# 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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## Scientific summary

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# 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.

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