**PRIZE AWARD: Best Clinical Abstract**

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# EFFECTS AND COST-EFFECTIVENESS OF PROTOCOLIZED ASSESSMENT AND EVIDENCE-BASED TREATMENT OF URINARY INCONTINENCE: THE URINARY INCONTINENCE IN OLDER WOMEN TRIAL (URINO)

Hypothesis / aims of study

Urinary incontinence is a very common health care problem among older women. However, this condition is underdiagnosed and undertreated, though effective treatments are available. Urinary incontinence is also a costly condition because of the widespread use of absorbent materials. This is why we designed a randomized controlled trial, to study the effects and cost-effectiveness of offering older women with urinary incontinence a protocolized assessment and evidence-based treatment, as compared to usual care according to the guidelines of the Dutch College of Dutch General Practitioners. It was called the URINO trial (URinary INcontinence in Older women).

This trial aimed to deliver effective care for older women with urinary incontinence by the general practitioner. The hypothesis was that a proactive approach to this population of older women in primary care, after which assessment by a diagnostic protocol and evidence based treatment advice followed, should decrease the burden of this disease in the individual patient.

Study design, materials and methods

The URINO trial concerned a primary care cluster-randomised controlled trial conducted in the northern part of The Netherlands.

All women 55 years of age and older, enlisted in 14 general practices, received an invitation letter from their GP. They were asked for symptoms of involuntary loss of urine and if they answered positively, they were invited to participate in the trial. The GPs were randomized to either an intervention group in which the women underwent a protocolized diagnostic investigation by a research physician and subsequently a treatment tailored to their type of incontinence or to a control group in which received care as usual. Treatment contained advices on micturition behaviour and fluid intake, pelvic floor physiotherapy, bladder training, medication or a referral to the pelvic floor center of the University Medical Center Groningen.

The primary outcome measurement was the reduction in the severity of involuntary loss of urine after 12 months according to the score on the Incontinence Severity Index (ISI). Secondary outcomes were costs of the incontinence, the number of incontinent episodes and quality of life. Costs and effects on health outcome and utility between patients in the intervention group and control group were compared after 12 months of study. Health outcome was expressed by the VAS score of the Incontinence Consultation Impact Questionnaire, transformed to Incontinence Impact Adjusted Life Years (IIALYs) by dividing it by 10, to be able to obtain disease specific quality of life weights. Utility was expressed by Quality Adjusted Life Years (QALYs), from EuroQol 5 Dimensions (EQ-5D) scores, valued by the Dutch EQ-5D tariff. All relevant costs over a 12 month time period were included. Incremental costs were calculated per gained IIALY and per gained QALY. Because of the cluster randomization, we used multilevel analyses to compare the intervention- and control group regarding the clinical effects and costs.

A clinically relevant effect was considered to be an improvement of one or more categories on the ISI, after 12 months. Based on previous research, this was expected for 65% of the included participants in the intervention group and for 40% of the participants in the control group. Given a significance level of 5% and a power of 80%, 70 participants per group were needed. Because of cluster randomization, a correction factor of 1.4 was calculated, based on the number of patients per GP (10) and the variation between GPs (0.1). Consequently, 98 participants per group were needed. Given a withdrawal rate of 20%, which is reasonable given the age of the participants, eventually 123 participants per group had to be included.

Results

In the inclusion phase, 73 % of the approached women returned a reply form. 31 % of them reported symptoms of involuntary loss of urine. 50 % of them were willing to participate in the trial. In the intervention group, 166 women were diagnosed and treated. The control group consisted of 184 women. One year after the inclusion in the study, 33.3 % of the women in the intervention group experienced an improvement of the severity of their incontinence, compared to 15.6 % in the control group. The percentage of women who reported an improvement of their quality of life, did not differ between the intervention and the control group. In the intervention group, 51.4 % of the women had less incontinent episodes per day than before. For the control group, this was 35.4 %.

Mean costs per patient in the intervention group were €417, compared to €87 in the control group. The main source of costs in the intervention group was pelvic floor physiotherapy (mean €183 per person per year) and in the control group it was the absorbent materials (mean €40 per person per year). The mean difference between the two study groups in effect on gained IIALYs was found 0.06. And to gain 1 IIALY on population level, €5,179 needs to be invested. The mean difference in gained QALYs was found 0.01 and €23,907 needs to be invested to gain 1 QALY on population level.

Interpretation of results

It seems meaningful to approach older women with urinary incontinence proactively, and to offer them a protocolized assessment and evidence based treatment. The intervention reduces the severity of incontinence symptoms and the number of incontinent episodes, against relatively low additional costs, as compared to usual care.

Concluding message

An active attitude of the GP towards older women with urinary incontinence is recommended, since women seem to be willing to accept an invitation for diagnosis and treatment. Treatment is effective in reducing the severity of urinary incontinence in more than one third of the patients, against reasonable costs. A diagnostic assessment of women with urinary incontinence is easily to perform in primary care as is treatment in most cases. Therefore, we suggest to add this active approach to the current primary care guidelines on incontinence in women.

Disclosures

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funded the URINO trial. **Clinical Trial:** Yes **Public Registry:** Yes **Registration Number:** Dutch Trial Register, registration number NTR1181 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Medical Ethical Review Committee of the University Medical Center of Groningen, The Netherlands **Helsinki:** Yes **Informed Consent:** Yes