Active encouragement of older women with urinary incontinence in primary care to undergo diagnosis and treatment

Visser, Els; de Bock, Geertruida H; Messelink, Embert J; Schram, Aaltje J; Kollen, Boudewijn J; Gemert, Sacha la Bastide-van; van den Heuvel, Edwin R; Berger, Marjolein Y; Dekker, Janny H

Published in:
Maturitas

DOI:
10.1016/j.maturitas.2014.11.015

Publication date:
2015

Maturitas 80 (2015) 212–219

Contents lists available at ScienceDirect

Maturitas

journal homepage: www.elsevier.com/locate/maturitas

Active encouragement of older women with urinary incontinence in primary care to undergo diagnosis and treatment: A matched-pair cluster randomized controlled trial

Els Visser[a], Geertruida H. de Bock[b], Embert J. Messelink[c], Aaltje J. Schram[d], Boudewijn J. Kollen[a], Sacha la Bastide-van Gemert[b], Edwin R. van den Heuvel[b], Marjolein Y. Berger[a], Janny H. Dekker[a,*]

[a] Department of General Practice, University of Groningen, University Medical Centre Groningen, PO Box 196, 9700 AD Groningen, The Netherlands
[b] Department of Epidemiology, University of Groningen, University Medical Centre Groningen, PO Box 30.001, 9700 RB Groningen, The Netherlands
[c] Department of Urology, University of Groningen, University Medical Centre Groningen, PO Box 30.001, 9700 RB Groningen, The Netherlands
[d] Department of Gynaecology, University of Groningen, University Medical Centre Groningen, PO Box 30.001, 9700 RB Groningen, The Netherlands

ARTICLE INFO

Article history:
Received 27 October 2014
Accepted 24 November 2014

Keywords:
Urinary incontinence
Female
Aged
General practice

ABSTRACT

Objectives: The URINO trial investigated the effect of offering treatment to older women with urinary incontinence in the general population, who had not sought help on their own initiative.
Study design: In a cluster randomized trial, 14 general practitioners were matched into pairs and randomly allocated to an intervention or a control group. Women aged ≥55 years registered in the participating practices were asked about urinary incontinence via a postal questionnaire. Patients in the intervention group were assessed and treated whereas patients in the control group received standard care.
Main outcome measures: Primary outcome was improvement (yes or no) of the severity of symptoms at 12-month follow-up measured with the Incontinence Severity Index. Secondary outcomes were the number of incontinence episodes per day and quality of life. The primary analysis was on an intention-to-treat basis with multiple imputation of missing data. A logistic regression model with correction for cluster randomization was fitted to estimate odds ratios (ORs).
Results: At 12 months, the severity of symptoms had improved in more patients in the intervention group ($n = 166$) than in the controls ($n = 184$) (OR 1.9; 95% CI 1.1–3.3). Also, the number of patients with fewer episodes of incontinence had increased (OR 2.5; 95% CI 1.5–4.1). No between-group differences in changes in quality of life were apparent ($p = 0.14$).
Conclusions: It is recommended to encourage women in the general population aged ≥55 years with urinary incontinence to undergo diagnosis and treatment.

1. Introduction

Urinary incontinence is a very common disorder in women. Most studies report a prevalence of 25–45% with approximately 10% of all adult women reporting involuntary leakage at least weekly [1,2]. The prevalence of urinary incontinence increases with age and a rise in the number of incontinent patients is expected with the aging population. Three main subtypes of urinary incontinence are distinguished: stress incontinence, urgency incontinence, and mixed urinary incontinence. Although the condition is not life-threatening the impact on daily life can be great: it may cause social isolation, lack of self-esteem, feelings of shame and, depression [3]. Reasons given by women for not seeking help include: not regarding incontinence as a serious problem, considering incontinence to be a normal part of aging, having low expectations of treatment, and thinking they should cope on their own. Embarrassment may also be an important reason for not seeking help [4].

Abbreviations: ISI, incontinence severity index; OR, odds ratio; CI, confidence interval; PFMT, pelvic floor muscle training; GP, general practitioner; IIQ, incontinence impact questionnaire; MOS, medical outcomes study.

* Correspondence to: University Medical Center Groningen, PO Box 196, 9700 AD Groningen, The Netherlands. Tel.: +31 50 363 8884; fax: +31 50 363 2964.
E-mail addresses: els.visser@umcg.nl (E. Visser), g.h.de.bock@umcg.nl (G.H. de Bock), e.j.messelink@umcg.nl (E.J. Messelink), a.j.schram@umcg.bnl (A.J. Schram), b.j.kollen@umcg.nl (B.J. Kollen), s.la.bastide@umcg.nl (S. la Bastide-van Gemert), e.r.van.den.heuvel@umcg.nl (E.R. van den Heuvel), m.y.berger@umcg.nl (M.Y. Berger), j.h.dekker@umcg.nl (J.H. Dekker).

http://dx.doi.org/10.1016/j.maturitas.2014.11.015
0378-5122/

The recommended first-line treatment for urinary incontinence is pelvic floor muscle training (PFMT) for stress urinary incontinence, and bladder training and anticholinergic drug therapy for urgency urinary incontinence. In case of mixed urinary incontinence, starting a treatment directed to the most dominant symptoms of the urinary incontinence component is recommended [5]. It is unknown whether or not these treatments have the same effects in women who do not seek help as they have in women consulting for urinary incontinence.

The aim of this trial was to study the effects on severity of incontinence and quality of life of diagnosing and treating older community-dwelling women with urinary incontinence who were invited to receive treatment, and to compare this to the effects in a group of women receiving standard care [6]. The hypothesis is that women will benefit from the active approach and that will reduce the severity of their urinary incontinence and improve their quality of life more than standard care alone.

2. Methods

2.1. Trial design and participants

The URinary INcontinence in Older women (URINO) trial is a matched-pair cluster randomized controlled trial in primary care, performed in 14 general practices in the northern part of the Netherlands. The design of this study has been published before [7,8]. In short, each participating general practitioner (GP) reviewed a list with all women aged ≥55 years (roughly 180 per GP) registered in his or her practice, to check the exclusion criteria: overflow incontinence, malignant diseases, currently being treated for urogynecological conditions, having an indwelling catheter, being severely demented, or in a poor physical condition. All eligible women received a questionnaire on involuntary loss of urine; if they had involuntary loss of urine once a month or more, they were asked to participate in the trial. Other inclusion criteria were: being able to fill in a questionnaire in Dutch, and written informed consent. Enrollment took place between February 2008 and December 2009; the last follow-up measurement was made in July 2011.

The trial is registered in the Dutch Trial Register (registration number NTR1181) and approval was obtained from the Medical Ethical Review board of the University Medical Center Groningen (UMCG), the Netherlands.

2.2. Randomization and blinding

To prevent contamination, the participating GPs were matched into pairs based on their age and sex, and urbanization grade of the practice. Within each pair, GPs were randomly allocated to either the intervention or the control group. In one case, three small practices in the same area and with same type of GPs were taken together as part of a pair, to prevent unequal distribution of the number of participants per group. Randomization was performed with a random numbers table (using the SAS system for Windows) by a researcher not involved in the study and blinded for the identity of the practices. GPs, participants and research employees were not blinded for the allocated arms. The researcher who analyzed the data was blinded for treatment allocation.

2.3. Baseline assessment for all patients

All patients completed validated questionnaires on the severity of urinary incontinence (the Incontinence Severity Index, ISI), urinary symptoms (Urinary Distress Inventory) and condition-specific and generic health-related quality of life (short form of the Incontinence Impact Questionnaire IIQ-7; and the MOS SF-20, respectively) [9–11]. These questionnaires measure patient-reported outcomes in urinary incontinence and are recommended by the ICI [12]. All patients were interviewed by a researcher for details of their medical history and all patients were asked to complete a three-day bladder diary. The number of incontinence episodes per day was derived from this bladder diary.

2.4. Assessments in the intervention group

Participants in the intervention group underwent a urogynecological examination by the research physician including a cough stress test (in supine and standing position, with a naturally filled bladder), uroflowmetry (with a naturally filled bladder, to measure maximum flow and voided volume), post-void residual measurement (with a Bladderscan®), urinalysis for urinary tract infections (with a dipslide), a pelvic examination with a standardized assessment of urogenital prolapse (POP-Q system), and an assessment of the pelvic floor muscle function [13–17]. A multidisciplinary team (consisting of a urologist, gynecologist, pelvic floor physiotherapist, and a GP) discussed the clinical and questionnaire findings [18]. Together they decided on the classification of the type of incontinence and formulated the diagnosis and a treatment plan.

Patients in the control group received standard care according to the Dutch Guidelines for General Practitioners, implying that diagnosis and treatment took place only when the patient decided to consult her GP for urinary incontinence [6].

Potential side-effects of any treatment were registered in the case record forms.

The primary outcome was improvement in the severity of urinary incontinence 12 months after the start of the treatment (intervention group) or after baseline (control group). Secondary outcomes were the number of incontinence episodes per day, the incontinence-specific quality of life (IIQ-7 score), and the general quality of life (MOS-SF-20 score). Improvement of the secondary outcomes was defined as a score at follow-up that was lower than that at baseline.

In the intervention group, the 12-month follow-up period started on the first day of the treatment; in the control group this started on the day of inclusion.

2.5. Sample size

Improvement in the severity of the incontinence was estimated to occur in 65% of those in the intervention group and in 40% of those in the control group [19]. Given a significance level of 5% and a power of 80%, 70 patients per group were needed. Because of the cluster randomization a correction factor of 1.4 was applied, based on the estimated number of patients per cluster (10) and the variation between the GPs (0.1) [20]. This meant that 98 patients per group were needed for analysis. With an expected loss to follow-up in this age group of 20%, 123 patients per group had to be included in the study. To reach this number of patients, an 18-month inclusion period was anticipated.

2.6. Statistical analysis

The intervention and control group were compared regarding the improvement of severity of incontinence symptoms, improvement in the number of incontinence episodes per day, and improvement of incontinence-specific and general quality of life. Outcome parameters were dichotomized to be able to perform logistic regression analyses with correction for matched-pairs clustering and to calculate odds ratios (ORs) with 95% confidence intervals (CIs). The primary analysis was an intention-to-treat analysis including all patients. Missing data were imputed with a multiple imputation analysis, based on the baseline and treatment

characteristics of the entire group of patients. Two sensitivity analyses were foreseen for the primary outcome measurement, the improvement in ISI category: a complete-case analysis among patients with a complete dataset at follow-up, and a multiple imputation analysis based on the success rates of the control group alone (no other variables involved), assuming that there was no treatment effect for the participants with missing outcomes. The second imputation analysis was planned to evaluate the missing at random (MAR) assumption, underlying the primary analysis. Data were analyzed with the SPSS version 20.0 for Windows. Statistical significance was set at a p-value < 0.05.

3. Results

The 14 participating GPs sent 3285 screening questionnaires to their female patients aged ≥55 years and 2390 (74%) were sent back (Fig. 1). Among the responders, 744 (31%) women reported symptoms of urinary incontinence and 350 (47%) of this group consented to participate in the trial and were included.

At baseline, the intervention and the control group were comparable (Table 1).

In the intervention group, of the 166 women, the clinical and questionnaire data of 153 women were discussed by the multidisciplinary team; 13 women decided to stop with the study before a treatment advice was given. After the evaluation, 75 women (49%) were referred for a behavioral intervention carried out by registered pelvic physiotherapists and including pelvic floor muscle training, bladder training and biofeedback. A total of 41 women (27%) were referred to secondary care for further diagnostic examinations, of which 30 were still advised to visit a pelvic physiotherapist. Thus, pelvic physiotherapy was the first-line therapy in 105 women (69%). The average number of treatments was seven (range 1–19). Six women (4%) were treated with medication, four (3%) received a pessary, and three women (2%) were operated. In the control group, three women (2%) received a treatment, two visited a pelvic physiotherapist and one was prescribed an anticholinergic drug (oxybutynin).

At the end of the follow-up period, 257 participants (73%) were still in the study and 254 of them had complete data regarding the primary outcome measurement. The major reason for leaving the study was that participation required too much time and effort, especially the keeping of a three-day frequency volume chart.

In the primary analysis of the main outcome measure (improvement in the ISI category), six imputation datasets were sufficient to obtain a high enough relative efficiency; they were pooled following Rubin's rule [21]. This analysis showed a nearly two-fold increase in the probability of a reduction in the severity of incontinence in the intervention group compared with the control group (OR 1.9; 95% CI 1.1–3.3) (Table 2). In the first sensitivity analysis with patients with a complete dataset, the number of patients that had improved one or more categories on the ISI at follow-up was 36 (34%) in the intervention group and 24 (17%) in the control group (OR 2.4; 95% CI 1.3–4.5) (Table 2). In the second sensitivity analysis with imputations based on the success rates in the control group of the six GP clusters, comparable results were found (OR 2.0; 95% CI 1.1–3.4); this implies that the MAR assumption is plausible.

More than 25% of the included women had only mild symptoms (ISI score ≤2). For this reason, we did a secondary complete-case analysis with women who had at least moderate to severe symptoms. In this latter analysis we found an improvement of one or more categories in 47% (36/76) of the women in the intervention group and in 24% (24/99) in the control group (OR 2.8; 95% CI 1.4–5.3).

The median number of incontinence episodes per day decreased from 1.0 to 0.0 in the intervention group whereas it remained at 1.0 episode per day in the control group. The probability of improvement was more than doubled for the intervention group as compared to the control group (OR 2.5; 95% CI 1.5–4.1) (Table 2).

The disease-specific quality of life (IIQ-7) improved during follow-up in both groups, but to a greater extent in the intervention than in the control group. However, after multiple imputation of missing values with correction for baseline scores, a non-significant difference was found in the change on the total IIQ score of 2.6 points (95% CI −6.2 to 1.0). Only the score on the emotional health subdomain showed a significantly larger change in the intervention group. After dichotomization, the proportion of patients who showed an improvement on this quality of life score was not significantly different between the intervention and control group (OR 1.5; 95% CI 0.8–3.1). For the generic quality of life scores (MOS SF-12), no differences in change were found between the intervention and control group (Table 2).

No side-effects of the treatments were reported.

4. Discussion

4.1. Main findings

This pragmatic, matched-pairs cluster randomized trial showed that, if older community-dwelling women with urinary incontinence are invited to be diagnosed and treated, the probability of improvement of the severity of symptoms after one year is two times higher than if they had received standard care. The probability that the number of incontinence episodes would decrease is more than doubled in the intervention group. In the intervention group, scores on disease-specific quality of life showed significantly more improvement compared with the control group; however, this difference disappeared after dichotomization. There was no change in generic quality of life in either of the groups. In most of the study patients the treatment was conservative (pelvic floor muscle training and bladder training).

4.2. Comparison with existing literature

In the present trial, the effects found (34% improvement in the intervention group, OR 1.9) are less than those reported by Dumoulin et al. in their systematic review on pelvic floor muscle training for urinary incontinence, although they did report a wide range of subjective cure rates (53–97%) [22]. In a review on non-surgical treatments for women with stress urinary incontinence, Imamura et al. found an OR of 4.5 for improvement or cure (95% CI 2·0–11·9)[5]. In a review by Shamliyan et al., conservative treatment of urinary incontinence in women was shown to be effective, although no pooled effect size could be estimated [23]. In our study, factors that might explain the relatively modest results are the age of the study population, the inclusion of all types of incontinence (results are generally better in stress incontinence than in urgency or mixed incontinence), the follow-up period of one year (most of the trials had a follow-up of 0.25–6 months; and results of PFMT are known to decrease over time) [22,24,25]. Furthermore, in our trial, more than 25% of the women had only mild incontinence, which limits the potential for improvement.

No trials with a population-based recruitment of older women were found with which to compare our study. Other studies on older women included referred patients, were clinic based and required urodynamic confirmation of stress incontinence, were 'recruited through local advertisements and professional referrals' and 'predominantly urge incontinent', or were recruited from university gynecological practices and included after urodynamic investigation [5,26–29]. Dougherty et al. recruited women 'from seven rural north Florida counties' who had urine loss at least

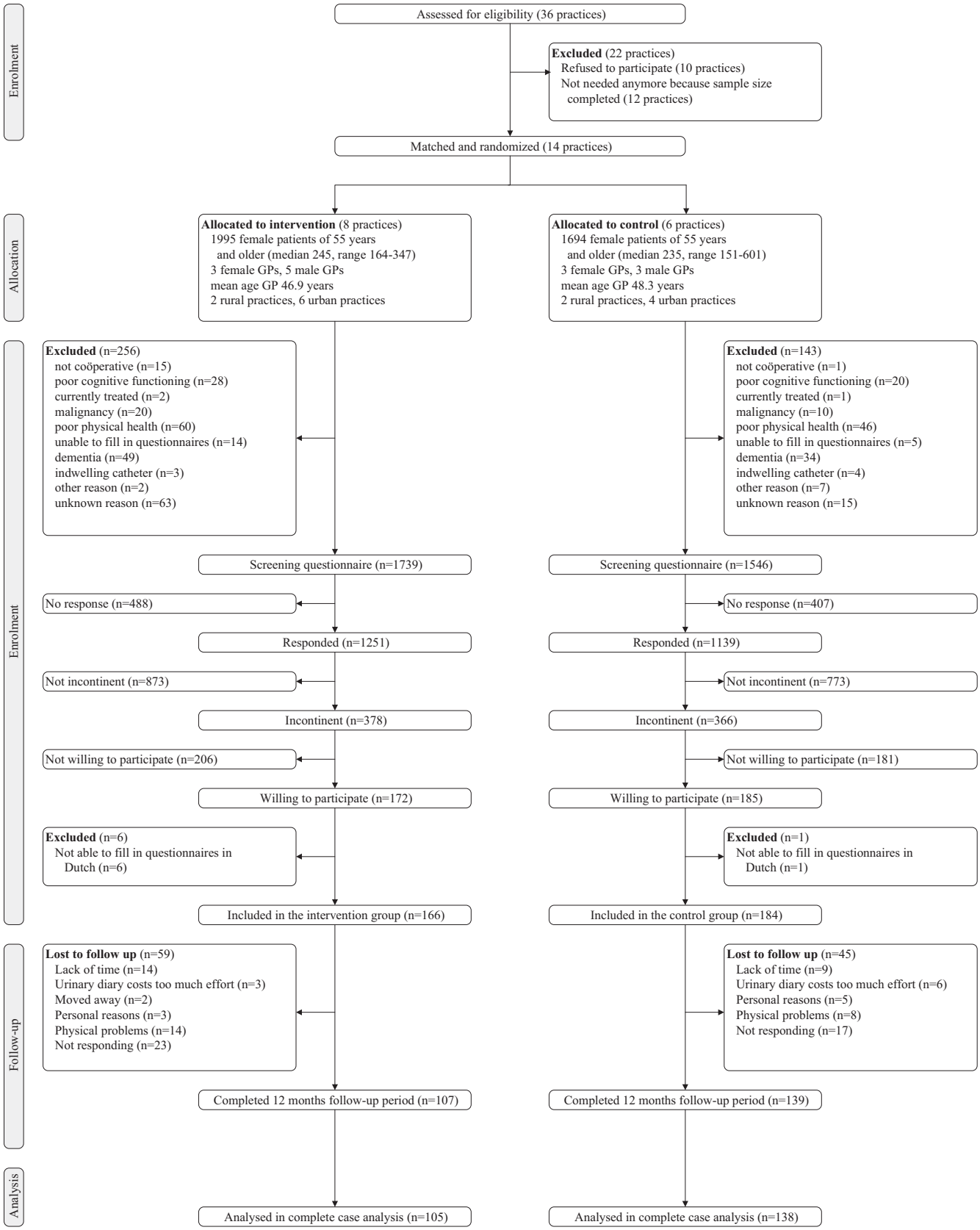

Fig. 1. Flowchart of the clusters and participants.

Table 1
Baseline characteristics of the study population of female patients aged ≥55 years with urinary incontinence ($n = 350$).

	Intervention group $n = 166$	Control group $n = 184$	p-value
Age at baseline in years; mean (SD)	65.7 (8.4)	65.9 (8.3)	0.98[a]
Menopause age in years; mean (SD)	50.2 (4.8)	48.9 (5.5)	0.02[a]
Years since menopause; mean (SD)	15.6 (10.4)	16.5 (9.7)	0.45[a]
Parity; median (IQR)	2.0 (2.0–3.0)	2.0 (2.0–3.0)	0.71[b]
Self-reported type of incontinence[c]			0.42[d]
Stress incontinence; *n* (%)	44 (26.5)	53 (28.8)	
Urgency incontinence; *n* (%)	36 (21.7)	29 (15.8)	
Mixed incontinence; *n* (%)	82 (49.4)	94 (51.1)	
Other; *n* (%)	4 (2.4)	8 (4.3)	
Urinary Distress Inventory score			
overactive bladder; median (IQR)	44.4 (22.2–66.7)	44.4 (22.2–66.7)	0.29[b]
Urinary incontinence; median (IQR)	26.7 (13.3–53.3)	26.7 (20.0–46.7)	0.98[b]
Discomfort and pain; median (IQR)	11.1 (0.0–33.3)	5.6 (0.0–22.2)	0.22[b]
Pelvic organ prolapse; median (IQR)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.92[b]
Obstructive micturition; median (IQR)	0.0 (0.0–50.0)	0.0 (0.0–33.3)	0.36[b]
Bed-wetting; median (IQR)	0.0 (0.0–0.0)	0.0 (0.0–0.0)	0.87[b]
Comorbidity[e]; median (IQR)	3.0 (2.0–5.0)	3.0 (1.0–4.0)	0.13[b]
Incontinence Severity Index			0.60[d]
Slight; *n* (%)	40 (24.1)	53 (28.8)	
Moderate; *n* (%)	83 (50.0)	90 (48.9)	
Severe; *n* (%)	35 (21.1)	36 (19.6)	
Very severe; *n* (%)	8 (4.8)	5 (2.7)	
Number of incontinence episodes per day; median (IQR)	1.0 (0.0–4.0)	1.0 (0.0–3.0)	0.47
Incontinence Impact Questionnaire score			
physical activity; median (IQR)	0.0 (0.0–16.7)	0.0 (0.0–16.7)	0.88[b]
Travel; median (IQR)	0.0 (0.0–33.3)	0.0 (0.0–33.3)	0.66[b]
Social and relationship; median (IQR)	0.0 (0.0–16.7)	0.0 (0.0–16.7)	0.94[b]
Emotional health; median (IQR)	0.0 (0.0–16.7)	0.0 (0.0–16.7)	0.17[b]
Overall; median (IQR)	4.8 (0.0–19.1)	4.8 (0.0–19.1)	0.93[b]
Medical Outcome Score			
physical functioning; median (IQR)	83.3 (37.5–100.0)	83.3 (50.0–100.0)	0.83[b]
Role performance; median (IQR)	100.0 (50.0–100.0)	100.0 (50.0–100.0)	0.81[b]
Social functioning; median (IQR)	100.0 (60.0–100.0)	100.0 (80.0–100.0)	0.79[b]
Mental health; median (IQR)	56.0 (52.0–60.0)	56.0 (52.0–64.0)	0.07[b]
Experienced health; median (IQR)	75.0 (50.0–90.0)	75.0 (55.0–90.0)	0.65[b]
Physical pain; median (IQR)	50.0 (0.0–75.0)	50.0 (0.0–75.0)	0.57[b]

[a] *t*-test.
[b] Mann–Whitney *U* test.
[c] The clinical history for stress incontinence was defined as positive when a patient marked "leaks when you cough or sneeze" or "leaks when you are physically active/exercising" on the items in question 4 of the ICIQ. Urgency incontinence was diagnosed when a patient answers "yes" on question 3 of the UDI ("Do you experience urine leakage related to the feeling of urgency?"). Mixed incontinence was diagnosed when answers were positive for both stress and urgency incontinence.
[d] Chi Square test.
[e] Number of diseases of the following list: recurrent urinary tract infections, kidney stones, urethral interferences, abnormal continence development, uterus extirpation, pelvic organ prolapse correction, diabetes, cerebral vascular incidents, myocardial infarction, angina pectoris, congestive heart failure, hypertension, atherosclerosis, COPD, dizziness with falling, severe or persistent back pain, joint problems, constipation, visual impairment, malignancies, and abdominal surgery.

twice a week and were aged ≥55 years; however, it is unclear how they were selected [30]. The intervention group received a comprehensive behavioral intervention in their own home; after 12 months Dougherty et al. found a significant decrease of incontinence episodes per day as compared to no treatment [30].

In the present study no significant difference was found in mean change in disease-specific quality of life score after imputation of missing values, except for the emotional subdomain; in addition, no significant difference was found in the percentage of improved patients. This means that, in our population, we could not show an effect of the intervention on the quality of life. Many women had a low baseline score on the quality of life questionnaires, implying that they experienced little impact of the incontinence on their daily life; this corresponds with the fact that many women in our trial had only mild symptoms. Explanation for the findings on the quality of life in our study and other trials may be that many women with urinary incontinence have found ways to cope with their problems and have adapted their activities to their condition [4]. Another explanation might be that the quality of life in older women is more defined by comorbid factors than by urinary incontinence [31].

4.3. Strengths and limitations of the study

The present study adds support to the effectiveness of diagnosing and treating older women with urinary incontinence that do not visit a caregiver. In view of the high response and participation rates, the active approach in our trial was apparently appreciated by the patients [7]. More than two thirds of the participants had never visited their GP with symptoms of incontinence [4]. With a follow-up period of one year, this is one of the few studies on incontinence reporting effects on the longer term.

This study was a cluster randomized trial: GPs were matched into pairs and then randomized to treatment or control, instead of randomizing patients. This may have influenced the decision of the patients to participate in the trial, because they knew in advance which arm of the trial their GP was allocated to [32]. However, no imbalances between the groups were observed at baseline.

Patients in the control group were of course informed about the study and were, thus, aware of the treatment options for incontinence offered in the intervention arm; this may have reduced the barriers for their seeking help. However, only three of them sought help of their own volition. This might mean that an

Table 2
Primary and secondary outcomes in the intervention and control group at follow-up after one year.

	Imputed data[a]			Complete cases					
	Intervention group $n = 166$ Control group $n = 184$			Intervention group $n = 105$ Control group $n = 138$					
	Improved OR (95% CI)	Difference in change between groups (95% CI)	p-value[b]	Improved Intervention; n (%)	Control; n (%)	OR (95% CI)	Numbers, median, c.q. change[c] Intervention	Control	p-value[b]
ISI[d]	1.9 (1.1–3.3)			36 (34)	24 (17)	2.4 (1.3–4.5)			
Slight							51 (56)	40 (29)	
Moderate							38 (37)	66 (48)	
Severe							14 (13)	29 (21)	
Very severe							2 (2)	3 (2)	
Incontinence episodes	2.5 (1.5–4.0)			46 (54)	44 (37)		0 (0–2)	1 (0–2)	
IIQ-7[e]									
Overall score	1.5 (0.8–3.1)	2.6 (−1.0 to 0.62)	0.14	41 (46)	40 (33)		−3.8 (9.5)	−0.4 (8.9)	<0.01
Subdomains									
Physical activity		1.0 (−1.8 to 4.7)	0.57	29 (29)	33 (25)		−4.3 (15.0)	−2.6 (15.9)	0.38
Travel		2.6 (−1.2 to 6.4)	0.76	20 (21)	18 (14)		−3.9 (13.9)	−0.3 (14.5)	0.06
Social and relationship		3.1 (−1.4 to 7.6)	0.17	14 (15)	14 (11)		−3.5 (17.8)	−0.0 (16.2)	0.13
Emotional health		3.3 (0.33–6.4)	0.03	27 (29)	19 (15)		−3.9 (12.9)	0.6 (10.9)	<0.01
MOS SF-20[f]									
Subdomains									
Physical functioning	1.3 (0.6–2.9)			10 (10)	21 (16)		6.1 (21.7)	3.5 (27.2)	0.43
Role performance	1.7 (0.5–5.4)			8 (8)	9 (7)		−0.49 (34.3)	4.9 (34.3)	0.26
Social functioning	1.1 (0.5–2.7)			15 (15)	24 (19)		−0.80 (18.6)	−0.46 (18.2)	0.89
Mental health	1.2 (0.7–2.1)			37 (37)	47 (35)		−0.23 (7.5)	0.12 (8.8)	0.75
Experienced health	1.3 (0.7–2.2)			35 (39)	55 (45)		0.81 (17.5	−3.0 (18.6)	0.13
Physical pain	1.3 (0.8–2.3)			36 (36)	42 (32)		−13.0 (38.3)	−10.9 (32.4)	0.65

[a] Multiple imputation of missing values based on baseline characteristics of the entire group.
[b] t-Test
[c] Number (%) of patients in the ISI categories after 12 months, median (IQR) number of incontinence episodes after 12 months and change (SD) on IIQ-7score and MOS-SF-20 score.
[d] Incontinence Severity Index.
[e] Incontinence impact questionnaire-7.
[f] Medical outcome score short form-20.

invitation for treatment is essential to increase the number of incontinent patients that may receive adequate care.

The dropout rate in our study was higher than expected (30% instead of 20%). The main reason given for stopping was the 'demands made by the trial', perhaps in combination with the length of the follow-up period. In comparison, a recent trial on pelvic organ prolapse had a dropout rate of 34% at one year [33]. However, our two analyses using different ways of imputing missing data had comparable results; this makes the findings on the effect of the intervention rather robust for missing data.

4.4. Implications and further research

Inviting older women with urinary incontinence who did not visit their GP for this problem, and then treating them, is effective, i.e. a treatment tailored to their needs gives a two fold chance of improvement of symptoms. However, in the present study the percentage of patients that improved is relatively modest. One explanation for this is that over 25% of the included women had relatively mild symptoms. Nevertheless, we think that the evidence is strong enough to conclude that older incontinent women should be stimulated to seek help and that GPs should be convinced that 'therapeutic nihilism' is not justified in this group of patients. Enquiring about incontinence at annual checks for chronic conditions (e.g. by the nurse practitioners) can be a first step in the process of identifying more women with urinary incontinence. Care providers should explain to their patients what the diagnosis and treatment of urinary incontinence involves and how probable it is that their symptoms will improve. Then, as a shared decision, they can decide whether to follow this path or not.

The role of the multidisciplinary team described in our trial can be taken over by the GP, as no assessments were used to advice on treatments other than those available in general practice. Consultation by telephone with a GP with special interest in urogynecology or a urogynecologist would be an option for the more difficult cases.

Future research should focus on how to identify women with an impact of symptoms severe enough to warrant treatment and how to stimulate them to seek help.

Trial registration

The URINO trial was registered at the Dutch Trial Register (registration number NTR1181). The full study protocol is on request to obtain from the corresponding author. A summary is available from the website of the Dutch Trial Register: http://www.trialregister.nl.

Contributors

I, Els Visser, declare that I participated in the implementation of the study, the data collection and drafting the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Geertruida de Bock, declare that I participated in designing the trial, I supervised Els Visser and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Embert Messelink, declare that I participated in designing the trial, was a member of the multidisciplinary team and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Aaltje Schram, declare that I participated in designing the trial, was a member of the multidisciplinary team and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Boudewijn Kollen, declare that I performed and supervised the analyses and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Sacha la Bastide-van Gemert, declare that I performed and supervised the analyses and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Edwin van den Heuvel, declare that I performed and supervised the analyses and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Marjolein Berger, declare that I participated in the supervision of Els Visser and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

I, Janny Dekker, declare that I participated in designing the trial, I supervised Els Visser and I read and gave comment upon the draft of the manuscript, and that I have seen and approved the final version. I have no conflicts of interest.

Competing interests

All authors declare they have no competing interests.

Funding

The Netherlands Organisation for Health Research and Development (ZonMw) funded the URINO trial (dossier number 170882301). The funding source approved the study design, but had no role in any aspect of the data analysis.

Ethical approval consent or animal equivalent

Approval was granted by the Medical Ethical Review Committee of the University Medical Centre Groningen, Groningen, The Netherlands (reference number METC2007.259). All participants gave their written informed consent.

Acknowledgments

The authors thank Janka A. Barentsen for assistance with data collection and entry, Marco Assmann for performing the randomization, and Marco H. Blanker for commenting on the draft of the manuscript. We also thank the participating general practitioners and pelvic floor physiotherapists, and the women who took part in this study.

References

[1] Milsom I, Altman D, Cartwright R, Lapitan MC, Nelson R, Sillen U, et al. Committee 1: epidemiology of urinary incontinence (UI) and other lower urinary tract symptoms (LUTS). Pelvic organ prolapse (POP) and anal incontinence (AI). In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence. Report of the 5th International Consultation on incontinence. Paris: ICUD-EAU; 2013. p. 15–08.
[2] Nygaard I, Barber MD, Burgio KL, Kenton K, Meikle S, Schaffer J, et al. Prevalence of symptomatic pelvic floor disorders in US women. J Am Med Assoc 2008;300:1311–6.
[3] Lagro-Janssen T, Smits A, Van Weel C. Urinary incontinence in women and the effects on their lives. Scand J Prim Health Care 1992;10:211–6.
[4] Visser E, de Bock GH, Kollen BJ, Meijerink M, Berger MY, Dekker JH. Systematic screening for urinary incontinence in older women: who could benefit from it? Scand J Prim Health Care 2012;30:21–8.
[5] Imamura M, Abrams P, Bain C, Buckley B, Cardozo L, Cody J, et al. Systematic review and economic modelling of the effectiveness and cost-effectiveness of non-surgical treatments for women with stress urinary incontinence. Health Technol Assess 2010;14(1):iii–v, 188.
[6] Lagro-Jansen ALM, Breedveldt Boer HP, Van Dongen JJAM, Lemain TJJ, Teunissen D, Van Pinxteren B. The guideline 'Urinary incontinence' of the Dutch College of General Practitioners (first revision). Huisarts Wet 2006;49:501–10.

[7] Visser E, Dekker JH, Vermeulen KM, Messelink EJ, Schram AJ, Berger MY, et al. The effect of systematic screening of older women for urinary incontinence on treatment uptake: the URINO trial. Maturitas 2013;74:334–40.
[8] Barentsen JA, Visser E, Hofstetter H, Maris AM, Dekker JH, de Bock GH. Severity, not type, is the main predictor of decreased quality of life in elderly women with urinary incontinence: a population-based study as part of a randomized controlled trial in primary care. Health Qual Life Outcomes 2012;10:153.
[9] Sandvik H, Espuna M, Hunskaar S. Validity of the incontinence severity index: comparison with pad-weighing tests. Int Urogynecol J Pelvic Floor Dysfunct 2006;17:520–4.
[10] Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA. Short forms to assess life quality and symptom distress for urinary incontinence in women: the incontinence impact questionnaire and the urogenital distress inventory. Continence program for Women Research Group. Neurourol Urodyn 1995;14:131–9.
[11] Kempen GI. Assessment of health status of the elderly. Application of a Dutch version of the MOS scale. Tijdschr Gerontol Geriatr 1992;23:132–40.
[12] Donovan J, Bosch R, Gotoh M, Jackson S, Naughton M, Radley S, et al. Committee 6: symptom and quality of life assessment. In: Abrams P, Cardozo L, Khoury S, Wein A, editors. Incontinence. Basics & evaluation. Report of the 3rd International Continence Society, 1. Paris: Health Publication Ltd; 2005. p. 519–84.
[13] Assessment and treatment of urinary incontinence. Scientific Committee of the First International Consultation on incontinence. Lancet 2000;355:2153–8.
[14] Bano F, Arunkalaivanan AS, Barrington JW. Comparison between bladderscan, real-time ultrasound and suprapubic catheterisation in the measurement of female residual bladder volume. J Obstet Gynaecol 2004;24:694–5.
[15] Coates KW, Harris RL, Cundiff GW, Bump RC. Uroflowmetry in women with urinary incontinence and pelvic organ prolapse. Br J Urol 1997;80:217–21.
[16] Messelink B, Benson T, Berghmans B, Bo K, Corcos J, Fowler C, et al. Standardization of terminology of pelvic floor muscle function and dysfunction: report from the pelvic floor clinical assessment group of the International Continence Society. Neurourol Urodyn 2005;24:374–80.
[17] Scotti RJ, Myers DL. A comparison of the cough stress test and single-channel cystometry with multichannel urodynamic evaluation in genuine stress incontinence. Obstet Gynecol 1993;81:430–3.
[18] DuBeau CE, Kuchel GA, Johnson 2nd T, Palmer MH, Wagg A. Incontinence in the frail elderly: report from the 4th International Consultation on incontinence. Neurourol Urodyn 2010;29:165–78.
[19] Seim A, Sivertsen B, Eriksen BC, Hunskaar S. Treatment of urinary incontinence in women in general practice: observational study. Br Med J 1996;312:1459–62.
[20] Van Houwelingen JC. Roaming through methodology. III. Randomization at the level of the physicians. Ned Tijdschr Geneeskd 1998;142:1662–5.
[21] Lipsitz SR, Parzen M, Ping Zhao L. A degrees-of-freedom approximation in multiple imputation. J Statist Comput Simul 2002;72:309–18.
[22] Dumoulin C, Hay-Smith J. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. Cochrane Database Syst Rev 2010;(1). CD005654.
[23] Shamliyan TA, Kane RL, Wyman J, Wilt TJ. Systematic review: randomized, controlled trials of nonsurgical treatments for urinary incontinence in women. Ann Intern Med 2008;148:459–73.
[24] Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U, et al. The standardisation of terminology in lower urinary tract function: report from the standardisation sub-committee of the International Continence Society. Urology 2003;61:37–49.
[25] Choi H, Palmer MH, Park J. Meta-analysis of pelvic floor muscle training: randomized controlled trials in incontinent women. Nurs Res 2007;56:226–34.
[26] Subak LL, Marinilli Pinto A, Wing RR, Nakagawa S, Kusek JW, Herman WH, et al. Decrease in urinary incontinence management costs in women enrolled in a clinical trial of weight loss to treat urinary incontinence. Obstet Gynecol 2012;120:277–83.
[27] Burns PA, Pranikoff K, Nochajski TH, Hadley EC, Levy KJ, Ory MG. A comparison of effectiveness of biofeedback and pelvic muscle exercise treatment of stress incontinence in older community-dwelling women. J Gerontol 1993;48:M167–74.
[28] Burgio KL, Locher JL, Goode PS, Hardin JM, McDowell BJ, Dombrowski M, et al. Behavioral vs drug treatment for urge urinary incontinence in older women: a randomized controlled trial. J Am Med Assoc 1998;280:1995–2000.
[29] Fantl JA, Wyman JF, McClish DK, Harkins SW, Elswick RK, Taylor JR, et al. Efficacy of bladder training in older women with urinary incontinence. J Am Med Assoc 1991;265:609–13.
[30] Dougherty MC, Dwyer JW, Pendergast JF, Boyington AR, Tomlinson BU, Coward RT, et al. A randomized trial of behavioral management for continence with older rural women. Res Nurs Health 2002;25:3–13.
[31] Labrie J, Fischer K, van der Vaart CH. Health-related quality of life. The effect of pelvic floor muscle training and midurethral sling surgery: a systematic review. Int Urogynecol J 2012;23:1155–62.
[32] Eldridge S, Kerry S, Torgerson DJ. Bias in identifying and recruiting participants in cluster randomised trials: what can be done? Br Med J 2009;339:b4006.
[33] Hagen S, Stark D, Glazener C, Dickson S, Barry S, Elders A, et al. Individualised pelvic floor muscle training in women with pelvic organ prolapse (POPPY): a multicentre randomised controlled trial. Lancet 2014;383:796–806.