# CLINICAL EVALUATION OF SMART UNDERWEAR

# Hypothesis / aims of study

Continence pads can leak for a variety of reasons, and fear of leakage is a major concern for individuals with continence difficulties. This fear can be a major social restriction, and is not related to the severity of incontinence (1). This study developed and manufactured prototype Smart Underwear designed to alert the wearer to a pad leak before it reached outer clothing or furniture.

# Figure – Smart Underwear



The Smart Underwear comprises a pair of washable fixation pants (Figure A) with an additional gusset embroidered with conductive threads that corresponds to the shape and size of most continence pads. These are connected to a removable signalling unit (Figure B) which, when connected, vibrates 3 times when any part of the conductive thread gets wet. The Smart Underwear conforms to the required device regulations, including CE marking, and is machine washable.

The aims of the study were to measure (1) the effectiveness of the device - using participant leakage event diaries, (2) the acceptability of the device - using participant evaluation questionnaires, (3) improvement in quality of life - using pre and post study quality of life questionnaires (ICIQ-UI Short form and ICIQ-LUTSqoI) and (4) the impact of the device - using the Psychosocial Impact of Assistive Devices Scale (PIADS).

# Study design, materials and methods

The study was a new device evaluation trial, conducted in two stages:

- A pilot study to assess functionality and general acceptability of the device. The pilot data was used to identify any initial modifications that could be made to optimise the device and the study design prior to a larger study.
- A larger scale study measuring effectiveness, acceptability, quality of life and psychosocial impact.

Participants (female only) were recruited from out-patient clinics, GP surgeries, community Continence Services, through charities and networks, primarily the Bladder and Bowel Foundation and an Older Peoples Group. All had experienced pad leakage at least once in the previous month.

Participants were supplied with one signalling unit and 5 pairs of underwear and asked to trial the Smart Underwear for a period of two weeks, washing underwear as required. They were asked to keep a daily diary of leakage events for the first 7 days. Quality of life questionnaires were completed before and after the trial period and an evaluation questionnaire and PIADs completed at the end.

#### **Results**

Of the 84 women who expressed an interest in participating in the study, 74 gave informed consent and 56 participants completed the study. The average age of participants entering the study was 66 years (range 38 – 98 years). Over 60% of participants had incontinence episodes once or more times a day and nearly 80% leaked urine a moderate or large amount. Leakage from the pad was a daily occurrence for 19% of participants, with the 67% saying that they experienced leaks between 1 and 6 times per week.

On average, participants were alerted by the Smart Underwear to wetness due to pad leakage 87% of the time, and this occurred before they were otherwise aware of the leakage on average 59% of the time. Participants were alerted in time to change their pad before leakage onto clothing or furnishings 85% of the time. The number of false alarms recorded was highly variable, with some patients experiencing high numbers of false alarms and others none or very few.

Over 80% of participants thought the appearance of the Smart Underwear was good or OK. All efforts were made to ensure participants had the correct size, and most found the underwear comfortable to wear; however a few were not satisfied with the size or fit. Ninety three per cent (93%) of participants thought the underwear was easy to wash and 98% thought the instructions for use were good or OK. One third of participants found the press stud mechanism for attaching the signalling unit to the underwear to be 'stiff' although this loosened after use. The majority of participants thought the size of the signalling unit was good or OK; a few thought it too heavy to be properly supported by the underwear. A proportion (14.5%) of participants reported that it showed through tight fitting clothes. The majority of participants found the vibration alert to be good, being sufficiently noticeable for the user but discreet, and with correct number and delivery of vibrations.

Over 90% of participants thought the Smart Underwear would or might make them feel more confident. The PIADS evaluation indicated a positive impact in all three domains: Competence (+0.45), Adaptability (+1.1) and Self-esteem (+0.93). The only significant change in quality of life status over the two week intervention period was on 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.

# Interpretation of results

In general the effectiveness (functionality) of the Smart Underwear and its acceptability to patients was very positive.

The specificity and sensitivity of the sensor are critical to user confidence in the product. Specificity was lower than anticipated probably due a minority of participants who found the signaling unit was alerted by excessive sweating – an explanation offered by the participants themselves. Sensitivity was high with few false negative signals reported; this remained high even after washing.

As a prototype, the study revealed design features that could be improved. These were: shape/fit of underwear to improve comfort for a greater number of women; attachment and size of the signaling unit and choice of material (weight, colour, style).

The aim of the Smart Underwear is to improve confidence in women who wear continence pads. This is supported both in the evaluation questionnaire and the PIADS. The Smart Underwear was found to improve self-perception of competence, adaptability and self-esteem while symptoms remained unaltered. The positive impact recorded in this study after such a short period of time in use is a good indication that the device would be taken up by the target market.

The Smart Underwear does not directly address UI symptoms and thus a significant change in quality of life was not expected. The change in relation to travel may be an indication that improved leakage detection means individuals are less worried about travelling, but further questioning is required to confirm this finding.

# Concluding message

The Smart Underwear is able to give a greater degree of confidence to pad wearers by alerting them to early pad leakage and has the potential to reduce laundry costs. The Smart Underwear design may be improved with some minor modification. It may not be suitable for individuals who sweat excessively.

# References

1. Lagro-Janssen T, Smits A, Van Weel C (1992) Urinary incontinence in women and the effects on their lives. Scand J Prim Health Care 10(3):211-6

# **Disclosures**

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