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Effectiveness and cost-effectiveness of a new framework for selecting absorbent urinary incontinence products compared to current practice: a cohort study

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3 **Effectiveness and cost-effectiveness of a new framework for selecting absorbent urinary**
4 **incontinence products compared to current practice: a cohort study**
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55 **Running title:** Selection of urinary incontinence products
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ABSTRACT

Objectives: To improve continence care in the Netherlands a new framework was developed. Central to this framework, there has been a shift in focus from incontinence severity as the sole criterion for selecting incontinence products to a focus on patient need for daily life activities. The impact of the framework on daily care has not been assessed. We aimed to compare treatment effectiveness and cost-effectiveness between participants who did and did not undergo re-evaluation according to the new framework.

Design: Cohort study

Setting: Twelve pharmacies in the Netherlands

Participants: Existing users of incontinence materials for urinary incontinence.

Interventions: Participants were offered the option to have their incontinence products re-evaluated within the new framework at their pharmacy.

Primary and secondary outcome measures: Effectiveness and costs outcomes were assessed at 3 and 6 months through questionnaires. These questionnaires included the ICIQ-LUTSqol, ICIQ-UI-SF, ICIQ-PadPROM, questions about satisfaction and the iPCQ and iMCQ.

Results: Three-hundred-and-three users consented and 279 completed the baseline questionnaire.

Of these participants 72 agreed to a re-evaluation of their incontinence materials. There was a small improvement at 3 months in the re-evaluation group compared to the other group on most outcomes. However, these improvements were not clinically relevant. Moreover, these differences did not change much from 3 to 6 months. Small differences were also observed in the changes in costs, but with very wide confidence intervals on both sides of zero (€99.38; 95% CI, -633.48 to 832.23).

Conclusions: The current study showed no clinically relevant effect of a newly implemented framework for selecting incontinence materials in pharmacies when compared to an existing method. Given that the study also showed no cost-effectiveness, introducing the new framework in

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3 pharmacies may not lead to better incontinence care.
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10 Keywords: Urinary incontinence; Incontinence pads; Continence care.
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12 Word count: 2793
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16 **Strengths and limitations of this study**

- 17 • We gathered information on a range of outcomes that are patient and clinically important
18 and that can be used by policy makers.
19
- 20 • As the study was performed in prevalent cases we cannot draw conclusions regarding the
21 effectiveness of the new framework in incident cases.
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- 23 • The use of an observational study design may have introduced bias because participants who
24 opted for re-evaluation had more symptoms and were less satisfied with their current
25 materials.
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INTRODUCTION

About 28% of women and 9% of men aged 60 years or over report involuntary urine loss at least twice a month [1], which can affect quality of life (QoL) and lead to social isolation and problems with intimacy [2, 3]. A considerable proportion of people in this group use absorbent incontinence products, which in the Netherlands, are reimbursed if prescribed by a physician for incontinence that has a large impact on life and persists for more than 2 months. In 2020, over 400,000 people used reimbursed products, bringing substantial costs of 100–150 million euros per year [4]. Prescriptions by doctors are usually non-specific, giving pharmacies or online providers the freedom to select products based on patient need and applicable reimbursement policies. Most health insurers reimburse a standard amount per day depending on the severity of incontinence.

To improve continence care in the Netherlands, the Ministry of Health, Welfare, and Sport initiated the development of a new framework in 2018 with support from the National Health Care Institute and input from patient advocates, healthcare professionals, suppliers, and insurers [5]. Central to this framework, there has been a shift in focus from incontinence severity as the sole criterion for selecting incontinence products to a focus on patient need for daily life activities. Highly specific goals regarding function must also be formulated before selecting products. All relevant stakeholders engaged in developing the framework, and its use is now considered obligatory for all providers of continence products. Nevertheless, its impact on daily care has not been assessed.

We aimed to compare treatment effectiveness and cost-effectiveness between participants who did and did not undergo re-evaluation according to the new framework, including a subgroup analysis comparing re-evaluated participants who did and did not require a change in materials.

METHODS

Study design

Twelve pharmacies participated in this cohort study of existing incontinence product users and

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3 identified eligible patients. To facilitate the inclusion of incontinence product users, we excluded new
4 users of continence products (incident cases); instead, we only applied the framework to existing
5 users of incontinence products and re-evaluated their products. This made it possible to invite all
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7 users at a single point. People with urinary incontinence, aged 18 years or older, and having received
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9 incontinence products for more than 3 months were eligible for the study, but we excluded users
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11 with terminal illnesses.
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17 Eligible patients received an invitation letter for the study. Non-responders then received a second
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19 invitation after 3–5 months that included an opt-out questionnaire in which they could indicate that
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21 they did not want to participate and select a reason from a prespecified list. The study will be
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23 conducted according to the principles of the Declaration of Helsinki. All participants gave written
24
25 informed consent. The study was approved by the Medical Ethical Committee of the University
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27 Medical Center Groningen (no. 2018/551).
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31 **Intervention**

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33 In each participating pharmacy, one or more employees who were actively involved and experienced
34
35 in continence care were invited for training to familiarize them with the new framework. The
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37 framework has seven steps: 1) Identify the Problem; 2) Formulate Care Demand; 3) Draft Care Plan;
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39 4) Select, Try, and Decide; 5) Deliver and Instruct; 6) Use; and 7) Evaluate. During re-evaluation, we
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41 used a standard form that was developed alongside the new framework.
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46 After providing consent, participants completed a baseline questionnaire (paper or digital, depending
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48 on their preference) in which they were offered the option to have their incontinence products re-
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50 evaluated within the new framework at their pharmacy. Those who reported an interest were invited
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52 by appointment to visit the pharmacy for re-evaluation.
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55 **Outcome measures**

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57 At baseline, we digitally collected information about demographics and comorbidity. Pharmacy
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59 employees collected information about the re-evaluation on a case report form. This included data
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3 on whether the existing product was in line with the new framework, together with any changes that
4 had been made following the re-evaluation. We also assessed patient-reported outcomes at baseline
5 by questionnaire and collected relevant information needed to assess effectiveness and costs. The
6 patient-reported outcome questionnaires and the collection of effectiveness and costs data were
7 repeated after 3 and 6 months. Specifically, the following instruments were used to assess outcomes
8 in this study.
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11 The International Consultation on Incontinence Questionnaire (ICIQ) Lower Urinary Tract Symptoms
12 Quality of Life Module (ICIQ-LUTSqol) was used to measure QoL [6]. This questionnaire includes 20
13 questions, giving an overall score of 19–76, with higher values indicating increased impact on QoL.
14 The approximate minimum clinically important difference for the ICIQ-LUTSqol in women with stress
15 incontinence has been reported to be 3.7 points in one study and 5–6 points in another [7, 8].
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18 The ICIQ Urinary Incontinence Short Form (ICIQ-UI-SF) was used to assess the frequency, severity,
19 and impact on QoL, of urinary incontinence [9]. The ICIQ-UI-SF consists of four questions and gives a
20 total score of 0–21, with lower scores indicating less severe incontinence. The minimum clinically
21 important difference for the ICIQ-UI-SF in women with stress incontinence has been reported to be
22 around 2.5 points in one study and around 4 points in another [7, 8].
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25 The ICIQ Absorbent Pads (ICIQ-PadPROM) was linguistically validated in Dutch and used to assess the
26 treatment effect of absorbent incontinence products on QoL [10]. It has 26 questions and 4
27 subdomains: pad design and physical effect (7 questions, score 0–31), psychological effects (4
28 questions, score 0–16), social effects (3 questions, score 0–12), and pad leakage and burden of pad
29 use (3 questions, score 0–12). A lower score indicates a better QoL.
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32 Satisfaction with incontinence care and incontinence products were each measured with three
33 specifically developed questions answered with 5-point Likert scales ranging from very unsatisfied (0
34 points) to very satisfied (4 points) and giving total scores ranging from 0 to 12 points (Supplementary
35 file 1).
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3 Information on incontinence-related healthcare use over the last 3 months was collected using
4 relevant questions from the iMTA Medical Consumption Questionnaire, and information about
5 productivity loss due to incontinence in the last 4 weeks was collected using the iMTA Productivity
6 Cost Questionnaire [11, 12]. Information about all urinary incontinence products and incontinence-
7 related medication provided from 3 months before baseline to 6 months after baseline was obtained
8 from the registries of each pharmacy.
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16 **Statistical analysis**

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19 All analyses were performed using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Participants
20 who underwent re-evaluation according to the new framework were compared to participants who
21 did not have a re-evaluation. We also performed subgroup analysis among re-evaluated participants
22 to compare those who did and did not require a change in materials, thereby mimicking an intention-
23 to-treat analysis. Because of the clustered data, a mixed model analysis was performed on the
24 change scores for outcome variables when assessing differences between groups. We included
25 intervention, time, and the intervention*time interaction as fixed effects. A random intercept at the
26 individual level was included in all analyses and we checked whether a random intercept at the
27 pharmacy level improved model fit, using the Akaike Information Criterion. These analyses were
28 adjusted for age, sex, and educational level.
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43 Cost analyses were performed according to the guidelines for economic evaluations of the Dutch
44 National Health Care Institute [13]. Data on the amount of care and productivity loss from the iPCQ
45 and iMCQ were multiplied with prices in the guideline to obtain the costs. The prices of incontinence
46 products were obtained from one of the participating pharmacies and the costs for medication were
47 taken from the pharmacotherapeutic information website of the Dutch National Health Care Institute
48 [14]. Costs are reported in euros based on the 2019 prices and calculated for 3 months prior to
49 baseline and 3 months prior to last follow-up. Differences in change of costs over time between
50 groups were calculated from baseline to compare participants who did and did not undergo re-
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3 evaluation, and a subgroup analysis was repeated among re-evaluated participants to compare those
4 who did and did not require a change in materials. Costs were bootstrapped 5,000 times to obtain
5 95% confidence intervals based on the 2.5th and 97.5th centiles.
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10 To assess the generalizability of the results, we compared study participants to all invited users by
11 sex, age, and continence product costs.
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15 **Patient and Public involvement statement**

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17 A patient representative (Bekkenbodem4All) was involved in the conception and design of the study
18 and the interpretation of the results.
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26 **RESULTS**

27 **Descriptive statistics**

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29 The 12 pharmacies invited 1,907 users of incontinence products to participate (range 71–270 users
30 per pharmacy). Of these, 303 (15.9%) users consented and 279 completed the baseline questionnaire
31 (Figure 1). Of those invited, another 404 (21.2%) completed the opt-out questionnaire. The most
32 cited reasons for not participating were satisfaction with current products (71%), lack of interest in
33 the research (35%), and lack of willingness to complete questions on incontinence (32%). About 25%
34 selected 'other reasons' and most selected old age or the presence of an age-related disease.
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44 Of the 12 participating pharmacies, 11 provided information on incontinence product users invited to
45 the study (n = 1,746). Four of these provided data on incontinence products, but not on age or sex,
46 so they were only included in the cost calculations. Based on the relevant data, 79% of the sample
47 was female, the mean age was 75.6 ± 12.5 years, and the mean cost of incontinence product use
48 every 3 months was €128.10 (95% CI, €121.95 to €134.03).
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56 Participant characteristics are shown in Table 1. Of the 279 who completed baseline questionnaires,
57 72 (25.8%) agreed to a re-evaluation of their incontinence materials. Those who underwent re-
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3 evaluation were older, had lower educational levels, more often lived alone than with others, had
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5 more severe symptoms with a higher impact on their lives, and were less satisfied with existing
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7 continence care compared to those who did not undergo re-evaluation.
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10 **Outcomes**

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12 After 3 and 6 months, the follow-up questionnaires were completed by 248 (88.9%) and 231 (82.8%)
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14 participants, respectively. Pharmacies could not provide information about incontinence products or
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16 related medication in three cases. No outcome data were available for 1 of the 72 participants who
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18 underwent re-evaluation. Of the remaining 71 participants, 26 required a change and 45 did not
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20 require a change based on the new framework. However, one participant who required a change was
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22 content with the current material and did not want to make the recommended change.
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26 There was a small improvement at 3 months in the re-evaluation group compared to the other group
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28 on most outcomes (Table 2). However, improvement did not approach the minimum clinically
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30 important difference scores of the ICIQ-LUTSqol or ICIQ-UI-SF and was small compared to the range
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32 of the scales for other outcomes. Moreover, these differences did not change much from 3 to 6
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34 months. We also observed small differences in both the change in total costs and the changes for all
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36 cost categories separately that favoured users who underwent re-evaluation, but with very wide
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38 confidence intervals on both sides of zero (€99.38; 95% CI, -633.48 to 832.23) (Table 3).
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42 Subgroup analysis in participants with re-evaluation showed that those who needed a change in
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44 materials (n = 26) experienced no clinically important differences in outcomes than those who did
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46 not need a change (n = 45, Supplementary file 2). Difference in total cost changes (€606.23; 95% CI, -
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48 €2062.85 to €772.60) and incontinence material costs (€6.44; 95% CI, -€56.65 to €45.98) were seen
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50 in favour of participants who did not need to change material, but again, this was with wide
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52 confidence intervals.
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55 **DISCUSSION**

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3 We found that the new framework for incontinence products had no clinically relevant effect on the
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5 QoL, severity, or satisfaction of users compared to the existing method of selecting materials.
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7 However, although there was no clear evidence, the new framework may have affected costs
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10 Research on the effectiveness and cost-effectiveness of methods for selecting incontinence materials
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12 in the general population is scarce. Fader et al. (2008) showed that the optimal absorbent product
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14 design varies by incontinence severity and sex [15]. There is also large variability in preference, and
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16 cost-effective management requires users to be able to choose combinations of designs for different
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18 circumstances. A trial in the Netherlands showed that it was cost-effective to employ a continence
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20 nurse in general practice [16], using an intervention based on a service specification for incontinence
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22 care developed by systematic review and expert consensus [17]. A key recommendations of that
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24 service specification was to take user and usage factors into account, which are both included in the
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26 new framework evaluated in the current study.
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30 We found no evidence that the new framework affected either patient-related outcomes or costs.
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32 Given that the framework has already been put in place as the new standard, our findings should be
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34 used to improve its content and implementation. Our findings suggest that the new framework does
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36 not go far enough to produce clinically important changes. One reason may be that pharmacy
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38 employees still had to work within the constraints of health insurers, where the severity of
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40 incontinence is key for reimbursement. In interviews after study completion, pharmacy employees
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42 indicated that (1) although they supported the idea of the framework, they were unsure whether
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44 reimbursement would be possible for all patients, and (2) they still had to use the old system
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46 alongside the new framework to comply with reimbursement regulations (unpublished data).
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48 Including activities of daily living in reimbursement regulations and reducing the administrative
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50 burden may increase the impact of the framework. Pharmacy employees also noted that the new
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52 framework is not dramatically different from the existing procedure for material selection. This too
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54 could have led to the failure to detect a clinically important change.
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59 Regarding the cost-effectiveness analyses, we used a societal perspective that included productivity
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3 losses, in accordance with guidelines. However, participants reported no productivity losses,
4 probably because most were older than 65 years and only a minority were not in retirement.
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8 Although the new framework was developed to improve incontinence care, our findings suggest that
9
10 users of incontinence materials are already quite satisfied with current care, as reflected in the
11
12 average baseline Likert score of 4 (satisfied) for satisfaction. Being satisfied was also the most cited
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14 reason for not participating in the study (71%). This may be another reason for the failure to detect a
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16 clinically relevant effect, with most participants having little to no room for improvement.
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20 A limitation of our study is that it was performed among existing users of incontinence materials and
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22 excluded incident cases. It is possible that the new framework will have a greater impact on new
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24 users or that pharmacy employees and participants did the re-evaluation with the current materials
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26 in mind, which could have led to them being more conservative when changing materials. Also, long-
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28 term users may have ended up with suitable materials through trial and error, and it may be that the
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30 framework will help this to occur sooner. Nevertheless, we cannot draw conclusions regarding the
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32 effectiveness of the new framework in incident cases based on the current study.
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36 The use of an observational study design may also have introduced bias. The main reason for
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38 choosing this design was that the new framework was about to be introduced as the new standard of
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40 care and a randomized controlled trial could not be started in time because allocation to the control
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42 condition (existing method of selecting materials) was not possible. Therefore, selection bias may
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44 have arisen because participants were free to choose their intervention. In the present study,
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46 participants who opted for re-evaluation had more symptoms and were less satisfied with their
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48 current materials. We hypothesize that this did not affect the study conclusions because the
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50 intervention likely had an even smaller effect in participants with fewer complaints and higher
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52 satisfaction. We also found that participants who choose the intervention more often lived alone,
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54 which may reflect a need for social interaction (e.g., with a caregiver). This could generate higher
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56 satisfaction at follow-up; but, given that we found no clinically relevant effect of the intervention,
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3 this does not appear to have had a major impact on the outcomes.
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6 To improve generalizability, we compared the characteristics of study participants against all those
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8 who were invited. This revealed that both groups were broadly comparable by age and sex, but that
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10 incontinence material costs were somewhat lower for participants, suggesting that they had less
11
12 severe incontinence or that they received less absorbent materials. Another issue is that since
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14 completing this study there has been a trend for insurers to move reimbursed continence care from
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16 local pharmacies to nationwide online suppliers, which may limit the generalizability of our results to
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18 current practice.
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21 22 **Conclusion**

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24 The current study showed no clinically relevant effect of a newly implemented framework for
25
26 selecting incontinence materials in pharmacies when compared to an existing method. Given that
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28 the study also showed no cost-effectiveness, introducing the new framework in pharmacies may not
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30 lead to better incontinence care. Future research should consider the experiences of incontinence
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32 material users through qualitative research to add further information on how to improve the
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34 framework.
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40 41 **Funding statement**

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Competing interest statement

The authors have no conflict of interest to declare

Data sharing statement

Statistical code, and dataset available from

<https://dataverse.nl/dataset.xhtml?persistentId=doi:10.34894/OVPONP>

Author Contributions

Study design: MCS, HW, BEWB, GGAM, JHD, KMV, MHB. Acquisition of data: MCS, HW, MHB.

Analysis and interpretation of data: MCS, HW, MRB, KMV, MHB. Drafting of the manuscript: MCS,

HW, MHB. Revision and approval of the final version of the manuscript to be published: all authors.

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Table 1. Descriptive characteristics of participants

| | | Re-evaluation | No re-evaluation |
|---------------------------------------|---|---------------|------------------|
| | | n = 72 | n = 207 |
| Age in years (Mean ± SD) | | 76.8 ± 9.6 | 74.3 ± 11.4 |
| Age groups (%) | 18–45 years | 0.0 | 1.9 |
| | 45–65 years | 8.3 | 16.4 |
| | 65–84 years | 66.7 | 64.7 |
| | >85 years | 25.0 | 16.9 |
| Female (%) | | 75.0 | 74.4 |
| Migration background (%) | Native Dutch | 98.6 | 91.3 |
| | First generation migrant | 1.4 | 2.9 |
| | Second generation migrant | 0.0 | 3.9 |
| | Unknown | 0.0 | 1.0 |
| Marital status (%) | Married | 40.3 | 52.7 |
| | Divorce | 11.1 | 10.1 |
| | Partner deceased | 43.1 | 29.5 |
| | Other ¹ | 5.6 | 7.7 |
| Housing (%) | Independence residence | 58.0 | 39.6 |
| | Residence with partner or children | 36.2 | 55.8 |
| | Residential care | 4.3 | 4.6 |
| | Other | 1.4 | 0.0 |
| Highest education² | Primary school or less | 25.0 | 14.5 |
| | Practical/secondary vocational training | 64.1 | 73.0 |
| | Some college/university degree | 10.9 | 12.5 |
| Daily living (%) | Employed/entrepreneur | 1.5 | 6.0 |
| | Houseman/-wife | 20.6 | 22.9 |
| | Unemployed | 1.5 | 1.0 |
| | (Partially) incapacitated for work | 7.4 | 10.0 |
| | (Pre)retirement | 67.6 | 58.7 |
| Other | | 1.5 | 1.5 |
| Multimorbidity³ (%) | | 69.7 | 74.4 |
| ICIQ-LUTSqol | | 50.2 ± 14.9 | 40.4 ± 15.1 |
| ICIQ-UI-SF | | 12.4 ± 4.3 | 11.1 ± 4.5 |
| ICIQ-PadPROM | Pad design and physical effects | 10.9 ± 4.7 | 9.5 ± 3.5 |
| | Psychological effects | 4.4 ± 3.6 | 3.2 ± 3.1 |
| | Social effects | 4.9 ± 3.2 | 4.7 ± 3.7 |
| | Leakage and burden of pad use | 5.0 ± 2.3 | 4.1 ± 2.3 |
| Satisfaction | with incontinence material | 8.3 ± 3.0 | 8.9 ± 2.9 |
| | with incontinence care | 7.5 ± 3.2 | 8.3 ± 3.1 |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; SD = standard deviation; UI-SF = Urinary Incontinence Short Form.

Higher scores represent worse status for the UI-SF and LUTSqol but higher satisfaction for the PadPROM.

Note 1: Includes single and sustainable living together unmarried; Note 2: Collapsed from seven Dutch educational categories; Note 3: Two or more diseases/conditions present, excluding urinary incontinence.

Table 2. Effect of re-evaluation on disease specific outcomes and satisfaction

| | Intervention | Absolute change [#] | Change per period with 95% confidence intervals | Intervention effect (p-value) |
|-------------------------------|---------------------------------|------------------------------|---|-------------------------------|
| | | T0–T2 | T0–T1 | T1–T2 |
| ICIQ-LUTSqol | Re-evaluation | 0.67 | 0.42 (-2.82; 3.65) | 0.15 (-2.99; 3.28) |
| | No re-evaluation | 1.73 | 1.14 (-1.06; 3.43) | 0.59 (-1.74; 2.91) |
| ICIQ-UI-SF | Re-evaluation | -1.16 | -0.72 (-1.68; 0.24) | -0.44 (-1.42; 0.54) |
| | No re-evaluation | 0.01 | -0.27 (-0.94; 0.41) | 0.28 (-0.42; 0.98) |
| ICIQ-PadPROM | | -1.01 | -1.15 (-1.91; -0.39) | 0.14 (-0.63; 0.92) |
| | Pad design and physical effects | | | |
| | Re-evaluation | 0.00 | -0.07 (-0.58; 0.44) | 0.07 (-0.42; 0.60) |
| | No re-evaluation | 0.00 | -0.07 (-0.58; 0.44) | 0.07 (-0.42; 0.60) |
| Psychological effects | Re-evaluation | -0.80 | -0.61 (-1.35; 0.14) | -0.19 (-0.92; 0.57) |
| | No re-evaluation | 0.03 | -0.02 (-0.50; 0.49) | 0.05 (-0.54; 0.44) |
| Social effects | Re-evaluation | -0.48 | -0.42 (-1.47; 0.64) | -0.06 (-1.11; 1.02) |
| | No re-evaluation | -0.13 | 0.24 (-0.50; 0.97) | -0.37 (-1.11; 0.38) |
| Leakage and burden of pad use | Re-evaluation | -0.10 | -0.46 (-1.12; 0.21) | 0.36 (-0.29; 1.01) |
| | No re-evaluation | -0.16 | 0.24 (-0.19; 0.68) | -0.40 (-0.88; 0.05) |
| Satisfaction | | 1.10 | 1.15 (0.43; 1.87) | -0.05 (-0.73; 0.69) |
| Incontinence material | Re-evaluation | 0.52 | 0.34 (-0.15; 0.83) | 0.18 (-0.33; 0.69) |
| | No re-evaluation | 0.52 | 0.34 (-0.15; 0.83) | 0.18 (-0.33; 0.69) |
| Incontinence care | Re-evaluation | 0.33 | 1.12 (0.42; 1.83) | -0.79 (-1.51; -0.06) |
| | No re-evaluation | 0.28 | 0.15 (-0.32; 0.63) | 0.13 (-0.38; 0.63) |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; T0 = baseline; T1 = 3 months' follow-up; 6 months' follow-up; UI-SF = Urinary Incontinence Short Form.

Improvement is a negative score for UI-SF, LUTSqol, and PadPROM and a positive score for satisfaction

Absolute change was calculated from the model estimates

Table 3. Cost analysis

| Costs | Re-evaluation | | No re-evaluation | | Difference in change in favour of intervention group |
|------------------------------------|----------------------------------|---------------------------------|----------------------------------|---------------------------------|--|
| | T0 | T2 | T0 | T2 | |
| Incontinence materials | 120.22 (97.74; 145.40) | 136.00 (110.62; 165.01) | 107.42 (93.21; 123.20) | 119.28 (104.98; 136.88) | -3.92 (-31.20; 23.37) |
| General practitioner | 19.74 (10.42; 30.71) | 9.87 (4.18; 17.00) | 8.34 (5.23; 11.96) | 6.84 (3.27; 10.24) | 8.37 (-2.07; 18.82) |
| Medication | 7.40 (1.01; 15.81) | 7.14 (0.98; 15.32) | 9.67 (4.74; 15.44) | 8.68 (4.07; 14.01) | -0.73 (-6.50; 5.04) |
| Physical Therapy | 10.97 (3.29; 20.40) | 4.39 (0.00; 11.15) | 4.92 (1.68; 8.92) | 6.84 (2.85; 11.55) | 8.51 (-1.74; 18.75) |
| Acupuncture/Homeopathic medication | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.43 (0.00; 1.34) | 0.00 (0.00; 0.00) | -0.43 (-1.78; 0.92) |
| Botox/PTNS/TVT/Other | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 24.45 (4.26; 51.84) | 20.37 (4.00; 42.94) | -4.08 (-34.36; 26.21) |
| Specialist visit | 47.90 (4.43; 101.80) | 56.61 (18.63; 104.52) | 59.43 (33.96; 88.94) | 52.64 (29.05; 80.65) | -15.50 (-80.96; 49.96) |
| Hospital admission | 336.68 (16.30; 896.15) | 88.18 (0.00; 248.5) | 296.95 (95.45; 554.33) | 200.83 (89.60; 348.53) | 152.38 (-351.31; 656.07) |
| Social work | 1.10 (0.00; 3.52) | 2.19 (0.00; 6.92) | 0.00 (0.00; 0.00) | 1.71 (0.00; 4.00) | 0.61 (-3.86; 5.09) |
| Occupational therapy | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.21 (0.00; 0.67) | 0.85 (0.00; 2.67) | 0.64 (-2.15; 3.43) |
| Home care | 546.19 (120.10; 1062.20) | 601.37 (135.44; 1194.28) | 449.55 (224.03; 719.63) | 458.24 (227.54; 734.74) | -46.49 (-483.93; 390.94) |
| Productivity losses | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) |
| Total costs | 1090.20 (495.32; 1825.11) | 905.75 (361.90; 1574.82) | 961.37 (623.74; 1364; 69) | 876.29 (596.82; 1194.30) | 99.38 (-633.48; 832.23) |

Abbreviations: PTNS = percutaneous tibial nerve stimulation; T0 = baseline; 6 months' follow-up; TVT = tension-free vaginal tape

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Figure legends

Figure 1. Flowchart of study participation

For peer review only

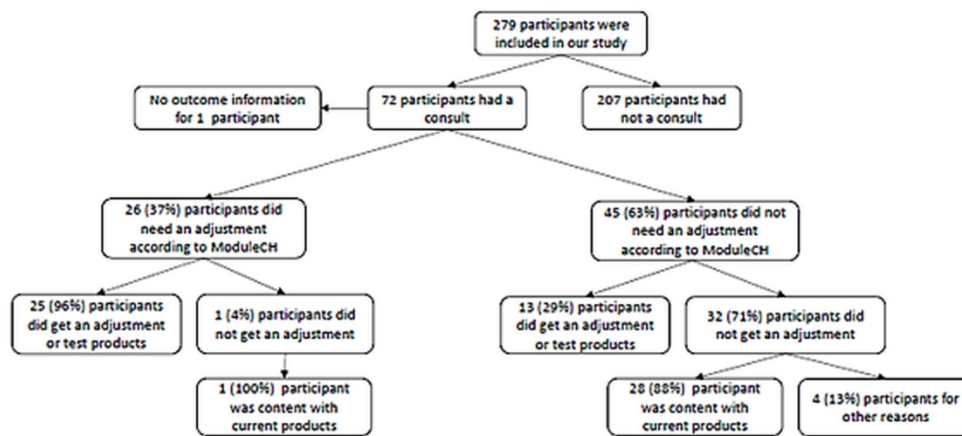


Figure 1. Flowchart of study participation

153x83mm (300 x 300 DPI)

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Supplementary file 1.

| | Very unsatisfied | Unsatisfied | Neutral | Satisfied | Very satisfied |
|---|------------------|-------------|---------|-----------|----------------|
| How satisfied are you with your treatment for incontinence? | | | | | |
| How satisfied are you with the incontinence materials you use? | | | | | |
| To what extent are you satisfied with the freedom of choice regarding the care/treatment of you incontinence? | | | | | |
| To what extent are you satisfied with the freedom of choice regarding the choice of incontinence materials? | | | | | |
| To what extent do the incontinence materials support your sleep? | | | | | |
| To what extent do the incontinence materials support your daytime activities? | | | | | |

Supplementary file 2.

| | Intervention | Absolute change [#] | Change per period (95% confidence intervals) | | Intervention effect (p-value) |
|-------------------------------|------------------|------------------------------|--|---------------------|-------------------------------|
| | | T0–T2 | T0–T1 | T1–T2 | |
| ICIQ-LUTSqol | Change needed | 0.12 | -0.39 (-5.33; 4.54) | 0.51 (-4.89; 5.91) | 0.960 |
| | No change needed | 0.34 | 0.89 (-2.81; 4.61) | -0.55 (-4.02; 2.92) | |
| ICIQ-UI-SF | Change needed | -2.37 | -1.57 (-3.31; 0.16) | -0.80 (-2.71; 1.11) | 0.176 |
| | No change needed | -0.31 | -0.17 (-1.32; 0.98) | -0.14 (-1.28; 1.01) | |
| ICIQ-PadPROM | | | | | |
| Pad design & physical effects | Change needed | -1.11 | -1.41 (-2.74; -0.09) | 0.30 (-1.05; 1.65) | 0.565 |
| | No change needed | 0.46 | -1.17 (-2.12; -0.21) | 0.71 (-0.24; 1.66) | |
| Psychological effects | Change needed | -0.91 | -0.99 (-2.08; 0.10) | 0.08 (-1.00; 1.17) | 0.159 |
| | No change needed | 0.41 | 0.31 (-0.49; 1.10) | 0.10 (-0.69; 0.89) | |
| Social effects | Change needed | 0.79 | -0.03 (-1.50; 1.43) | 0.82 (-0.67; 2.31) | 0.236 |
| | No change needed | -0.69 | -0.37 (-1.41; 0.66) | -0.32 (-1.33; 0.68) | |
| Leakage and burden of pad use | Change needed | -0.70 | -0.60 (-1.74; 0.55) | -0.10 (-1.26; 1.07) | 0.494 |
| | No change needed | -0.02 | -0.38 (-1.21; 0.44) | 0.36 (-0.44; 1.17) | |
| Satisfaction | | | | | |
| Incontinence material | Change needed | 1.02 | 1.37 (0.14; 2.59) | -0.35 (-1.62; 0.92) | 0.656 |
| | No change needed | 0.55 | 0.65 (-0.21; 1.50) | -0.10 (-0.97; 0.76) | |

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|-------------------|------------------|------|--------------------|----------------------|-------|
| Incontinence care | Change needed | 1.33 | 1.13 (-0.01; 2.27) | 0.20 (-0.95; 1.35) | 0.209 |
| | No change needed | 0.11 | 1.00 (0.22; 1.77) | -0.89 (-1.67; -0.11) | |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; T0 = baseline; T1 = 3 months' follow-up; 6 months' follow-up; UI-SF = Urinary Incontinence Short Form.

Improvement is a negative score for UI-SF, LUTSqol, and PadPROM and a positive score for satisfaction

Absolute change was calculated from the model estimates

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STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

| | Item No | Recommendation | Page No |
|------------------------------|---------|--|-------------------------------------|
| Title and abstract | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 1 3 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 4 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5/6 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5/6 |
| Participants | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-8 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 6,7 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 7,8 |
| Study size | 10 | Explain how the study size was arrived at | 9 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | NA |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses | 8,9 8,9 8,9 8,9 8,9 |
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram | 9, Fig 1 9, Fig 1 Fig 1 |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount) | Table 1 9 10 |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | tab 2 |

| | | | | |
|----|--------------------------|----|--|--------------|
| 1 | Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | Tabl 2 |
| 2 | | | (b) Report category boundaries when continuous variables were categorized | NA |
| 3 | | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |
| 4 | | | | |
| 5 | Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 10, suppl |
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| 11 | Discussion | | | |
| 12 | Key results | 18 | Summarise key results with reference to study objectives | 10,11 |
| 13 | Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 12,13 |
| 14 | | | | |
| 15 | Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 13 |
| 16 | | | | |
| 17 | Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 13 |
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| 21 | Other information | | | |
| 22 | Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 2 |
| 23 | | | | |
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*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

BMJ Open

Effectiveness and costs of a new framework for selecting absorbent urinary incontinence products compared to current practice: a cohort study

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|---------------------------------|--|
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| Primary Subject Heading: | Urology |
| Secondary Subject Heading: | Health services research |
| Keywords: | Urinary incontinences < UROLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT |
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3 **Effectiveness and costs of a new framework for selecting absorbent urinary incontinence products**
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5 **compared to current practice: a cohort study**
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55 **Running title:** Selection of urinary incontinence products
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ABSTRACT

Objectives: To improve continence care in the Netherlands a new framework has been developed in which a shift has been made from incontinence severity as the sole criterion for selecting incontinence products to a focus on patient need for daily life activities. The impact of the framework on daily care has not been assessed. We aimed to compare treatment effectiveness and costs between participants who did and did not undergo re-evaluation according to the new framework.

Design: Cohort study

Setting: Twelve pharmacies in the Netherlands

Participants: Existing users of absorbent incontinence materials for urinary incontinence.

Interventions: Participants were offered the option to have their incontinence products re-evaluated within the new framework at their pharmacy.

Primary and secondary outcome measures: Effectiveness and costs outcomes were assessed at 3 and 6 months through questionnaires. These questionnaires included the ICIQ-LUTSqol, ICIQ-UI-SF, ICIQ-PadPROM, questions about satisfaction and the IPCQ and iMCQ.

Results: Three-hundred-and-three users consented and 279 completed the baseline questionnaire. Of these participants 72 agreed to a re-evaluation of their incontinence materials. There was a small improvement at 3 months in the re-evaluation group compared to the other group on most outcomes. However, these improvements were not clinically relevant. Moreover, these differences did not change much from 3 to 6 months. Small differences were also observed in the changes in costs, but with very wide confidence intervals on both sides of zero (€99.38; 95% CI, -633.48 to 832.23).

Conclusions: The current study showed no clinically relevant effect of a newly implemented framework for selecting incontinence materials in pharmacies when compared to an existing method. Given that the study also showed no differences in effectiveness and costs, introducing the new framework in pharmacies may not lead to better incontinence care.

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8 Keywords: Urinary incontinence; Incontinence pads; Continence care.

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10 Word count: 2793

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14 **Strengths and limitations of this study**

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- 17 • We gathered information on a range of outcomes that are patient and clinically important
18 and that can be used by policy makers.
 - 21 • As the study was performed in prevalent cases we cannot draw conclusions regarding the
22 effectiveness of the new framework in incident cases.
 - 25 • The use of an observational study design may have introduced bias because participants who
26 opted for re-evaluation had more symptoms and were less satisfied with their current
27 materials.
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INTRODUCTION

About 28% of women and 9% of men aged 60 years or over report involuntary urine loss at least twice a month [1], which can affect quality of life (QoL) and lead to social isolation and problems with intimacy [2, 3]. A considerable proportion of people in this group use absorbent incontinence products, which in the Netherlands, are reimbursed if prescribed by a physician for incontinence that has a large impact on life and persists for more than 2 months. In 2020, over 400,000 people used reimbursed products, bringing substantial costs of 100–150 million euros per year [4]. Prescriptions by doctors are usually non-specific, giving pharmacies or online providers the freedom to select products based on patient need and applicable reimbursement policies. Most health insurers reimburse a standard amount per day depending on the severity of incontinence.

To improve continence care in the Netherlands, the Ministry of Health, Welfare, and Sport initiated the development of a new framework in 2018 with support from the National Health Care Institute and input from patient advocates, healthcare professionals, suppliers, and insurers [5]. Central to this framework, there has been a shift in focus from incontinence severity as the sole criterion for selecting incontinence products to a focus on patient need for daily life activities. Highly specific goals regarding function must also be formulated before selecting products. All relevant stakeholders engaged in developing the framework, and its use is now considered obligatory for all providers of continence products. Nevertheless, its impact on daily care has not been assessed.

We aimed to compare treatment effectiveness and costs between participants who did and did not undergo re-evaluation according to the new framework, including a subgroup analysis comparing re-evaluated participants who did and did not require a change in materials.

METHODS

Study design

Twelve pharmacies participated in this cohort study of existing absorbent incontinence product users

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3 and identified eligible patients. To facilitate the inclusion of incontinence product users, we excluded
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5 new users of continence products (incident cases); instead, we only applied the framework to
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7 existing users of incontinence products and re-evaluated their products. This made it possible to
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9 invite all users at a single point. People with urinary incontinence, aged 18 years or older, and having
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11 received incontinence products for more than 3 months were eligible for the study, but we excluded
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13 users with terminal illnesses.
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17 Eligible patients received an invitation letter for the study. Non-responders then received a second
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19 invitation after 3–5 months that included an opt-out questionnaire in which they could indicate that
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21 they did not want to participate and select a reason from a prespecified list. The study was
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23 conducted according to the principles of the Declaration of Helsinki. All participants gave written
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25 informed consent. The study was approved by the Medical Ethical Committee of the University
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27 Medical Center Groningen (no. 2018/551).
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30 31 **Intervention**

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33 In each participating pharmacy, one or more employees who were actively involved and experienced
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35 in continence care were invited for training to familiarize them with the new framework. The
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37 framework has seven steps: 1) Identify the Problem; 2) Formulate Care Demand; 3) Draft Care Plan;
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39 4) Select, Try, and Decide; 5) Deliver and Instruct; 6) Use; and 7) Evaluate. During re-evaluation, we
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41 used a standard form that was developed alongside the new framework.
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46 After providing consent, participants completed a baseline questionnaire (paper or digital, depending
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48 on their preference) in which they were offered the option to have their incontinence products re-
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50 evaluated within the new framework at their pharmacy. Those who reported an interest were invited
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52 by appointment to visit the pharmacy for re-evaluation.
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55 **Outcome measures**

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57 At baseline, we digitally collected information about demographics and comorbidity. Pharmacy
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59 employees collected information about the re-evaluation on a case report form. This included data
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3 on whether the existing product was in line with the new framework, together with any changes that
4 had been made following the re-evaluation. We also assessed patient-reported outcomes at baseline
5 by questionnaire and collected relevant information needed to assess effectiveness and costs. The
6 patient-reported outcome questionnaires and the collection of effectiveness and costs data were
7 repeated after 3 and 6 months. Specifically, the following instruments were used to assess outcomes
8 in this study.
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11 The International Consultation on Incontinence Questionnaire (ICIQ) Lower Urinary Tract Symptoms
12 Quality of Life Module (ICIQ-LUTSqol) was used to measure QoL [6]. This questionnaire includes 20
13 questions, giving an overall score of 19–76, with higher values indicating increased impact on QoL.
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15 The approximate minimum clinically important difference for the ICIQ-LUTSqol in women with stress
16 incontinence has been reported to be 3.7 points in one study and 5–6 points in another [7, 8].
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19 The ICIQ Urinary Incontinence Short Form (ICIQ-UI-SF) was used to assess the frequency, severity,
20 and impact on QoL, of urinary incontinence [9]. The ICIQ-UI-SF consists of four questions and gives a
21 total score of 0–21, with lower scores indicating less severe incontinence. The minimum clinically
22 important difference for the ICIQ-UI-SF in women with stress incontinence has been reported to be
23 around 2.5 points in one study and around 4 points in another [7, 8].
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26 The ICIQ Absorbent Pads (ICIQ-PadPROM) was linguistically validated in Dutch and used to assess the
27 treatment effect of absorbent incontinence products on QoL [10]. It has 26 questions and 4
28 subdomains: pad design and physical effect (7 questions, score 0–31), psychological effects (4
29 questions, score 0–16), social effects (3 questions, score 0–12), and pad leakage and burden of pad
30 use (3 questions, score 0–12). A lower score indicates a better QoL.
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33 Satisfaction with incontinence care and incontinence products were each measured with three
34 specifically developed questions answered with 5-point Likert scales ranging from very unsatisfied (0
35 points) to very satisfied (4 points) and giving total scores ranging from 0 to 12 points (Supplementary
36 file 1).
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3 Information on incontinence-related healthcare use over the last 3 months was collected using
4 relevant questions from the iMTA Medical Consumption Questionnaire, and information about
5 productivity loss due to incontinence in the last 4 weeks was collected using the iMTA Productivity
6 Cost Questionnaire [11, 12]. Information about all urinary incontinence products and incontinence-
7 related medication provided from 3 months before baseline to 6 months after baseline was obtained
8 from the registries of each pharmacy.
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16 **Statistical analysis**

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19 All analyses were performed using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Participants
20 who underwent re-evaluation according to the new framework were compared to participants who
21 did not have a re-evaluation. We also performed subgroup analysis among re-evaluated participants
22 to compare those who did and did not require a change in materials, thereby mimicking an intention-
23 to-treat analysis. Because of the clustered data, a mixed model analysis was performed on the
24 change scores for outcome variables when assessing differences between groups. We included
25 intervention, time, and the intervention*time interaction as fixed effects. A random intercept at the
26 individual level was included in all analyses and we checked whether a random intercept at the
27 pharmacy level improved model fit, using the Akaike Information Criterion. These analyses were
28 adjusted for age, sex, and educational level to control for potential confounding.
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43 **Cost analyses**

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45 Cost analyses were performed using a societal perspective according to the guidelines for economic
46 evaluations of the Dutch National Health Care Institute [13]. Data on the amount of care and
47 productivity loss from the iPCQ and iMCQ were multiplied with prices in the guideline to obtain the
48 costs. The prices of incontinence products were obtained from one of the participating pharmacies
49 and the costs for medication were taken from the pharmacotherapeutic information website of the
50 Dutch National Health Care Institute [14]. An overview of the unit costs is presented in
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59 Supplementary file 2. Costs are reported in euros based on the 2019 prices and calculated for 3
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3 months prior to baseline and 3 months prior to last follow-up. Differences in change of costs over
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5 time between groups were calculated from baseline to compare participants who did and did not
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7 undergo re-evaluation, and a subgroup analysis was repeated among re-evaluated participants to
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9 compare those who did and did not require a change in materials. Costs were bootstrapped 5,000
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11 times to obtain 95% confidence intervals based on the 2.5th and 97.5th centiles.
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15 To assess the generalizability of the results, we compared study participants to all invited users by
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17 sex, age, and continence product costs.
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20 **Patient and Public involvement statement**

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22 A patient representative (Bekkenbodem4All) was involved in the conception and design of the study
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24 and the interpretation of the results.
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30 **RESULTS**

31 **Descriptive statistics**

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33 The 12 pharmacies invited 1,907 users of incontinence products to participate (range 71–270 users
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35 per pharmacy). Of these, 303 (15.9%) users consented and 279 completed the baseline questionnaire
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37 (Figure 1). Of those invited, another 404 (21.2%) completed the opt-out questionnaire. The most
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39 cited reasons for not participating were satisfaction with current products (71%), lack of interest in
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41 the research (35%), and lack of willingness to complete questions on incontinence (32%). About 25%
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43 selected 'other reasons' and most selected old age or the presence of an age-related disease.
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49 Of the 12 participating pharmacies, 11 provided information on incontinence product users invited to
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51 the study (n = 1,746). Four of these provided data on incontinence products, but not on age or sex,
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53 so they were only included in the cost calculations. Based on the relevant data, 79% of the sample
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55 was female, the mean age was 75.6 ± 12.5 years, and the mean cost of incontinence product use
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57 every 3 months was €128.10 (95% CI, €121.95 to €134.03).
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Participant characteristics are shown in Table 1. Of the 279 who completed baseline questionnaires, 72 (25.8%) agreed to a re-evaluation of their incontinence materials. Those who underwent re-evaluation were older, had lower educational levels, more often lived alone than with others, had more severe symptoms with a higher impact on their lives, and were less satisfied with existing continence care compared to those who did not undergo re-evaluation.

Outcomes

After 3 and 6 months, the follow-up questionnaires were completed by 248 (88.9%) and 231 (82.8%) participants, respectively. Pharmacies could not provide information about incontinence products or related medication in three cases. No outcome data were available for 1 of the 72 participants who underwent re-evaluation. Of the remaining 71 participants, 26 required a change and 45 did not require a change based on the new framework. However, one participant who required a change was content with the current material and did not want to make the recommended change.

There was a small improvement at 3 months in the re-evaluation group compared to the other group on most outcomes (Table 2). However, improvement did not approach the minimum clinically important difference scores of the ICIQ-LUTSqol or ICIQ-UI-SF and was small compared to the range of the scales for other outcomes. Moreover, these differences did not change much from 3 to 6 months.

Subgroup analysis in participants with re-evaluation showed that those who needed a change in materials (n = 26) experienced no clinically important differences in outcomes than those who did not need a change (n = 45, Supplementary file 3).

Costs

We also observed small differences in both the change in total costs and the changes for all cost categories separately that favoured users who underwent re-evaluation, but with very wide confidence intervals on both sides of zero (€99.38; 95% CI, -633.48 to 832.23) (Table 3).

Difference in total cost changes (€606.23; 95% CI, -€2062.85 to €772.60) and incontinence material

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3 costs (€6.44; 95% CI, -€56.65 to €45.98) were seen in favour of participants who did not need to
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5 change material, but again, this was with wide confidence intervals.
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10 **DISCUSSION**

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13 We found that the new framework for incontinence products had no clinically relevant effect on the
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15 QoL, severity, or satisfaction of users compared to the existing method of selecting materials.

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17 However, although there was no clear evidence, the new framework may have affected costs

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20 Research on the effectiveness and cost-effectiveness of methods for selecting incontinence materials
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22 in the general population is scarce. Fader et al. (2008) showed that the optimal absorbent product
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24 design varies by incontinence severity and sex [15]. There is also large variability in preference, and
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26 cost-effective management requires users to be able to choose combinations of designs for different
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28 circumstances. A trial in the Netherlands showed that it was cost-effective to employ a continence
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30 nurse in general practice [16], using an intervention based on a service specification for incontinence
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32 care developed by systematic review and expert consensus [17]. A key recommendations of that
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34 service specification was to take user and usage factors into account, which are both included in the
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36 new framework evaluated in the current study.
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41 We found no evidence that the new framework affected either patient-related outcomes or costs.

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43 Given that the framework has already been put in place as the new standard, our findings should be
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45 used to improve its content and implementation. Our findings suggest that the new framework does
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47 not go far enough to produce clinically important changes. One reason may be that pharmacy
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49 employees still had to work within the constraints of health insurers, where the severity of
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51 incontinence is key for reimbursement. In interviews after study completion, pharmacy employees
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53 indicated that (1) although they supported the idea of the framework, they were unsure whether
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55 reimbursement would be possible for all patients, and (2) they still had to use the old system
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57 alongside the new framework to comply with reimbursement regulations (unpublished data).
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3 Including activities of daily living in reimbursement regulations and reducing the administrative
4 burden may increase the impact of the framework. Pharmacy employees also noted that the new
5 framework is not dramatically different from the existing procedure for material selection. This too
6 could have led to the failure to detect a clinically important change.
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12 Regarding the costs, we used a societal perspective that included productivity losses, in accordance
13 with guidelines. However, participants reported no productivity losses, probably because most were
14 older than 65 years and only a minority were not in retirement.
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19 Although the new framework was developed to improve incontinence care, our findings suggest that
20 users of incontinence materials are already quite satisfied with current care, as reflected in the
21 average baseline Likert score of 4 (satisfied) for satisfaction. Being satisfied was also the most cited
22 reason for not participating in the study (71%). This may be another reason for the failure to detect a
23 clinically relevant effect, with most participants having little to no room for improvement.
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30 A limitation of our study is that it was performed among existing users of incontinence materials and
31 excluded incident cases. It is possible that the new framework will have a greater impact on new
32 users or that pharmacy employees and participants did the re-evaluation with the current materials
33 in mind, which could have led to them being more conservative when changing materials. Also, long-
34 term users may have ended up with suitable materials through trial and error, and it may be that the
35 framework will help this to occur sooner. Nevertheless, we cannot draw conclusions regarding the
36 effectiveness of the new framework in incident cases based on the current study.
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48 The use of an observational study design may also have introduced bias. The main reason for
49 choosing this design was that the new framework was about to be introduced as the new standard of
50 care and a randomized controlled trial could not be started in time because allocation to the control
51 condition (existing method of selecting materials) was not possible. Therefore, selection bias may
52 have arisen because participants were free to choose their intervention. In the present study,
53 participants who opted for re-evaluation had more symptoms and were less satisfied with their
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3 current materials. We hypothesize that this did not affect the study conclusions because the
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5 intervention likely had an even smaller effect in participants with fewer complaints and higher
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7 satisfaction. We also found that participants who choose the intervention more often lived alone,
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9 which may reflect a need for social interaction (e.g., with a caregiver). This could generate higher
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11 satisfaction at follow-up; but, given that we found no clinically relevant effect of the intervention,
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13 this does not appear to have had a major impact on the outcomes. However, the observational study
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15 design does not allow to make causal claims.
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19 To improve generalizability, we compared the characteristics of study participants against all those
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21 who were invited. This revealed that both groups were broadly comparable by age and sex, but that
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23 incontinence material costs were somewhat lower for participants, suggesting that they had less
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25 severe incontinence or that they received less absorbent materials. However, it is possible that those
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27 who did not participate and those who did participate differ on other characteristics which might
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29 have an impact on generalizability. Another issue is that since completing this study there has been a
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31 trend for insurers to move reimbursed continence care from local pharmacies to nationwide online
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33 suppliers, which may limit the generalizability of our results to current practice.
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36 37 **Conclusion**

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39 The current study showed no clinically relevant effect of a newly implemented framework for
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41 selecting absorbent incontinence materials in pharmacies when compared to an existing method.
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43 Given that the study also showed no difference in effectiveness and costs, introducing the new
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45 framework in pharmacies may not lead to better incontinence care. Future research should consider
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47 the experiences of incontinence material users through qualitative research to add further
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49 information on how to improve the framework.
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54 55 **Funding statement**

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17 **Competing interest statement**

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19 The authors have no conflict of interest to declare
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23 **Data sharing statement**

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25 Statistical code, and dataset available from
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27

28 <https://dataverse.nl/dataset.xhtml?persistentId=doi:10.34894/OVPONP>
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33 **Author Contributions**

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35 Study design: MCS, HW, BEWB, GGAM, JHD, KMV, MHB. Acquisition of data: MCS, HW, MHB.
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38 Analysis and interpretation of data: MCS, HW, MRB, KMV, MHB. Drafting of the manuscript: MCS,
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41 HW, MHB. Revision and approval of the final version of the manuscript to be published: all authors.
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Table 1. Descriptive characteristics of participants

| | Re-evaluation | No re-evaluation |
|---|---------------|------------------|
| | n = 72 | n = 207 |
| Age in years (Mean ± SD) | 76.8 ± 9.6 | 74.3 ± 11.4 |
| Age groups (%) | | |
| 18–45 years | 0.0 | 1.9 |
| 45–65 years | 8.3 | 16.4 |
| 65–84 years | 66.7 | 64.7 |
| >85 years | 25.0 | 16.9 |
| Female (%) | 75.0 | 74.4 |
| Migration background (%) | | |
| Native Dutch | 98.6 | 91.3 |
| First generation migrant | 1.4 | 2.9 |
| Second generation migrant | 0.0 | 3.9 |
| Unknown | 0.0 | 1.0 |
| Marital status (%) | | |
| Married | 40.3 | 52.7 |
| Divorce | 11.1 | 10.1 |
| Partner deceased | 43.1 | 29.5 |
| Other ¹ | 5.6 | 7.7 |
| Housing (%) | | |
| Independence residence | 58.0 | 39.6 |
| Residence with partner or children | 36.2 | 55.8 |
| Residential care | 4.3 | 4.6 |
| Other | 1.4 | 0.0 |
| Highest education² | | |
| Primary school or less | 25.0 | 14.5 |
| Practical/secondary vocational training | 64.1 | 73.0 |
| Some college/university degree | 10.9 | 12.5 |
| Daily living (%) | | |
| Employed/entrepreneur | 1.5 | 6.0 |
| Houseman/-wife | 20.6 | 22.9 |
| Unemployed | 1.5 | 1.0 |
| (Partially) incapacitated for work | 7.4 | 10.0 |
| (Pre)retirement | 67.6 | 58.7 |
| Other | 1.5 | 1.5 |
| Multimorbidity³ (%) | 69.7 | 74.4 |
| ICIQ-LUTSqol | 50.2 ± 14.9 | 40.4 ± 15.1 |
| ICIQ-UI-SF | 12.4 ± 4.3 | 11.1 ± 4.5 |
| ICIQ-PadPROM | | |
| Pad design and physical effects | 10.9 ± 4.7 | 9.5 ± 3.5 |
| Psychological effects | 4.4 ± 3.6 | 3.2 ± 3.1 |
| Social effects | 4.9 ± 3.2 | 4.7 ± 3.7 |
| Leakage and burden of pad use | 5.0 ± 2.3 | 4.1 ± 2.3 |
| Satisfaction | | |
| with incontinence material | 8.3 ± 3.0 | 8.9 ± 2.9 |
| with incontinence care | 7.5 ± 3.2 | 8.3 ± 3.1 |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; SD = standard deviation; UI-SF = Urinary Incontinence Short Form.

Higher scores represent worse status for the UI-SF and LUTSqol but higher satisfaction for the PadPROM.

Note 1: Includes single and sustainable living together unmarried; Note 2: Collapsed from seven Dutch educational categories; Note 3: Two or more diseases/conditions present, excluding urinary incontinence.

Table 2. Effect of re-evaluation on disease specific outcomes and satisfaction

| | Intervention | Absolute change [#] | Change per period with 95% confidence intervals | Intervention effect (p-value) |
|-------------------------------|------------------|------------------------------|---|-------------------------------|
| | | T0–T2 | T0–T1 | T1–T2 |
| ICIQ-LUTSqol | Re-evaluation | 0.67 | 0.42 (-2.82; 3.65) | 0.15 (-2.99; 3.28) |
| | No re-evaluation | 1.73 | 1.14 (-1.06; 3.43) | 0.59 (-1.74; 2.91) |
| ICIQ-UI-SF | Re-evaluation | -1.16 | -0.72 (-1.68; 0.24) | -0.44 (-1.42; 0.54) |
| | No re-evaluation | 0.01 | -0.27 (-0.94; 0.41) | 0.28 (-0.42; 0.98) |
| ICIQ-PadPROM | Re-evaluation | -1.01 | -1.15 (-1.91; -0.39) | 0.14 (-0.63; 0.92) |
| | No re-evaluation | 0.00 | -0.07 (-0.58; 0.44) | 0.07 (-0.42; 0.60) |
| Psychological effects | Re-evaluation | -0.80 | -0.61 (-1.35; 0.14) | -0.19 (-0.93; 0.57) |
| | No re-evaluation | 0.03 | -0.02 (-0.50; 0.49) | 0.05 (-0.54; 0.44) |
| Social effects | Re-evaluation | -0.48 | -0.42 (-1.47; 0.64) | -0.06 (-1.11; 1.02) |
| | No re-evaluation | -0.13 | 0.24 (-0.50; 0.97) | -0.37 (-1.11; 0.38) |
| Leakage and burden of pad use | Re-evaluation | -0.10 | -0.46 (-1.12; 0.21) | 0.36 (-0.29; 1.01) |
| | No re-evaluation | -0.16 | 0.24 (-0.19; 0.68) | -0.40 (-0.88; 0.05) |
| Satisfaction | | 1.10 | 1.15 (0.43; 1.87) | -0.05 (-0.73; 0.69) |
| Incontinence material | Re-evaluation | 0.52 | 0.34 (-0.15; 0.83) | 0.18 (-0.33; 0.69) |
| | No re-evaluation | | | |
| Incontinence care | Re-evaluation | 0.33 | 1.12 (0.42; 1.83) | -0.79 (-1.51; -0.06) |
| | No re-evaluation | 0.28 | 0.15 (-0.32; 0.63) | 0.13 (-0.38; 0.63) |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; T0 = baseline; T1 = 3 months' follow-up; 6 months' follow-up; UI-SF = Urinary Incontinence Short Form.

Improvement is a negative score for UI-SF, LUTSqol, and PadPROM and a positive score for satisfaction

Absolute change was calculated from the model estimates

Table 3. Mean costs of the two evaluation groups per cost unit and time point

| Costs | Re-evaluation | | No re-evaluation | | Difference in change in favour of intervention group |
|------------------------------------|----------------------------------|---------------------------------|----------------------------------|---------------------------------|--|
| | T0 | T2 | T0 | T2 | |
| Incontinence materials | 120.22 (97.74; 145.40) | 136.00 (110.62; 165.01) | 107.42 (93.21; 123.20) | 119.28 (104.98; 136.88) | -3.92 (-31.20; 23.37) |
| General practitioner | 19.74 (10.42; 30.71) | 9.87 (4.18; 17.00) | 8.34 (5.23; 11.96) | 6.84 (3.27; 10.24) | 8.37 (-2.07; 18.82) |
| Medication | 7.40 (1.01; 15.81) | 7.14 (0.98; 15.32) | 9.67 (4.74; 15.44) | 8.68 (4.07; 14.01) | -0.73 (-6.50; 5.04) |
| Physical Therapy | 10.97 (3.29; 20.40) | 4.39 (0.00; 11.15) | 4.92 (1.68; 8.92) | 6.84 (2.85; 11.55) | 8.51 (-1.74; 18.75) |
| Acupuncture/Homeopathic medication | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.43 (0.00; 1.34) | 0.00 (0.00; 0.00) | -0.43 (-1.78; 0.92) |
| Botox/PTNS/TVT/Other | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 24.45 (4.26; 51.84) | 20.37 (4.00; 42.94) | -4.08 (-34.36; 26.21) |
| Specialist visit | 47.90 (4.43; 101.80) | 56.61 (18.63; 104.52) | 59.43 (33.96; 88.94) | 52.64 (29.05; 80.65) | -15.50 (-80.96; 49.96) |
| Hospital admission | 336.68 (16.30; 896.15) | 88.18 (0.00; 248.5) | 296.95 (95.45; 554.33) | 200.83 (81.60; 348.53) | 152.38 (-351.31; 656.07) |
| Social work | 1.10 (0.00; 3.52) | 2.19 (0.00; 6.92) | 0.00 (0.00; 0.00) | 1.71 (0.00; 4.00) | 0.61 (-3.86; 5.09) |
| Occupational therapy | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.21 (0.00; 0.67) | 0.85 (0.00; 2.67) | 0.64 (-2.15; 3.43) |
| Home care | 546.19 (120.10; 1062.20) | 601.37 (135.44; 1194.28) | 449.55 (224.03; 719.63) | 458.24 (227.54; 734.74) | -46.49 (-483.93; 390.94) |
| Productivity losses | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) |
| Total costs | 1090.20 (495.32; 1825.11) | 905.75 (361.90; 1574.82) | 961.37 (623.74; 1364; 69) | 876.29 (596.82; 1194.30) | 99.38 (-633.48; 832.23) |

Abbreviations: PTNS = percutaneous tibial nerve stimulation; T0 = baseline; 6 months' follow-up; TVT = tension-free vaginal tape

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Figure legends

Figure 1. Flowchart of study participation

For peer review only

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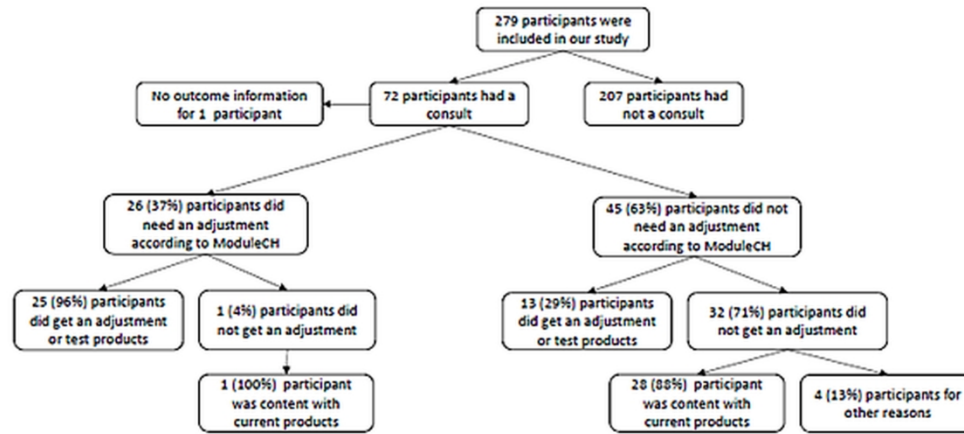


Figure 1. Flowchart of study participation

153x83mm (600 x 600 DPI)

Supplementary file 1.

| | Very unsatisfied | Unsatisfied | Neutral | Satisfied | Very satisfied |
|---|------------------|-------------|---------|-----------|----------------|
| How satisfied are you with your treatment for incontinence? | | | | | |
| How satisfied are you with the incontinence materials you use? | | | | | |
| To what extent are you satisfied with the freedom of choice regarding the care/treatment of you incontinence? | | | | | |
| To what extent are you satisfied with the freedom of choice regarding the choice of incontinence materials? | | | | | |
| To what extent do the incontinence materials support your sleep? | | | | | |
| To what extent do the incontinence materials support your daytime activities? | | | | | |

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| Specification of costs | Unit costs |
|---|--------------------|
| <i>First-line services</i> | |
| General practitioner | €34/consultation |
| Social work | €68/consultation |
| Occupational therapy | €34/consultation |
| Domestic help | €21/hour |
| Personal care | €52/hour |
| Nursing | €76/hour |
| Physical therapy for UI | €34/consultation |
| Acupuncture or homeopath for UI | €68/treatment |
| <i>Medication for UI¹</i> | |
| Darafenacin 15 mg | €0.55/per day |
| Darafenacin 7.5 mg | €0.87/per day |
| Fesoterodin 8 mg | €0.58/per day |
| Fesoterodin 4 mg | €0.89/per day |
| Oxybutinin 1 mg/ml oral solution | €2.50/per day |
| Oxybutinin 5 mg | €0.23/per day |
| Oxybutinin 2.5 mg | €0.35/per day |
| Oxybutinin 3.9 mg transdermal patch | €1.27/per day |
| Solifenacin (generic) 10 mg | €0.40/per day |
| Solifenacin (Vesicare) 10 mg | €0.58/per day |
| Solifenacin (generic) 5 mg | €0.59/per day |
| Solifenacin (Vesicare) 5 mg | €0.85/per day |
| Solifenacin (Vesicare) 1 mg/ml oral solution | €0.89/per day |
| Tolterodin (generic) 4 mg controlled release | €0.30/per day |
| Tolterodin (Detrusitol) 4 mg controlled release | €0.71/per day |
| Tolterodin (generic) 2 mg | €0.46/per day |
| Tolterodin (Detrusitol) 2 mg | €0.89/per day |
| Tolterodin (generic) 2 mg | €0.76/per day |
| Tolterodin (Detrusitol) 2 mg | €0.89/per day |
| Tolterodin (generic) 1 mg | €0.73/per day |
| Tolterodin (Detrusitol) 1mg | €1.08/per day |
| Flavoxaat 200 mg | €0.83/per day |
| Mirabegron 5 mg | €0.89/per day |
| Costs of dispensing by pharmacy | €6.25/per delivery |
| <i>Incontinence pads²</i> | |
| Sanitary pad | €0.14/per piece |
| Disposable pads - small | €0.26/per piece |
| Disposable pads – medium | €0.45/per piece |
| Disposable pads – large | €0.63/per piece |
| Insert pads | €0.27/per piece |
| T-shaped pads | €1.19/per piece |
| Disposable pants | €1.43/per piece |
| All-in-ones | €1.31/per piece |
| Washable pants | €0.99/per piece |
| Bed underlays | €0.49/per piece |

Second-line care

| | |
|--|------------|
| Specialist consultation | €270/visit |
| Admission in hospital | €497/day |
| Other treatment for UI: Botox/PTNS/TVT | €324 |

Other costs

| | |
|---------------------|----------|
| Productivity losses | €34/hour |
|---------------------|----------|

Unit costs are based on reference prices of the cost manual of the Dutch Healthcare Institute, except when stated otherwise. Costs have indexed for 2019.

1. Prices obtained from pharmacotherapeutic information website of the Dutch National Health Care Institute [14]

2. Prices obtained from one of the participating pharmacies

Supplementary file 2.

| | Intervention | Absolute change [#] | Change per period (95% confidence intervals) | | Intervention effect (p-value) |
|-------------------------------|------------------|------------------------------|--|---------------------|-------------------------------|
| | | T0–T2 | T0–T1 | T1–T2 | |
| ICIQ-LUTSqol | Change needed | 0.12 | -0.39 (-5.33; 4.54) | 0.51 (-4.89; 5.91) | 0.960 |
| | No change needed | 0.34 | 0.89 (-2.81; 4.61) | -0.55 (-4.02; 2.92) | |
| ICIQ-UI-SF | Change needed | -2.37 | -1.57 (-3.31; 0.16) | -0.80 (-2.71; 1.11) | 0.176 |
| | No change needed | -0.31 | -0.17 (-1.32; 0.98) | -0.14 (-1.28; 1.01) | |
| ICIQ-PadPROM | | | | | |
| Pad design & physical effects | Change needed | -1.11 | -1.41 (-2.74; -0.09) | 0.30 (-1.05; 1.65) | 0.565 |
| | No change needed | 0.46 | -1.17 (-2.12; -0.21) | 0.71 (-0.24; 1.66) | |
| Psychological effects | Change needed | -0.91 | -0.99 (-2.08; 0.10) | 0.08 (-1.00; 1.17) | 0.159 |
| | No change needed | 0.41 | 0.31 (-0.49; 1.10) | 0.10 (-0.69; 0.89) | |
| Social effects | Change needed | 0.79 | -0.03 (-1.50; 1.43) | 0.82 (-0.67; 2.31) | 0.236 |
| | No change needed | -0.69 | -0.37 (-1.41; 0.66) | -0.32 (-1.33; 0.68) | |
| Leakage and burden of pad use | Change needed | -0.70 | -0.60 (-1.74; 0.55) | -0.10 (-1.26; 1.07) | 0.494 |
| | No change needed | -0.02 | -0.38 (-1.21; 0.44) | 0.36 (-0.44; 1.17) | |
| Satisfaction | | | | | |
| Incontinence material | Change needed | 1.02 | 1.37 (0.14; 2.59) | -0.35 (-1.62; 0.92) | 0.656 |
| | No change needed | 0.55 | 0.65 (-0.21; 1.50) | -0.10 (-0.97; 0.76) | |

| | | | | | |
|-------------------|------------------|------|--------------------|----------------------|-------|
| Incontinence care | Change needed | 1.33 | 1.13 (-0.01; 2.27) | 0.20 (-0.95; 1.35) | 0.209 |
| | No change needed | 0.11 | 1.00 (0.22; 1.77) | -0.89 (-1.67; -0.11) | |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; T0 = baseline; T1 = 3 months' follow-up; 6 months' follow-up; UI-SF = Urinary Incontinence Short Form.

Improvement is a negative score for UI-SF, LUTSqol, and PadPROM and a positive score for satisfaction

Absolute change was calculated from the model estimates

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

| | Item No | Recommendation | Page No |
|------------------------------|---------|--|-------------------------------------|
| Title and abstract | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract | 1 |
| | | (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 3 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 4 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5/6 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5/6 |
| Participants | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-8 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 6,7 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 7,8 |
| Study size | 10 | Explain how the study size was arrived at | 9 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | NA |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses | 8,9 8,9 8,9 8,9 8,9 |
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram | 9, Fig 1 9, Fig 1 Fig 1 |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount) | Table 1 9 10 |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | tab 2 |

| | | | | |
|----|--------------------------|----|--|--------------|
| 1 | Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | Tabl 2 |
| 2 | | | (b) Report category boundaries when continuous variables were categorized | NA |
| 3 | | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |
| 4 | | | | |
| 5 | Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 10, suppl |
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| 11 | Discussion | | | |
| 12 | Key results | 18 | Summarise key results with reference to study objectives | 10,11 |
| 13 | Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 12,13 |
| 14 | | | | |
| 15 | Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 13 |
| 16 | | | | |
| 17 | Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 13 |
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| 21 | Other information | | | |
| 22 | Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 2 |
| 23 | | | | |
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*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.

BMJ Open

Effectiveness and costs of a new framework for selecting absorbent urinary incontinence products compared to current practice: a cohort study

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|---------------------------------|--|
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| Secondary Subject Heading: | Health services research |
| Keywords: | Urinary incontinences < UROLOGY, Health policy < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Health economics < HEALTH SERVICES ADMINISTRATION & MANAGEMENT |
| | |

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3 **Effectiveness and costs of a new framework for selecting absorbent urinary incontinence products**
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5 **compared to current practice: a cohort study**
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55 **Running title:** Selection of urinary incontinence products
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ABSTRACT

Objectives: To improve continence care in the Netherlands a new framework has been developed in which a shift has been made from incontinence severity as the sole criterion for selecting incontinence products to a focus on patient need for daily life activities. The impact of the framework on daily care has not been assessed. We aimed to compare treatment effectiveness and costs between participants who did and did not undergo re-evaluation according to the new framework.

Design: Cohort study

Setting: Twelve pharmacies in the Netherlands

Participants: Existing users of absorbent incontinence materials for urinary incontinence.

Interventions: Participants were offered the option to have their incontinence products re-evaluated within the new framework at their pharmacy.

Primary and secondary outcome measures: Effectiveness and costs outcomes were assessed at 3 and 6 months through questionnaires. These questionnaires included the ICIQ-LUTSqol, ICIQ-UI-SF, ICIQ-PadPROM, questions about satisfaction and the IPCQ and iMCQ.

Results: Three-hundred-and-three users consented and 279 completed the baseline questionnaire. Of these participants 72 agreed to a re-evaluation of their incontinence materials. There was a small improvement at 3 months in the re-evaluation group compared to the other group on most outcomes. However, these improvements were not clinically relevant. Moreover, these differences did not change much from 3 to 6 months. Small differences were also observed in the changes in costs, but with very wide confidence intervals on both sides of zero (€99.38; 95% CI, -633.48 to 832.23).

Conclusions: The current study showed no clinically relevant effect of a newly implemented framework for selecting incontinence materials in pharmacies when compared to an existing method. Given that the study also showed no differences in effectiveness and costs, introducing the new framework in pharmacies may not lead to better incontinence care.

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8 Keywords: Urinary incontinence; Incontinence pads; Continence care.
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10 Word count: 2793
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14 **Strengths and limitations of this study** 15

- 16 • We gathered information on a range of outcomes that are patient and clinically important
17 and that can be used by policy makers.
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- 19 • As the study was performed in prevalent cases we cannot draw conclusions regarding the
20 effectiveness of the new framework in incident cases.
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- 22 • The use of an observational study design may have introduced bias because participants who
23 opted for re-evaluation had more symptoms and were less satisfied with their current
24 materials.
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INTRODUCTION

About 28% of women and 9% of men aged 60 years or over report involuntary urine loss at least twice a month [1], which can affect quality of life (QoL) and lead to social isolation and problems with intimacy [2, 3]. A considerable proportion of people in this group use absorbent incontinence products, which in the Netherlands, are reimbursed if prescribed by a physician for incontinence that has a large impact on life and persists for more than 2 months. In 2020, over 400,000 people used reimbursed products, bringing substantial costs of 100–150 million euros per year [4]. Prescriptions by doctors are usually non-specific, giving pharmacies or online providers the freedom to select products based on patient need and applicable reimbursement policies. Most health insurers reimburse a standard amount per day depending on the severity of incontinence.

To improve continence care in the Netherlands, the Ministry of Health, Welfare, and Sport initiated the development of a new framework in 2018 with support from the National Health Care Institute and input from patient advocates, healthcare professionals, suppliers, and insurers [5]. Central to this framework, there has been a shift in focus from incontinence severity as the sole criterion for selecting incontinence products to a focus on patient need for daily life activities. Highly specific goals regarding function must also be formulated before selecting products. All relevant stakeholders engaged in developing the framework, and its use is now considered obligatory for all providers of continence products. Nevertheless, its impact on daily care has not been assessed.

We aimed to compare treatment effectiveness and costs between participants who did and did not undergo re-evaluation according to the new framework, including a subgroup analysis comparing re-evaluated participants who did and did not require a change in materials.

METHODS

Study design

Twelve pharmacies participated in this cohort study of existing absorbent incontinence product users

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3 and identified eligible patients. To facilitate the inclusion of incontinence product users, we excluded
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5 new users of continence products (incident cases); instead, we only applied the framework to
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7 existing users of incontinence products and re-evaluated their products. This made it possible to
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9 invite all users at a single point. People with urinary incontinence, aged 18 years or older, and having
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11 received incontinence products for more than 3 months were eligible for the study, but we excluded
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13 users with terminal illnesses.
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17 Eligible patients received an invitation letter for the study. Non-responders then received a second
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19 invitation after 3–5 months that included an opt-out questionnaire in which they could indicate that
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21 they did not want to participate in the cohort study and select a reason from a prespecified list. The
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23 study was conducted according to the principles of the Declaration of Helsinki. All participants gave
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25 written informed consent. The study was approved by the Medical Ethical Committee of the
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27 University Medical Center Groningen (no. 2018/551).
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30 31 **Intervention**

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33 In each participating pharmacy, one or more employees who were actively involved and experienced
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35 in continence care were invited for training to familiarize them with the new framework. The
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37 framework has seven steps: 1) Identify the Problem; 2) Formulate Care Demand; 3) Draft Care Plan;
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39 4) Select, Try, and Decide; 5) Deliver and Instruct; 6) Use; and 7) Evaluate. During re-evaluation, we
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41 used a standard form that was developed alongside the new framework.
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45 After providing consent, participants completed a baseline questionnaire (paper or digital, depending
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47 on their preference) in which they were offered the option to have their incontinence products re-
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49 evaluated within the new framework at their pharmacy. Those who reported an interest were invited
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51 by appointment to visit the pharmacy for re-evaluation.
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54 55 **Outcome measures**

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57 At baseline, we digitally collected information about demographics and comorbidity. Pharmacy
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59 employees collected information about the re-evaluation on a case report form. This included data
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3 on whether the existing product was in line with the new framework, together with any changes that
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5 had been made following the re-evaluation. We also assessed patient-reported outcomes at baseline
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7 by questionnaire and collected relevant information needed to assess effectiveness and costs. The
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9 patient-reported outcome questionnaires and the collection of effectiveness and costs data were
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11 repeated after 3 and 6 months. Specifically, the following instruments were used to assess outcomes
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13 in this study.
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17 The International Consultation on Incontinence Questionnaire (ICIQ) Lower Urinary Tract Symptoms
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19 Quality of Life Module (ICIQ-LUTSqol) was used to measure QoL [6]. This questionnaire includes 20
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21 questions, giving an overall score of 19–76, with higher values indicating increased impact on QoL.
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23 The approximate minimum clinically important difference for the ICIQ-LUTSqol in women with stress
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25 incontinence has been reported to be 3.7 points in one study and 5–6 points in another [7, 8].
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29 The ICIQ Urinary Incontinence Short Form (ICIQ-UI-SF) was used to assess the frequency, severity,
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31 and impact on QoL, of urinary incontinence [9]. The ICIQ-UI-SF consists of four questions and gives a
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33 total score of 0–21, with lower scores indicating less severe incontinence. The minimum clinically
34
35 important difference for the ICIQ-UI-SF in women with stress incontinence has been reported to be
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37 around 2.5 points in one study and around 4 points in another [7, 8].
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41 The ICIQ Absorbent Pads (ICIQ-PadPROM) was linguistically validated in Dutch and used to assess the
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43 treatment effect of absorbent incontinence products on QoL [10]. It has 26 questions and 4
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45 subdomains: pad design and physical effect (7 questions, score 0–31), psychological effects (4
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47 questions, score 0–16), social effects (3 questions, score 0–12), and pad leakage and burden of pad
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49 use (3 questions, score 0–12). A lower score indicates a better QoL.
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53 Satisfaction with incontinence care and incontinence products were each measured with three
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55 specifically developed questions answered with 5-point Likert scales ranging from very unsatisfied (0
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57 points) to very satisfied (4 points) and giving total scores ranging from 0 to 12 points (Supplementary
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59 file 1).
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3 Information on incontinence-related healthcare use over the last 3 months was collected using
4 relevant questions from the iMTA Medical Consumption Questionnaire, and information about
5 productivity loss due to incontinence in the last 4 weeks was collected using the iMTA Productivity
6 Cost Questionnaire [11, 12]. Information about all urinary incontinence products and incontinence-
7 related medication provided from 3 months before baseline to 6 months after baseline was obtained
8 from the registries of each pharmacy.
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16 **Statistical analysis**

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19 All analyses were performed using IBM SPSS version 26.0 (IBM Corp., Armonk, NY, USA). Participants
20 who underwent re-evaluation according to the new framework were compared to participants who
21 did not have a re-evaluation. We also performed subgroup analysis among re-evaluated participants
22 to compare those who did and did not require a change in materials, thereby mimicking an intention-
23 to-treat analysis. Because of the clustered data, a mixed model analysis was performed on the
24 change scores for outcome variables when assessing differences between groups. We included
25 intervention, time, and the intervention*time interaction as fixed effects. A random intercept at the
26 individual level was included in all analyses and we checked whether a random intercept at the
27 pharmacy level improved model fit, using the Akaike Information Criterion. These analyses were
28 adjusted for age, sex, and educational level to control for potential confounding.
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43 **Cost analyses**

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45 Cost analyses were performed using a societal perspective according to the guidelines for economic
46 evaluations of the Dutch National Health Care Institute [13]. Data on the amount of care and
47 productivity loss from the iPCQ and iMCQ were multiplied with prices in the guideline to obtain the
48 costs. The prices of incontinence products were obtained from one of the participating pharmacies
49 and the costs for medication were taken from the pharmacotherapeutic information website of the
50 Dutch National Health Care Institute [14]. An overview of the unit costs is presented in
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59 Supplementary file 2. Costs are reported in euros based on the 2019 prices and calculated for 3
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3 months prior to baseline and 3 months prior to last follow-up. Differences in change of costs over
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5 time between groups were calculated from baseline to compare participants who did and did not
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7 undergo re-evaluation, and a subgroup analysis was repeated among re-evaluated participants to
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9 compare those who did and did not require a change in materials. Costs were bootstrapped 5,000
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11 times to obtain 95% confidence intervals based on the 2.5th and 97.5th centiles.
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14 To assess the generalizability of the results, we compared study participants to all invited users by
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16 sex, age, and continence product costs.
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19 **Patient and Public involvement statement**

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21 A patient representative (Bekkenbodem4All) was involved in the conception and design of the study
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23 and the interpretation of the results.
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30 **RESULTS**

31 **Descriptive statistics**

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33 The 12 pharmacies invited 1,907 users of incontinence products to participate (range 71–270 users
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35 per pharmacy). Of these, 303 (15.9%) users consented and 279 completed the baseline questionnaire
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37 (Figure 1). Of those invited but not consenting, the non-responders, 404 (21.2%) completed the opt-
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39 out questionnaire. The most cited reasons for not participating were satisfaction with current
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41 products (71%), lack of interest in the research (35%), and lack of willingness to complete questions
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43 on incontinence (32%). About 25% selected 'other reasons' and most selected old age or the
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45 presence of an age-related disease.
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51 Of the 12 participating pharmacies, 11 provided information on incontinence product users invited to
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53 the study (n = 1,746). Four of these provided data on incontinence products, but not on age or sex,
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55 so they were only included in the cost calculations. Based on the relevant data, 79% of the sample
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57 was female, the mean age was 75.6 ± 12.5 years, and the mean cost of incontinence product use
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59 every 3 months was €128.10 (95% CI, €121.95 to €134.03).
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Participant characteristics are shown in Table 1. Of the 279 who completed baseline questionnaires, 72 (25.8%) agreed to a re-evaluation of their incontinence materials. Those who underwent re-evaluation were older, had lower educational levels, more often lived alone than with others, had more severe symptoms with a higher impact on their lives, and were less satisfied with existing continence care compared to those who did not undergo re-evaluation.

Outcomes

After 3 and 6 months, the follow-up questionnaires were completed by 248 (88.9%) and 231 (82.8%) participants, respectively. Pharmacies could not provide information about incontinence products or related medication in three cases. No outcome data were available for 1 of the 72 participants who underwent re-evaluation. Of the remaining 71 participants, 26 required a change and 45 did not require a change based on the new framework. However, one participant who required a change was content with the current material and did not want to make the recommended change.

There was a small improvement at 3 months in the re-evaluation group compared to the other group on most outcomes (Table 2). However, improvement did not approach the minimum clinically important difference scores of the ICIQ-LUTSqol or ICIQ-UI-SF and was small compared to the range of the scales for other outcomes. Moreover, these differences did not change much from 3 to 6 months.

Subgroup analysis in participants with re-evaluation showed that those who needed a change in materials (n = 26) experienced no clinically important differences in outcomes than those who did not need a change (n = 45, Supplementary file 3).

Costs

We also observed small differences in both the change in total costs and the changes for all cost categories separately that favoured users who underwent re-evaluation, but with very wide confidence intervals on both sides of zero (€99.38; 95% CI, -633.48 to 832.23) (Table 3).

Difference in total cost changes (€606.23; 95% CI, -€2062.85 to €772.60) and incontinence material

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3 costs (€6.44; 95% CI, -€56.65 to €45.98) were seen in favour of participants who did not need to
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5 change material, but again, this was with wide confidence intervals.
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10 **DISCUSSION**

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13 We found that the new framework for incontinence products had no clinically relevant effect on the
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15 QoL, severity, or satisfaction of users compared to the existing method of selecting materials.

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17 However, although there was no clear evidence, the new framework may have affected costs

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20 Research on the effectiveness and cost-effectiveness of methods for selecting incontinence materials
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22 in the general population is scarce. Fader et al. (2008) showed that the optimal absorbent product
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24 design varies by incontinence severity and sex [15]. There is also large variability in preference, and
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26 cost-effective management requires users to be able to choose combinations of designs for different
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28 circumstances. A trial in the Netherlands showed that it was cost-effective to employ a continence
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30 nurse in general practice [16], using an intervention based on a service specification for incontinence
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32 care developed by systematic review and expert consensus [17]. A key recommendations of that
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34 service specification was to take user and usage factors into account, which are both included in the
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36 new framework evaluated in the current study.
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41 We found no evidence that the new framework affected either patient-related outcomes or costs.

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43 Given that the framework has already been put in place as the new standard, our findings should be
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45 used to improve its content and implementation. Our findings suggest that the new framework does
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47 not go far enough to produce clinically important changes. One reason may be that pharmacy
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49 employees still had to work within the constraints of health insurers, where the severity of
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51 incontinence is key for reimbursement. In interviews after study completion, pharmacy employees
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53 indicated that (1) although they supported the idea of the framework, they were unsure whether
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55 reimbursement would be possible for all patients, and (2) they still had to use the old system
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57 alongside the new framework to comply with reimbursement regulations (unpublished data).
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3 Including activities of daily living in reimbursement regulations and reducing the administrative
4 burden may increase the impact of the framework. Pharmacy employees also noted that the new
5 framework is not dramatically different from the existing procedure for material selection. This too
6 could have led to the failure to detect a clinically important change.
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12 Regarding the costs, we used a societal perspective that included productivity losses, in accordance
13 with guidelines. However, participants reported no productivity losses, probably because most were
14 older than 65 years and only a minority were not in retirement.
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19 Although the new framework was developed to improve incontinence care, our findings suggest that
20 users of incontinence materials are already quite satisfied with current care, as reflected in the
21 average baseline Likert score of 4 (satisfied) for satisfaction. Being satisfied was also the most cited
22 reason for not participating in the study (71%). This may be another reason for the failure to detect a
23 clinically relevant effect, with most participants having little to no room for improvement.
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31 A limitation of our study is that it was performed among existing users of incontinence materials and
32 excluded incident cases. It is possible that the new framework will have a greater impact on new
33 users or that pharmacy employees and participants did the re-evaluation with the current materials
34 in mind, which could have led to them being more conservative when changing materials. Also, long-
35 term users may have ended up with suitable materials through trial and error, and it may be that the
36 framework will help this to occur sooner. Nevertheless, we cannot draw conclusions regarding the
37 effectiveness of the new framework in incident cases based on the current study.
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48 The use of an observational study design may also have introduced bias. The main reason for
49 choosing this design was that the new framework was about to be introduced as the new standard of
50 care and a randomized controlled trial could not be started in time because allocation to the control
51 condition (existing method of selecting materials) was not possible. Therefore, selection bias may
52 have arisen because participants were free to choose their intervention. In the present study,
53 participants who opted for re-evaluation had more symptoms and were less satisfied with their
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3 current materials. We hypothesize that this did not affect the study conclusions because the
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5 intervention likely had an even smaller effect in participants with fewer complaints and higher
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7 satisfaction. We also found that participants who choose the intervention more often lived alone,
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9 which may reflect a need for social interaction (e.g., with a caregiver). This could generate higher
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11 satisfaction at follow-up; but, given that we found no clinically relevant effect of the intervention,
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13 this does not appear to have had a major impact on the outcomes. However, the observational study
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15 design does not allow to make causal claims.
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19 We encountered a low response rate, with only 16% of invitees participating in the full study. To
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21 provide insight in the reasons for non-participation, the opt-out questionnaire send to the non-
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23 responders was only returned by 21% of people. In this opt-out survey, acquiescence bias could have
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25 impacted the outcomes, with a high percentage of respondents claiming to be satisfied with the
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27 current care. To improve generalizability, we compared the characteristics of study participants
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29 against all those who were invited. This revealed that both groups were broadly comparable by age
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31 and sex, but that incontinence material costs were somewhat lower for participants, suggesting that
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33 they had less severe incontinence or that they received less absorbent materials. However, it is
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35 possible that those who did not participate and those who did participate differ on other
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37 characteristics which might have an impact on generalizability. Another issue is that since completing
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39 this study there has been a trend for insurers to move reimbursed continence care from local
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41 pharmacies to nationwide online suppliers, which may limit the generalizability of our results to
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43 current practice.
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48 49 **Conclusion**

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51 The current study showed no clinically relevant effect of a newly implemented framework for
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53 selecting absorbent incontinence materials in pharmacies when compared to an existing method.

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55 Given that the study also showed no difference in effectiveness and costs, introducing the new
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57 framework in pharmacies may not lead to better incontinence care. Future research should consider
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3 the experiences of incontinence material users through qualitative research to add further
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5 information on how to improve the framework.
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10 **Funding statement**

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22
23 for their help with the logistics of the study and data collection.
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30 **Competing interest statement**

31 The authors have no conflict of interest to declare
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37 **Data sharing statement**

38 Statistical code, and dataset available from
39

40 <https://dataverse.nl/dataset.xhtml?persistentId=doi:10.34894/OVPONP>
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45 **Author Contributions**

46 Study design: MCS, HW, BEWB, GGAM, JHD, KMV, MHB. Acquisition of data: MCS, HW, MHB.
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48 Analysis and interpretation of data: MCS, HW, MRB, KMV, MHB. Drafting of the manuscript: MCS,
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50 HW, MHB. Revision and approval of the final version of the manuscript to be published: all authors.
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56 **Ethics statement**

57 The study was approved by the Medical Ethical Committee of the University Medical Center
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Table 1. Descriptive characteristics of participants

| | Re-evaluation | No re-evaluation |
|---|---------------|------------------|
| | n = 72 | n = 207 |
| Age in years (Mean ± SD) | 76.8 ± 9.6 | 74.3 ± 11.4 |
| Age groups (%) | | |
| 18–45 years | 0.0 | 1.9 |
| 45–65 years | 8.3 | 16.4 |
| 65–84 years | 66.7 | 64.7 |
| >85 years | 25.0 | 16.9 |
| Female (%) | 75.0 | 74.4 |
| Migration background (%) | | |
| Native Dutch | 98.6 | 91.3 |
| First generation migrant | 1.4 | 2.9 |
| Second generation migrant | 0.0 | 3.9 |
| Unknown | 0.0 | 1.0 |
| Marital status (%) | | |
| Married | 40.3 | 52.7 |
| Divorce | 11.1 | 10.1 |
| Partner deceased | 43.1 | 29.5 |
| Other ¹ | 5.6 | 7.7 |
| Housing (%) | | |
| Independence residence | 58.0 | 39.6 |
| Residence with partner or children | 36.2 | 55.8 |
| Residential care | 4.3 | 4.6 |
| Other | 1.4 | 0.0 |
| Highest education² | | |
| Primary school or less | 25.0 | 14.5 |
| Practical/secondary vocational training | 64.1 | 73.0 |
| Some college/university degree | 10.9 | 12.5 |
| Daily living (%) | | |
| Employed/entrepreneur | 1.5 | 6.0 |
| Houseman/-wife | 20.6 | 22.9 |
| Unemployed | 1.5 | 1.0 |
| (Partially) incapacitated for work | 7.4 | 10.0 |
| (Pre)retirement | 67.6 | 58.7 |
| Other | 1.5 | 1.5 |
| Multimorbidity³ (%) | 69.7 | 74.4 |
| ICIQ-LUTSqol | 50.2 ± 14.9 | 40.4 ± 15.1 |
| ICIQ-UI-SF | 12.4 ± 4.3 | 11.1 ± 4.5 |
| ICIQ-PadPROM | | |
| Pad design and physical effects | 10.9 ± 4.7 | 9.5 ± 3.5 |
| Psychological effects | 4.4 ± 3.6 | 3.2 ± 3.1 |
| Social effects | 4.9 ± 3.2 | 4.7 ± 3.7 |
| Leakage and burden of pad use | 5.0 ± 2.3 | 4.1 ± 2.3 |
| Satisfaction | | |
| with incontinence material | 8.3 ± 3.0 | 8.9 ± 2.9 |
| with incontinence care | 7.5 ± 3.2 | 8.3 ± 3.1 |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; SD = standard deviation; UI-SF = Urinary Incontinence Short Form.

Higher scores represent worse status for the UI-SF and LUTSqol but higher satisfaction for the PadPROM.

Note 1: Includes single and sustainable living together unmarried; Note 2: Collapsed from seven Dutch educational categories; Note 3: Two or more diseases/conditions present, excluding urinary incontinence.

Table 2. Effect of re-evaluation on disease specific outcomes and satisfaction

| | Intervention | Absolute change [#] | Change per period with 95% confidence intervals | Intervention effect (p-value) |
|-------------------------------|---------------------------------|------------------------------|---|-------------------------------|
| | | T0–T2 | T0–T1 | T1–T2 |
| ICIQ-LUTSqol | Re-evaluation | 0.67 | 0.42 (-2.82; 3.65) | 0.15 (-2.99; 3.28) |
| | No re-evaluation | 1.73 | 1.14 (-1.06; 3.43) | 0.59 (-1.74; 2.91) |
| ICIQ-UI-SF | Re-evaluation | -1.16 | -0.72 (-1.68; 0.24) | -0.44 (-1.42; 0.54) |
| | No re-evaluation | 0.01 | -0.27 (-0.94; 0.41) | 0.28 (-0.42; 0.98) |
| ICIQ-PadPROM | | -1.01 | -1.15 (-1.91; -0.39) | 0.14 (-0.63; 0.92) |
| | Pad design and physical effects | | | |
| | Re-evaluation | 0.00 | -0.07 (-0.58; 0.44) | 0.07 (-0.42; 0.60) |
| | No re-evaluation | 0.00 | -0.07 (-0.58; 0.44) | 0.07 (-0.42; 0.60) |
| Psychological effects | Re-evaluation | -0.80 | -0.61 (-1.35; 0.14) | -0.19 (-0.92; 0.57) |
| | No re-evaluation | 0.03 | -0.02 (-0.50; 0.49) | 0.05 (-0.54; 0.44) |
| Social effects | Re-evaluation | -0.48 | -0.42 (-1.47; 0.64) | -0.06 (-1.11; 1.02) |
| | No re-evaluation | -0.13 | 0.24 (-0.50; 0.97) | -0.37 (-1.11; 0.38) |
| Leakage and burden of pad use | Re-evaluation | -0.10 | -0.46 (-1.12; 0.21) | 0.36 (-0.29; 1.01) |
| | No re-evaluation | -0.16 | 0.24 (-0.19; 0.68) | -0.40 (-0.88; 0.05) |
| Satisfaction | | 1.10 | 1.15 (0.43; 1.87) | -0.05 (-0.73; 0.69) |
| Incontinence material | Re-evaluation | 0.52 | 0.34 (-0.15; 0.83) | 0.18 (-0.33; 0.69) |
| | No re-evaluation | 0.52 | 0.34 (-0.15; 0.83) | 0.18 (-0.33; 0.69) |
| Incontinence care | Re-evaluation | 0.33 | 1.12 (0.42; 1.83) | -0.79 (-1.51; -0.06) |
| | No re-evaluation | 0.28 | 0.15 (-0.32; 0.63) | 0.13 (-0.38; 0.63) |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; T0 = baseline; T1 = 3 months' follow-up; 6 months' follow-up; UI-SF = Urinary Incontinence Short Form.

Improvement is a negative score for UI-SF, LUTSqol, and PadPROM and a positive score for satisfaction

Absolute change was calculated from the model estimates

Table 3. Mean costs of the two evaluation groups per cost unit and time point

| Costs | Re-evaluation | | No re-evaluation | | Difference in change in favour of intervention group |
|---------------------------------------|----------------------------------|---------------------------------|----------------------------------|---------------------------------|---|
| | T0 | T2 | T0 | T2 | |
| Incontinence materials | 120.22 (97.74; 145.40) | 136.00 (110.62; 165.01) | 107.42 (93.21; 123.20) | 119.28 (104.98; 136.88) | -3.92 (-31.20; 23.37) |
| General practitioner | 19.74 (10.42; 30.71) | 9.87 (4.18; 17.00) | 8.34 (5.23; 11.96) | 6.84 (3.27; 10.24) | 8.37 (-2.07; 18.82) |
| Medication | 7.40 (1.01; 15.81) | 7.14 (0.98; 15.32) | 9.67 (4.74; 15.44) | 8.68 (4.07; 14.01) | -0.73 (-6.50; 5.04) |
| Physical Therapy | 10.97 (3.29; 20.40) | 4.39 (0.00; 11.15) | 4.92 (1.68; 8.92) | 6.84 (2.85; 11.55) | 8.51 (-1.74; 18.75) |
| Acupuncture/Homeopathic medication | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.43 (0.00; 1.34) | 0.00 (0.00; 0.00) | -0.43 (-1.78; 0.92) |
| Botox/PTNS/TVT/Other | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 24.45 (4.26; 51.84) | 20.37 (4.00; 42.94) | -4.08 (-34.36; 26.21) |
| Specialist visit | 47.90 (4.43; 101.80) | 56.61 (18.63; 104.52) | 59.43 (33.96; 88.94) | 52.64 (29.05; 80.65) | -15.50 (-80.96; 49.96) |
| Hospital admission | 336.68 (16.30; 896.15) | 88.18 (0.00; 248.5) | 296.95 (95.45; 554.33) | 200.83 (89.60; 348.53) | 152.38 (-351.31; 656.07) |
| Social work | 1.10 (0.00; 3.52) | 2.19 (0.00; 6.92) | 0.00 (0.00; 0.00) | 1.71 (0.00; 4.00) | 0.61 (-3.86; 5.09) |
| Occupational therapy | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.21 (0.00; 0.67) | 0.85 (0.00; 2.67) | 0.64 (-2.15; 3.43) |
| Home care | 546.19 (120.10; 1062.20) | 601.37 (135.44; 1194.28) | 449.55 (224.03; 719.63) | 458.24 (227.54; 734.74) | -46.49 (-483.93; 390.94) |
| Productivity losses | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) | 0.00 (0.00; 0.00) |
| Total costs | 1090.20 (495.32; 1825.11) | 905.75 (361.90; 1574.82) | 961.37 (623.74; 1364; 69) | 876.29 (596.82; 1194.30) | 99.38 (-633.48; 832.23) |

Abbreviations: PTNS = percutaneous tibial nerve stimulation; T0 = baseline; 6 months' follow-up; TVT = tension-free vaginal tape

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Figure legends

Figure 1. Flowchart of study participation

For peer review only

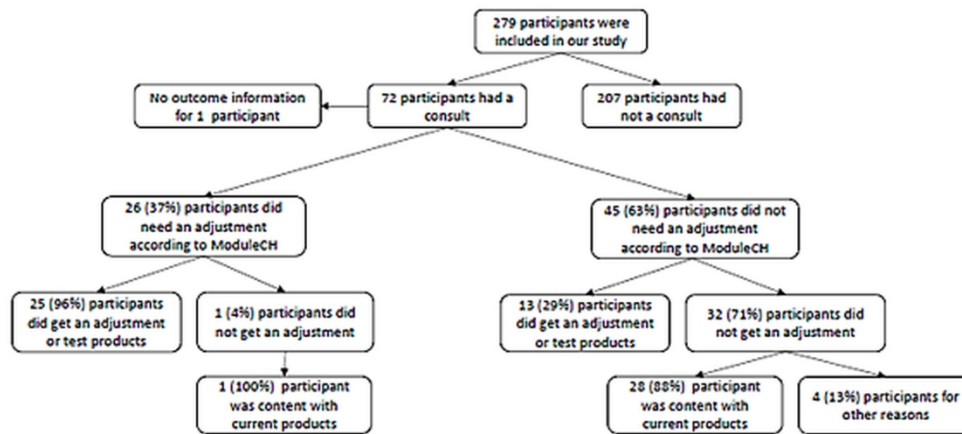


Figure 1. Flowchart of study participation

153x83mm (600 x 600 DPI)

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Supplementary file 1.

| | Very unsatisfied | Unsatisfied | Neutral | Satisfied | Very satisfied |
|---|------------------|-------------|---------|-----------|----------------|
| How satisfied are you with your treatment for incontinence? | | | | | |
| How satisfied are you with the incontinence materials you use? | | | | | |
| To what extent are you satisfied with the freedom of choice regarding the care/treatment of you incontinence? | | | | | |
| To what extent are you satisfied with the freedom of choice regarding the choice of incontinence materials? | | | | | |
| To what extent do the incontinence materials support your sleep? | | | | | |
| To what extent do the incontinence materials support your daytime activities? | | | | | |

| Specification of costs | Unit costs |
|---|--------------------|
| <i>First-line services</i> | |
| General practitioner | €34/consultation |
| Social work | €68/consultation |
| Occupational therapy | €34/consultation |
| Domestic help | €21/hour |
| Personal care | €52/hour |
| Nursing | €76/hour |
| Physical therapy for UI | €34/consultation |
| Acupuncture or homeopath for UI | €68/treatment |
| <i>Medication for UI¹</i> | |
| Darafenacin 15 mg | €0.55/per day |
| Darafenacin 7.5 mg | €0.87/per day |
| Fesoterodin 8 mg | €0.58/per day |
| Fesoterodin 4 mg | €0.89/per day |
| Oxybutinin 1 mg/ml oral solution | €2.50/per day |
| Oxybutinin 5 mg | €0.23/per day |
| Oxybutinin 2.5 mg | €0.35/per day |
| Oxybutinin 3.9 mg transdermal patch | €1.27/per day |
| Solifenacin (generic) 10 mg | €0.40/per day |
| Solifenacin (Vesicare) 10 mg | €0.58/per day |
| Solifenacin (generic) 5 mg | €0.59/per day |
| Solifenacin (Vesicare) 5 mg | €0.85/per day |
| Solifenacin (Vesicare) 1 mg/ml oral solution | €0.89/per day |
| Tolterodin (generic) 4 mg controlled release | €0.30/per day |
| Tolterodin (Detrusitol) 4 mg controlled release | €0.71/per day |
| Tolterodin (generic) 2 mg | €0.46/per day |
| Tolterodin (Detrusitol) 2 mg | €0.89/per day |
| Tolterodin (generic) 2 mg | €0.76/per day |
| Tolterodin (Detrusitol) 2 mg | €0.89/per day |
| Tolterodin (generic) 1 mg | €0.73/per day |
| Tolterodin (Detrusitol) 1mg | €1.08/per day |
| Flavoxaat 200 mg | €0.83/per day |
| Mirabegron 5 mg | €0.89/per day |
| Costs of dispensing by pharmacy | €6.25/per delivery |
| <i>Incontinence pads²</i> | |
| Sanitary pad | €0.14/per piece |
| Disposable pads - small | €0.26/per piece |
| Disposable pads – medium | €0.45/per piece |
| Disposable pads – large | €0.63/per piece |
| Insert pads | €0.27/per piece |
| T-shaped pads | €1.19/per piece |
| Disposable pants | €1.43/per piece |
| All-in-ones | €1.31/per piece |
| Washable pants | €0.99/per piece |
| Bed underlays | €0.49/per piece |

Second-line care

| | |
|--|------------|
| Specialist consultation | €270/visit |
| Admission in hospital | €497/day |
| Other treatment for UI: Botox/PTNS/TVT | €324 |

Other costs

| | |
|---------------------|----------|
| Productivity losses | €34/hour |
|---------------------|----------|

Unit costs are based on reference prices of the cost manual of the Dutch Healthcare Institute, except when stated otherwise. Costs have indexed for 2019.

1. Prices obtained from pharmacotherapeutic information website of the Dutch National Health Care Institute [14]

2. Prices obtained from one of the participating pharmacies

Supplementary file 2.

| | Intervention | Absolute change [#] | Change per period (95% confidence intervals) | | Intervention effect (p-value) |
|-------------------------------|------------------|------------------------------|--|---------------------|-------------------------------|
| | | T0–T2 | T0–T1 | T1–T2 | |
| ICIQ-LUTSqol | Change needed | 0.12 | -0.39 (-5.33; 4.54) | 0.51 (-4.89; 5.91) | 0.960 |
| | No change needed | 0.34 | 0.89 (-2.81; 4.61) | -0.55 (-4.02; 2.92) | |
| ICIQ-UI-SF | Change needed | -2.37 | -1.57 (-3.31; 0.16) | -0.80 (-2.71; 1.11) | 0.176 |
| | No change needed | -0.31 | -0.17 (-1.32; 0.98) | -0.14 (-1.28; 1.01) | |
| ICIQ-PadPROM | | | | | |
| Pad design & physical effects | Change needed | -1.11 | -1.41 (-2.74; -0.09) | 0.30 (-1.05; 1.65) | 0.565 |
| | No change needed | 0.46 | -1.17 (-2.12; -0.21) | 0.71 (-0.24; 1.66) | |
| Psychological effects | Change needed | -0.91 | -0.99 (-2.08; 0.10) | 0.08 (-1.00; 1.17) | 0.159 |
| | No change needed | 0.41 | 0.31 (-0.49; 1.10) | 0.10 (-0.69; 0.89) | |
| Social effects | Change needed | 0.79 | -0.03 (-1.50; 1.43) | 0.82 (-0.67; 2.31) | 0.236 |
| | No change needed | -0.69 | -0.37 (-1.41; 0.66) | -0.32 (-1.33; 0.68) | |
| Leakage and burden of pad use | Change needed | -0.70 | -0.60 (-1.74; 0.55) | -0.10 (-1.26; 1.07) | 0.494 |
| | No change needed | -0.02 | -0.38 (-1.21; 0.44) | 0.36 (-0.44; 1.17) | |
| Satisfaction | | | | | |
| Incontinence material | Change needed | 1.02 | 1.37 (0.14; 2.59) | -0.35 (-1.62; 0.92) | 0.656 |
| | No change needed | 0.55 | 0.65 (-0.21; 1.50) | -0.10 (-0.97; 0.76) | |

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|-------------------|------------------|------|--------------------|----------------------|-------|
| Incontinence care | Change needed | 1.33 | 1.13 (-0.01; 2.27) | 0.20 (-0.95; 1.35) | 0.209 |
| | No change needed | 0.11 | 1.00 (0.22; 1.77) | -0.89 (-1.67; -0.11) | |

Abbreviations: ICIQ = The International Consultation on Incontinence Questionnaire; LUTSqol = Lower Urinary Tract Symptoms Quality of Life Module; PadPROM = Absorbent Pads; T0 = baseline; T1 = 3 months' follow-up; 6 months' follow-up; UI-SF = Urinary Incontinence Short Form.

Improvement is a negative score for UI-SF, LUTSqol, and PadPROM and a positive score for satisfaction

Absolute change was calculated from the model estimates

For peer review only

STROBE Statement—Checklist of items that should be included in reports of *cohort studies*

| | Item No | Recommendation | Page No |
|------------------------------|---------|--|-------------------------------------|
| Title and abstract | 1 | (a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found | 1 3 |
| Introduction | | | |
| Background/rationale | 2 | Explain the scientific background and rationale for the investigation being reported | 4 |
| Objectives | 3 | State specific objectives, including any prespecified hypotheses | 4 |
| Methods | | | |
| Study design | 4 | Present key elements of study design early in the paper | 5/6 |
| Setting | 5 | Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection | 5/6 |
| Participants | 6 | (a) Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up (b) For matched studies, give matching criteria and number of exposed and unexposed | 6 |
| Variables | 7 | Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable | 6-8 |
| Data sources/ measurement | 8* | For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group | 6,7 |
| Bias | 9 | Describe any efforts to address potential sources of bias | 7,8 |
| Study size | 10 | Explain how the study size was arrived at | 9 |
| Quantitative variables | 11 | Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why | NA |
| Statistical methods | 12 | (a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, explain how loss to follow-up was addressed (e) Describe any sensitivity analyses | 8,9 8,9 8,9 8,9 8,9 |
| Results | | | |
| Participants | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram | 9, Fig 1 9, Fig 1 Fig 1 |
| Descriptive data | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) Summarise follow-up time (eg, average and total amount) | Table 1 9 10 |
| Outcome data | 15* | Report numbers of outcome events or summary measures over time | tab 2 |

| | | | | |
|----|--------------------------|----|--|--------------|
| 1 | Main results | 16 | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | Tabl 2 |
| 2 | | | (b) Report category boundaries when continuous variables were categorized | NA |
| 3 | | | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period | NA |
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| 9 | Other analyses | 17 | Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses | 10, suppl |
| 10 | | | | |
| 11 | Discussion | | | |
| 12 | | | | |
| 13 | Key results | 18 | Summarise key results with reference to study objectives | 10,11 |
| 14 | Limitations | 19 | Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias | 12,13 |
| 15 | | | | |
| 16 | Interpretation | 20 | Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence | 13 |
| 17 | | | | |
| 18 | | | | |
| 19 | Generalisability | 21 | Discuss the generalisability (external validity) of the study results | 13 |
| 20 | | | | |
| 21 | Other information | | | |
| 22 | Funding | 22 | Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based | 2 |
| 23 | | | | |
| 24 | | | | |

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at <http://www.strobe-statement.org>.