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THE C-POP STUDY: A MULTI METHOD STUDY TO EXPLORE THE ACCEPTABILITY AND FEASIBILITY OF A FUTURE TRIAL COMPARING COLPOCLEISIS WITH SACROSPINOUS FIXATION FOR TREATMENT OF APICAL PELVIC ORGAN PROLAPSE

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BACKGROUND:

Apical pelvic organ prolapse (APOP) is a type of prolapse in which the uterus, cervix, or vaginal vault bulge into the vagina. Incidence peaks at 70-79 years and negatively impacts quality of life. Vaginal surgical options for older women with APOP include colpocleisis and sacrospinous fixation (SFF). Colpocleisis has lower complication and recurrence rates than SSF, but removes a patient's ability to have penetrative vaginal sex. Key uncertainties remain about the effectiveness of vaginal surgical options. It is therefore important to explore the acceptability and feasibility of a future effectiveness trial comparing colpocleisis with SSF.

AIM:

To explore the feasibility and acceptability of conducting a study comparing the effectiveness of colpocleisis with SSF in women with APOP. This aim will be addressed via five objectives and delivered via four work packages (WP1-4).

METHODS:

Multi-method feasibility study aligned with the 2021 MRC/NIHR Framework for Developing and Evaluating Complex Interventions. The study is supported by a patient advisory group. WP1 and 2 are qualitative interview studies exploring insights from a diverse sample of women with APOP (n~60) and HCPs caring for women with APOP (n~30) recruited through NHS and non-NHS pathways. WP3 aims to estimate the number of patients potentially eligible for a future study via NHS clinics. Qualitative data from WP1 and 2 will be analysed using reflexive thematic analysis. Quantitative data (WP3) will be analysed descriptively. The draft programme theory and findings will be presented in WP4 at a national stakeholder event for further discussion (participants~30).

ANTICIPATED IMPACT:

Improved understanding of APOP impact and treatment options for women and their HCPs. Development of a final programme theory and recommendations to inform any future effectiveness trial.

FUNDING:

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