Clinical evaluation of Smart UnderWear
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Introduction
Despite having high absorbency and efficiency in containing urine, pads can leak for a variety of reasons, including high volume challenge due to uncontrolled full bladder emptying, pads used past their absorbency level and movement of pad within the fixation pant resulting in uneven absorbency. These factors can be mitigated; however, continence pad wearers report a fear of pad leakage, as in cases of urgency with incontinence, being unable to access a toilet, or movement of the pad during physical activity.

The TACT3 consortium developed Smart UnderWear (SUW) that senses urine leakage from the absorbent pad before it spreads onto outer clothes and furnishings (1). The purpose was to reduce embarrassment and alleviate the burden of the additional washing, changing and cleaning involved in a major pad leakage.

The SUW comprises a pair of washable fixation pants with an additional gusset embroidered with conductive threads that correspond to the shape and size of most continence pads. These are connected to a removable signalling unit which, when connected, vibrates 3 times when any part of the conductive thread becomes wet.

Aims
The aim of this study was to evaluate the performance and acceptability of SUW.

Methods
Female participants were recruited from patients attending out-patient clinics at Southmead Hospital, GP Surgeries and Community Continence Services (Bristol) and charities and networks - primarily the Bladder and Bowel Foundation (UK-wide) and the Brunel Older Peoples Group (Uxbridge and environs).

A pilot study was undertaken to test study method and to check that the SUW were functioning as expected. Consenting participants were provided with five pairs of the underwear and one signalling unit and asked to complete two quality of life questionnaires: the ICIQ-Urinary Incontinence (UI) Short Form (SF) and the ICIQ-LUTSqol before using the SUW, to provide baseline data.

Participants were asked to wear the SUW for a period of two weeks, using the device during the day for at least five days in each week, and to wash the underwear as many times as they wished. During the trial period, participants were asked to complete a diary of leakage events for the first week only, recording whether the signalling unit had alerted them, their position at the time of the leakage (lying, sitting, standing or exercising) and the extent of the leakage (underwear, outer clothing, furnishings).

At the end of the trial period, participants were asked to complete an evaluation questionnaire and the Psychosocial Impact of Assistive Devices Scale (PIADS) and repeat the two ICIQ questionnaires.

Results
Cohort
240 female pad-wearers were approached, 84 expressed an interest, 74 consented and 56 completed the study. Severity and frequency of leakage of participants is shown in Fig. 1.

Performance of SUW
On average, participants experienced a pad leak on 77% of the days that they completed their diaries. 87% of the time participants were alerted to pad leakage events by the SUW; on 59% of occasions they were not otherwise aware of the leakage. On average, 85% of the time participants were alerted in time to change their pad before leakage onto outer clothing or furnishings.

The number of false alarms recorded was highly variable, with some patients experiencing a high number and others none or very few.

Acceptance of SUW
Over 90% of participants thought the SUW would or might make them feel more confident.

“"The smart underwear and sensor made me feel more confident as I had warning about leakage; incontinence is something that is embarrassing, this product gives you more confidence to lead a normal life”
Participant SUW2 37, aged 57 years

“First time in years found comfortable product to assist with condition”
Participant SUW1 03, aged 85 years, severe incontinence

Acceptability of different aspects of the smart underwear

Quality of Life and Psychosocial Impact
Data from the ICIQ-LUTSqol revealed no significant changes in quality of life status over the two week intervention period (baseline 15.2; end of study 15.1), with the exception of travel restrictions. There was a significant difference in the ‘effect on ability to travel’ (P<0.05, Wilcoxon signed ranks test) with most improvement observed in those who initially reported ‘moderate’ effects on travel.

PIADS data showed positive psychosocial impact: Competence: +0.44; Adaptability: +1.1; Self-esteem: +0.93.

Conclusions
The SUW performed well and was acceptable for the majority of wearers and gave them a greater degree of confidence.

References