Absorbent products for urinary/faecal incontinence

Absorbent products for urinary/faecal incontinence: a comparative evaluation of key product designs

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Executive summary

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Executive summary

Background

The UK health service, nursing homes and public spend around £94 million per year on incontinence pads (absorbent products) to contain urine and/or faeces, but the research base for making informed choices between different product designs is very weak.

Objectives

The aim of this trial was to compare the performance and cost-effectiveness of the key absorbent product designs to provide a more solid basis for guiding selection and purchase.

A further aim was to carry out the first stage in the development of a quality of life instrument for measuring the impact of absorbent product use on users' lives.

Design

The work involved three clinical trials focusing on the three biggest market sectors. Each trial had a similar crossover design in which each participant tested all products within their group in random order.

Settings, participants and methods

In Trial 1, 85 women with light urinary incontinence living in the community tested three products from each of the four design categories available (total of 12 test products): disposable inserts (pads); menstrual pads; washable pants with integral pad; and washable inserts. In Trial 2a, 85 moderate/heavily incontinent adults (urinary or urinary/faecal) living in the community (49 men and 36 women) tested three (or two) products from each of the five design categories available (total of 14 test products): disposable inserts (with mesh pants); disposable diapers (nappies); disposable pull-ups (similar to toddlers' trainer pants); disposable T-shaped diapers (nappies with waist-band); and washable diapers. All products were provided in a daytime and a (mostly more absorbent) night-time variant. In these first two trials, the test products were selected on the basis of data from pilot studies. In Trial 2b, 100 moderate/heavily incontinent adults (urinary or urinary/faecal) living in 10 nursing homes (27 men and 73 women) evaluated one product from each of the four disposable design categories from Trial 2a. Products were selected on the basis of product performance in Trial 2a and, again, daytime and night-time variants were provided. The first phase of work to develop a quality of life tool for measuring the impact of using different pad designs was carried out by interviewing participants from Trials 1 and 2a.

Outcome measures

Product performance was characterised using validated questionnaires, which asked the participants (in Trials 1 and 2a) or carers (all participants in Trial 2b, except for the few who could report for themselves) to evaluate various aspects of pad performance (leakage, ease of putting on, discreetness, etc.) using a five-point scale (very good–very poor) at the end of the week (or 2 weeks for Trial 2b) of product testing. In addition, participants/carers were asked to save individual used pads in bags for weighing and to indicate the severity of any leakage from them on a three-point scale (none, a little, a lot). These data were used to determine differences in leakage performance. Numbers of laundry items and pads used were recorded to estimate costs, and skin health changes were recorded by the participant or by the researchers (Trial 2b). At the end of testing, participants were interviewed and ranked their preferences (with and without costs), stated the acceptability of each design (highly acceptable–totally unacceptable) and recorded their overall opinion on a visual analogue scale (VAS) of 0–100 points (worst design–best design). This VAS score was used with product costs to estimate cost-effectiveness. In addition, a timed pad changing exercise was conducted with 10 women from Trial 2b to determine any differences between product designs.

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Results

Results presented are for statistically and clinically significant findings.

Trial 1

Disposable inserts are currently the mainstay of management for lightly incontinent women and they were better for leakage and other variables (but not discreetness) and better overall than the other three designs. However, some women preferred menstrual pads (6/85) or washable pants (13/85), both of which are cheaper to use. Washable inserts were worse both overall and for leakage than the other three designs (72/85 found them unacceptable).

Trials 2a and 2b

Disposable inserts and disposable diapers are the designs currently most commonly used by moderate/heavily incontinent adults. Findings from the community (Trial 2a) and nursing home trials (Trial 2b) were broadly similar. The leakage performance for the disposable inserts was worse than that of the other designs for day and night and pull-ups were preferred over inserts for the daytime. The new T-shaped diaper was not better overall than the traditional disposable diaper. However, there were important differences in performance and preference findings for men and women from both trials and the community-dwelling men had more severe urinary incontinence than the women – mean daytime urine mass 375 g for men and 215 g for women [difference 148 g, 95% confidence interval (CI) 79.8 to 217.7]. Pull-ups (the most expensive) were better overall than the other designs for women during the day and for community-dwelling women during the night also. Although disposable diapers were better for leakage than disposable inserts (the cheapest), women did not prefer them (except in nursing homes at night) but for men the diapers were better both overall and for leakage and were the most cost-effective design. No firm conclusions could be drawn about the performance of designs for faecal incontinence and there was no firm evidence that there were differences in skin health problems between designs.

In the nursing home trial, the carers found pull-ups and inserts easier to apply (in the standing position) and quicker (in the pad change experiment) than the diaper designs, and ability to stand was associated with preference for pull-ups or inserts. Despite being designed for ease of changing, the T-shaped diaper was not easier or quicker to change than the diaper.

The washable products (Trial 2a) gave diverse results. The washables were better for leakage at night than the other designs, but were worse overall for daytime than the other designs. Three-quarters of the women (27/36) found them unacceptable, but nearly two-thirds of men (31/49) found them highly acceptable at night.

Findings from the two community trials (Trials 1 and 2a) showed that there were many practical problems in dealing with washable products but, together with the less effective and less expensive products, such as menstrual pads, they were more acceptable at home (and, in the case of washables, at night). This suggests that cost-effective management may involve combining products by using more effective (for a given user) but more expensive designs (e.g. pull-ups) when out and less effective but less expensive designs when at home.

The interviews examining the impact of pad use on quality of life provided themes and domains (such as hiding the problem, perceptions of normality, coping with incontinence) that can be further developed into a tool for further evaluation of absorbent products.

Conclusions

This study showed that there were significant and substantial differences between the designs of absorbent products and for moderate/heavy incontinence some designs are better for men/women than others. There was considerable individual variability in preferences, and cost-effective management may best be achieved by allowing users to choose combinations of designs for different circumstances within a budget.

Implications for healthcare

There is evidence that:

- A range of disposable and washable designs need to be provided to cost-effectively meet the needs of men and women with incontinence.
- Men may require more, or more absorbent, products than women.
- Although some users prefer washables, current products have important limitations and a blanket policy of providing only washables is not recommended.

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- Allowing men and women to choose combinations of designs for day and night and for different circumstances, within a limited budget, is likely to be economical for the NHS.

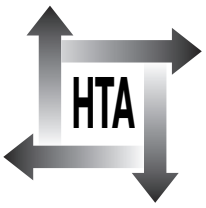
Recommendations for research

The following areas need to be addressed.

- Translational research: to pilot the feasibility of providing choice and combinations of designs to users
- Development of more effective washables for women with light incontinence and more effective and appealing (particularly to women) washables for moderate/heavy incontinence.
- Development of specifically male disposable products for moderate/heavy incontinence.
- Further development of a tool to measure quality of life for users of absorbent products.
- Clinical trial of designs for community-dwelling carer-dependent men and women with moderate/heavy incontinence.

Publication

Fader M, Cottenden A, Getliffe K, Gage H, Clarke-O'Neill S, Jamieson K, *et al*. Absorbent products for urinary/faecal incontinence: a comparative evaluation of key product designs. *Health Technol Assess* 2008;**12**(29).



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NIHR Health Technology Assessment Programme

The Health Technology Assessment (HTA) Programme, part of the National Institute for Health Research (NIHR), was set up in 1993. It produces high-quality research information on the effectiveness, costs and broader impact of health technologies for those who use, manage and provide care in the NHS. 'Health technologies' are broadly defined as all interventions used to promote health, prevent and treat disease, and improve rehabilitation and long-term care.

The research findings from the HTA Programme directly influence decision-making bodies such as the National Institute for Health and Clinical Excellence (NICE) and the National Screening Committee (NSC). HTA findings also help to improve the quality of clinical practice in the NHS indirectly in that they form a key component of the 'National Knowledge Service'.

The HTA Programme is needs-led in that it fills gaps in the evidence needed by the NHS. There are three routes to the start of projects.

First is the commissioned route. Suggestions for research are actively sought from people working in the NHS, the public and consumer groups and professional bodies such as royal colleges and NHS trusts. These suggestions are carefully prioritised by panels of independent experts (including NHS service users). The HTA Programme then commissions the research by competitive tender.

Secondly, the HTA Programme provides grants for clinical trials for researchers who identify research questions. These are assessed for importance to patients and the NHS, and scientific rigour.

Thirdly, through its Technology Assessment Report (TAR) call-off contract, the HTA Programme commissions bespoke reports, principally for NICE, but also for other policy-makers. TARs bring together evidence on the value of specific technologies.

Some HTA research projects, including TARs, may take only months, others need several years. They can cost from as little as £40,000 to over £1 million, and may involve synthesising existing evidence, undertaking a trial, or other research collecting new data to answer a research problem.

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this issue of the journal was commissioned by the HTA Programme as project number 01/11/02. The contractual start date was in April 2003. The draft report began editorial review in February 2007 and was accepted for publication in December 2007. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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