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Medina Lucena H[1], Williams K[1], Tincello D[1], Lipp A[2], Shaw C[2]
1. *University of Leicester,* ***2.*** *University of South Wales*

EVALUATION OF INCOSTRESS DEVICE FOR URINARY INCONTINENCE: A FEASIBILITY STUDY AND PILOT RANDOMISED CONTROLLED TRIAL

Hypothesis / aims of study
IncoStress is an intravaginal device designed to support the bladder neck and to control or stop urinary incontinence. This was a feasibility study for an RCT of the IncoStress device to collect pilot data on effectiveness and recruitment as well as patient views on its acceptability and utility (1,2).

Study design, materials and methods
Women attending continence services were invited to participate and gave fully informed consent, before randomisation to usual care (the control group) or usual care plus use of the IncoStress device (the intervention group). Randomisation was computer generated, using sealed envelopes and undertaken in blocks of 9 (2:1 intervention/control ratio). Process outcomes of recruitment, retention and compliance with treatments were recorded plus primary outcomes of IQOL and ICIQ-FLUTS questionnaires at baseline and follow-up (three months and six months). Data were analysed using SPSSv22, and descriptive statistics provided. A sub sample of participants were invited to take part in a qualitative interview to better understand frequency and ease of use of the device as well as, overall satisfaction, and recommendations for changes to the research processes which could be incorporated into a future large multi-centre trial.

Results
80 women (51 intervention: 29 control) were recruited. Median age was 45 years (27-70 years) and median BMI was 26.4 Kg/m^2 (16.5-43.8kg/m^2). Follow-up responses were obtained from 34 intervention group patients (66.7%) and 17 (58.6%) controls. Women used the device for a median three days a week (0-7); seven hours a day (0-12). 22 patients (64.7%) reported no vaginal discomfort, 18 (53%) found it easy to use and 21 (61.8%) were satisfied with the device. Median IQOL score in the intervention group improved from a baseline of 42.4 (0-94) to 68.2 (5-98) at follow-up and in the control group from baseline 45.5 (0-88) to 53.0 (0-94). Median ICIQ-FLUTS score in the intervention group improved from 14.5 (6-35) to 12.5 (4-26) and in the control group from 15.0 (5-35) to 14.0 (6-38). (Table1)

Twelve interviews were carried out with women between the ages of 33-78 years. Ten of the women had used the device to some extent. Regarding frequency and ease of use and cleaning, most participants found the device easy to use and clean. Two reported difficulties with the device falling out, so they used it more during the night. Most participants reported that they would be prepared to pay around £30 for the device as it had improved their quality of life. Eight would recommend the device to others suggesting it would prevent further invasive treatment

Interpretation of results
The improvements in both outcome measures were greater in the intervention group than in the control group, suggesting that the IncoStress device is effective. Most of the patients used the device during the day finding it acceptable, some found it quite uncomfortable but overall easy to use and 61% of those who used it were satisfied with it.

The small qualitative study of interviews with users allowed us to assess women's experiences of using the device and to identify the extent of compliance and reasons for non-compliance, in addition we were able to assess the support and information required to facilitate compliance as well as treatment fidelity to ensure reliability and validity. The interviews indicate that the device is acceptable to women and could be used within a large multi-centre RCT.

Concluding message
Recruitment was feasible and randomisation processes were robust. Symptom response was significant but loss to follow up could be improved using a retention strategy in a better-resourced larger study. This pilot demonstrates the potential value of IncoStress and confirms the feasibility of a larger RCT of the effectiveness of vaginal devices for urinary incontinence.

Table 1: Demographic data, IQOL and ICIQ-FLUTS score at baseline and follow up

Factor	Intervention(51)	Control(29)
Age (years)	44 (27-68)	48 (28-70)
BMI kg/m2	26.2(20-44)	29.0 (17-43)
PFE	41 (80%)	22 (76%)
BT	22 (43%)	16 (55%)
IQOL score	0-100	0-100
IQOL at baseline	42.4 (0-94)	45.5 (0-88)
IQOL follow up	68.2 (5-98)	53.0 (0-94)
ICIQ-FLUTS score	0-48	0-48
ICIQ at baseline	14.5 (6-35)	15.0 (5-35)
ICIQ follow up	12.5 (4-26)	14.0 (6-38)

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