnaire and interview data to evaluate potential effectiveness of the PFME intervention for improving women's practice of, adherence to, and confidence with PFME.
4. Assess midwife support for PFME in both trial groups using qualitative interviews with midwives and women, and women's questionnaire data, to inform feasibility, including possible acceptability of collecting outcome data from women.
5. Investigate possible intervention contamination between trial arms.

Methods

Multiple methods were used with qualitative and quantitative data sources and analytical methods (see [Appendix 5](#)). Research questions, methods used to answer questions, and data source and type are described and were mapped to relevant components of the process evaluation framework for designing and reporting process evaluations in cluster trials.⁴⁷ This mapping was tabulated (see [Appendix 5, Tables 16 and 17](#)) to show how the multiple methods of data collection fitted together to inform the overall analyses reported here. Reporting followed this sequence: first, the processes involving trial clusters (1a delivery to, and 1b response of, midwifery teams); second, the processes involving the target population of midwives (2a delivery to, and 2b response of, midwives); and third, for the target population of women (3a delivery to, and 3b responses of, women) to meet the first four objectives.

Key findings

Delivery to trial clusters (midwifery teams) (objective 1)

Training was delivered to midwives as intended (mean score 86.4%, SD 9.2%) for training session fidelity observed in the three sessions evaluated during the main training period (January–March 2021), although the first training session observation revealed lower fidelity to the training protocol (75.8%) compared to sessions observed later (92.4%).⁴⁸ Only minor refinements were needed: addition of a myth-buster slide, and adjusting the 'red flag' screening slide. Throughout the intervention period, 3750 resource packs were provided to intervention midwife teams.

Response of trial clusters (midwifery teams) (objectives 1 and 2)

Uptake of training was successful, with all 95 midwives working in intervention teams during the implementation period receiving training. Those on short-term sick leave were trained when they returned to work. Seven intervention team midwives were on long-term sick leave or maternity leave so did not work during the implementation period. In addition, 11 MSWs were trained because in some teams they provided translation for women who did not speak English. Each team recruited an APPEAL midwife champion.

Delivery to midwives and response of midwives (objectives 2 and 4)

Delivery and content of initial training sessions were evaluated⁴⁸ among the midwives ($n = 65/71$, 91.5% of those in the initial training phase). Most midwives reported acceptability for most training aspects, although some expressed preference for in-person training (see [Appendix 6, Tables 19 and 20](#)). Positive factors affecting acceptability of training delivery were: flexibility of booking in; offering training at different times of day/days of week; not having to travel to training session. Reasons for six midwives not completing the evaluation were internet connectivity or system login problems; none refused to participate.

Midwives showed clear increases in confidence about PFME following training, with median increase of at least 1 point (on a 0–4 scale) for each of the eight questions. A Wilcoxon signed-rank test produced z -scores for each question which were converted to p -values (see [Appendix 6, Table 21](#)). All p -values (< 0.001) indicated a significant change in confidence following training.

Champions were provided with a role description (see [Report Supplementary Material 3](#)) and found meetings useful for peer support. Champion activity was monitored and summarised (see [Appendix 7, Tables 22–25](#)). Interviews with intervention midwives revealed benefits of having a champion for

support and advice, and that self-nominated champions were more enthusiastic about the role, which was not regarded as a big commitment (see [Appendix 9, Table 29](#)).

At the end of the intervention period, an implementation evaluation questionnaire was completed by intervention midwives and MSWs ($n = 59$, 62% of those originally trained and remaining in team) (see [Appendix 8, Table 26](#)). Respondents self-reported which steps of APPEAL they delivered to women (never, few, some, most, or all, of the women): raising the topic (89%), giving the resource bag (68%), teaching a PFME contraction (68%), and practising a contraction in antenatal clinic (45%) with most/all of the women. In free-text space (see [Appendix 8, Table 27](#)), respondents also reported the APPEAL resource bag ($n = 31$), prompt cards ($n = 17$) and team champions ($n = 16$) as being the most important resources to support implementation. The top three most reported barriers to implementation were: 'lack of time' ($n = 39$), 'forgetting' ($n = 29$), and 'language barriers' ($n = 26$), with 'other priorities' and not being on maternity record system 'to act as a prompt' also mentioned. Midwives ($n = 18$) reported making 44 referrals to physiotherapy services.

Interviews were conducted with a sample of intervention midwives ($n = 13$) during trial implementation (see [Appendix 9, Table 28](#)). Responses to initial structured questions about acceptability, engagement, knowledge, attitude and suggestions to improve training are shown in [Appendix 9, Table 29](#). They indicated positive responses (see [Appendix 9, Table 30](#)): 'I'm enthusiastic about it' and 'it's a very good fit' (with personal and professional values) and importance to women; it was perceived to be effective ('I think it should help get that message across') and to increase personal self-efficacy ['I do feel confident' (about the intervention)]; and it made sense ['I've never thought about the impact of pregnancy on the pelvic floor' (before the training)]. However, there was some ambivalence – the burden of delivery ('it just feels a bit impossible') mainly due to workload volume, limited appointment time, system pressures, remembering everything and opportunity costs ('so many other priorities') – and a sense of hopefulness rather than certainty, with some concerns that midwives would not be able to put it into practice or that women would not do it (see [Appendix 9, Table 31](#)).

Post-trial interviews were conducted with a sample of intervention ($n = 6$) and control midwives ($n = 12$) (see [Appendix 10, Tables 32 and 33](#)). Findings from intervention midwives reiterated their positive experiences of the training but there was an increasing inconsistency with implementation as time passed since training. Control midwives reported a range of previous PFME experience, from no PFME training to extensive knowledge, but they confirmed lack of consistency for implementing into standard care. Control midwives reiterated earlier WP findings regarding the challenges of teaching PFME and how to best support implementation (see [Appendix 10, Table 33](#)).

Delivery to women and response of women (objectives 3 and 4)

Considering responses of women in the intervention group who returned the trial outcome questionnaire (see [Table 3](#)), it is clear that delivery to women did often occur: most indicated that they were advised to do PFME by their midwives (83%); many were taught how to do PFME (64.8%) and given a resource pack (57.7%); and some reported that their midwives talked to them about PFME occasionally (37.5%) or at every appointment (20.5%). All these figures were higher than responses made by women from the control group, suggesting an impact of APPEAL implementation, with trained midwives delivering more PFME teaching and support than was occurring in standard care during the same period.

Findings from post-trial interviews with women (intervention $n = 13$, control $n = 16$) (see [Appendix 11, Tables 34 and 35](#)) revealed that some aspects of PFME advice were delivered in both groups, but it was apparent that remembering was problematic. Intervention group women recalled specific APPEAL resources: the bag, leaflet or App QR codes (see [Appendix 11, Table 36](#)). A much stronger and more consistent finding from all interviews (including midwives' interviews) was consensus acknowledgement of the importance of understanding why and how to do PFME and that an APPEAL-type intervention is what is wanted.

Reflecting further on the WP4.2 results, 50% of intervention group women self-reported practice of and adherence to PFME during pregnancy (see [Table 3](#)), indicating a degree of fidelity to the intended APPEAL intervention (see [Appendix 5, Table 18](#)). Dilution of fidelity was not unexpected: both quantitative and qualitative data sources indicated some midwives did not deliver the APPEAL intervention fully and even when it was delivered, some women did not change their behaviour to do PFME. However, women's level of PFME adherence was higher than the standard care group women reported (see [Table 3](#)). Differences in PFME adherence levels between intervention and control groups were similar to the differences these groups reported regarding receipt of information and support from their midwife to do PFME (see [Table 3](#)). As these results are all aligned, it suggests that an explanatory factor for the observed between-group differences is the APPEAL intervention training and implementation. Although women's responses reported imperfect fidelity for intervention delivery, there was an indication that PFME adherence by the intervention group had been sufficient for more women to report benefits in UI symptoms than those receiving standard care. Such promising findings indicated APPEAL was facilitating required behaviour changes, but more work is needed to optimise and synchronise these change processes at all levels: services, midwives and women.

Feasibility and acceptability of collecting outcome data from women (objective 4)

Only a small proportion of women (17.5%) returned the questionnaire; therefore, as already described, a future trial would not be feasible. However, most respondents completed the questionnaire fully. Furthermore, a very high proportion (132/175, 77%) indicated permission to be approached for follow-up interview. We cannot determine whether low questionnaire return rates were due to the burden imposed by the data collection method (paper-based, requiring return by prepaid post) or to that imposed by the questions asked. However, the lack of missing data in returned questionnaires suggests that to increase return rates in any future evaluations the first step would be to improve data collection methods (e.g. using mobile phones) rather than changing the number and type of questions.

Contamination between trial arms (objective 5)

Minimal evidence of between-group contamination was found in the post-trial interviews with midwives and women. There was an occurrence of one midwife who changed from intervention to a control team, but this occurred very late in the intervention period. There was no indication from interviewed women assigned to standard care that any received resources badged as APPEAL, but some did report receiving advice about PFME (as per standard care).

Limitations

The APPEAL training was adapted for remote delivery due to NHS requirements in response to COVID-19 that researchers could not meet staff on site, and while this was acceptable to most midwives, some would have preferred in-person training. We cannot assess whether in-person training would have resulted in higher levels of implementation, but evaluations of the training itself were positive.

Several processes were compromised by factors outside the control of the researchers, for example: internet problems (for midwives completing online consent forms and questionnaires); excessive length of information sheets (prescribed by BCTU) affecting time available for midwives to complete the implementation questionnaire and inability to offer the women's questionnaire electronically (due to BCTU consideration of data protection requirements); failure to include all items of the self-efficacy scale meant this theory of change could not be evaluated; and delays resulting from hospital trust governance policies in obtaining women's contact details for interview increased the time lag for women to recall their antenatal care.

Inter-relationship with other parts of the programme

Work package 4.3 was mainly informed by WP3 but also WP1 and WP4.1 and ran in parallel with WP4.2. Findings from WP4.3 showed that during the pilot feasibility trial (WP4.2) the APPEAL intervention was delivered to midwives as planned and that they responded with positive evaluations of their training. This increased midwives' confidence regarding teaching of PFME to

women in their care and there was evidence from WP4.3 findings that some midwives changed their practice behaviour, which also translated into some women changing their behaviour (WP4.2 results). As reported in earlier WPs, the main challenge with delivering the intervention was lack of time in appointments, suggesting that service-level constraints still need to be addressed in any post-programme implementation.

Account of involvement of patients and the public

The APPEAL team aimed to embed patient and public involvement throughout the programme, from funding application preparation (2012–4) to dissemination (2022). Multiple methods were used depending on work stage: an existing adviser joined the co-applicant team to help prepare the application; an adviser joined the programme steering group (2016–22); a local group ($n = 7$) was convened to support WPs 1 and 3 (2016–8); and there were further groups for WP 4 (2022).

We used a variety of approaches to facilitate engagement during the early WPs. We used in-person 'focus group' style community meetings ($n = 9$) to incorporate women's perspectives into the research process, with mothers able to bring their children to facilitate engagement. We held a citizens' jury style event to select electronic resources, and there was wider public consultation in the form of a national stakeholder event with 20 delegates representing 18 UK organisations with an interest in maternity services (including APPEAL public advisers, clinicians, charities, and health professional bodies) to inform and help endorse implementation. Subsequently, when COVID-19 impacted, we held small-group follow-up meetings virtually to review results of WP4 and help plan dissemination.

Impact was highly positive. Our co-applicant adviser designed the waterdrop logo, after consulting with pregnant women who were clear the logo should not depict a baby or pregnant mother as they did not want to 'blame the baby' for incontinence. During WP1 ethnography, public involvement was an integral part of the process, ensuring the research was relevant and important to them. The seven women were from an established mother and toddler group at a community centre and remained as advisers throughout this WP. They represented a diverse socioeconomic group, but we were not able to recruit a diverse ethnic group. This group's input had direct impact on the ethnography: they critiqued interview schedules, discussed challenges of implementing PFME into antenatal care, and contributed to emerging themes. During WP3, advisers co-developed resources for women: a citizens' jury style event considered what smartphone apps should be included; advisers helped design the women's leaflet and recommended that all resources be contained in a cloth bag big enough to hold a clean nappy. Following the practice training event (for midwives), the advisory group contributed to improving the video clips used for the training. Wider impacts have arisen from the huge enthusiasm we experienced from our advisers: additional public advisory groups were convened to discuss implementing APPEAL-style education for teenagers and young women (i.e. before pregnancy) and more recently to support related funding to implement APPEAL-style training into primary care.

Public involvement was critical to ensuring we met our aim to embed patient and public perspectives from the outset. It informed the content of what resources women received during antenatal care and what they said they needed from their midwives.

Reflections on our public involvement work included a strong sense that our research was doing what mattered: that what we were asking of pregnant women (and midwives) was not just evidence-based but reflected what mattered to them. By including them in all the development work and choice of resources, we had an intervention and supporting materials that had credibility and would be acceptable and feasible for pregnant women and midwives to make use of, and we would not be asking too much of these busy people. We also benefitted from working with the highly experienced Peninsula Applied Research Collaboration (ARC) and ARC West Midlands public involvement teams who supported recruitment and running of our local activities.

The degree of contributions and commitment from the public were also important for motivating the research team when hitting barriers to progressing the research (funding review, COVID-19 pauses and lockdown complications, governance, and data collection/data access issues). These problems impacted our ability to sustain, during WP4, the high level of public involvement achieved in earlier WPs. Sustainability was also an issue from the representativeness perspective, in that over the 10 years from inception to completion of APPEAL our advisers were not always going to be recent antenatal care recipients; and after serving a period of time, the co-applicant adviser did resign. Thus, there is a trade-off between achieving continuity in representation versus ongoing recruitment of newly pregnant women, which we partly overcame by having criteria to include women who had recently experienced antenatal care (toddlers under 5 years) and keeping the invitation open to anyone who wished to remain.

Several of our earlier advisers remained and, with new recruits, have helped plan dissemination. In this they have made many suggestions (see [Appendix 12](#), [Tables 37](#) and [Table 39](#)) for how we can get the main messages of APPEAL into the public space, rather than for people to necessarily attend dissemination events which they felt could be too much of a time burden. Examples of their suggestions include: videos and posters for women's health events, GP surgeries, back of toilet doors and TV adverts; to approach charities, incontinence product suppliers (e.g. TENA®) and folic acid vitamin suppliers to include key PFME messages, including QR codes for further information; and for midwives to wear badges saying 'Have you done your PFME?'. Finally, the group reviewed the Lay Summary and Abstract of this report, and one adviser also reviewed the Scientific Summary. We thank members of the APPEAL public advisory group for their insights and commitment.

Reflections on what was and was not successful in the programme

What was successful?

Our major success within the programme was that we have developed an intervention of training midwives to advise and support women in undertaking PFME which most midwives were able to implement, in full or at least in part, within routine antenatal care. Almost 100 midwives were trained in our programme, and our evaluation showed that their knowledge and confidence after the training were substantially increased relative to before training.

We feel that this success was based on having a large multidisciplinary international research team that comprised academics with experience in childbirth-related incontinence, psychologists, qualitative researchers, trialists, clinical experts (obstetric physiotherapists, midwives, obstetricians and GPs) and implementation scientists. Our international collaborators included a world-leading academic obstetric physiotherapist in PFME (Jean-Hay Smith from New Zealand), who has led several Cochrane Reviews on PFME. We were also able to co-opt another world-leading clinical academic expert on pelvic floor function and dysfunction (Helena Frawley, University of Melbourne) part way through the programme.

Due to the commencement of the NHSE Ten-Year Long Term Plan, there have been new 'early adopter' and 'fast follower' perinatal pelvic health services funded in 23 LMNSs across England, and we have been able to use our findings in implementation work sooner than would typically be the case. To date, around 170 specialist health professionals from these LMNSs have attended workshops we have provided for them to consider how they might adopt the APPEAL training intervention for midwives in their areas.

We managed to include substantial PPIE and stakeholder engagement at various stages, as described above.

We have won conference prizes with our abstracts, specifically at the International Continence Society which leads multidisciplinary continence research and education worldwide. We have also been successful in obtaining NIHR School of Primary Care funding for spin-off research to develop a similar intervention for use in general practices.

What was not successful?

In attempting to do PFME, we know that some women are unable to locate their PFMs. Our attempt to find a diagnostic test to assist midwives in assessing whether women were able to locate their PFMs was not successful. A comprehensive systematic review was undertaken but failed to find a single diagnostic test for use in this way.

The other lack of success was our ability to obtain a high return rate from questionnaires sent to women. This, together with the NHS Long Term Plan roll-out, means that we would be unable to undertake a full cluster RCT as originally planned.

To obtain the highest possible return rate, we had hoped to be able to use optional online questionnaire completion methods as women in earlier WPs had recommended. However, BCTU protocols meant that they would not allow us to provide this online version. The reason was that women's consent to take part was by returning a completed questionnaire and completion by using online questionnaire methods would have allowed each woman's IP address to be detected, hence it was not considered to be compliant with GDPR. The APPEAL team were extremely disappointed by this. Since COVID-19 and lockdown, people's use of online methods has become even more prevalent, and it was considered that many women busy with young babies would have preferred it and had it been available a higher proportion of questionnaires would likely have been returned.

Reflections on issues relating to equality, diversity and inclusion

Participant representation

There were two main sets of participants in our research: the midwives who provided antenatal care and the PFME intervention to the women, and the women included in the trial.

We included all midwives who were employed to deliver antenatal care by the Trusts where the trial was undertaken. These participants were all women and ranged in terms of their ages and ethnic backgrounds. All those in the intervention team clusters received the APPEAL training and, among those who completed training evaluation and included demographic details, there was a wide range of ethnic and age groups.

It was realised early on in training the midwives that in caring for women who did not speak English, MSWs in their team would assist in translating or interpreting, and would hence be involved in care. In the teams where this occurred, we also trained a small number of MSWs so that they could assist in intervention delivery for non-English-speaking women.

In sending out the questionnaires, to maximise the likelihood that non-English speakers could participate, we translated the main parts of the questionnaire into the four main languages prevalent in the local areas.

Research team

Our co-applicants were mostly women, with only three males. None were from ethnic minority groups. Among the researchers appointed to the work, all were women and two were from an ethnic minority group. There was a wide range of expertise and experience, including both clinical and non-clinical backgrounds, in the team. Junior research staff were encouraged and supported to develop their expertise through mentoring from senior team members and supported to attend training opportunities. One research midwife was appointed to a senior position in the Royal College of Midwives. Another research midwife has just been successful in obtaining an advanced NIHR fellowship. Another research midwife has been appointed to another NIHR programme research post. Another junior staff member has obtained promotion to another organisation. The team supported five interns to undertake some of the research, one of whom was successful in having an abstract and presentation of her APPEAL programme work accepted at a prestigious international conference.

The PPIE representatives included during the research were all women because we wanted lived experience of pregnancy. Steps were taken to ensure that we included representatives from underserved populations, in terms of women living in deprived areas and ethnic minority groups. We were successful in the former but, despite our efforts, only had limited ethnic minority representation.

Limitations relating to the method or execution of the research

Limitations in the research methods varied for the different WPs in the programme. In the critical interpretive synthesis review in WP1.1, the quantitative studies found were limited by small sample size, few details regarding reasons for declining participation, lack of details regarding calibre of survey tools/outcome measures, and variable response rates. For qualitative studies, many did not consider the impact or relevance of contextual factors or demonstrate reflexivity.

Ethnographic research in WP1.2 suffered from the general limitation of this methodology: that the presence of a researcher can impact the behaviour of those being observed. This could result in the midwife care observed in relation to PFME being more extensive than would usually occur in their practice. In terms of our interviews, a limitation throughout was that we were not able to interview women who did not speak English.

In WP2 the lack of any studies to assist in assessment of PFM localisation that might be used to assist in the trial intervention was an obvious limitation such that any inclusion of assessment of correctness of pelvic muscle contraction was not possible.

The main limitations of WP3 were the challenges identified by midwives regarding wider system pressures, and time constraints within clinic appointments limiting the range and complexity of the intervention that could be produced. Despite these constraints, midwives and women believed that implementing PFME in routine antenatal care would be beneficial for many women.

Once we reached WP4, the main limitation was the low proportion of women who returned a trial questionnaire. As described earlier, in the data collection pilot (WP4.1) the return rate from women was 31% at the 'data lock' point, rising to 35% with latecomers, in keeping with other recent post-partum studies.^{2,3} The original application had proposed a much higher return rate, so the second stage of the programme was amended to a feasibility and pilot cluster trial with substantial additional process outcomes (WP4.3), still with the aim of consideration of a full cluster trial to follow. The return rate in the feasibility trial was even lower, at only 17%, though with balance between trial arms, meaning that a trial with the same design would not have been worthwhile. We had not been allowed by the BCTU to try to increase return rate by using online data collection methods due to GDPR concerns (see [What was not successful?](#)). However, because of the new perinatal pelvic health service being established by NHSE, the cluster trial originally planned would not anyway have been possible in view of the change in the standard care comparator; a definitive randomised controlled cluster trial would have provided best evidence of effectiveness of the APPEAL intervention. Evidence on how this new perinatal pelvic health service should be developed, however, is minimal, such that even with the limitation of a low questionnaire return rate from women, the overall findings and outputs of the APPEAL programme will make an important contribution to assist in the new service development.

Conclusions from the whole programme

This programme has demonstrated that training and resourcing standard antenatal care midwives appropriately to support women to undertake PFME in pregnancy is feasible, acceptable and could improve PFME adherence and reduce post-partum UI. To do this required the development of a complex intervention to influence behaviour change at two levels: the midwives and the women. Although there

were limitations in the programme as described above, this probably represents the best available evidence on whether it is feasible to embed a PFME intervention in standard antenatal care in England.

Recommendations for future research

It is now no longer possible to undertake a future definitive RCT in England, because of the changes occurring as part of NHSE's new perinatal pelvic health services. Numerous 'early adopter' and 'fast follower' local maternity systems are in the process of setting up this new service, and we have already provided some with our intervention package. More research evaluation is required to follow up on this and we are proposing working with NHSE to assist in undertaking this. It may be that a future definitive RCT could take place in other similar maternity care settings internationally, such as Australia or New Zealand, or in other parts of the UK.

Research is also needed to evaluate the adaptation and roll-out of PFME training to other HCPs so that others as well as midwives can provide appropriate pelvic health care for women across their life course (in accordance with the NHS Long Term Plan). Finally, women and midwives have consistently told us that they think the prevention of UI should be raised with much younger women; this concurs with recent National Institute for Health and Care Excellence (NICE) guidance about pelvic floor dysfunction which recommends research into promoting this topic in schools.⁵⁰

In view of our findings in WP2 that there was no diagnostic test to help midwives identify whether women can locate their PFMs and the knowledge that some women are not able to locate these muscles, this is an area of practice in which further research is needed. In addition, it may have been that explanation of how to contract the pelvic floor given by the midwives would have been more difficult for women whose first language was not English. This is another area for further research; although we did train MSWs who were able to speak other languages to reduce the impact of this, other methods need to be investigated.

Implications for practice

The programme of work undertaken for APPEAL shows much promise for changing the practice of midwives who are clearly keen to do this and, after receiving the APPEAL training, much more confident to take on this role. As is often the case in this type of research, the APPEAL team cannot claim that optimal behaviour change occurred for all midwives. There were various barriers for midwives in attempting to change their practice at service and policy level. With the changes now happening as part of the NHSE new perinatal pelvic health services, many of the opportunities for optimising implementation into practice, raised by midwives and women during the APPEAL programme, could be actioned. For midwives, priority for PFME care, prompts on maternity record systems, regular training updates, and improved understanding of what happens in physiotherapy consultations to aid interprofessional communication are some examples. Women wanted resources to be more accessible, for example, digital format for leaflets and app card, videos in clinic waiting rooms, and reminder texts between appointments (see [Appendix 12, Table 39](#)).

Our promising findings indicate the APPEAL intervention is operating on the right lines. With imminent changes to NHS service provision, there is now opportunity to optimise behaviour change by both midwives and the women they care for. Supporting all pregnant women to do their PFME, by implementation of APPEAL, has potential for reducing UI for large numbers of women.

Additional information

Contributions of authors

Christine MacArthur (<https://orcid.org/0000-0003-0434-2158>) (Professor of Maternal and Child Epidemiology) was chief investigator and, with the help of other co-applicants, conceived the programme. She supervised the Birmingham-based research team and took overall responsibility for the programme. She led the writing of this final report.

Debra Bick (<https://orcid.org/0000-0002-8557-7276>) (Professor of Evidence Based Midwifery) was midwife lead involved in conceiving the programme, chief investigator for the pilot and feasibility trial in WP4.2 and contributed to the writing of this final report.

Victoria Salmon (<https://orcid.org/0000-0002-1536-4750>) (Research Fellow) was involved in the research in WP1, WP3 and WP4.3, led the design of the training intervention and resources for midwives and women and assisted in the preparation of this final report.

Ellie Jones (<https://orcid.org/0000-0003-2552-8322>) (Research Midwife/Fellow) was involved in conducting the pilot and feasibility cluster trial in WP4.2 trial, training intervention midwives, supporting Trust research midwives and assisted in the preparation of this final report.

Jean Hay-Smith (<https://orcid.org/0000-0002-9009-2812>) (Professor in Rehabilitation and Professor in Women's Health, University of Otago, New Zealand) was involved in conceiving the programme, contributed across the programme, attended the National Stakeholder event, contributed the mobile phone app review in the APPEAL resources for women and commented on the draft report.

Jon Bishop (<https://orcid.org/0000-0003-1789-5886>) (Trial Statistician) undertook the analyses in WP4.1, supervised the analyses of the pilot and feasibility cluster trial in WP4.2 and contributed to the writing of this final report.

Eleni Gkini (<https://orcid.org/0000-0001-8083-2947>) (Trainee Trial Statistician) undertook the pilot and feasibility trial analysis in WP4.2 supervised by the other statisticians, was involved in preparing the report of WP 4.2 and commented on the draft report.

Karla Hemming (<https://orcid.org/0000-0002-2226-6550>) (Professor of Biostatistics) was co-applicant and senior statistician with specific expertise in cluster trial analysis; was responsible for this methodology and commented on the draft report.

Sara Webb (<https://orcid.org/0000-0002-4924-3017>) (Head of Research at Royal College of Midwives) was research midwife in the earlier parts of the programme, was lead for WP4.1 and commented on the draft report.

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Tim Coleman (<https://orcid.org/0000-0002-7303-4805>) (Professor of Primary Care) gave expert support of behaviour change and trial methodology and general support across the programme and commented on the draft report.

Rohini Terry (<https://orcid.org/0000-0003-4188-8504>) (Research Fellow) was involved in the research in WP1.2, supported the intervention development and practice training event (WP3), was involved with interviews in WP4.3 and assisted in the preparation of this final report.

Libby Edwards (<https://orcid.org/0000-0001-9380-7732>) (Research Midwife) was involved in training the intervention midwives in WP4.2, assisted with interviews in WP4.3 and supporting Trust research midwife work and commented on the draft report.

Helena Frawley (<https://orcid.org/0000-0002-7126-6979>) (Associate Professor, Women's Health Physiotherapy, University of Melbourne, Australia) contributed expert advice on intervention development and delivery, attended the National Stakeholder event, contributed to the APPEAL video resources for women and commented on the draft report.

Eivor Oborn (<https://orcid.org/0000-0003-0566-4327>) (Professor of Implementation Science) gave expert implementation science support across the work of the programme and commented on the draft report.

Sarah Dean (<https://orcid.org/0000-0002-3682-5149>) (Professor of Psychology Applied to Rehabilitation and Health) was involved in conceiving the programme, led the Exeter-based research in WP1, WP3 and WP4.3, supported the research in WP2 and WP4.2 and co-ordinated the international team involvement. In addition, she is senior author of this final report.

Acknowledgements

We would like to thank all the midwives who took part in the intervention, all the women who returned the questionnaires and all other participants and Trusts who supported the programme in various ways.

The study team acknowledges the study delivery support given by Birmingham Clinical Trials Unit, in particular William McKinnon and Mary Nulty.

We also acknowledge the work undertaken by early-phase researchers Lucy Hope, Rachael Jarvie and Chidubem Okeke Ogwulu and by students on supervised research placements with the University of Exeter team: Lauren Chandler, Alex Sherrell, Saskia Chapman, Clodagh Smith and Rohan May.

We acknowledge the support by the NIHR Applied Research Collaborations in the West Midlands, Southwest Peninsula, and South London.

Patient and Public Advisory Group members

Thanks to the APPEAL public advisory group for their ongoing valuable contribution and commitment to this project. Thanks to the PenARC Public Involvement Team, researchers Kate Boddy and Emma Cockcroft, for their support recruiting PPI members, setting up and running the PPI advisory group meetings.

Programme Steering Committee members

Professor Nadine Foster (Chair) Professor Suzanne Hagen, Professor Helen Cheyne, Ms Sarah Skinner.

National Stakeholder Group members

We would like to thank the women, healthcare professionals and the following organisations for their contribution to the national stakeholder consultation event: Birmingham Women's and Children's NHS Foundation Trust (Grete Drewett, Sue Smithson); Camden Clinical Commissioning Group; Chartered Society of Physiotherapy; Gusset Grippers (Elaine Miller); Mumsnet; Mumsnet guest blogger (Sarah

Haselwood); National Childbirth Trust; NHS Education for Scotland (Helene Marshall); NHS England, Head of Maternity, Children and Young People (Jacqueline Dunkley-Bent); NHS England Maternity team (Clare Capito); Pelvic, Obstetric and Gynaecological Physiotherapy; Royal College of Midwives President (Kathryn Gutteridge); Royal College of Midwives professional adviser for education (Gail Johnson); Royal College of Obstetricians and Gynaecologists (RCOG); RCOG Women's Voices; Sandwell and West Birmingham NHS Trust; University Hospitals Birmingham; Virgincare/University College London (Health visitor).

We would also like to acknowledge Professor Jane Daniels, Professor Tracy Roberts, Professor Doug Tincello, Dr Clare Davenport and Ms Joanne Kidd-Chadwick who were involved as co-applicants in the first stage of the programme but did not continue into the second stage of the work.

Data-sharing statement

All data requests should be submitted to the corresponding author for consideration. Access to anonymised data may be granted following review.

Ethics statement

Ethics statements have been included in the WP to which they are relevant.

Information governance statement

The University of Birmingham and The University of Exeter are joint data controllers and are committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679.

Under the Data Protection Legislation The University of Birmingham is the Data Processor and the Data Controller for information relating to midwife participants' data and we process personal data in accordance with their instructions. The University of Birmingham is the Data Controller and Data Processor for information relating to outcomes of pregnant participants' data. The University of Exeter is the Data Processor and the Data Controller for information relating to midwife participants' data including audio files/transcripts arising from the telephone interviews. Birmingham Women's and Children's NHS Foundation Trust is also a Data Processor for information relating to outcomes of pregnant participants' data.

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Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at <https://doi.org/10.3310/TJDH7946>.

Primary conflicts of interest: Christine MacArthur was a member of the NIHR Policy Research Units Commissioning Panel 2017–8 and 2022–3 and declares NIHR funding grants (NIHR202869,

NIHR129182 and NIHR200165). Sarah Dean is on the NIHR Programme Grant for Applied Research funding Panel Committee and The Stroke Association Funding Panel and declares NIHR funding grants (NIHR151938, NIHR204099, NIHR202020, NIHR201038, NIHR201070 and NIHR 200428). Debra Bick was a HS&DR Researcher-Led Panel Member (1 April 2020–30 April 2023) and is Chair of Trustees of MASIC charity and declares NIHR funding grants (NIHR202172, NIHR206660, NIHR202165, NIHR134298, NIHR150979, NIHR131250, NIHR131352, NIHR128721, NIHR16/77/02 and NIHR131161). Victoria Salmon has received funding from the Academic Health Science Network South-West to develop video resources related to APPEAL Grant. Ellie Jones has received a NIHR Advanced Fellowship (NIHR1906817). Rohini Terry declares NIHR funding grants (NIHR204030, NIHR151938, NIHR856766 and NIHR200428). Mark Pearson is a member of the NIHR HS&DR Funding Committee and declares NIHR funding grants (NIHR 131606, NIHR132931, NIHR135128, NIHR206122, NIHR203682, NIHR158758, NIHR203123, NIHR204349, NIHR204312 and NIHR206252). Karla Hemming declares NIHR funding grants (NIHR204156, NIHR202826 and NIHR203062). Tim Coleman is on the NIHR HTA Clinical Evaluation and Trials Committee (2015–9), Programmes for Applied Health Research Committee (2022 to date) and NIHR Research for Patient Benefit Committee (2022 to date) and declares NIHR funding grants (NIHR129210, NIHR206513, RP-PG-0109-10020 and RP-PG-0615-20003).

Publications

Salmon V, Hay-Smith J, Jarvie R, Dean S, Oborn E, Bayliss S, *et al.*; APPEAL study. Opportunities, challenges and concerns for the implementation and uptake of pelvic floor muscle assessment and exercises during the childbearing years: protocol for a critical interpretive synthesis. *Syst Rev* 2017;**6**:18. <https://doi.org/10.1186/s13643-017-0420-z>

Salmon VE, Hay-Smith J, Jarvie R, Dean S, Oborn E, Bayliss SE, *et al.* Opportunities, challenges and concerns for implementing pelvic floor muscle assessment and training during childbearing years: a critical interpretive synthesis. ICS conference, Florence Sept 2017. *Neurourol Urodyn* 2017;**36**:S280–1. <https://doi.org/10.1186/s13643-017-0420-z>. **Won best scientific abstract prize for health services research.**

Hay-Smith J PL, Farmery D, Dean S, Grainger R. Apps-olutely fabulous? – the quality of PFMT smartphone app content and design rated using the Mobile App Rating Scale, behaviour change taxonomy, and guidance for exercise prescription. ICS 2019 Gothenburg Scientific Programme. *Neurourol Urodyn* 2019;**38**:S1–532. <https://doi.org/10.1002/nau.24118>

Terry R, Jarvie R, Hay-Smith J, Salmon V, Pearson M, Boddy K, Salmon V, Pearson M, MacArthur C, Dean S. Are you doing your pelvic floors? An ethnographic exploration of discussions between health professionals and pregnant women about pelvic floor muscle exercise during pregnancy. International Continence Society (ICS) Conference 2019, Gothenburg. *Neurourol Urodyn* 2019;**38**:S1–532 <https://doi.org/10.1002/nau.24118>.

Terry R, Jarvie R, Hay-Smith J, *et al.* 'Are you doing your pelvic floor?' An ethnographic exploration of the interaction between women and midwives about pelvic floor muscle exercises (PFME) during pregnancy. *Midwifery* 2020;**83**:102647. <https://doi.org/10.1016/j.midw.2020.102647>

Salmon V, Hay-Smith EJ, Jarvie R, Dean S, Terry R, Frawley H, *et al.* Implementing pelvic floor muscle training in women's childbearing years: a critical interpretive synthesis of individual, professional, and service issues. *Neurourol Urodyn* 2020;**39**(2):863–70. <https://doi.org/10.1002/nau.24256>

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Dean S, Salmon V, Terry R, Hay-Smith J, Frawley H, Chapman S, *et al.*; on behalf of the Research Programme Team. Teaching effective pelvic floor muscle exercises in antenatal care: design and development of a training package for community midwives in the UK. ICS Conference 2022, Vienna. **Won Best in Category prize.** *Continence* 2022;**2**:100204. <https://doi.org/10.1016/j.cont.2022.100204>

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Appendix 1 Work package 3 phase 1 focus groups: quotes from four themes arising from the focus groups with women and midwives

Major theme	Subtheme	Example data
1. 'Knowing' about PFME and UI	1.a What: Information/guidance required by midwives and women about pelvic floor health	... a reminder about the anatomy of the muscle structure, I know it sounds really back to student days but it's quite complex and that ... which would be a good prompt as to why it's so important because of its complexity. Midwife, FGMid1a ... understanding what the pelvic floor is and does ... like, how pregnancy affects it, how age affects it as well is, kind of, quite important. Woman, FGW2
	1.b Why: Importance of PFME and its relationship to pelvic floor health	... you really want to know why are you doing them [PFME], you don't just want to be told that you should be doing this because you want to know why you should keep doing them afterwards, why you should do them during pregnancy, [...] and what the consequences can be if you're not doing it. Women, FGW1b At the end of the day, whatever we can do that saves the NHS some money down the line, it's worth investing in us being given the time to have the training, because potentially we're saving tens of thousands with a woman having surgery later on in life because of something that could potentially have been prevented. Midwife, FGMid1a
2. 'Doing' PFME	2.a How to teach/ assess/perform PFME	Technique (Midwife) It's knowing that you've got the correct information, because there is no sort of formal anything at the moment [about teaching PFME]. There's no updates, there's nothing. (Midwife) And the best way to teach them [PFME]. [...] So if you know it's actually the right way, then you're probably more confident. Midwives, FGMid1a Explaining which bits you should feel tightening and which bits you shouldn't because I've, I don't know, I've heard all kinds of things about how your tummy should be tensed or your tummy should be relaxed or this should be this and this. Woman, FGW1b Assessment I think that [pelvic floor assessment skills] would be useful, it would be useful for any midwife to have that [...] knowledge and understanding wouldn't it, so that she could use it with women, yeah. Midwives, FGMid2 I wouldn't ever [do a vaginal assessment], that to me is a completely unnecessary internal examination. Midwife, FGMid1b I think they [midwives] need to have it [PFME assessment] in their repertoire to be able to do really [...] If you have someone who says, 'Actually, I don't get it', you know, 'I don't mind you examining me'. Woman, FGW1a
	2.b When to teach PFME	I think you have to mention it [PFME and UI] at booking because it gives it importance ... if you don't it's 'Oh it's something that's not bothered until now'. Midwife, FGMid1a Almost the initial talk about it [PFME/UI] has to be quite gentle so it might be at your booking appointment, yeah, you mention it and say perhaps you'd like to go and look it up, here's the website or whatever, at our next appointment perhaps we'll go through it, you know, or if you've got any questions and sort of feed it through, maybe like a drip feed at the beginning sort of and put that idea in there that it might be something that's really important, obviously say about the consequences but even if you're embarrassed by something it might get you thinking. Woman, FGW1b
3. 'Remembering' PFME	3.a Prompting engagement and participation in PFME by women, and implementation of PFME teaching by midwives	... a little reminder at each appointment to say, are you remembering to do them because I find that every time. I kind of need a reminder and then I start doing them for a while and then it kind of fades out and I lose track. Woman, FGW1b I also struggle without a prompt when somebody says, do something twice [e.g. being asked to teach PFME], like I'll remember the first time without a doubt but if you've not told me when to do it the next time and some kind of prompt on that appointment then I will have every intention of doing it, but I will likely forget. Midwife, FGMid2

Major theme	Subtheme	Example data
4. 'Supporting' PFME implementation and delivery	4.a Methods and resources to deliver information and training to midwives and information to women	<p><u>Delivery of information to women:</u></p> <p>Multimedia visual resources I suppose like a properly done video of some sort, you wouldn't have to take up any more time in your appointments then, you could watch the videos [. . .] like you'd get on the NHS website or something. Woman, FGW1b The other thing, I know in some waiting rooms they've got screens up, would it be worthwhile [. . .], if you had just a short video with your pelvic floor exercises, [. . .]. And probably a conversation starter as well with them, did you see the video, and if there's a link that we can provide for them, for that video. Midwife, FGMid2</p> <p>Leaflets I, personally, prefer, like, a leaflet or something, and if they did it in at an appointment, they would go through it with you. Woman, FGW1a . . . if you give someone a leaflet then they'll be like, 'OK, great, thanks for the leaflet', - put them in their bag, and they'll find it maybe at the bottom of their bag, [. . .] I mean, like, oh well, you never look at that, and just kind of, throw it away [. . .] Woman, FGW2</p> <p>Practising PFME in the appointment (Woman) In the first [antenatal class] session we went through pelvic floor exercises, and she got everyone to stand up. So, we stood up behind chairs, and then she talked, talked us through it. So, it was like, you weren't just sitting there, getting information, you actually had to, had to at least physically move yourself. (Woman) That's a really good idea to actually, sort of, make somebody stand up, and actually physically, do it in front of you, which some people, you know, wouldn't want to do it, but I do think that's a good idea. Women, FGW1a</p> <p>Smartphone apps . . . the biggest game-changer for me, and I still wasn't that good at doing them, was someone telling me to download the Squeezy app. Woman, FGW2 (Midwife) . . . we know women access apps, you know, very readily when they are pregnant. [. . .] (Midwife) So a really good one [to recommend] would be useful. Midwives, FGMid2</p> <p><u>Delivery of training to midwives:</u></p> <p>Credible source I think we perhaps have quite a bit of myths that we say, and to see a practitioner who's expert in pelvic floor videoed doing a consultation with a woman, I think would be really useful. Midwives, FGMid1a</p> <p>Training duration (Midwife) You'd get an hour, tops [on a mandatory study day]. [. . .] (Midwife) Half an hour is more realistic. (Midwife) They're usually 45 minutes each slot, aren't they on study day. Midwives, FGMid1a . . . it's [PFME] not entirely new, it's something that, I think, if a really good programme is put together, then, actually, half an hour, 45 minutes could be enough. Midwife, FGMid1b</p> <p>Face to face vs. online training (Midwife) I don't think it's appropriate to do it with something like e-learning. Because it's too . . . (Midwife) No. It's the practical-ness, a skill, yeah. Midwives, FGMid1a Online might help, but I do think it's often people engage better with something when they've had perhaps a half a day study, or a whole day study initially which is quite in-depth and gives them a good knowledge and understanding, and then, yes you could catch up or top it up with some online training, . . . Midwife, FGMid2</p> <p>Role play to facilitate learning (Midwife) So it should almost be a prompt scenario, you know, [. . .]. (Midwife) Like a role play and how you would explain, you know, how to do. [. . .] (Midwife) And the impact on the woman, as well. Midwives, FGMid2 I hate role-plays! Midwife, FGMid1a</p>

Major theme	Subtheme	Example data
	4.b Support requirements for implementation of training and delivery in antenatal care	<p>Access to training So you'd need support from a director of midwifery, [. . .]. So either midwives decide to pay for the study day themselves, or the Trust might pay for the study day, but that's highly unlikely given the current budgets. If you were to go to some external agency that has a vested interest like the Health Education [name of location], that that sort of organi . . . that sort of body might be able to fund it, but money is going to be a challenge. Midwife, FGMid2</p> <p>Mandatory training (Midwife) [. . .] so if something like this [PFME training] was made as part of that mandatory study day you know that after a year you technically should have delivered that training to all midwives in the Trust. [. . .] (Midwife) The other thing about having it as part of our mandatory days is that everybody has to do it. Midwives, FGMid1a I don't think it's going to be made mandatory, I think realistically . . . mandatory training is absolutely chock-a-block full in terms of the training package and it's been pared down to, used to be four days, it's gone down to three days . . . so I think incorporating this into mandatory training is going to be a big ask, at this hospital, I can't speak for other hospitals. Midwife, FGMid2 I think, I know it's really, you know, difficult with mandatory training but if something's so important that's why, that's where it should be, because otherwise you don't do it. Midwife, FGMid2</p> <p>Train the trainer and PFME champions I think so maybe you need a kind of like, a core of people who know perhaps and then who can then . . . And then disseminate that knowledge out. Midwife, FGMid1a (Midwife) I think to not have it [training] being passed down. (Midwife) Like Chinese whispers [laughs]. (Midwife) Yeah, and you train your trainers and then your trainers are training someone else and then they're then training women to try and keep that step-down as short as possible so that it doesn't get diluted as it goes down the line to the actual women who need that information. Midwives, FGMid1a (Midwife) Yeah, we have different champions for different things, like there's somebody that does a [group] training for each team, [. . .] (Midwife) Usually there's somebody who's a bit interested in it, like having a lead makes a big difference in all honesty. Midwives, FGMid1a</p> <p>Multidisciplinary approach I'd need all my GPs who I would probably refer them to antenatally to understand the pathway and to be able to know that this isn't normal. Midwife, FGMid1a (Midwife) I also think you need multidisciplinary buy-in, because there's no point midwives alone doing this, anything that's going to be rolled out effectively needs to have input from . . . (Midwife) GPs as well. (Midwife) . . . GPs, obstetricians, gynaecologists, and anybody who comes into contact with the women during the antenatal period really. Midwives, FGMid2</p> <p>National public health campaign It [promoting PFME] needs to be a massive public health campaign really, doesn't it? On buses and things like that, so it's just normalised, and integrated into normal life, rather than just when you get pregnant and you realise, 'Oh, it's quite important!' Woman, FGW2</p> <p>Ideas for fidelity checking No, you're not having me on a video, but you can listen to me, you can watch me and you can tape me Midwife, FGMid1a That's the only way, is to actually have it as a checklist item on an antenatal clinic appointment and then you can audit the notes to see whether that's been ticked or not, I can't think how else you could do it, . . . Midwife, FGMid2</p>
FGMid, focus group with midwives; FGW, focus group with women.		

Appendix 2 Logic model illustrating theory of change for APPEAL training intervention

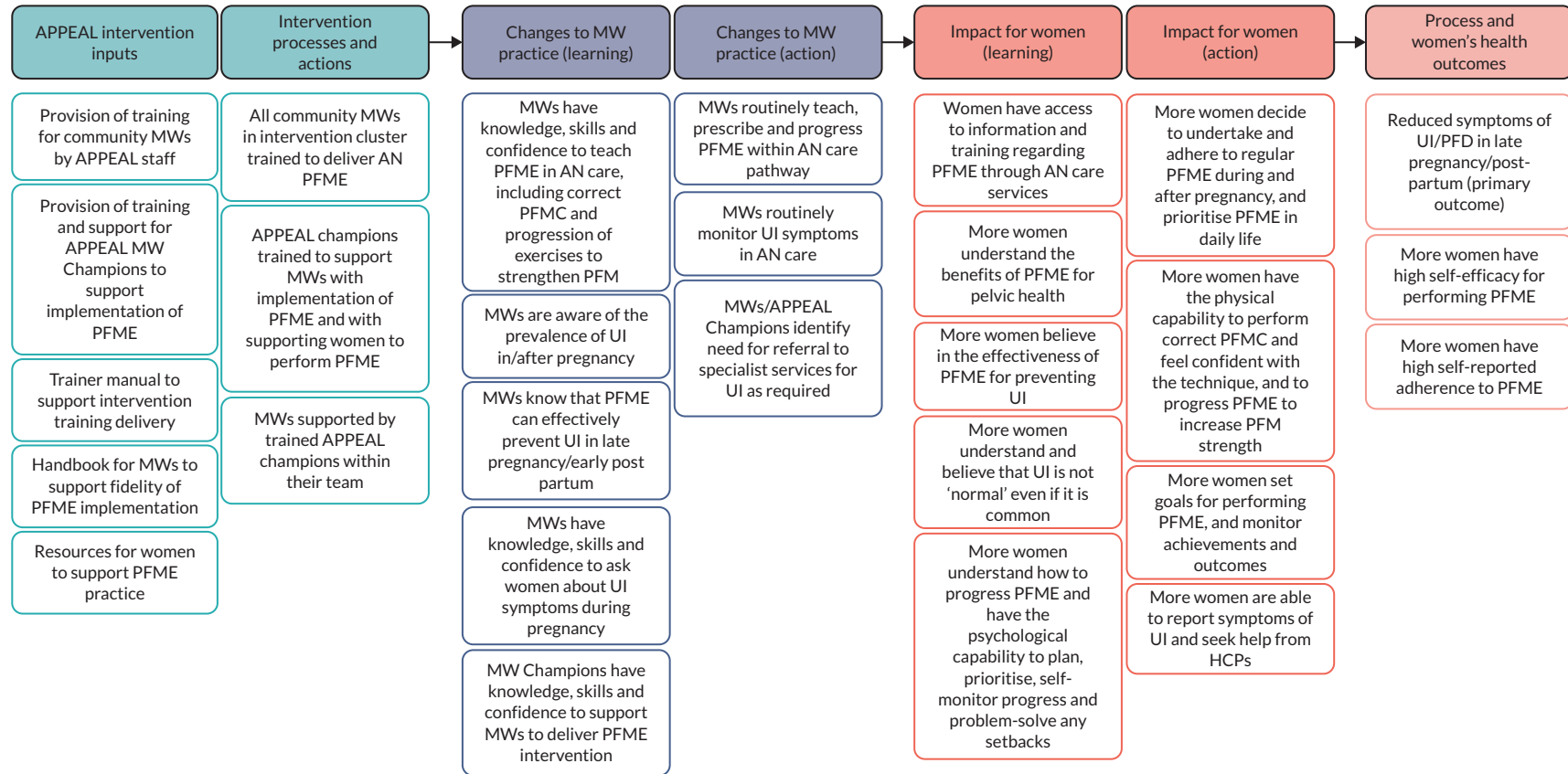


FIGURE 4 Logic model illustrating theory of change for APPEAL training intervention. AN, antenatal; MW, midwife; PFD, pelvic floor dysfunction; PFMC, pelvic floor muscle contraction.

Appendix 3 Full report of work package 4.1

What is the response rate for trial questionnaire and intraclass correlation coefficient?

Aims

The primary aim of WP4.1 was to consider what the response rate to the study questionnaire would be and in so doing to estimate the ICC for a full trial. Because it was realised from other studies in similar populations that response rates have been dropping, it was decided to assess whether a long or shorter questionnaire would give a higher response in a subsequent full cluster RCT. A second objective was to assess the prevalence of urinary stress incontinence to be used in the subsequent cluster trial. This study was in the first stage of the programme before there was a change to a feasibility and pilot trial for the second stage of the programme.

Methods

This study was a parallel group trial which took place in two NHS Trusts with maternity services which would be part of the subsequent trial. Women who delivered while under the care of all 15 community midwifery teams in the Trusts during the study period who met the eligibility criteria were included. Not eligible were those under 16 years, or who did not have a live baby on hospital discharge.

The first 54 consecutive women to give birth during July 2018 in each midwife team (see later for sample size) were informed by their midwife at their first postnatal home visit that they would receive a postal questionnaire 10–12 weeks after birth. There were 54 women in each team to ensure representativeness, as teams varied in size and in the demographics of the population they served.

The questionnaires comprised several validated measures to assess UI (ICIQ-UI SF⁴⁰), FI (RFIS⁴¹), self-efficacy of PFME (PFMESES⁴²), and adherence (EARS⁴³) and general health (SF-12⁴⁴) and questions about advice that women may have received on PFME in pregnancy and their PFME practice.

The long questionnaire comprised two double-sided pages and included all the above measures. The short questionnaire comprised one double-sided page and did not include PFMESES, EARS or SF-12 (part A). For women who returned this questionnaire, a second questionnaire (part B) which included PFMESES, EARS and SF-12 was sent.

Randomisation was by a computer program at the BCTU. Individual participants were randomised to the long or the short questionnaire. The randomisation procedure was stratified by community midwife team to account for potential variation between the midwife teams in different sociodemographic areas.

Based on allocation, women were sent the long or short questionnaire by local Trust research midwives 10–12 weeks after birth, with a cover letter, £10 voucher, and stamped return envelope. The Trust research midwives sent a reminder questionnaire to women if they had not responded within 2 weeks. Women allocated to the short questionnaire arm were only sent the second part of the questionnaire if they returned their initial questionnaire.

An original sample size of 800 women with anticipated response rate between 30% and 60% would allow return of between 240 and 480 questionnaires. With a sample size of 800, with 400 allocated to each trial arm, at 80% power and 5% significance, the study would be able to detect a 10% absolute change in the percentage response rate.

Urinary incontinence was assessed using the ICIQ-UI SF⁴⁰ questionnaire, which asks four questions about aspects of UI; based on which, women were dichotomised into two groups with 'absence' or 'presence' of UI. 'Absence' was a response of 'never', 'none' or score 0 to all four urinary questions, and 'presence' was a response of anything other than 'never', 'none' or score 0 to any of the four urinary questions. Analysis was performed using SAS[®] (SAS Institute Inc., Cary, NC, USA; SAS and all other SAS Institute Inc. product or service names are registered trademarks or trademarks of SAS Institute Inc. in the USA and other countries; [®] indicates USA registration). Permission was obtained from the Proportionate Review Subcommittee of the London – Brighton & Sussex Research Ethics Committee (18/LO/0934).

Results

There were 777 women randomised and sent either a long or short questionnaire, and the overall response rate was 31.3% (243/777). The number of questionnaires sent was less than the planned 810 because two small midwife teams had not reached 54 eligible births by the end of the sample month. There was no difference in the response rate either overall or to the UI questions according to questionnaire length. In the long compared with the short questionnaire arm, 30.8% (119/387) women responded overall relative to 31.8% (124/390) (odds ratio 0.95, 95% CI 0.70 to 1.29, absolute difference in return rate: -1.05%, 95% CI -7.6% to 5.5%), and 30.8% (119/387) answered the UI questions relative to 31.5% (123/390) (odds ratio 0.96, 95% CI 0.71 to 1.31, absolute difference in return rate: -0.79%, 95% CI -7.3% to 5.7%). Of the 124 women in the short questionnaire arm who responded, only 31 (25%) returned the second part (part B) of the questionnaire. [Figure 5](#) shows the CONSORT flow diagram for WP4.1.

[Table 5](#) shows baseline characteristics of all women who returned a questionnaire and compares those who returned a long questionnaire to those who returned the short part A questionnaire. Baseline characteristics were similar between groups.

Of total responders, 49% (119/243) reported some leaking of urine in the 4-week period prior to questionnaire completion and this was similar between trial arms ([Table 6](#)). There were 20.6% who reported some degree of FI ([Table 7](#)).

A total of 64.2% (156/243) women reported that they had been advised to perform PFME during their pregnancy by a midwife, and this was similar between trial arms. There were 42.4% (103/243) of women who reported doing PFME often enough (a few times a day, once a day, a few times a week) to possibly reduce post-partum UI ([Table 8](#)).

Conclusion

The overall questionnaire response was low at 31.3%, despite incorporating Cochrane Review recommendations to increase responses to postal and electronic questionnaires, namely: first-class postage; first-class stamped envelopes for return; £10 voucher sent with initial mailing as incentive; and reminder questionnaire.

This pilot study showed, therefore, that questionnaire response rate was relatively low, and a different length questionnaire made no difference. The estimate of the ICC for the return rate was 0.007 (95% CI 0.0005 to 0.094).

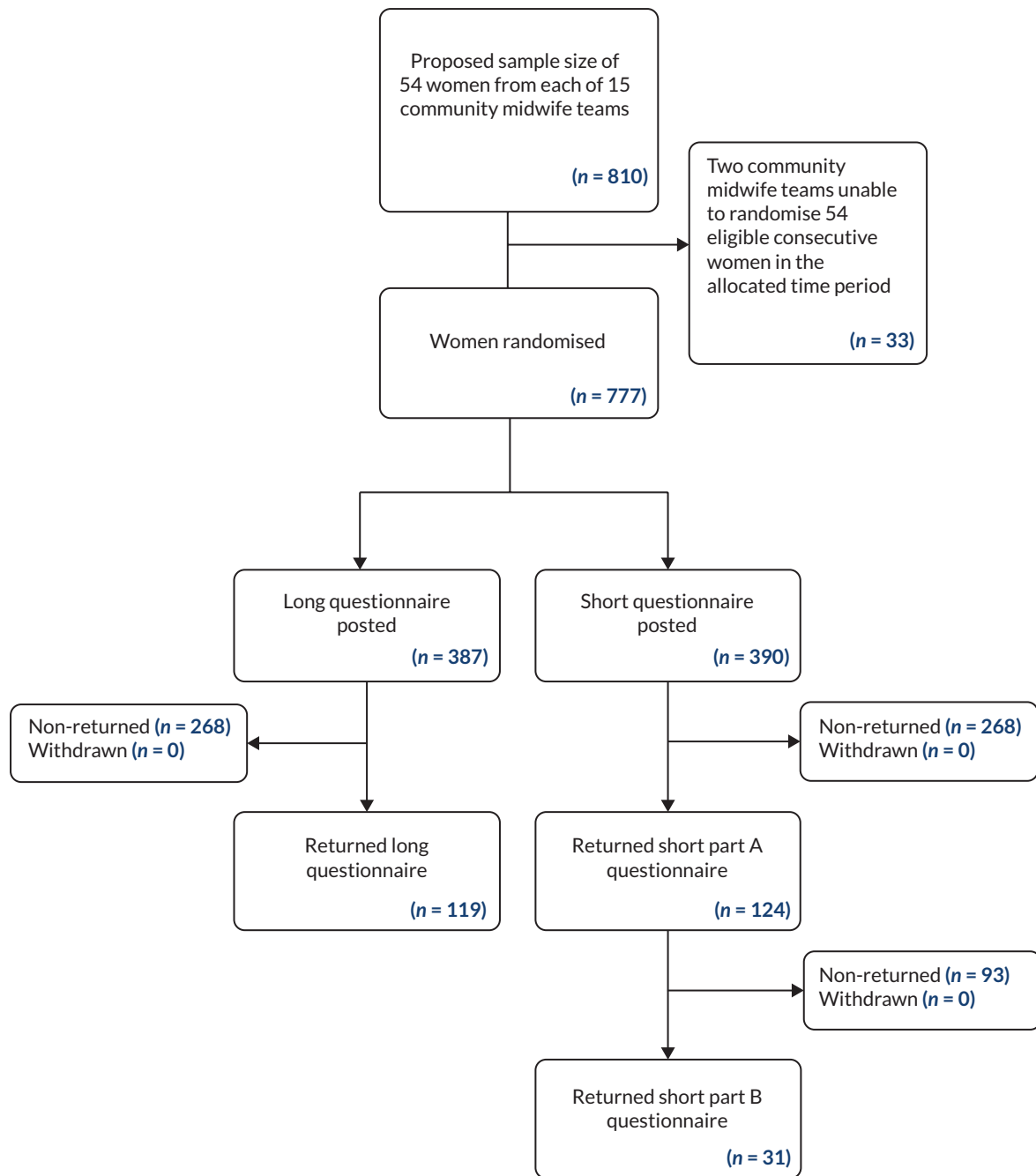


FIGURE 5 Work package 4.1 CONSORT flow diagram.

TABLE 5 Birth baseline characteristics of women: long questionnaire and short questionnaire

Birth baseline characteristic	Long (N = 119)	Short part A (N = 124)	Total (N = 243)
Labour onset			
Spontaneous onset	55 (46.2%)	61 (49.2%)	116 (47.7%)
Induced	26 (21.8%)	22 (17.7%)	48 (19.8%)
Not applicable – elective caesarean section	14 (11.8%)	12 (9.7%)	26 (10.7%)
Missing	24 (20.2%)	29 (23.4%)	53 (21.8%)
Mode of birth			
Spontaneous vaginal	63 (52.9%)	65 (52.4%)	128 (52.7%)
Instrumental vaginal	13 (10.9%)	14 (11.3%)	27 (11.1%)
Caesarean section	21 (17.6%)	20 (16.1%)	41 (16.9%)
Missing	22 (18.5%)	25 (20.2%)	47 (19.3%)
Analgesia			
Yes	26 (21.8%)	28 (22.6%)	54 (22.2%)
No	52 (43.7%)	48 (38.7%)	100 (41.2%)
Missing	41 (34.5%)	48 (38.7%)	89 (36.6%)
Perineum			
Intact perineum	31 (26.1%)	28 (22.6%)	59 (24.3%)
Labial tear	0 (0%)	1 (0.8%)	1 (0.4%)
First-degree tear	7 (5.9%)	10 (8.1%)	17 (7%)
Second-degree tear	34 (28.6%)	38 (30.6%)	72 (29.6%)
Third- and fourth-degree tear (OASI)	3 (2.5%)	1 (0.8%)	4 (1.6%)
Not applicable	19 (16%)	18 (14.5%)	37 (15.2%)
Missing	25 (21%)	28 (22.6%)	53 (21.8%)
Episiotomy			
Yes	16 (13.4%)	16 (12.9%)	32 (13.2%)
No	76 (63.9%)	80 (64.5%)	156 (64.2%)
Missing	27 (22.7%)	28 (22.6%)	55 (22.6%)
Birthweight (n)	(n = 97)	(n = 100)	(n = 197)
Mean (SD), g	3232 (457)	3348 (482)	3291 (472)
Missing	22 (18%)	24 (19%)	46 (19%)
Head circumference (n)	(n = 90)	(n = 95)	(n = 185)
Mean (SD), cm	34 (1.44)	34 (1.40)	34.1 (1.42)
Missing	29 (24%)	29 (23%)	58 (24%)
Length of active second stage (n)	(n = 53)	(n = 50)	(n = 103)
Median (IQR), minutes	15 (7–53)	19 (5–42)	19 (6–49)
Missing	66 (55%)	74 (60%)	140 (58%)
IQR, interquartile range; OASI, obstetric anal sphincter injury.			

TABLE 6 Results of ICIQ-UI SF questionnaire for UI

Outcome	Long (N = 119), n (%)	Short part A (N = 124), n (%)	Total (N = 243), n (%)
Urinary incontinence			
Present	59 (49.5)	59 (48.4)	119 (49.0)
Absent	60 (50.4)	64 (51.6)	124 (51.0)
Missing	0 (0)	1 (0.8)	1 (0.4)
Bladder function questions			
<i>How often do you leak urine?</i>			
Never	65 (54.6)	69 (55.6)	134 (55.1)
About once a week or less often	30 (25.2)	33 (26.6)	63 (25.9)
Two or three times a day	12 (10.1)	8 (6.5)	20 (8.2)
About once a day	5 (4.2)	4 (3.2)	9 (3.7)
Several times a day	6 (5)	7 (5.6)	13 (5.3)
All of the time	0 (0)	1 (0.8)	1 (0.4)
Missing	1 (0.8)	2 (1.6)	3 (1.2)
<i>How much urine do you usually leak?</i>			
None	64 (53.8)	63 (50.8)	127 (52.3)
A small amount	47 (39.5)	46 (37.1)	93 (38.3)
A moderate amount	6 (5)	8 (6.5)	14 (5.8)
A large amount	0 (0)	0 (0)	0 (0)
Missing	2 (1.7)	7 (5.6)	9 (3.7)
<i>Overall, how much does leaking urine interfere with your everyday life?</i>			
0 (not at all)	72 (60.5)	73 (58.9)	145 (59.7)
1	14 (11.8)	20 (16.1)	34 (14)
2	9 (7.6)	8 (6.5)	17 (7)
3	7 (5.9)	8 (6.5)	15 (6.2)
4	5 (4.2)	2 (1.6)	7 (2.9)
5	1 (0.8)	3 (2.4)	4 (1.6)
6	2 (1.7)	3 (2.4)	5 (2.1)
7	3 (2.5)	2 (1.6)	5 (2.1)
8	2 (1.7)	0 (0)	2 (0.8)
9	1 (0.8)	1 (0.8)	2 (0.8)
10 (a great deal)	0 (0)	2 (1.6)	2 (0.8)
Missing	3 (2.5)	2 (1.6)	5 (2.1)
<i>When does urine leak?</i>			
Never	60 (50.4)	68 (54.8)	128 (52.7)
Before you can get to the toilet	22 (18.5)	19 (15.3)	41 (16.9)

continued

TABLE 6 Results of ICIQ-UI SF questionnaire for UI (continued)

Outcome	Long (N = 119), n (%)	Short part A (N = 124), n (%)	Total (N = 243), n (%)
When you sneeze	40 (33.6)	31 (25)	71 (29.2)
When you are asleep	3 (2.5)	1 (0.8)	4 (1.6)
When you are physically active/ exercising	21 (17.6)	16 (12.9)	37 (15.2)
When you have finished urinat- ing and are getting dressed	7 (5.9)	7 (5.6)	14 (5.8)
For no obvious reason	6 (5)	4 (3.2)	10 (4.1)
All of the time	0 (0)	1 (0.8)	1 (0.4)

TABLE 7 Results of RFIS questionnaire for FI

Outcome	Long (N = 119), n (%)	Short part A (N = 124), n (%)	Total (N = 243), n (%)
Faecal incontinence			
Present	31 (26)	19 (15.3)	50 (20.6)
Absent	88 (74)	104 (83.9)	192 (79)
Missing	0 (0)	1 (0.8)	1 (0.4)
Bowel function questions			
<i>Do you leak, have accidents or lose control with solid stool?</i>			
Never	101 (84.9)	117 (94.4)	218 (89.7)
Rarely	9 (7.6)	5 (4)	14 (5.8)
Sometimes	6 (5)	0 (0)	6 (2.5)
Often or usually	2 (1.7)	1 (0.8)	3 (1.2)
Always	1 (0.8)	0 (0)	1 (0.4)
Missing	0 (0)	1 (0.8)	1 (0.4)
<i>Do you leak, have accidents or lose control with liquid stool?</i>			
Never	100 (84)	110 (88.7)	210 (86.4)
Rarely	11 (9.2)	10 (8.1)	21 (8.6)
Sometimes	5 (4.2)	1 (0.8)	6 (2.5)
Often or usually	2 (1.7)	2 (1.6)	4 (1.6)
Always	1 (0.8)	0 (0)	1 (0.4)
Missing	0 (0)	1 (0.8)	1 (0.4)
<i>Do you leak stool if you don't get to the toilet in time?</i>			
Never	99 (83.2)	114 (91.9)	213 (87.7)
Rarely	10 (8.4)	6 (4.8)	16 (6.6)
Sometimes	9 (7.6)	1 (0.8)	10 (4.1)
Often or usually	0 (0)	0 (0)	0 (0)
Always	1 (0.8)	2 (1.6)	3 (1.2)
Missing	0 (0)	1 (0.8)	1 (0.4)

TABLE 7 Results of RFIS questionnaire for FI (continued)

Outcome	Long (N = 119), n (%)	Short part A (N = 124), n (%)	Total (N = 243), n (%)
<i>Does stool leak so that you have to change your underwear?</i>			
Never	100 (84)	114 (91.9)	214 (88.1)
Rarely	11 (9.2)	5 (4)	16 (6.6)
Sometimes	6 (5)	2 (1.6)	8 (3.3)
Often or usually	1 (0.8)	1 (0.8)	2 (0.8)
Always	1 (0.8)	1 (0.8)	2 (0.8)
Missing	0 (0)	1 (0.8)	1 (0.4)
<i>Does bowel or stool leakage cause you to alter your lifestyle?</i>			
Never	107 (89.9)	116 (93.5)	223 (91.8)
Rarely	6 (5)	2 (1.6)	8 (3.3)
Sometimes	3 (2.5)	2 (1.6)	5 (2.1)
Often or usually	2 (1.7)	1 (0.8)	3 (1.2)
Always	1 (0.8)	1 (0.8)	2 (0.8)
Missing	0 (0)	2 (1.6)	2 (0.8)

TABLE 8 Pelvic floor muscle exercises during the pregnancy and post partum

Outcome	Long (N = 119), n (%)	Short part A (N = 124), n (%)	Total (N = 243), n (%)
<i>Did your midwife advise you to perform PFME when you were pregnant?</i>			
Yes	77 (64.6)	79 (63.7)	156 (64.2)
No	21 (17.7)	22 (17.7)	43 (17.7)
Missing	21 (17.7)	23 (18.6)	44 (18.1)
<i>How often did you perform PFME when you were pregnant?</i>			
Never – was never advised to	17 (14.3)	22 (17.7)	39 (16.0)
Never – other reasons	9 (7.6)	12 (9.7)	21 (8.6)
A few times a month	38 (31.9)	22 (17.7)	60 (24.7)
Once a week	4 (3.4)	4 (3.2)	8 (3.3)
Few times a week	24 (20.2)	29 (23.4)	53 (21.8)
Once a day	10 (8.4)	12 (9.7)	22 (9.1)
A few times a day	13 (10.9)	15 (12.1)	28 (11.5)
Can't remember	3 (2.5)	8 (6.5)	11 (4.5)
Missing	1 (0.8)	0 (0)	1 (0.4)
<i>Do you currently perform PFME?</i>			
Yes	73 (61.3)	73 (58.8)	146 (60.1)
No	36 (30.3)	38 (30.7)	74 (30.4)
Missing	10 (8.4)	13 (10.5)	23 (9.5)

continued

TABLE 8 Pelvic floor muscle exercises during the pregnancy and post partum (*continued*)

Outcome	Long (N = 119), n (%)	Short part A (N = 124), n (%)	Total (N = 243), n (%)
<i>How often did you do PFME over the last month?</i>			
Never – was never advised to	10 (8.4)	13 (10.5)	23 (9.5)
Never – other reasons	15 (12.6)	18 (14.5)	33 (13.6)
A few times a month	41 (34.5)	33 (26.6)	74 (30.5)
Once a week	25 (21.0)	22 (17.7)	47 (19.3)
Few times a week	5 (4.2)	8 (6.4)	13 (5.4)
Once a day	11 (9.2)	14 (11.3)	25 (10.3)
A few times a day	12 (10.1)	15 (12.1)	27 (11.1)
Missing	0 (0)	1 (0.8)	1 (0.4)

Appendix 4 Additional work package 4.2 tables

TABLE 9 General information on sending/receiving women's questionnaire

Number of women in the database	1304
Number of women in the database who received maternity care from one of the midwifery teams randomised to APPEAL	1005
Number of out of area women in the database	269
Number of new team's ^a women in the database	4
Number of women in the database for whom no midwifery team recorded	26
Number of women to whom the questionnaire was sent	1294^b
Number of women to whom the questionnaire was sent, who received maternity care from one of the midwifery teams randomised to APPEAL	998
Number of out of area women to whom the questionnaire was sent	266
Number of new team's ^a women to whom the questionnaire was sent	4
Number of women to whom the questionnaire was sent but no midwifery team recorded	26
Number of women who returned the questionnaire	231
Number of women who returned the questionnaire, who received maternity care from one of the midwifery teams randomised to APPEAL	175
Number of out of area women who returned the questionnaire	56
Number of new team's ^a women who returned the questionnaire	0
Number of women to whom the short, translated version of the questionnaire was sent	111
Number of women to whom the short, translated version of the questionnaire was sent, who received maternity care from one of the midwifery teams randomised to APPEAL	90
Number of out of area women to whom the short, translated version of the questionnaire was sent	17
Number of new team's ^a women to whom the short, translated version of the questionnaire was sent	3
Number of women to whom the short, translated version of the questionnaire was sent but no midwifery team recorded	1
Number of women who returned the short, translated version of the questionnaire	10
Number of women who returned the short, translated version of the questionnaire and who received maternity care from one of the midwifery teams randomised to APPEAL	8
Number of out of area women who returned the short, translated version of the questionnaire	2
Number of new team's ^a women who returned the short, translated version of the questionnaire	0
Number of women to whom the standard questionnaire was sent	1179
Number of women to whom the standard questionnaire was sent, who received maternity care from one of the midwifery teams randomised to APPEAL	905
Number of out of area women to whom the standard questionnaire was sent	248
Number of new team's ^a women to whom the standard questionnaire was sent	1
	continued

TABLE 9 General information on sending/receiving women's questionnaire (continued)

Number of women to whom the standard questionnaire was sent but no midwifery team recorded	25
Number of women who returned the standard questionnaire	221
Number of women who returned the standard questionnaire and who received maternity care from one of the midwifery teams randomised to APPEAL	167
Number of out of area women who returned the standard questionnaire	54
Number of new team's ^a women who returned the standard questionnaire	0

a A new continuity of care team was created in the last month of the trial.

b 296 women have been excluded from the analysis because either they did not receive maternity care from any of the midwifery teams randomised to APPEAL or the midwifery team name was not reported.

TABLE 10 Information on sending/receiving women's questionnaire by group

	Intervention (N = 531)	Control (N = 467)	Overall (N = 998)
Number of women to whom the questionnaire was sent	531	467	998
Number of women to whom the short, translated version of the questionnaire was sent	52	38	90
Number of women to whom the standard questionnaire was sent	479	426	905
Number of women to whom the questionnaire was sent one time	98	76	174
Number of women to whom the questionnaire was sent one time, who returned the questionnaire	62	48	110
Number of women to whom the questionnaire was sent two times	433	391	824
Number of women to whom the questionnaire was sent two times, who returned the questionnaire	26	39	65
Total number of questionnaires returned	88	87	175
Number of women who returned the short questionnaire	5	3	8
Number of women who returned the standard questionnaire	83	84	167
Number of women recorded on the database and the questionnaire was not sent to them ^a :	6	1	7

a The questionnaire was not sent to these women due to serious health issues; see [Table 11](#).

TABLE 11 Details on women's exclusion

	Site 1	Site 2
Stillbirth	0	0
Neonatal death	0	5
Infant death	0	1
Fetal abnormality	1	0

TABLE 11 Details on women's exclusion (continued)

	Site 1	Site 2
Women whose infants were taken into care due to safeguarding concerns	1	0
Women who have severe mental health problems	8	0
Restricted address	1	0
Twin pregnancy – one twin intrauterine death	0	1

TABLE 12 Minimisation variables used in the randomisation by group and overall

Minimisation variables	Women who returned questionnaire			Women who did not return questionnaire	
	Intervention (N = 88), n (%)	Control (N = 87), n (%)	Overall (N = 175), n (%)	Overall (N = 823), n (%)	
Midwifery team size	Small	35 (39.8)	25 (28.7)	60 (34.3)	276 (33.5)
	Large	53 (60.2)	62 (71.3)	115 (65.7)	547 (66.5)
Trust	Site 1	46 (52.3)	23 (26.4)	69 (39.4)	300 (36.5)
	Site 2	42 (47.7)	64 (73.6)	106 (60.6)	523 (63.5)

TABLE 13 Other baseline characteristics by group and overall

		Women who returned questionnaire			Women who did not return questionnaire
		Intervention (N = 88)	Control (N = 87)	Overall (N = 175)	Overall (N = 1063)
Women's demographics and other baseline characteristics					
<i>Maternal</i>					
Age, years	<i>n</i>	78	77	155	1063
	Mean (SD)	31.6 (4.9)	31.9 (5.5)	31.8 (5.2)	29.6 (N/A ^a)
	Minimum, maximum	22, 45	19, 48	19, 48	15, 46
	Median (IQR)	32 (28–35)	32 (29–35)	32 (28–35)	N/A ^a
	Missing	10	10	20	0
Ethnicity	<i>n</i>	88	87	175	1063
	British	40 (52.0%)	37 (48.1%)	77 (50.0%)	371 (34.9%)
	Irish	1 (1.3%)	0 (0%)	1 (0.7%)	5 (0.5%)
	White other	5 (6.5%)	1 (1.3%)	6 (3.9%)	46 (4.3%)
	White and Black Caribbean	0 (0%)	0 (0%)	0 (0%)	11 (1.0%)
	White and Black African	0 (0%)	0 (0%)	0 (0%)	4 (0.4%)
	White and Asian	0 (0%)	0 (0%)	0 (0%)	5 (0.5%)
	Mixed other	0 (0%)	0 (0%)	0 (0%)	8 (0.8%)

continued

TABLE 13 Other baseline characteristics by group and overall (continued)

		Women who returned questionnaire			Women who did not return questionnaire
		Intervention (N = 88)	Control (N = 87)	Overall (N = 175)	Overall (N = 1063)
Parity	Indian	0 (0%)	3 (3.9%)	3 (2.0%)	33 (3.1%)
	Pakistani	3 (3.9%)	7 (9.1%)	10 (6.5%)	205 (19.3%)
	Bangladeshi	2 (2.6%)	0 (0%)	2 (1.3%)	16 (1.5%)
	Asian other	6 (7.8%)	7 (9.1%)	13 (8.4%)	29 (2.7%)
	Black Caribbean	0 (0%)	1 (1.3%)	1 (0.7%)	10 (0.9%)
	Black African	1 (1.3%)	1 (1.3%)	2 (1.3%)	37 (3.5%)
	Black other	3 (3.9%)	1 (1.3%)	4 (2.6%)	16 (1.5%)
	Chinese	0 (0%)	0 (0%)	0 (0%)	6 (0.6%)
	Any other ethnic group	6 (7.8%)	1 (1.3%)	7 (4.6%)	56 (5.3%)
	Not stated	6 (7.8%)	4 (5.2%)	10 (6.5%)	193 (18.2%)
	Declined to answer	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	Not known	4 (5.2%)	14 (18.2%)	18 (11.7%)	12 (1.1%)
	Missing	11	10	21	0
	<i>n</i>	88	87	175	1063
	0	34 (45.3%)	28 (36.8%)	62 (41.0%)	367 (34.5%)
	1	28 (37.3%)	33 (43.4%)	61 (40.4%)	317 (29.8%)
	2	9 (12.0%)	7 (9.2%)	16 (10.6%)	181 (17.0%)
3	4 (5.4%)	5 (6.6%)	9 (6.0%)	91 (8.6%)	
4	0 (0%)	1 (1.4%)	1 (0.7%)	35 (3.3%)	
5 or more	0 (0%)	2 (2.6%)	2 (1.3%)	72 (6.8%)	
Missing	13	11	24	0	
Obstetric					
Onset of labour	<i>n</i>	88	87	175	1063
	Spontaneous	42 (55.3%)	39 (50.0%)	81 (52.6%)	429 (41.7%)
	Induced	12 (15.8%)	23 (29.5%)	35 (22.7%)	307 (29.8%)
	N/A - elective caesarean section (including failed induction)	22 (28.9%)	16 (20.5%)	38 (24.7%)	293 (28.5%)
	Missing	12	9	21	34
Mode of birth	<i>n</i>	88	87	175	1063
	Ventouse	10 (13.3%)	11 (14.1%)	21 (13.7%)	61 (5.7%)
	Forceps	4 (5.3%)	4 (5.1%)	8 (5.2%)	49 (4.6%)
	Caesarean section	26 (34.7%)	24 (30.8%)	50 (32.7%)	405 (38.1%)
	Spontaneous vaginal birth	35 (46.7%)	39 (50.0%)	74 (48.4%)	547 (51.5%)
	Missing	13	9	22	1

TABLE 13 Other baseline characteristics by group and overall (continued)

		Women who returned questionnaire			Women who did not return questionnaire
		Intervention (N = 88)	Control (N = 87)	Overall (N = 175)	Overall (N = 1063)
Anaesthetic ^b	<i>n</i>	88	87	175	1063
	Spinal	23 (79.3%)	23 (76.7%)	46 (78.0%)	345 (69.4%)
	Epidural	5 (17.2%)	7 (23.3%)	12 (20.3%)	122 (24.5%)
	General	1 (3.5%)	0 (0%)	1 (1.7%)	30 (6.0%)
	Missing	59	57	116	566
Analgesia ^c	<i>n</i>	88	87	175	1063
	Yes	39 (72.2%)	50 (80.7%)	89 (76.7%)	524 (49.3%)
	No	15 (27.8%)	12 (19.3%)	27 (23.3%)	539 (50.7%)
	Missing	34	25	59	0
Perineal trauma	<i>n</i>	88	87	175	1063
	First degree	6 (8.3%)	7 (9.1%)	13 (8.7%)	86 (15.2%)
	Second degree	21 (29.2%)	27 (35.1%)	48 (32.2%)	223 (39.5%)
	3a	1 (1.4%)	1 (1.3%)	2 (1.3%)	5 (0.9%)
	3b	1 (1.4%)	0 (0%)	1 (0.7%)	2 (0.4%)
	3c	1 (1.4%)	0 (0%)	1 (0.7%)	0 (0%)
	Fourth degree	0 (0%)	0 (0%)	0 (0%)	1 (0.2%)
	Labial lacerations	0 (0%)	0 (0%)	0 (0%)	0 (0%)
	None	42 (58.3%)	42 (54.5%)	84 (56.4%)	248 (43.9%)
	Missing	16	10	26	498
Episiotomy	<i>n</i>	88	87	175	1063
	Yes	17 (23.3%)	16 (21.1%)	33 (22.2%)	143 (24.0%)
	No	56 (76.7%)	60 (78.9%)	116 (77.8%)	453 (76.0%)
	Missing	15	11	26	467
Duration of second stage (minutes)	<i>n</i>	26	37	63	809
	Minimum, maximum	0, 1260	0, 1860	0, 1860	0, 300
	Median (IQR)	35 (2–143)	36 (10–77)	36 (8–94)	N/A ^a
	Missing	62	50	112	254
Infants					
Gestation at birth (weeks)	<i>n</i>	78	78	156	1063
	Mean (SD)	39.6 (1.6)	39.3 (2.2)	39.4 (1.9)	36.0 (N/A ^a)
	Minimum, maximum	34.6, 42.1	24.1, 41.9	24.1, 42.1	23.0, 42.0
	Missing	10	9	19	0

continued

TABLE 13 Other baseline characteristics by group and overall (*continued*)

		Women who returned questionnaire			Women who did not return questionnaire
		Intervention (N = 88)	Control (N = 87)	Overall (N = 175)	Overall (N = 1063)
Birthweight (g)	<i>n</i>	78	78	156	1063
	Mean (SD)	3356 (435)	3325 (499)	3340 (467)	3171 (N/A ^a)
	Minimum, maximum	2170, 4550	700, 4150	700, 4550	550, 4850
	Missing	10	9	19	0
Head circumference (cm)	<i>n</i>	73	74	147	1015
	Mean (SD)	34.5 (1.3)	34.2 (1.2)	34.4 (1.2)	33.3 (N/A ^a)
	Minimum, maximum	32.0, 38.0	30.5, 36.5	30.5, 38.0	21.0, 52.0
	Missing	15	13	28	48

a The two sites were unable to provide this number.

b Women can have a combination of anaesthetic methods or none. The specific types of each method have not been reported.

c Types of analgesia used: APPEAL intervention: aromatherapy, combined spinal and epidural, paracetamol, pethidine, paracetamol codeine, codeine, diamorphine, Entonox[®], TENS, birthing pool, gas and air. Standard care: epidural, combined spinal and epidural, pethidine, paracetamol, codeine, Entonox, TENS, birthing pool.

TABLE 14 Prevalence of UI at 10–12 weeks using ICIQ-UI SF⁴⁰, EARS⁴³ and PFMESES⁴²

Prevalence of UI using the ICIQ-UI SF		Intervention (n = 88)	Control (n = 87)
Total ICIQ-UI SF score ^a	<i>N</i>	87	86
	Mean (SD)	3.3 (4.5)	4.2 (4.3)
	Missing	1	1
	95% CI	2.1 to 4.5 ^b	2.9 to 5.6 ^c
How often do you leak urine?	Never	49 (55.7%)	40 (46.0%)
	About once a week or less	22 (25.0%)	21 (24.1%)
	Two or three times a week	8 (9.0%)	15 (17.2%)
	About once a day	5 (5.7%)	4 (4.6%)
	Several times a day	2 (2.3%)	7 (8.1%)
	All of the time	2 (2.3%)	0 (0%)
	Missing	0	0
	How much urine do you usually leak (whether you wear protection or not)?	None	49 (53.3%)
A small amount		35 (40.2%)	44 (51.2%)
A moderate amount		3 (23.5%)	6 (7.0%)
A large amount		0 (0%)	0 (0%)
Missing		1	1
Overall, how much does leaking urine interfere with your everyday life? Please tick a number between 0 (not at all) and 10 (a great deal)	0	53 (60.2%)	39 (45.3%)

TABLE 14 Prevalence of UI at 10–12 weeks using ICIQ-UI SF⁴⁰, EARS⁴³ and PFMESES⁴² (continued)

Prevalence of UI using the ICIQ-UI SF		Intervention (n = 88)	Control (n = 87)
	1	6 (6.8%)	10 (11.6%)
	2	5 (5.7%)	9 (10.5%)
	3	8 (9.1%)	10 (11.6%)
	4	3 (3.4%)	4 (4.7%)
	5	6 (6.8%)	6 (7.0%)
	6	0 (0%)	4 (4.7%)
	7	2 (2.3%)	2 (2.3%)
	8	3 (3.4%)	0 (0%)
	9	0 (0%)	0 (0%)
	10	2 (2.3%)	2 (2.3%)
	Missing	0	1
When does urine leak? ^d	Never – urine does not leak	47 (53.4%)	36 (41.4%)
	Leaks before you can get to the toilet	16 (18.2%)	25 (28.7%)
	Leaks when you sneeze	25 (28.4%)	34 (39.1%)
	Leaks when you are asleep	1 (1.1%)	4 (4.6%)
	Leaks when you are physically active/exercising	20 (22.7%)	21 (24.1%)
	Leaks when you have finished urinating and are getting dressed	7 (8.0%)	11 (12.6%)
	Leaks for no obvious reason	5 (5.7%)	3 (3.5%)
	Leaks all of the time	1 (1.1%)	2 (2.3%)
	Missing	0	1
Prevalence of UI ^e	Yes	39 (44.3%)	47 (54.0%)
	No	49 (55.7%)	40 (46.0%)
	Missing	0	0
	95% CI	32.0% to 56.1% ^f	42.2% to 65.8% ^g
Women's EARS score	N	82	82
	Mean (SD)	10.8 (5.6)	9.4 (5.4)
	Missing	6	5
	95% CI	9.1 to 12.4 ^f	5.3 to 15.0 ^g
Total score of self-efficacy (PFMESES): women's confidence in their practice of performing PFME ^h	N	19	22
	Mean (SD)	65.7 (9.1)	65.6 (8.1)
	Missing	69	65
	95% CI	58.0 to 73.2 ^e	61.0 to 70.3 ^f

continued

TABLE 14 Prevalence of UI at 10–12 weeks using ICIQ-UI SF⁴⁰, EARS⁴³ and PFMESES⁴² (continued)

Prevalence of UI using the ICIQ-UI SF		Intervention (n = 88)	Control (n = 87)
Subscore of self-efficacy (PFMESES): women's belief in PFME execution and its benefits ⁱ	N	79	76
	Mean (SD)	41.6 (7.5)	41.6 (6.8)
	Missing	9	11
	95% CI	38.9 to 44.2 ^e	37.9 to 45.4 ^f
Subscore sum of self-efficacy (PFMESES) in performing PFME as scheduled and despite barriers ^j	N	19	24
	Mean (SD)	22.4 (4.5)	23.2 (4.0)
	Missing	69	63
	95% CI	17.9 to 27.0 ^e	21.3 to 25.1 ^f

a The total UI score was calculated using the ICIQ-UI SF, and a higher score indicates a greater impairment from incontinence, with a possible total from 0 to 21.

b 95% CI around the mean was estimated using a *t*-distribution with 7 degrees of freedom.

c 95% CI around the mean was estimated using a *t*-distribution with 6 degrees of freedom.

d Responses were not mutually exclusive.

e UI prevalence was determined by the question 'How often do you leak urine?' and defined as 'no' if the answer was 'never' and 'yes' if it was any other response.

f 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 7 degrees of freedom.

g 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 6 degrees of freedom.

h The total score of women's confidence in their practice of PFME was calculated using the self-efficacy (PFMESES) questionnaire. Higher scores indicate greater confidence of women's practice of PFME (score can range from 17 to 85).

i The subscore of belief in PFME execution and its benefits was calculated using 11 of the 17 questions of the self-efficacy (PFMESES) questionnaire. Higher scores indicate a greater belief in PFME execution and its benefits (score can range from 11 to 55).

j The subscore sum of belief in performing PFME as scheduled and despite barriers was calculated using 6 of the 17 questions of the self-efficacy (PFMESES) questionnaire. Higher scores indicate greater belief in performing PFME as scheduled and despite barriers (score can range from 6 to 30).

Note

All 95% CIs are estimated using cluster-level analyses, weighted by the cluster size, after natural log transformations of the data.

TABLE 15 Prevalence of FI at 10–12 weeks using RFIS

		Intervention (n = 88)	Control (n = 87)
Prevalence of FI at 10–12 weeks using the RFIS⁴¹			
Total RFI score ^a	N	82	82
	Mean (SD)	1.2 (3.1)	0.7 (2.2)
	Missing	6	5
	Total score < 4	72 (87.8%)	78 (95.1%)
	4 ≤ Total score ≤ 6	4 (4.9%)	2 (2.5%)
	7 ≤ Total score ≤ 12	4 (4.9%)	1 (1.2%)
	Total score ≥ 13	2 (2.4%)	1 (1.2%)
	95% CI	0.2 to 2.0 ^b	0.2 to 0.9 ^c

TABLE 15 Prevalence of FI at 10–12 weeks using RFIS (continued)

		Intervention (n = 88)	Control (n = 87)
Prevalence of FI ^d	Yes	15 (18.1%)	11 (13.3%)
	No	68 (81.9)	72 (86.7%)
	Missing	5	4
	95% CI	6.6% to 28.9% ^e	4.8% to 21.2% ^f
Prevalence of flatus incontinence			
Prevalence of flatus incontinence ^g	Yes	34 (41.0%)	30 (35.7%)
	No	49 (59.0%)	54 (64.3%)
	Missing	5	3
	95% CI	17.9% to 64.6% ^e	25.5% to 45.8% ^f

a Total RFI score was calculated using the RFIS, and a higher score indicates greater impairment from incontinence, with a possible total score from 0 to 20.

b 95% CI around the mean was estimated using a *t*-distribution with 7 degrees of freedom.

c 95% CI around the mean was estimated using a *t*-distribution with 6 degrees of freedom.

d Prevalence of FI was determined by the following two questions: 'Do you leak, have accidents or lose control with solid stool?' and 'Do you leak, have accidents or lose control with liquid stool?' and was defined as 'no' if the answer to the above question was 'never' and 'yes' if it was any of the other options.

e 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 7 degrees of freedom.

f 95% CI around the proportion who responded 'yes' was estimated using a *t*-distribution with 6 degrees of freedom.

g Prevalence of flatus incontinence was determined by the question: 'Do you leak, have accidents or lose control with gas (flatus or wind)?' and defined as 'no' if the answer to the above question was 'never' and 'yes' if it was not.

Note

All 95% CIs are estimated using cluster-level analyses, weighted by the cluster size, after natural log transformations of the data.

Appendix 5 Data collection and analysis methods (work package 4.3)

Work package 4.3 comprised a process evaluation undertaken in parallel with the WP4.2 pilot feasibility trial (see Bick *et al.* for protocol⁴⁵). This process evaluation focused on exploring the feasibility and acceptability of the intervention and implementation structures, in line with Medical Research Council guidance.³⁴ It aimed to identify facilitators and concerns or challenges regarding implementation that might be addressed prior to a future evaluation of intervention effectiveness.

Research questions and methods used to answer the questions

Tables 16 and 17 summarise the data collection sources and analysis methods. The left-hand column of the tables lists the research questions which have been broken down and mapped onto relevant components of the Grant *et al.* (2013) framework for designing and reporting process evaluations:⁴⁷ processes involving clusters: delivery to clusters, response of cluster (see Table 16); processes involving target population: delivery to individuals and response of individuals (see Table 17). Data collection sources are listed across the tables (top row) according to four stages of the study: during training, post training, implementation phase and end of study. The second row indicates whether the data source was predominantly quantitative (Qt) or qualitative (Ql). The tables therefore present an overview of how the multiple methods of data collection fitted together to inform overall understanding as it showed which research question they aimed to address and which phase of the study they referred to, and the type of data source.

Data collection and analysis methods

The following refers to data sources presented in column headings in Tables 16 and 17.

Training attendance

Data sample: attendance records were recorded by research midwives for all training sessions they delivered.

To analyse training attendance, we descriptively summarised the number of midwives who attended training from each community midwife team in the intervention cluster [e.g. 89 of 92 (97%) of midwives from $n = xx$ community teams].

Training observation

One of two members of the research team joined and silently observed four of the main training sessions. The researchers checked whether key statements were articulated, which were listed in bold on the midwives' training presentation slide notes. The key statements were ticked off once delivered, permitting quantitative monitoring of training fidelity. The researcher also qualitatively described the spirit of delivery as intended by the protocol.

The quantitative data constituted the number of key statements delivered – this was summarised descriptively via the proportion (%) of key statements delivered, as well as any key statements that were consistently omitted by the facilitators.

The qualitative data gathered from this source were evaluated via content analysis⁵¹ to assess: (1) what went well, (2) whether any aspects of the mode of delivery needed improvement and (3) what barriers

TABLE 16 Process evaluation reporting framework: processes involving clusters

		During training			Post training			Implementation phase			End of study			
		Training attendance	Training observation	Pre-/post-training questionnaires	Training evaluation questionnaire	I/V MW interviews	Champion interviews	Champion monitoring	Distribution of resource packs	Implementation questionnaires	I/V MW interview	Champion interview	Control MW interview	Women's questionnaires and interviews
RQ no	RQ	Qt	Qt and QI	Qt	Qt and QI	QI	QI	Qt and QI	Qt	Qt and QI	QI	QI	QI	Qt
<i>Delivery to clusters</i>														
2a	What training is delivered to community MWs?		Qt		Qt and QI	QI	QI				QI	QI	QI	
2b	Who receives training?	Qt				QI	QI	Qt and QI			QI	QI	QI	
2b	What are the opportunities/challenges for MWs receiving training as planned?	Qt				QI	QI							
<i>Response of clusters</i>														
2c	Do MWs feel more confident to implement PFME in AN care following training?			Qt		QI	QI				QI	QI		

TABLE 16 Process evaluation reporting framework: processes involving clusters (*continued*)

RQ no	RQ	During training		Post training			Implementation phase			End of study				
		Training attendance	Training observation	Pre-/post-training questionnaires	Training evaluation questionnaire	I/V MW interviews	Champion interviews	Champion monitoring	Distribution of resource packs	Implementation questionnaires	I/V MW interview	Champion interview	Control MW interview	Women's questionnaires and interviews
		Qt	Qt and Ql	Qt	Qt and Ql	Ql	Ql	Qt and Ql	Qt	Qt and Ql	Ql	Ql	Ql	Qt
1a	Is training delivery and content and implementation of PFME acceptable to midwives/champions?				Qt and Ql	Ql	Ql			Qt and Ql	Ql	Ql		
2c, 1a	What factors affect the acceptability of training delivery and content for MWs/champions?				Ql	Ql	Ql			Qt and Ql	Ql	Ql		

AN, antenatal; I/V, interview; MW, midwife; Ql, qualitative; Qt, quantitative; RQ, research question.

TABLE 17 Process evaluation reporting framework: processes involving target population (continued)

RQ no	RQ	During training			Post training			Implementation phase			End of study				
		Training attendance	Training observation	Pre-/post-training questionnaires	Training evaluation questionnaire	I/V MW interviews	Champion interviews	Champion monitoring	Distribution of resource packs	Implementation questionnaire	I/V MW interview	Champion interview	Control MW interview	Women's questionnaires	Women's interviews
		Qt	Qt and QI	Qt	Qt and QI	QI	QI	Qt and QI	Qt	Qt and QI	QI	QI	QI	Qt	QI
2d, 2e, 3	What factors might explain/contribute to differences in number of women told about PFME in intervention vs. control group?	Qt	Qt	Qt	Qt and QI	QI	QI	Qt and QI	Qt	Qt and QI	QI	QI	QI	Qt	QI
2e	How many women did MWs want to/were able to refer for specialist advice/management of UI?							Qt		Qt					
2d, 2e	Were women who perform PFME now, and those who practised regularly (\geq a few times a week) during pregnancy and in the past month, told about PFME by their MW?													Qt	QI
2d, 2e	How often were women who perform PFME now, and those who practised regularly (\geq a few times a week) during pregnancy and in the past month, told about PFME?													Qt	QI

continued

TABLE 17 Process evaluation reporting framework: processes involving target population (*continued*)

RQ no	RQ	During training		Post training			Implementation phase			End of study					
		Training attendance	Training observation	Pre-/post-training questionnaires	Training evaluation questionnaire	I/V MW interviews	Champion interviews	Champion monitoring	Distribution of resource packs	Implementation questionnaire	I/V MW interview	Champion interview	Control MW interview	Women's questionnaires	Women's interviews
		Qt	Qt and QI	Qt	Qt and QI	QI	QI	Qt and QI	Qt	Qt and QI	QI	QI	QI	Qt	QI
2d, 2e	Did more women practise PFME during pregnancy in intervention vs. control group?													Qt	
2d, 2e	Did more women adhere to PFME during pregnancy in intervention vs. control group?													Qt	
2d, 2e	Did women report more self-efficacy for PFME in intervention group?													Qt	
2d, 2e	What factors might explain differences in women's practice, adherence, and self-efficacy for PFME (if any) between intervention and control group?	Qt	Qt and QI	Qt	Qt and QI	QI	QI	Qt	Qt	Qt and QI	QI	QI	QI	Qt	QI

AN, antenatal; I/V, interview; MW, midwife; QI, qualitative; Qt, quantitative; RQ, research question.

could pose a challenge to training implementation. The data were coded deductively, as well as checked inductively, to establish the main themes that arose from that data set.

Both analyses were synthesised narratively, highlighting any points for training refinement.

Pre-/post-training confidence questionnaires

The questionnaires were completed by consenting intervention midwives before and after the training sessions. There were eight questions that were a part of the survey, scored using a 5-point Likert scale (0 = not at all confident to 4 = completely confident), giving a range from 0 to 34. Therefore, a higher overall score implies a greater confidence in discussing and teaching PFME in antenatal care. The data collected from this source allowed for individual question quantitative summaries.

A summary score was produced for each question for both the pre- and post-training questionnaire. The question summary scores were summarised with descriptive statistics (e.g. median, IQR, mean, SD). Box charts and bar charts were used to visualise these findings. The pre- and post-training confidence scores were used to calculate any change in confidence before and after training, per question. The appropriate parametric or non-parametric repeated measures inferential statistic was used, with $p < 0.05$ indicating a significant change in confidence.

Training evaluation questionnaire

An anonymous questionnaire was completed post training by intervention midwives. The questionnaire involved six 10-point Likert scale questions (0 = negative response, through to 10 = very positive response, to the training) as well as free-text responses about the acceptability of the training content and delivery. The data from this questionnaire allowed quantitative analyses for each question, but the six Likert scale questions were not designed to be summed; the free-text data were analysed qualitatively.

Each Likert scale question was summarised descriptively (e.g. median, IQR, mean, SD). The free-text responses were analysed using content analysis⁵¹ for each question individually and then administered on the data set as a whole. It was initially an inductive analysis, using a subset of questionnaires to develop categories and a coding framework for use with the remaining questionnaires. Text was analysed for the appearance and frequency of specific content, and the process followed the four steps outlined below.

1. Inductive analysis to identify codes. Coding focused on capturing manifest content (i.e. content which was visible and obvious rather than implicit). This is the most appropriate level of analysis where brief, possibly single-word, responses were recorded. Codes were grouped into categories for each question.
2. The first round of analysis grouped codes into categories for each question to create a coding framework, using a subset of questionnaires.
3. The coding framework was applied to the remaining questionnaires and the frequency of occurrence of coding categories was recorded.
4. A second round of analysis was conducted to look at the data set as a whole (rather than by question). Data were analysed deductively based on the BCW, and inductively to identify any additional themes arising within the data.

Quantitative and qualitative analyses were synthesised narratively, highlighting any points for training refinement.

Interviews were conducted with intervention midwives and champions (post training and end of study), and control midwives (end of study) and women (end of study, post questionnaire completion).

Thirteen interviews, each for 30–60 minutes, were conducted with intervention midwives and champions post training. They aimed to gather information on the midwives' experience of the training

and of implementing the training into their practice, including any limitations they experienced and suggestions to improve the training. The interviews also focused on midwives' views on the acceptability of the training session and its content. Interview topic guides were informed by the logic model (see [Appendix 2, Figure 4](#)), BCW theoretical framework and Sekhon's acceptability framework.⁴⁹

Data were analysed using a hybrid thematic approach, combining deductive and inductive analyses.⁵² Deductive (or theoretical) thematic analysis was driven by the logic model for the intervention (see [Appendix 2, Figure 4](#)), the BCW theoretical framework that was used to guide intervention development,³⁶ and Sekhon's acceptability framework,⁴⁹ which helped inform the topic guides. Inductive thematic analysis enabled identification and analysis of any novel themes that did not fit into the predefined theoretical framework.¹¹ Telephone interviews were transcribed by an approved transcription service. Online interviews conducted via Zoom were auto transcribed and checked for accuracy.

The phases of thematic analysis were as follows:

1. checking and reading of transcripts and data familiarisation
2. initial coding using deductive and inductive approaches
3. 10% of transcripts will be coded by a second analyst
4. identification of themes
5. reviewing of themes
6. theme definition and naming
7. finalising and reporting of analysis.

Analysis was discussed by analysts and research team members to support the interpretation of the data.

Champion monitoring

Data source: champions recorded their activities related to this role using a template form provided in the champions' manual. Entries included, for example, the number and nature of requests for support from the midwives in their team (number of requests for advice or onward referral) plus any open-text data reflective journal detailing the support they offered to midwives, any observations regarding any possible contamination between intervention and control teams, as well as their general experiences of being a champion.

Quantitative data were summarised descriptively. Free-text and qualitative data were summarised using content analysis (as detailed previously).

Distribution of resource bags for women

Data source: the trial research team recorded the number of resource bags given to teams. These data were summarised descriptively.

Fidelity of intervention implementation questionnaire

An anonymous questionnaire was completed during the implementation period by 59 intervention midwives. The questionnaire involved seven 5-point scale questions about implementing APPEAL training to the women in their care (4 = 'yes, all women' through to 0 = 'no women'); one 4-point scale question about appointments (3 = 'at all appointments' through to 0 = 'never'); one 'yes/no' question about referrals made (including frequency of referral if yes); two questions, one on barriers and one on facilitators to implementation, each with nine categorical response options (tick as many that apply) and a twelfth question inviting any other comments (free-text responses). The data from this questionnaire allowed quantitative analyses for each question, but the questions were not designed to be summed; the free-text data were analysed qualitatively using content analysis as detailed previously.

Quantitative and qualitative analyses were synthesised narratively, highlighting any points for training refinement.

Women's questionnaires

Sections 3–5 of the APPEAL outcomes questionnaire for women were further analysed within the process evaluation in conjunction with, and after, the preliminary statistical analysis had taken place. Summaries of intervention and control arm responses to sections 3–5 (PFME performance, information received from midwife, PFME self-efficacy and adherence) were undertaken as part of the main trial analyses and then incorporated into this process evaluation.

Responses to section 3 supported identification of midwife fidelity to the PFME intervention for women and possible contamination between clusters (see [Table 18](#)); section 4 would indicate women's self-efficacy for PFME; and section 5 would indicate women's adherence to PFME. Response rates to these sections indicated the feasibility and possible acceptability of collecting PFME outcome data from women.

Responses to questions in section 3 were reported narratively using descriptive summaries (e.g. range with mean and SD or mode and median) where appropriate.

Section 4 contained the 17-item Chen PFMESES.⁴² Items are scored using a 5-point Likert scale (1 = strongly disagree, 2 = disagree, 3 = neutral, 4 = agree, and 5 = strongly agree), with a possible summed score range from 17 to 85 (higher score indicating greater self-efficacy for performing PFME). The scale contains two factors: (1) belief in PFME execution and benefits (items 1–4, 10, 12–17); and (2) belief in performing PFME as scheduled and despite barriers (items 5–9, 11). Missing data were examined and reported, and any imputation undertaken in accordance with the main trial analysis. A total self-efficacy score and subscores for each factor were summarised for the intervention and control arms. (NB as described earlier, the omission by BCTU of four questions rendered this full scale invalid.)

Section 5 contained the six-item EARS.⁴³ Items are scored using a 5-point Likert scale (from 0 = completely agree to 4 = completely disagree) with a possible summed score range from 0 to 24. Items 1 and 5 are reverse scored. A higher overall adherence score indicated better adherence to exercise. Missing data were examined and reported, and any imputation undertaken prior to statistical analysis in accordance with the main trial analysis.

Associations between variables that may explain differences in PFME practice, adherence and self-efficacy were explored descriptively. For example, for women who performed regular PFME: (1) what proportion were told about PFME by their midwife? (including how often they were told to perform PFME), and (2) what proportion were given a resource bag? Did women who reported being told about PFME by their midwife and/or who were given a resource bag, also report greater adherence and/or self-efficacy for PFME? These data were summarised descriptively.

Reporting

Results for training attendance, training observation, and distribution of resource bags for women were reported as text. Quantitative questionnaire results (pre- and post-training confidence; training evaluation, fidelity of intervention implementation, and women's outcomes) were presented in tables. Qualitative results (questionnaire free text or interviews) were presented in tables for content analyses and in text boxes for thematic analyses. Results arising from the champion monitoring notes were presented in accordance with the data source arising (e.g. in tables for numerical summaries and for free-text content analyses).

TABLE 18 Identifying fidelity to PFME intervention – interpretation of responses to women’s questionnaire section 3

Section 3	Intervention	Control
How often did you perform pelvic floor muscle exercises when you were pregnant? (Tick one option)	Never advised = off protocol Never (other), a few times a month, once a week = off protocol ≥ a few times a week = on protocol	≥ a few times a week = indicative of possible contamination? (but it is in NICE guidelines so they may have received some other leaflet/information)
Do you currently perform pelvic floor muscle exercises? (Tick one option)	Never advised = off protocol Never (other), a few times a month, once a week = off protocol ≥ a few times a week = on protocol	≥ a few times a week = indicative of possible contamination? (but it is in NICE guidelines so they may have received some other leaflet/information)
How often did you do pelvic floor muscle exercises over the last month? (Tick one option)	Never advised = off protocol Never (other), a few times a month, once a week = off protocol ≥ a few times a week = on protocol	≥ a few times a week = indicative of possible contamination? (but it is in NICE guidelines so they may have received some other leaflet/information)
Did your midwife advise you to perform pelvic floor muscle exercises when you were pregnant? (Tick one option)	No = off protocol	Yes = indicative of possible contamination? (but it is in NICE guidelines so they may have received some other leaflet/information)
Did your midwife explain how to perform pelvic floor muscle exercises when you were pregnant? (Tick one option)	No = off protocol	Yes = indicative of possible contamination? (but it is in NICE guidelines so they may have received some other leaflet/information)
Did your midwife give you a pack of information on pelvic floor muscle exercises when you were pregnant? (Tick one option)	No = off protocol	Yes = indicative of possible contamination? (but it is in NICE guidelines so they may have given some other leaflet/information)
When did your midwife give you the pack of information on pelvic floor muscle exercises? (Tick one option)	Never, at another appointment = off protocol At my first or second appointment = on protocol	At my first or second appointment = indicative of possible contamination? (but it is in NICE guidelines so they may have given some other leaflet/information)
How often did your midwife talk to you about pelvic floor muscle exercises when you were pregnant? (Tick one option)	Never, once only, occasionally = off protocol At every appointment = on protocol	Yes = indicative of possible contamination? (but it is in NICE guidelines so they may have received some other leaflet/information)
Did your midwife ever ask you if you had any difficulties with performing pelvic floor muscle exercises? (Tick one option)	No = off protocol	Yes = indicative of possible contamination? (but it is in NICE guidelines so they may have received some other leaflet/information)
Before you were pregnant have you ever been taught or learned how to perform pelvic floor muscle exercises? (Tick one option)	Compare intervention vs. control to assess baseline self-reported PFME performance	

Appendix 6 Summary of training evaluation

TABLE 19 Contact questionnaire results: midwives' reported PFME experience

Midwives reported PFME training and experience (n = 68)	Mean (SD)	Median (IQR)
Years as a midwife	11.3 (9.2)	8 (5–14)
Years as a community midwife	6.2 (6.4)	5 (1–8.25)
Midwives' previous PFME training (n = 47) ^a	Frequency, n	Percentage, %
None	34	72.3
Non-specific	3	6.4
Specific – minimal	7	14.9
Specific – substantial	3	6.4

a 21 missing responses.

TABLE 20 Descriptive summary of midwives' post-training evaluation questionnaire

Topic ratings from midwives' post-training evaluation questionnaire	Numerical response (range 0–10) Mean (SD)
Overall, did you find the training useful? (n = 64)	9.4 (1.2)
How did you find the training content? (n = 64)	9.3 (1.0)
How helpful did you find the method of training delivery? (n = 64)	8.7 (2.0)
Will the midwives' resource pack be useful? (n = 63)	9.1 (1.4)
Overall, would you recommend the training? (n = 65)	9.4 (1.0)

Note
0, Negative score (e.g. 'not useful at all'), through to 10, positive score (e.g. 'very useful').

TABLE 21 Change in midwives' confidence ratings

Midwives' confidence ratings question ^a	Pre training	Post training	z score ^b , (p-value)
	Median confidence score (IQR)	z score ^b , (p-value)	
1. Raising the topic	3 (2–3)	4 (3–4)	–5.3 (p < 0.001)
2. Raising the topic of UI	3 (2–3)	4 (3–4)	–5.3 (p < 0.001)
3. Understanding pelvic floor anatomy	2 (1–2)	3 (3–4)	–6.3 (p < 0.001)
4. Assessing a PFM contraction	2 (1–2)	3 (3–4)	–6.4 (p < 0.001)
5. Teaching pregnant women to do PFME	2 (2–3)	4 (3–4)	–5.9 (p < 0.001)
6. Giving further advice about how to do PFME	2 (2–2)	3 (3–4)	–6.2 (p < 0.001)
7. Referring women who cannot do a PFM contraction for further help	2 (1–2)	3 (3–4)	–6.1 (p < 0.001)
8. Advising women on how to manage UI	2 (1–2)	3 (2–4)	–6.2 (p < 0.001)

a Likert scale, five response options: 0 = 'not at all confident' through to 4 = 'completely confident'.
b Difference in before and after training confidence ratings: Wilcoxon signed rank test results.

Appendix 7 Champion monitoring data (including interview data)

TABLE 22 Time spent on champion role and number of queries and referrals reported to champions

	April	May	June	July	August	September	October	November	December
Mean time spent on champion role (minutes) (n = 8 teams)	48.4	63.8	64.4	61.3	52.5	63.0	75.0	40.0	32.9
Range of time (minutes) spent on champion role (n = 8 teams)	27–60	30–120	15–120	0–240	0–180	15–120	10–180	0–60	0–60
Total APPEAL queries recorded by champions (n = 8 teams)	7	1	5	1	1	0	0	0	0
Total referrals to pelvic health physiotherapist reported to champions (n = 8 teams)	2	3	4	0	2	5	1	2	1

TABLE 23 Activities reported by champions

Activity/nature of query	Frequency
Supporting training dates	1
Answering general team queries/discussing/reminding team re APPEAL in team meetings	9
Sending reminders to team, for example via WhatsApp	1
Attending champion meeting	1
Ordering resources for women, including resource bags and leaflets in different languages	2
Addressing queries:	
What appointment do I raise topic of PFME?	1
Do I start PFME if someone transfers to me at 34/40 weeks' gestation	1
Do I discuss APPEAL at every appointment?	1
Referral criteria for specialist pelvic health physio, including how and when to refer	3
Reminder of what to say in APPEAL	1
How to document PFME/APPEAL	3
Troubleshooting/peer support, for example fitting APPEAL into busy appointments	2
Support for MSWs/assistants trained in APPEAL	1

TABLE 24 Acceptability of champion role (from qualitative interviews)

Summary of findings	Illustrative quotes (participant identification number not included to avoid possibility of identification due to small numbers of champions interviewed)
Not a big commitment: Role does not take too much time Approx 1 hour per month	<ul style="list-style-type: none"> • [champion role] probably not too much time, it might take an hour a month, I'd have thought. • [champion role is] not that bad, because it's not a lot of work that you have to do.
Less enthusiasm if did not volunteer for the role	<ul style="list-style-type: none"> • I was a bit annoyed because I was like, was my name picked out of a hat or was it just because I was on annual leave, and I couldn't stand up, I couldn't say that I didn't want to do it.
Champion training was useful: Helped understand documentation and referral processes Champions highlighted gaps in APPEAL training re documentation and referral – modified accordingly	<ul style="list-style-type: none"> • Yeah [champion training] was good. It gave us the right information I think that we needed and, especially, because we could all say well, is this correct for us to be doing that? And one person might say about this idea and I've started that with my team, so then it's helped, you know, others say yeah that works. • it was good to hear [at the champion training], like, everybody else's tips, and like, and see how everybody else is doing, and to sort of see that you're not the only one that's like, it's like getting blood out of the stone. Um, but yeah, so it was just useful, just to see what everybody else was doing really.
Champion meetings are useful for peer support and shared learning	<ul style="list-style-type: none"> • the meetings have been good since and hearing how other people are getting on. And like, we're all having similar challenges with like time constraints, but then other people have good ideas about what you can say and how to talk to women and, like we talked about, like, sending out text messages. The [champion] training was good. The meetings are helpful.
Champions see their role to support team with reminders for APPEAL and support for referrals	<ul style="list-style-type: none"> • we have our weekly meetings and I'm always that person who's like, 'remember your APPEAL'. • the feedback that I got from, like, my team itself, we were like, 'Oh, we don't know how to document it'. The champion training sort of, like, tells you how to [document]. • People have come to me if they've needed to but it tends to be for the referrals or just to check do we refer at this point, or 'could you send this referral across, I've got this information' [. . .] I've only had to do the one referral so far, and the other two we're just seeing. • I've made this [laminated card] for all of the team as well. So they can just refer to it themselves, and I think just by sort of saying to it, saying to them each week, like, look if you refer anyone, let me know, if you have any problems like let me know, is there anything that you're struggling with.
Champions may experience challenges motivating teams	<ul style="list-style-type: none"> • I literally have to be like, 'how are you all getting on?' like, you know . . . I literally have to ask them questions and like I'll send them videos and stuff but nobody ever really says much about it. Like in the team meetings I'll ask and they'll be like, to be honest, I keep forgetting or, um, they'll be like 'yeah I do do it', but you know that's sort of the response that I get, to be honest. • I just feel like it goes over people's heads a little bit. Um, so I would always try to talk about, I do try to talk about it, like I'll put messages in the WhatsApp group and like we talk about it at the team meetings and things, but I feel like you talk about it and then it's just [makes 'swoosh' sound] . . . • it's difficult because [communication is] all over messages at the moment, so obviously face to face with your team, it's a little bit different. They might . . . whether we, when we have our team meeting this month, I might be able to approach it again because, at the last team meeting that's when a couple of people were like 'I've not managed to get it into my clinic', so I think this team meeting, which is going to be over Zoom again, by approaching it again I might be able to get more of an insight to that really as opposed to now because it's just messages . . .

TABLE 25 Challenges and solutions reported and/or discussed by champions in team meetings

Challenges	Suggested solutions
Language barriers	<ul style="list-style-type: none"> • Leaflets/training of MSWs/link workers • Translating screening questions, especially for languages not covered by translated leaflets • Are there other members of research team that could support with translation needs? Perhaps across champions or within midwifery teams?
Time – being able to fit into booking/16-week appointment	<ul style="list-style-type: none"> • Brief mention of PFME at booking and to raise again at 16 weeks • Don't try to do it all at booking • Encouraged midwives to voice issues of time – in order to make long-term change to policy and appointment length • Change 16-week appointment to 20 minutes if possible
Reluctant team members/hostility of team Feels like nagging the team	<ul style="list-style-type: none"> • Reminder that it is not champions who are responsible for increased/change in workload. The Trusts have been asked to do it • Fund for cake/biscuits to support champions to take to APPEAL meetings with midwives
Gaining trust as new member in the team	<ul style="list-style-type: none"> • Opportunity to speak at team meeting to introduce role
Worry about contamination	<ul style="list-style-type: none"> • To deliver intervention to all women in home birth team unless asked otherwise
Lack of opportunities to ask multiparous women	<ul style="list-style-type: none"> • Text/phone during second trimester to remind women/ask about how they're getting on • Set up automated text on Badgernet
Remembering to do the intervention/behaviour change for midwives	<ul style="list-style-type: none"> • Bookmark idea (laminated the A5 sheet with info about how to do APPEAL) • Reminder of A5 leaflet available in midwives training folder, for midwives to carry round with them • Reminders on WhatsApp • Team meetings • Separate APPEAL meetings • Asking for data on referrals by giving them a template for them to fill in • Keep APPEAL leaflet in women's notes to remind her and midwife • Champion created prompt card for all midwives
Getting the women on board – women paying lip service to the midwives when asked about PFME	<ul style="list-style-type: none"> • Remember to ask open questions • Asking about UI may help women to engage (especially if struggling with UI symptoms)
Lack of face-to-face time with team to keep APPEAL fresh in team members' minds	<ul style="list-style-type: none"> • Set up a Zoom call with team • WhatsApp group specifically for APPEAL • Utilise team WhatsApp
Needing quick answers to PFME issues in clinic	<ul style="list-style-type: none"> • Sharing mobile numbers of champions for a resource/support in clinic
Getting feedback from team midwives re implementation of APPEAL	<ul style="list-style-type: none"> • Questionnaire filled in by midwives prior to team meeting • Audit of notes re APPEAL documentation, prizes for teams with highest recorded documentation

Appendix 8 Implementation questionnaire results

TABLE 26 Summary of implementation questionnaire response scores from midwives in the APPEAL intervention trial arm

Response options	Questions from the implementation questionnaire							
	Q1. PFME raised first antenatal appointment? (n = 52)	Q2. Women given resource bag? (n = 56)	Q3. Contents of the resource bag discussed? (n = 55)	Q4. How often do you ask women about UI? (n = 55)	Q5. Teach women to do a PFM contraction? (n = 57)	Q6. Women practise PFM contraction at appointment? (n = 56)	Q7. Do you set a PFME programme? (n = 54)	Q8. Do you review progress throughout pregnancy? (n = 53)
No women	0 (0%)	2 (4%)	0 (0%)	2 (4%)	0 (0%)	5 (9%)	5 (9%)	3 (6%)
Yes, a few women	2 (4%)	4 (7%)	3 (5%)	N/A ^a	4 (7%)	8 (14%)	5 (9%)	9 (17%)
Yes, some women	4 (8%)	12 (21%)	3 (5%)	18 (33%)	14 (25%)	18 (32%)	12 (22%)	16 (30%)
Yes, most	21 (40%)	28 (50%)	22 (38%)	30 (55%)	24 (42%)	21 (38%)	25 (46%)	21 (40%)
Yes, all	25 (48%)	10 (18%)	27 (51%)	5 (9%)	15 (26%)	4 (7%)	7 (13%)	4 (8%)

^a Response option not available for this question.

TABLE 27 Summary of implementation questionnaire numerical and related free-text responses from midwives in the APPEAL intervention arm

Topics from implementation questionnaire	Numerical response summary	Comments reported in association with numerical responses	Additional free-text comments
Women practise pelvic floor muscle contractions at appointment (Q6: Are you managing to get women to practise a PFM contraction during an antenatal appointment with you?) (n = 56)	Of those midwives that completed the question, 45% stated that all or most women were practising pelvic floor muscle contractions at their appointments compared to the other response options.	'Not time to do in clinic' 'Clinic is constantly over-run' 'We don't have enough time to discuss this regularly, or to spend assessing PFME' 'Language barrier is sometimes an issue' 'Quite time-consuming with already limited time and language barriers'	'Most women are receptive to PFME information and advice' 'Most if not all women I have discussed PFME with have been receptive and enthusiastic about PFME and I have found it a very easy topic to discuss' 'Concerns regarding restrictions' 'A video would be helpful' 'Need a prompt on Badgernet so I remember'
Referrals to a physiotherapist (Q9: Have you needed to refer women to the physiotherapy department for managing incontinence? If yes, how many?) (n = 50)	Of those midwives that completed the question, 36% referred women to physiotherapy. The total number referred was 44. Mean = 2 SD = 1.5	N/A	N/A

continued

TABLE 27 Summary of implementation questionnaire numerical and related free-text responses from midwives in the APPEAL intervention arm (*continued*)

Topics from implementation questionnaire	Numerical response summary	Comments reported in association with numerical responses	Additional free-text comments
Barriers to implementation (Q10: Are there any barriers to you implementing the APPEAL intervention and if so, what?)	Top three: <ul style="list-style-type: none"> • Lack of time (<i>n</i> = 39) • Forgetting (<i>n</i> = 29) • Language barriers (<i>n</i> = 26) 	'Generally, I feel like I don't have time to complete this and all the other checks we have to do' 'It is very difficult to teach PF during a 20/30 [minute] appointment still' 'It would eventually be very helpful if the APPEAL intervention was available via a tick box on Badgernet. This would save precious time and more likely not to be forgotten. Sometimes on odd occasion would discuss PFM with women but forget to document on Badger' 'Short staffing within the team therefore picking up more visits made it difficult to remember.' 'Language barriers were also a major impact on asking about UI and PFME'	'I do not think the resource pack was effective' 'I think more leaflets and different languages as not all people have access to a smartphone to download app. Visual leaflets would be more beneficial. Statistics would also help encourage women' 'Need more resource packs'
Helping implementation (Q11: Is there anything that helps you implement the APPEAL intervention?)	Top three: <ul style="list-style-type: none"> • APPEAL women's resource bag (<i>n</i> = 31) • APPEAL prompt card (<i>n</i> = 17) • Team champion (<i>n</i> = 16) 	There were no comments associated with the numerical responses for this question.	'I think this will really benefit women and will have a big impact on improving UI' 'This intervention has helped increase my knowledge and understanding e.g. women with hyperemesis. I would not have originally referred to physio'

Appendix 9 Interviews with intervention midwives during implementation

TABLE 28 Experience of midwives interviewed during implementation

Intervention midwives: implementation phase (N = 13) ^a	
Role description (n)	Team lead (2) Community midwife (7) APPEAL champion (4)
Years as midwife, mean (range)	10.62 (2–31)
Midwives with > 5 years' experience as midwife, n	8
Midwives with ≤ 5 years' experience as midwife, n	5
Years as community midwife, mean (range)	4.69 (0–12)
Midwives with > 5 years' experience in community, n	5
Midwives with ≤ 5 years' experience in community, n	8

a n = 2 intervention midwives interviewed in both implementation phase and end of study.

TABLE 29 Themes developed from interviews with midwives during implementation

Major themes	Subthemes	Supporting quotes
Theme 1: past training and experiences	Range of past experience and training history	'Um, 3 years ago, so yeah, 2018' (124) '20 years this year' (103) 'No, . . . no actual training' (120) 'Um, I remember making models . . . with like Playdoh of the pelvic floor . . . we all had like a session where we were all doing pelvic floor exercises'. (140)
Theme 2: acceptability of online delivery of training session	Benefits of online delivery, positive comparisons with in- person delivery Limitations of online delivery, negative comparisons with in- person delivery	'uh, and I think it probably works better for some people, as opposed to getting to venues. Um, it's a little bit easier'. (124) 'I found it really good especially how they were able to share their screen. I felt like was able to concentrate a little bit more . . .' (112) 'So, I actually think it worked better virtually. Yeah'. (103) 'I think anything is better face to face'. (120) 'I think while on the training was difficult because there was a group of us and, you know, connections, and it dropping out . . . people saying the same thing about 10 times . . . it would have been much better to just do it face to face'. (137) 'I think you do lose some of the non-verbal things that you would have in a face-to-face environment'. (113) 'I think a lot of people tend to be more quiet online . . . we don't like the online speaking and seeing ourselves. I think that makes a difference'. (120)
Theme 3: midwives' engagement	Engagement with content Engagement with delivery style	'I thought we probably should have had something like that during our actual midwifery training, rather than kind of years and years on. It would have been really helpful'. (122) 'I thought it was very much a two-way thing, rather than just being lectured at or talked to . . .' (136)

continued

TABLE 29 Themes developed from interviews with midwives during implementation (continued)

Major themes	Subthemes	Supporting quotes
Theme 4: how the training influenced PFME knowledge	Knowledge New attitude/skills	'... especially because I've got no children myself... you always hear like I can't cough or I can't sneeze... but actually looking at the statistics it was mind-blowing how many women are actually affected by it'. (112) 'I swear when I was a student we was only ever taught like postnatally'. (162) 'I don't know, even if they told me they were leaking urine, I wouldn't have even considered referring them to a physiotherapist. I wouldn't have known what to... I'd have been like, "do your pelvic floors. It'll get better, if not speak to your GP"'. (112)
Theme 5: midwives' attitude towards training	Positive attitude towards training Negative attitude towards training	'I thought it was really helpful. I think [PFME] is really important. I think... pelvic floor exercises can make a massive difference to women in their whole life, not just in pregnancy'. (122) 'I think it should be something that we should include in mandatory training as well'. (120) 'Boring' (162) (References were also made to the statistics being confusing, and the video scenario not being representative of practice conditions.)
Theme 6: suggestions to improve training	Training on anatomy and physiology is important for PFME to support labour	'I think all of that is essential really as part of the training, you need to know anatomy and physiology to understand what you're teaching, and then the practical advice as well... I think it was all essential'. (140) 'I think that's what swaying a [lot] of ladies as well, because a lot are interested in labour and how they can improve labour...'. (167)

TABLE 30 Concurrent acceptability of implementing PFME following APPEAL training

Construct of acceptability ^a	Summary of findings	Illustrative quotes
Affective attitude 'I'm enthusiastic about it'	<ul style="list-style-type: none"> Mostly positive and enthusiastic Some ambivalence – based on negative personal experience, and another thing to fit in 	<ul style="list-style-type: none"> 'I think being able to have more knowledge to be able to do [teach PFME] more effectively, um it's beneficial to both me and my ladies, so yeah, enthusiastic' (136) 'I had, um, a prolapse after my first one, um, And then, my second even worse, so I ended up having, um, surgery to correct that and I felt at the time that I, you know, done my pelvic floors and that it, you know, no matter how hard I tried it just wasn't enough. And then I always felt like afterwards, you know you're trying to fight a losing battle so from my point of view I almost feel like in some aspects you've kind of got stretchy skin or good muscles, or you haven't, ...'. (103) 'I just think, like I remember everybody saying, because everything got cancelled for COVID, and then we were like, because it wasn't necessary, and then they were like "Oh, but this is necessary", like why? Everybody, I just remember everybody saying this doesn't feel like this is something that we have to be doing right now with everything that's sort of going on'. (162)

TABLE 30 Concurrent acceptability of implementing PFME following APPEAL training (continued)

Construct of acceptability ^a	Summary of findings	Illustrative quotes
Burden 'it just feels a bit impossible'	<p>Intervention itself requires little effort, not a big change to practice, easy to incorporate. In principle, no extra effort to put into practice. However, significant level of burden required to implement:</p> <p>Current overwhelming environment and system pressures limit midwives' ability to implement as trained</p> <p>High burden mainly due to volume of workload, limited appointment times, system pressures, for example Ockenden report</p> <p>While time pressure is cited, often challenge is remembering everything – prompts on IT system likely to reduce this burden of remembering</p> <p>Duration of experience as community midwife – midwives new to community see it as less effort to incorporate into their practice</p>	<ul style="list-style-type: none"> • '[APPEAL is] not a massive change in how we practice, it's just [. . .] more how we give information to women [. . .] which can easily be, be incorporated into our day-to-day activity, it was nothing that we suddenly have to do, we have to do a procedure differently, for example, it's a very easy way to go about it in our everyday appointments with our women'. (112) • 'I think if it became a thing, you'd just get used to it and it becomes part of your daily practice, so you don't feel those time constraints'. (120) • 'So, you know, it is something that I'm happy to touch on, I think at booking, you know, and dip in and out as we can, but am I going to spend five minutes every antenatal appointment discussing their pelvic floor? Not in the current climate, no, I think that I would find that really difficult to do'. (113) • '[current workload] it just feels a bit impossible sometimes . . .' (122) • 'again it's the time and the stress. Because I'm a very stressed person at the moment. [yeah] It's just the thing, the time is my issue and the number of the things that we need to do, but I will do it' (157) • 'I think it's manageable, but for me because I'm new to community, I'm adapting my practice anyway, so I can . . . it's okay, but some people might have been here 15/20 years. So, adding that extra question to their practice might seem like a complete minefield, I don't know. [. . .] Because of it being routine, but for me it's new anyway so another question in there doesn't matter because I'm learning as it is'. (124) • ' . . . there's a lot of older, sort of like, midwives in the team who don't like change [. . .] realistically it's not that much effort to ask a couple of questions. I think it's definitely a generation thing'. (112) • 'we've got two people starting [. . .] I think, because they're both new into community I'm not going to mention things like time constraints because it will be their norm, so they'll come in and that's what they will have always done it at 16 weeks is they will have talked about pelvic floor exercises'. (120)
Ethicality 'it's a very good fit'	<ul style="list-style-type: none"> • Excellent fit with personal and professional values system • Belief that important for women • Appropriate part of antenatal care 	<ul style="list-style-type: none"> • 'I think it's a very good fit. Yeah, yeah it's good, I mean good information, necessary information and necessary, um, how do you say, um, kind of care that you, I think it can actually be the same as, um, if I'm not exaggerating, the same as if you're asking if the baby is moving, like baby movements. Because the incontinence is one of the things that, you know, can affect women for life' (157) • 'I think people just need to understand the importance of it [PFME training] more. So it's just as important as everything else that we talk about'. (162) • 'I do think pregnancy and midwifery is the right place for it to be, because then hopefully you can avoid the issues that will then involve gynae referrals, GP appointments, and I think we're the right place to do it, while things for most people are OK'. (120) • 'at the end of the day, it's for the benefit of your women and everything we do should be for the benefit of our women. So we should try whatever we can to make that a better outcome at the end of the day, so yeah, healthy mum, healthy baby, promote anything you can as you go along'. (136) • 'it's a standard routine that actually, why were we not taught this before, and why have we never been giving this level of information to women' (112) • 'Yeah I think it's just as appropriate as anything else that we talk about really because it could be, it could mean the difference from a woman not suffering postnatally with urinary incontinence, you know, not being embarrassed to leave the house because you think she's going to have an accident or plan her visits to places because of needing the toilet [mmh]. So I think it's really important as a part of our practice to be honest [yeah]' (124)

continued

TABLE 30 Concurrent acceptability of implementing PFME following APPEAL training (continued)

Construct of acceptability ^a	Summary of findings	Illustrative quotes
Intervention coherence 'I've never thought about the impact of pregnancy on the pelvic floor'	<ul style="list-style-type: none"> • Training improved knowledge and awareness, better understanding of UI and PFME • Acknowledge importance of PFME 	<ul style="list-style-type: none"> • 'I didn't realise actually how much of an effect pelvic floor exercises had on women. And, especially because I've not got children myself, like, I don't sort of like, you always hear the, like, oh yeah I can't cough or I can't sneeze or anything, but actually like looking at the statistics, like, it was mind-blowing, how many women are actually affected by it' (112)
Opportunity costs 'so many other priorities'	<ul style="list-style-type: none"> • Nothing else can be dropped. If anything, APPEAL is first to go as not on priority list 	<ul style="list-style-type: none"> • 'I think I'm going to struggle to do, to make it an every appointment thing. I've got so many other priorities' (113)
Perceived effectiveness 'I think it should help to get that message across'	<ul style="list-style-type: none"> • Mixed views • Hopeful rather than certain • Some concerns that women won't do it 	<ul style="list-style-type: none"> • 'I think for the women who we identify problems with, and we refer to physio, I think they're the groups that are going to benefit the most because they're in that system of being followed up. However, the women who you speak about it every appointment, they're the ones who forget, I feel like that isn't going to really make much of a difference. Um, but I'm hoping that . . . because if it becomes part of standard care, it's approached at every appointment, it's only so many times you tell someone something before they start to remember it so I'm hoping that would, like . . . it would help them. Um, and especially if all women are being given that information, that when they speak among their friends, like outside of a midwife, they're like "Oh, are you doing your pelvic floor?" Like, because they talk about stuff like that, don't they?' (112) • 'I think we weren't doing anything before were we, so you know, I think it should help to get that message across more and for women to know that, you know, it's not normal and that we can do things to help prevent it, and that, you know, it might just open the conversation if they are having issues what pathways they can go down, you know, post-delivery'. (113) • 'It's like everything, a dripping tap isn't it, hopefully you'll get the message through at some point, um, you're going to get those that are enthusiastic and you're going to get those that just have a lifestyle that it doesn't fit into, and then you'll get those that will be, you know tick the boxes as you go along really, but it's quite verbal, it's quite difficult in a way to really know if they are doing pelvic floor properly, but you can only assist or inform or advise, at that point anyway'. (136)
Self-efficacy 'I do feel confident'	<ul style="list-style-type: none"> • Mixed – confident but uncertain about putting into practice due to system pressures (see Burden) 	<ul style="list-style-type: none"> • 'I do feel confident yeah, right, I do understand it, and I will be able to implement this with the women'. (122) • 'I'm quite confident that I can continue, um, again, as long as I've got enough time to do so [laughs]. Yeah it's literally, it's not an issue, it's just the timing'. (137) • 'I feel confident knowledge-wise, um, to do it, as I said it's just the timing. That's the biggest issue' (167)

^a Deductive analysis using Sekhon's theoretical framework of acceptability.⁴⁹

TABLE 31 What are the challenges, concerns and opportunities for midwives implementing PFME following training?

Theme	Summary of findings	Illustrative quotes
Challenges	<ul style="list-style-type: none"> • Difficult to implement as trained – system pressures, short appointment time, system inefficiencies impacting on clinic time – admin tasks, like chasing scan appointments and results within 20-minute antenatal appointment; habit formation – not embedded in routine practice yet, easy to forget with so much else to remember • Sustainability – maintaining momentum and enthusiasm • Diverse caseload – language, social circumstances can make it challenging to implement • Consistency of implementation within/across teams – hard to monitor who is implementing/ quality of implementation 	<ul style="list-style-type: none"> • 'I hope I didn't sound too negative saying, it wouldn't be a high priority but the fact of the matter is, we have got a lot of information to deliver, but certainly, you know, it should be included, and it should be up there, whether we can put as much time as perhaps the study and people who that's their passion would want us to, probably is a slightly different thing'. (113) • 'So a lot of people have commented about having 30-minute appointments, but that, it just wouldn't work. We'd never see all our women. But we do, most of us do 20-minute appointments at the moment, um, but they're saying for, especially for that one, like, 30-minute appointments, but a lot of that is because we're chasing the things, rather than just doing the midwife part of it, but having to chase admin parts of it as well'. (120) • 'Um, I think in the beginning to get started, is a lot of effort and it is another thing to remember isn't it. And they have so many things you have to remember for each appointment and it's just another thing to remember, but I suppose, the more you do it, it becomes part and parcel of your consultations and stuff. It becomes the norm doesn't it, so it might take a bit of a while to get used to, don't get me wrong, I'm still getting used to having to mention it each time, but it does come with time'. (137) • 'When you have so much going, like today, my clinic was just, I didn't do it with one lady because I just couldn't, I just forgot because I had so much going on, and some days it's literally like that, when you just can't, you just, you do a clinic and you're at the end, and you're like "I haven't done it today", because you just have so much else going on. But then other days you can do it with every lady, so it just . . . Swings and roundabouts really'. (162) • ' . . . suppose it's the same isn't it, to start off with you have that extra confidence and you say it, and then another thing comes in that we have to kind of do, and it kind of gets a little bit pushed back and then pushed back [. . .] when you've just done your training and then it sort of takes . . . you're really enthusiastic and then it sort of tapers off a bit'. (103) • 'the area that I work, it's quite a multicultural area, so I've found what's really difficult is people who aren't English speakers' (112) • 'I think some people [midwives] are more reluctant to make changes or doing something additional to what they're doing, but um, I don't know if anyone's not doing it, but equally I don't know whether they would say "Oh, by the way, then I'm not doing it"'. (140)
Concerns	<ul style="list-style-type: none"> • Accountability for pelvic health – fear of blame – physio should be more involved/visible in antenatal care • Uncertainty re effectiveness – concern that women won't engage (forget, not interested, difficulty understanding) • Sustainability – needs to be mandatory in order to prioritise 	<ul style="list-style-type: none"> • 'Like I don't understand why, like, our physios aren't more kind of like involved, do you know what I mean? Um, and especially with COVID, like one of my poor women, she got such bad pelvic girdle pain and I've referred to physio and they won't even see her face to face, [. . .] I suppose that, that's why I'm a bit like, oh, if I identify these women with a problem, which I need to do, but don't have trust in the process, [. . .] I feel like it's going to come back to me, "Oh you need to do this" and I just feel like, well actually I've had a two-hour session about pelvic floor and what I learned at uni like, seven, eight years ago'. (139) • ' . . . whether some people [women] are going to commit to it as well as others, that's another question, I don't know. They might just nod and say "yes I'm doing it"'. (124) • 'The training is a start, I think, as a start and it's a good start, especially with like kind of, again the app is one of the things that can help a lot. I think it can improve, but because it's a start now I can't comment on that because it takes time, the time is very important thing, and then for us to actually get used to the idea of doing this regularly and fitting it into our practice and become like a mandatory thing that we think that is necessary, we're not putting, like prioritising this to other things, or maybe as a, like, the whole antenatal check use that as one of like, um, into one of the necessary things we need to do in there'. (157)

continued

TABLE 31 What are the challenges, concerns and opportunities for midwives implementing PFME following training? (continued)

Theme	Summary of findings	Illustrative quotes
Opportunities	<ul style="list-style-type: none"> • APPEAL is changing antenatal care: midwives are asking about PFME/UI more frequently, raising the importance of PFME for women. Women's response is mixed, but seem interested (especially affluent caseloads) and accepting resources packs, some women have reported improvements in incontinence; change in referral practices supports better care; focus has moved from postnatal to antenatal care in line with evidence • APPEAL resources and structures facilitate implementation: champion role; multilevel prompts for midwives help create a routine – for example team lead, champion, urine dip, stickers on notes; whole-team approach promotes consistency of messaging/ avoids conflicting advice; women's resources, especially apps and online resources and language resources (APPEAL-trained interpreters, APPEAL leaflet in different languages) • Opportunities for improving implementation beyond APPEAL: longer appointment times; prompt for midwives on Badgernet; training all staff to ensure consistency of messaging – whole-team approach, plus beyond midwifery/ pregnancy; training updates – add to refresher training; make women's resources more accessible – put leaflets online (Badgernet) 	<ul style="list-style-type: none"> • 'I probably only used to really mention it [UI and PFME] at booking before and then maybe in late pregnancy and then after. I wouldn't mentioned it as regularly. So that's definitely changed my practice' (137) • 'I've had positive feedback from women. I've had a couple who've already had incontinence and they've noticed a difference from doing exercises . . .' (120) • 'I didn't even realise before that we could do that [refer to physio]. I don't know, even if they told me they were leaking urine, I wouldn't have even considered referring them to a physiotherapist. I wouldn't have even known what to . . . I'd have been, like, "do your pelvic floors. It'll get better. If not speak to your GP". That's all I would have . . . but actually being able to do that direct referral myself, and getting feedback that they've received the referral as well' (112) • ' . . . it's made me realise how important it is to do it in the antenatal period. I think, I swear when I was a student, we was only ever taught like postnatally, you know. And I do think it's crazy how it doesn't get touched on antenatally' (162) • 'I think, by having that one dedicated member in the team to remember to remind people to do it it's worked out really well'. (112) • ' . . . after I've checked to see if they've got any symptoms with urine, then if they're at the 16-week appointment I'll just say, "have you started any pelvic floor exercises" or "how are you getting on with them" or "if you haven't started". Because some people might say "I'm doing them, but not that often", um, so then I'll talk more about getting into a routine with it, but I think once I've done the urine sample it triggers me for that conversation'. (124) • Interviewer: ' . . . you mentioned, the, the MSWs will have been trained in your, your team as well, is that, is that useful?' 162: 'Yeah, massively useful, um, especially in regards to they [MSWs] can give the bags out and mention [PFME] [. . .] and then it's less, it's less for us to do then, when they [women] come for their the 16-week appointment'. (162) • 'I think there's an app on their, in their [women's resources] little bags that we've got, isn't there? And I've kind of said there are resources that you can use to kind of remind yourself to do it every now and again' (122) • ' . . . we spoke to [research midwife], sort of, about having the leaflets printed in different languages, which she was able to arrange, which was really helpful'. (112) • ' . . . we maybe start, need to start thinking a little bit differently, having longer, in my clinic now I actually have half an hour slots and, you know, that is giving me a little bit more to do, time to do these things' (113) • 'I do think if you get on the Badgernet, I think it will have an impact, because once there's a box and it has to be ticked [oh yeah] it's very different to . . . not having a box' (136) • ' . . . we have three maternity assistants who do a lot of birth talks and things like that, so we midwives, time is quite difficult, which is why we introduced maternity assistants. Maternity assistants will probably be perfectly placed to do more of the pelvic floor discussion than the midwife because they've got time, they do, you know, birth talks with the women, and you know I definitely think it would have been better from a maternity assistant point of view'. (103) • ' . . . maybe even like, it just doesn't come down to the community midwife, you know, making sure that, you know, when women go up to the hospital for a triage appointment, if everything's okay, that the triage midwives says "Oh, are you doing your pelvic floor exercises?" You know that's what, that's what is difficult and, especially, being a community midwife, we're asked to do these things' (139) • 'I think it should be something that we should include in mandatory training as well. So there's three days' mandatory training a year, whether it can be put in, as one of the sessions that we do as part of our training'. (120) • 'But if it was to, rolled out to everybody, I think if you put it [APPEAL leaflet] on the app . . . we can see what people have accessed on the app, and they [women] access a lot of leaflets' (120)

Appendix 10 Interviews with intervention and control midwives at the end of the APPEAL study

TABLE 32 Experience of midwives interviewed at the end of the APPEAL pilot and feasibility RCT

	Intervention midwives: end of study (N = 6) ^a	Control midwives: end of study (N = 12)
Role description (n)	Team lead (1) Community midwife (3) APPEAL champion (2)	Team lead (1) Community midwife (11)
Years as midwife, mean (range)	12.33 (5–31)	12.42 (2–32)
Midwives with > 5 years' experience as midwife, n	4	8
Midwives with ≤ 5 years' experience as midwife, n	2	4
Years as community midwife, mean (range)	5.5 (1–16)	7.42 (0–22)
Midwives with > 5 years' experience in community, n	3	5
Midwives with ≤ 5 years' experience in community, n	3	7

a n = 2 intervention midwives interviewed in both implementation phase and end of study.

TABLE 33 Summary themes from interviews with midwives at the end of the APPEAL pilot and feasibility RCT

Theme	Intervention midwives		Control midwives	
	Summary of findings	Illustrative quotes	Summary of findings	Illustrative quotes
Background/experience of PFME/UI	<ul style="list-style-type: none"> • Attended APPEAL training • Positive experience of training 	<ul style="list-style-type: none"> • '[APPEAL trainers] approached it [PFME/UI] in a very sensitive, a very sensitive and caring way. I was quite worried to do the training to start with, how it would, how they would bring it across to us, but they had such a lovely mannerism, very gentle and non-threatening that I actually thought the training was very, very good. As I said, I wouldn't change anything'. (104) • 'I just think [the training] was really good about, and it was really clear about what we should be recommending to women rather than just, I've seen lots of variation in practice, so I like that it was quite definite about this is what you should be aiming for with numbers, of, like, this many seconds and this long, and yeah, it was quite, it was really clear about what we should be recommending and where that had come from, like the fact that it was evidence-based and that was really good'. (154) 	<ul style="list-style-type: none"> • Report of range of previous experience from no PFME training to extensive knowledge 	<ul style="list-style-type: none"> • 'I think just maybe during uni we had like one lecture on [PFME], but that's probably it, I haven't had any training on it since qualifying. Definitely not'. (1004) • 'I think when I done my yoga training, that's probably when I started to get a little bit more thorough I would say, and I think it's just because it's personally in my daily practice, and when I teach pregnancy yoga it's something we talk about so much, I think because I've been practising it more and talking about it more, it's kind of come through my clinical practice as well'. (1010) • 'I've done some, I did a training day with chartered physiotherapists, which was a quite a while back. Um, I did work with them, it's probably five years old, we did a conference I worked with [name] with the, the female genital mutilation safeguarding team, and we did a conference about urinary continence and the availability of toilets, and how women secretly hold these issues and problems around strength of the pelvic floor and weakness of the pelvic floor'. (1019) • 'The training I've received with pelvic floor exercises and the pelvic floor was at the university and when I studied my postgrad, um, my undergraduate midwifery degree'. (1028)

TABLE 33 Summary themes from interviews with midwives at the end of the APPEAL pilot and feasibility RCT (continued)

Theme	Intervention midwives		Control midwives	
	Summary of findings	Illustrative quotes	Summary of findings	Illustrative quotes
Consistency of teaching PFME/asking about UI	<ul style="list-style-type: none"> Some midwives report less consistency with increasing time since training Teaching PFME in line with APPEAL but inconsistency progressing exercises and asking about UI 	<ul style="list-style-type: none"> '... at the time when we first implemented APPEAL and we were giving out the packs and there was obviously much more discussion around the trial and around the training and around what we were talking to women about and where we were documenting, and I think that's probably just those conversations haven't happened or aren't happening now'. (140) 'So at every appointment, every contact we discuss pelvic floor exercise and if there was any instances of incontinence or anything. I found that a lot of women, a lot of the first pregnancy ladies didn't have any issues at all. The sort of para 1, para 2 ladies, they start, they were sort of, they had maybe a slight bit of leakage initially but sort of by sort of 28 weeks it had sort of resolved, sort of not completely or completely sort of thing'. (115) 'We don't really mention leaking outright'. (104) 	<ul style="list-style-type: none"> Confirm lack of consistency teaching PFME in standard AN care, i.e. not all midwives teach PFME or ask about UI; PFME/UI focus is at booking only, PN only or not at all Not routinely asking about UI Level of detail for PFME varies, for example no specific instruction for PFME versus describing and explaining PFME in detail 	<ul style="list-style-type: none"> 'I mean I do just discuss it [PFME] with women but it's not something, definitely in the antenatal period, I have to admit that is on, because we've got so much other questions that we need to ask that it's just not something that's on your radar for every antenatal'. (1002) 'I'll be honest, I find from speaking to them about it at bookings when they're first pregnant, and then I'll speak to them, I'd love to speak to them every appointment about it, but I just do not have the time, so I'll probably speak to them again about it at the birth talk if I, if I complete a birth talk for them and then the next time would be postnatally'. (1004) 'Um, probably depends very much on their understanding of English and, what else is going on, we always mention it, it's one of the questions we mentioned postnatally more than antenatally I would say, but we do mention it antenatally. Sometimes it is just a more of a passing comment though, it is "are you doing pelvic floor exercises?", if they say yes they are, then you tend to move on, you don't tend to question so much what they're doing'. (1007) '... we don't normally routinely asking [sic] them [about UI] again for the rest of the pregnancy and normally would mention it on the visit of the postnatal'. (1031)

continued

TABLE 33 Summary themes from interviews with midwives at the end of the APPEAL pilot and feasibility RCT (continued)

Theme	Intervention midwives		Control midwives	
	Summary of findings	Illustrative quotes	Summary of findings	Illustrative quotes
Acceptability of APPEAL/teaching PFME in AN care	<ul style="list-style-type: none"> • Positive attitude to APPEAL programme enhanced by personal interest in PFME/UI • Appropriate to fit PFME into AN care • Some midwives report unable to implement APPEAL within AN care • Others report implementing at every appointment as trained • Consistent challenges for implementation relating to increased workload since COVID; time constraints; making PFME a priority; language barriers and remembering APPEAL • Prioritisation may be due to attitude and motivation rather than time • Positive response from women is motivating • Confident to deliver APPEAL 	<ul style="list-style-type: none"> • 'I would probably say the pelvic floor exercises rings quite true with myself, because I've had issues, so it was actually after the training I put myself forward to be the champion, rather than being allocated, so I actually spoke to my boss and said I've got an interest, and that's how come I became the champion, so the training must have had some impact for me to then volunteer to be a champion'. (136) • 'I think it's definitely appropriate [to fit PFME into AN care], you know it's hand in hand really with pregnancy it's, it's the, I think it's the optimum time to discuss it and sort of embed it into their [women's] sort of, you know, their life really'. (115) • 'I know it's [PFME] really important, I know, but it's just having, we just have so much information'. (104) • 'So in antenatal visits, so the intervention specifically, after having the training I would, I discussed it a few times with people, and it took so much time that I then didn't, I just didn't have time, I just didn't have time'. (158) • 'I think so, and it's, again, purely because of the time factor, because with COVID and having much more strenuous cleaning in between every patient and donning and doffing PPE and talking about COVID vaccines, and so, and anxiety levels, yeah. So probably pre-COVID it might have been a bit, a bit more effective in trying to deliver it'. (158) • '... we did discuss the time wasn't really a good enough excuse, because at the end of the day it's quite easy to drop it [PFME] in at the end while you're doing your paperwork, or while you're talking to the mum'. (136) • 'I must admit I never did referrals, I did have one or two ladies that said they had incontinence issues, but not enough to be referred was their sort of attitude, but they're the ones that said since I've started doing the exercises I've noticed an improvement'. (136) • 'Yeah, I'm very confident I shall carry on [delivering APPEAL], yeah, absolutely, especially when you know that you're helping people, you know, it's public health, isn't it, so it's part of our role'. (104) 	<ul style="list-style-type: none"> • Perceived challenges to teaching PFME consistent with early APPEAL work (WP1, WP3) • Challenges relate to complexity of caseload, volume of information to cover in AN care, time constraints • Recognition that midwives well placed for teaching PFME • Uncertain if women will practise PFME, especially if continent 	<ul style="list-style-type: none"> • 'I'm getting really a lot of the ladies, these days, tend to have social issues or other issues that take up your time over pelvic floor, to be honest'. (1002) • 'I'd love to speak to them every appointment about it [PFME/UI], but I just do not have the time' (1004) • 'I do, I do find it [PFME/UI] harder to bring up, apart from the booking, because you know we normally have a good hour aside for booking appointments so it's easy to talk about it, um, at an antenatal clinic appointment if we talk about other things sometimes it is a bit difficult to talk about pelvic floor when, when there's other things going on the pregnancy, so I do find that more difficult during pregnancy'. (1028) • 'I just think [APPEAL] it's good, anything that's going to try and kind of get it more on the agenda, get, get us talking to women, get women aware, not kind of leaving it until postnatally when potentially they would have benefited from my antenatal input is obviously a good thing'. (1004)

TABLE 33 Summary themes from interviews with midwives at the end of the APPEAL pilot and feasibility RCT (continued)

Theme	Intervention midwives		Control midwives	
	Summary of findings	Illustrative quotes	Summary of findings	Illustrative quotes
Feasibility of research/evidence of contamination	<ul style="list-style-type: none"> Not all midwives able to implement APPEAL as trained 	<ul style="list-style-type: none"> 'So the day I did the training I had, my clinic that day, I think I had about five women or six women that were all 16 weeks coming in that day and I was like, okay I've got my student, I'm going to be really good and we'll do it, and I said to her, right, let's do this together, we've just had the training, this'll be great, and in the training they'd said, oh it'll take about five minutes to do it, and that is true and I was half an hour late with my clinic because every woman took an extra five minutes and we were running half an hour late by the end and then that knocks onto everything else. So I think, I really struggled to integrate it at the 16-week appointment because there just wasn't time and I've got to be honest I didn't do it after that, I would just, or I did, I did do it, I just did a shortened version' (154) 	<ul style="list-style-type: none"> No previous awareness of APPEAL until contacted by researcher $n = 1$ midwife had contact with intervention group and knew about APPEAL Awareness of APPEAL has not changed practice 	<ul style="list-style-type: none"> Interviewer: 'Moving on to the APPEAL study then, and I'm just wondering when you first heard about it?' 1028: 'Actually, when you e-mailed me.' 1012: 'I just heard about [APPEAL] it from [midwife], who is part of the group who are encouraging women to do their pelvic floors.' Interviewer: 'And after hearing about the study did it change the way you practice, did it jog anything for you?' 1012: 'No, not particularly because I know that we're not part, we're just continue on doing our standard care, yeah'. (1012)

continued

TABLE 33 Summary themes from interviews with midwives at the end of the APPEAL pilot and feasibility RCT (continued)

Theme	Intervention midwives		Control midwives	
	Summary of findings	Illustrative quotes	Summary of findings	Illustrative quotes
Making it happen – ideas for supporting implementation adoption and spread	<ul style="list-style-type: none"> • Access to Trust-wide champions • Longer appointments • Consistent messages – training for all including midwifery support workers/ assistants • Prompts for midwives, for example Badgernet • Refresher training • Leaflet in other languages helpful 	<ul style="list-style-type: none"> • ‘Yeah, so our champion was one of our community midwife colleagues on our team, and she was, I felt like she was quite proactive at reminding us and encouraging us and reminding us about the bags and, yeah, I felt like she was sort of reminding us and supporting us’. (158) • ‘I mean, yeah, the ideal would be longer appointments, which, yeah, again it’s another thing, that those three things, enough time, giving all the information and building a rapport, in today’s world, today’s NHS, won’t happen, so I don’t know, short answer’. (158) • ‘But obviously needs everybody to be doing the same thing as well, doesn’t it, because this has just been a trial so if that feedback comes back that it’s been useful then it should be rolled out to all midwives should be doing it’. (104) • ‘they [midwifery support workers] all had training, yeah, so yeah that was quite good because a lot of them will do sort of 28-week bloods and things like that so they were able to sort of at that point ask about the pelvic floor, so yeah it did. I think it got all of the team involved because there’s, sometimes there’s a bit of disparity between sort of the midwifery, midwives and the support workers so it kind of helped to include them as well’. (115) • ‘I do think it’s something that should be embedded into mandatory training, particularly for community midwives who are having those conversations with women every day. So I do think that should be kind of just part of your induction training, so when people join the Trust, they’re new to the Trust, but also specifically for community-based midwives, I think that should be part of mandatory training, and definitely, you know, refresher training’. (140) • ‘I also think we did mention it because it was a research, it wasn’t on the Badgernet sort of checklist, as other things are, so because it was on the Badgernet checklist things were probably taken priority as the APPEAL wasn’t on the checklist, so as an individual you tick your boxes, the APPEAL was like an extra did you remember it, or didn’t you?’ (136) • ‘I think, including, as we’ve discussed before, in terms of the documentation, so having something raised with Clevermed, who manages Badgernet Notes, or Badger Notes, to have something implemented on there, for the women and for the staff, to, a) remind us to do it and, but also for us to be able to refer via that same system’. (140) 	<ul style="list-style-type: none"> • A prompt would be helpful, for example Badgernet • Proactive attitude to PFME and enthusiasm for APPEAL, would like as part of standard care – would value training/ resources • Suggestion to teach PFME in group setting 	<ul style="list-style-type: none"> • ‘And it is useful, in our booking appointments it is useful, we use Badgernet and one of the things that we have, we have to discuss is pelvic floor exercises and, um, I think, because I think it’d be good, you know, sometimes you can’t save something unless you’ve acknowledged it, so it could be have you discussed pelvic floor exercises and you can tick yes or no. But you’d have to, you’d have to tick yes or no before pressing save’. (1028) • ‘Yeah I think that would be brilliant [APPEAL being part of standard AN care] just to make it a standardised practice and to approach it and it will help with their understanding, I guess, because everybody’s understanding and what you’ve heard and been told from, you know, family members and sisters and all sorts, so it would just set the bar, I guess, as to what the advice should be and how we should give it’. (1006) • ‘I can see that [APPEAL] it’s really valuable because I think a lot of women do suffer with incontinence, particularly after having a baby and it’s sometimes they don’t realise it’s something that they need to get help for. So I think that’s quite important and I think it would be really helpful for us midwives to have more training actually as well’. (1012) • ‘Is there any chance that you can have, now that the pandemic is sort of opening up a bit more it’s for like classes that we can, so for midwives to be trained and run classes for them [PFME] [. . .] because I think in, is it doing it in a fun way and in the group then they [women] normally would do it, and hopefully they’ll practise a bit more’. (1031)

AN, antenatal; PN, postnatal.

Appendix 11 Findings from postnatal interviews with women in the APPEAL feasibility and pilot trial

TABLE 34 Postnatal interviews with women in the APPEAL intervention and control arms: participant characteristics

APPEAL group	NHS Trust 1	NHS Trust 2	Age (years), mean (range)	Parity, mean (range)	Total interviewed
Control	8	8	31.3 (23–27)	1.7 (1–3)	16
Intervention	8	5	33.3 (23–40)	1.7 (1–3)	13
Total	16	13	32.2 (23–40)	1.7 (1–3)	29

TABLE 35 Illustrative quotes arising from postnatal interviews with women relating to the degree of fidelity of delivery of PFME during antenatal care

Theme	Intervention group quotes: receiving APPEAL-based PFME antenatal care	Control group quotes: receiving standard PFME antenatal care
Degrees of fidelity (delivery and receipt of PFME interventions)	<p>'She gave me a bit of information about kind of doing the exercises, didn't go into too much around kind of the anatomy and the purpose, because I think it was assumed I already knew that, and then gave me a little bag and some leaflets in that about kind of different things you could get to help train with the pelvic floor and told me the kind of repetitions that I needed to do, so when I was cleaning my teeth in the morning, those kind of things. That was about it, that I got'. (355)</p> <p>'I got a leaflet about pelvic floor exercises and they talked me through it, and that was, I think, the first midwife face-to-face visit, and then the second appointment, I think subsequent appointments they just asked, have you got any problems, are you managing to do your exercises, that kind of thing. So they sort of just checked in with whether I was managing the exercises and if I had any problems . . .' (026)</p> <p>'When I was about 28 weeks I got given like a pack of, I don't really remember exactly what was in there, but there was also like a QR code for an app to download. Yeah it was like near the end of the pregnancy . . . I liked the resources that I was given, but by the midwife I wasn't told much about it. Like she didn't tell me what it was for, she just gave it to me and mentioned how she got in trouble for not giving it to someone else before . . . didn't really know what the pack was for until I got home and, yeah and then I read it but, but I feel like if she would've told me and talked to me about it as well then I would have been more able to, be more excited about it, if that makes sense, like read it and understand it more'. (117)</p> <p>'Oh gosh, I think she mentioned it once, you know, she mentioned just to do the pelvic floor exercises and that's it really to be honest'. (030)</p> <p>'I remember that she did speak to me about the pelvic floor exercises, [in a previous pregnancy] whereas this time it was just sheets given out'. (Interviewer: 'We have, the study is a sort of quite a big study it's called APPEAL and it has got the, it's got a little logo on it with a water droplet, and that's on the information sheet and I think there's some stickers and some an app card and things, can you remember any of that?') 'I don't recall but I wouldn't be 100% certain, I just, I don't remember being given any of that'. (121)</p>	<p>' . . . after I had the baby and then when I had my midwife and health visitor come and see me at home, then I was, I was told then. They just said, they said, you know, make sure that you start doing your pelvic floor exercises and that you're regularly doing them and even if it's, you know, just for a couple of minutes a day' (19)</p> <p>'No, no, all I was told is after having my daughter that, the midwife goes, she goes, "oh, when you just sit down, it's like you just squeeze your bottom together as you're sitting down". And that's basically like supposed to put your pelvic muscles back together'. (011)</p> <p>' . . . my midwife asked me if I was doing pelvic floor exercises. I can't remember the exact nature of the conversation but I think because I said yes and expressed sort of knowledge about it we didn't go any further, but she was a friend, very friendly woman and I think if I had said what on earth's that then she would have given me more information, but I think because I just said, yes I know what to do, it's fine, we didn't go any further but I think the opportunity was there'. (098)</p> <p>'I would say it was very rushed. It was kind of "oh make sure you do your pelvic floor exercises", "yeah", and there wasn't much more information than that in terms of what the midwife said or what was expected of me in pregnancy'. (128)</p> <p>'I mean probably briefly in my midwife appointment, I think, I definitely remember the midwife encouraging me to do them at least in one of my appointments, maybe more of them, and I did kind of ask for clarification around it . . . did I get a piece of paper, I don't know, yeah, definitely verbally, I might have got an information sheet although I don't think I did' (319)</p> <p>'I wasn't given any information about pelvic floor exercises because I felt that I knew it already. So I believe there would have been, if I'd have asked I would have been given bountiful information but I didn't ask, so. And it was mentioned, you know, my midwife did say "oh, you know, make sure you're doing your pelvic floors" and there might have been a point where she said, "do you know how to do those?" and I would have said yes and I think that's why no more further information was given'. (248)</p>

TABLE 36 Themes and illustrative quotes arising from postnatal interviews with women relating to the barriers and enablers of doing PFME

Themes	Intervention group quotes: receiving APPEAL-based PFME antenatal care	Control group quotes: receiving standard PFME antenatal care
Making PFME a priority would help (The impact of midwives' lack of prioritisation acting as a barrier)	'I think if the midwife would have mentioned it probably every appointment, like have you been doing your, your pelvic floor, I think, if she would have mentioned it, then I probably would have done it more regularly'. (30)	'I started off enthusiastically and then I just kind of gave up because I just, you know, it hadn't been stressed as being important and I had many other things on my mind'. (128)
PFME knowledge and awareness matters (Lack of knowledge hinders or negatively impacts on doing PFME)	'... and then as soon as I knew more about, about it, like, I would do it more often as well, because before I knew information about it, I would just do it like once a week or once every couple of months, to just, whenever I would remember or read about it or see about it, or whatever. But yeah, and now I do it more often now that I know more information about it'. (117)	'I'd say I didn't find them easy because I wasn't overly sure about what I'm supposed to be doing. So it kind of left me feeling a bit silly I guess because I was just a bit like "well I don't really know what I'm doing right now", so it became a thing that in the end I just didn't bother to do because of that reason'. (128) But knowledge is not always enough: 'I think hearing the midwife say to me that as I get older, my pelvic floor muscles won't be as strong, therefore the risk of me leaking as I'm older gets higher, so you should do them. That was enough for me to go, "OK, yeah, I should really do them". But for me, that's the reason why I want to do them because when I get older, I don't want to leak... I don't ever want to be incontinent so I know I should do it but I don't'. (017)
Knowing how to do PFME (mastery) (Lack of mastery reduces motivation to do the exercises)	'I think, knowing about how important it is to relax those muscles and understanding how to relax them, would have been useful, but I don't know how easy that is to do through a leaflet, because it wasn't really until someone examined me and saying, now those muscles are relaxing, that I understood how to do it. I think, you know, sometimes you're holding on and you don't realise'. (026)	'... if there were like diagrams, maybe, or, you know, just if there was, like, some kind of like leaflet with diagrams on there or information telling you exactly how to perform them and, you know, how to get the best, you know, the most effectiveness out of them as well, even like if they, you know, gave us some links to videos that we could watch, demonstrating it, you know, even, yeah, leaflets, even...'. (019)
Knowing how and why matters (The need to understand 'why' reinforces the doing)	'Probably how to do the pelvic floors and why they were important... like it's a pretty standard thing to do. But you see it's only easy if you know how to do it. I think people, women would probably benefit to learn how to do it in the first place, which then would enable them to just sort of bring it into their daily routine I guess'. (032) 'I think if you speak to any pregnant woman they know that you need to do pelvic floor, but I don't think they understand the reasons why you have to do it during pregnancy and why it's important. I think it becomes more apparent once you've given birth what kind of the main function and things is of it...'. (355) 'I don't think you want to scare women but I think it might be valuable to sort of warn the, sort of warn what the risks are if you don't do enough exercise... I'm not sure, and, you know, and then the midwives who delivered my baby were, you know, were very, they were sure to tell me how important it would be to do my pelvic floor after that. But I can't, I perhaps hadn't realised prior to having my second baby that, you know, that was something that might happen...'. (544)	'Honestly, I would have loved to receive more information like how to do it. Because it's good, at least when they explain it to you it's good, rather than having to go on YouTube and look at it yourself. So I prefer like the, just like physical exercise they can show it to you or if they can tell you there's like antenatal classes you can go do and they can show you what exercises you can do, that would really help'. (50)

continued

TABLE 36 Themes and illustrative quotes arising from postnatal interviews with women relating to the barriers and enablers of doing PFME (*continued*)

Themes	Intervention group quotes: receiving APPEAL-based PFME antenatal care	Control group quotes: receiving standard PFME antenatal care
Importance of resources to support women to do PFME (Examples: leaflets, apps or other physical resources)	<p>'Yes, definitely, I think my midwife said from the get-go that I should be doing my pelvic floor exercises, sent me a video to watch and, yeah, sent me links that were really useful, so I think that was quite clear'. (314)</p> <p>'... then gave me a little bag and some leaflets in that about kind of different things you could get to help train with the pelvic floor and told me the kind of repetitions that I needed to do, so when I was cleaning my teeth in the morning, those kind of things. That was about it, that I got'. (355)</p> <p>'I got given like a pack of, I don't really remember exactly what was in there, but there was also like a QR code for an app to download. Yeah it was like near the end of the pregnancy... I liked the resources that I was given...'. (117)</p>	<p>'I think that the leaflet that I received the first time was very, very helpful so I think everyone should have that, like, no matter whether it's their first or ninth pregnancy, I think that should always be provided'. (347)</p> <p>'I should have just had stickers in places where I sit down, reminding me to do them. And I had every intention of doing that, I just never got round to it'. (017)</p> <p>'I think maybe if, if we were given like some kind of, like a checklist or something that, you know, this many times a day, try to complete them, that would have been good'. (019)</p> <p>'... if there was like some kind of like leaflet with diagrams on there or information telling you exactly how to perform them and, you know, how to get the best, you know, the most effectiveness out of them as well'. (019)</p>
Importance of additional support from services and clinicians (Examples: classes, physical checks)	<p>'... like antenatal appointments and, you know, where you all get together and you talk about pain relief, things like that, it would be, it would've been quite useful to have, you know, maybe a session on pelvic floors and, because then I think we'd see it as more important, because, you know, just being given a leaflet in passing just doesn't show how severe it is and it was only when people tell you "oh, you need to do it because it will affect you later in life", so I think maybe like a bit of a little group session talking about it, you know, opportunities to, if it was, you know, ... sessions to talk about things and actually just time with somebody to ask questions because I feel sometimes the midwives, particularly when it's antenatal appointments, they're so rushed and by the time you see them they're already late with their appointments so you feel like you don't want to keep up any more of their time, so I think dedicated sessions would be really good and would show how important they are to do'. (006)</p> <p>'... so the information was fine. I felt like it would have been, yeah, it might have been nice to sit with your midwives, perhaps, and just gone through a few exercises together'. (413)</p> <p>'I would say to be perhaps given some material and then a conversation had, so it's in your mind so that then you, you don't then just put it, the leaflet, you know, down and never look at it again, that it's, the conversation would, the discussion would, with your midwife would then prompt you to actually read the leaflet and, you know, keep it at the forefront of your mind because I think you do tend to get quite a lot of material around pregnancy and birth, so I think it's easy to sort of just sort of stash it all away in a folder and not really pay that much attention to it, but if you have a conversation with your midwife I think that, about it, that would encourage you to pay more attention to it'. (544)</p>	<p>'... even if there were like online Zoom classes, because I remember I joined them for breastfeeding support and like baby massage classes, I joined them on Zoom. So, even if there were classes like that, that would have been really useful'. (019)</p> <p>'But in some ways it's kind of physical demonstration, of kind of sitting with women and talking them through it and making them aware of the feeling of it being correct etc., because I think something like a leaflet for that is very difficult and hands-off and doesn't necessarily do the job'. (128)</p> <p>'But then I think without someone examining so that you know that you're doing them correctly it's difficult to reassure yourself that you're doing them right. But then you know, you can't really examine women during pregnancy, you know, because of the risk of infection and things so it's difficult'. (52)</p> <p>'I went to this private physio which obviously is not available to everybody... a quick procedure for her to check internally the strength of your pelvic floor muscles and also any gaps in your abdominal muscles, ... and it's really quick to check and I feel like it would be really helpful it that was offered by the GP at the six-week check-up, you know to start women on that path to recovery again, really early on, would be really helpful'. (098)</p>

TABLE 36 Themes and illustrative quotes arising from postnatal interviews with women relating to the barriers and enablers of doing PFME (*continued*)

Themes	Intervention group quotes: receiving APPEAL-based PFME antenatal care	Control group quotes: receiving standard PFME antenatal care
Women's request for ongoing support to maintain PFME (Support and reminders to continue and go beyond pregnancy)	'I think keep reminding and come back to us when we've got the breastfeeding sorted and we're not as, you know, completely absorbed in our babies'. (026)	'I feel that you need until you get into a good habit, so anything that can be continually exposing women to the idea of it and the benefits I suppose, and I guess also the risks, not to scare people, but the risks of not doing it, or of having weak pelvic floor muscles, you know, what that means after pregnancy, incontinence and what-ever, I think, yeah, just constant exposure to the whole thing, probably in different ways because I think if you constantly see the same something, that it's the same, you just become sort of immune to it don't you'. (098)

Appendix 12 APPEAL refinements and recommendations for future development

TABLE 37 Changes to APPEAL following training and factors facilitating implementation of APPEAL

Changes to APPEAL following training	Factors that facilitated implementation in clinical practice during APPEAL
<ul style="list-style-type: none"> • Greater emphasis on champion role • Addition of 'myths and misconceptions' • 'Documenting PFME' activity added • Additional information for women who report symptoms of UI • Referral criteria for physiotherapy added 	<ul style="list-style-type: none"> • Organisational support to implement PFME • Service-level approach to training so that antenatal PFME is part of routine practice and viewed as everyone's responsibility <ul style="list-style-type: none"> ◦ Mandatory training to ensure it is both required and free of charge for all midwives to enable a standardised approach ◦ Training must take a collective approach – whole team training, not individual midwives ◦ Train other healthcare workers involved in antenatal care to support delivery, for example support workers/assistants • Establish referral pathway for specialist services, including clear referral criteria for women who need additional support • Team PFME champion supports teams with implementation, training and onward referral • Resources for women help midwives deliver PFME, especially leaflets (in different languages) and apps. • Regular reminders and prompts for midwives help remember to ask about UI and teach PFME until it becomes part of practice (especially beyond initial booking/16-week appointment). Example prompts used by midwives: <ul style="list-style-type: none"> ◦ APPEAL sticker on front of notes ◦ Prompts from team leader and/or champion, for example via WhatsApp or team meeting ◦ Prompt card developed by APPEAL champion

TABLE 38 Recommendations from midwives for ongoing improvement to APPEAL

Midwife recommendations for ongoing improvement
<ul style="list-style-type: none"> • Increase appointment time to help fit PFME into routine care. • Explicit prompts within antenatal checklists, for example Badgernet: <ul style="list-style-type: none"> ◦ help midwives remember to teach PFME ◦ facilitate continuity of care by encouraging documentation of conversations about PFME/UI that can be followed up by different healthcare practitioners. • Extend training to include all support workers/maternity assistants (some trained within APPEAL – was reported to be helpful). • Extend training to other maternity care providers, for example hospital-based midwives, health visitors, GPs, to support delivery and ensure consistent messaging. • Set up reminder texts to be sent to women between appointments, for example at 18 or 20 weeks. • Make women's resources available in digital format (e.g. leaflets and app card to put on women's Badgernet app). • Make videos available for viewing in antenatal clinic waiting room.

TABLE 39 Recommendations from postnatal women to improve support and resources for PFME during pregnancy

Recommendations	Suggestions for improvements to supporting PFME by control arm women	Suggestions for improvements to supporting PFME by APPEAL intervention arm women
Presentation of resources related to PFME	Written format ^a Video for presentation format ^a	Eye-catching resources Resources should be provided online (e.g. videos) Fluidity in information provision
Types of physical resources required by women	Useful apps (i.e. ones that work), appropriate reminders to develop habits ^a Checklist to complete daily	Classes Online information
Input from health professionals to support PFME	Taught by midwife ^a Constant reminders during pregnancy to highlight importance, making sure they were 'keeping on top of them' ^a Midwife 'sitting down with you' to make sure you can feel it working; physical demonstration to accompany any leaflets etc. ^a	Midwife showing resources ^a Option for physical examination ^a Follow-up post partum Signposting to range of resources suitable for the individual woman ^a Early mention antenatally (then repeated) ^a Health professional asking questions to the woman about how they are getting on ^a Referral options, switching between health professionals ^a Detailed conversation by midwives in antenatal period ^a
Guidance and support regarding performing (how to do) PFME	Preparation for labour, description of range of benefits ^a When to do them (i.e. not on the toilet) ^a Description of why and how they are helpful ^a	Learning how to relax muscles ^a Relaxation Information on benefits, importance, not just UI, prolapse, sexual function, post-partum healing ^a

a Already covered within APPEAL.

EME
HSDR
HTA
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PHR

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