HIPS/23/30 – FEEL-GOOD study: Female Empowerment through Enhanced Living: a comparison of vaGinal mechanical devices and pelvic flOOr muscle training (PFMT) versus PFMT only for female stress urinary incontinence: a feasibility and pilot StuDy

Urinary incontinence(UI) is common and debilitating, affecting >6million UK women over age of 40 years, causing embarrassment, low self-esteem, social isolation, and reduced productivity. First-line treatment is pelvic floor muscle training(PFMT), but currently one in three women still proceed to surgery.

Vaginal mechanical devices(VMDs), worn inside the vagina, support the bladder to help achieve continence. Guidelines recommend VMDs are used when PFMT is not effective. Combining VMDs with PFMT might be more effective for treating UI than PFMT alone, improving quality of life(QoL) and reducing the need for surgery. VMDs are widely used, despite little evidence about their benefits, risks and whether they provide value-for-money.

Providing such evidence requires a complex and expensive clinical trial. A preliminary study is needed to ensure that such study is feasible and can be conducted successfully. Working closely with our PPI partners “Women Voices” and “Bladder Health-UK”, we co-developed a two-stage preliminary study. Stage-1 explores women’s and clinicians’ views on VMDs and a potential larger clinical trial, using interviews and focus groups. Stage-2 uses stage-1 findings to undertake a small version of the future clinical trial. 74 women with UI from four UK hospitals will take part: 37 will receive PFMT alone and 37 PFMT plus VMD, with equal chance of being in either group. We will collect information on women’s symptoms and QoL before and after treatment (at 3 and 6 months). The results will help us design a clinical trial to fill the gap in evidence about effectiveness of VMDs combined with PFMT.