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Effectiveness of involving a nurse specialist for patients with urinary incontinence in primary care: results of a pragmatic multicentre randomised controlled trial

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Effectiveness of involving a nurse specialist for patients with urinary incontinence in primary care: results of a pragmatic multicentre randomised controlled trial

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Abstract

Background

Urinary incontinence (UI) primary care management is substandard, offering care rather than cure despite the existence of guidelines that help to improve cure. Involving nurse specialists on incontinence in general practice could be a way to improve care for UI patients.

Aims

We studied whether involving nurse specialists on UI in general practice reduced severity and impact of UI.

Methods

Between 2005 and 2008 a pragmatic multicentre randomised controlled trial was performed comparing a one-year intervention by trained nurse specialists with care-as-usual after initial diagnosis and assessment by general practitioners in adult patients with stress, urgency or mixed UI in four Dutch regions (Maastricht, Nijmegen, Helmond, The Hague). Simple randomisation was computer-generated with allocation concealment. Analysis was done by intention-to-treat principles. Main outcome measure was the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) severity sum score.

Results

186 patients followed the intervention and 198 received care-as-usual. Patients in both study groups improved significantly in UI severity and impact on [health-related](#) quality of life. After correction for effect modifiers (type of UI, Body Mass Index) we found significant differences between groups in favour of the intervention group at three months ($p = 0.04$); no

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2 differences were found in the one-year linear trend ($p = 0.15$). Patients in the intervention
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4 group without baseline anxiety/depression improved significantly better compared to care-as-
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6 usual after one year ($p = 0.03$).
7

8 9 Conclusion

10
11 Involving nurse specialists in care for UI patients supplementary to general practitioners can
12
13 improve severity and impact of UI, after correction for effect modifiers. This is also the
14
15 case in specific situations such as anxiety/depression.
16
17

18 19 Ethical approval and Clinical Trial Registration Number:

20
21 The study protocol was approved by the Medical Ethical Committees of all involved centres.
22
23 Included patients gave their written informed consent. The trial is registered at
24
25 <http://www.controlled-trials.com/isrctn/62722772> and is reported following CONSORT
26
27 guidelines for RCTs.
28
29

30 31 What's known?

32
33 Urinary incontinence (UI) primary care management is substandard, offering care rather than
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35 cure despite the existence of guidelines that help to improve cure. Main reasons for
36
37 substandard care are lack of time of general practitioners and lack of targeted implementation
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39 strategies to adopt and practice guideline recommendations.
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42 43 What's new?

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45 Involving nurse specialists in care for UI patients supplementary to general practitioners can
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47 improve severity and impact of UI:
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2 involving nurse specialists in UI primary care reduced severity and impact of UI after three
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4 months of intervention, after correction for effect modifiers; this is also the case in specific
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6 situations such as anxiety/depression.
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For Peer Review Only

Introduction

Urinary incontinence (UI) is a frequent clinical condition. The estimated prevalence of 'any UI' in middle-aged and older women in the general population appears to be in the range of 30% to 50% (increasing with age). UI is at least twice as prevalent in women as compared with men.[1] Considering the ageing population a further increase is expected.[1] UI is infamous for its impact on general well being and social activities. If not treated and monitored, UI is a chronic dynamic disorder, complicated by co-morbidities, with a strong tendency to increase over time.[1, 2] National and international primary care guidelines on UI indicate that for most UI patients pelvic floor muscle and/or bladder training is the best non-invasive initial treatment to solve the problem.[2, 3] So far, despite guidelines, training is only incidentally offered.[4-6] Most GPs choose a non-curative alternative: prescribing incontinence pads. More than 50% of UI patients use incontinence pads, especially older people.[6, 7]

Although UI threatens health-related quality of life, it is not life threatening.[6, 7] Adequate treatment of UI can be complex and time consuming. So far, UI has not been receiving much attention in general practice, despite the large number of patients who suffer from it. Probably, there are several reasons, such as lack of knowledge, other clinical priorities, lack of time and lack of targeted implementation strategies to adopt and practice guideline recommendations.[4, 5, 8-12] Therefore, employing nurse specialists may offer a solution to improve the quality of care in general practice provided to UI patients. We envisioned that nurse specialists, after thorough training, would be well equipped to support GPs after the initial consultation and assessment of a UI patient by the GP. Nurse specialists have specific skills and have extra time to inform and motivate patients compared to GPs. Their general

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1
2 acceptance by patients and GPs, feasibility, usefulness in management[13, 14] and the
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4 specific effectiveness in treating UI have been reported.[15]
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6 However, little information is available from randomised controlled trials (RCT) with long-
7
8 term follow-up on the effectiveness of involving nurse specialists for UI compared to usual
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10 care in general practice.[15, 16] Therefore, we set up a trial to study whether involving nurse
11
12 specialists for UI could improve the quality of care for adult UI patients in general
13
14 practice.[17] We envisioned that this change in process of care would also improve quality of
15
16 care in terms of treatment outcome.
17
18 We addressed the following main research question: “Does the involvement of a nurse
19
20 specialist for adult persons with UI reduce the overall UI severity including symptoms of
21
22 frequency, volume and the impact on the health-related quality of life compared to care-as-
23
24 usual?”.

25 26 27 **Materials and Methods**

28
29 From May 2005 until March 2008 we performed a pragmatic multicentre RCT comparing UI
30
31 patients (randomly assigned following simple randomisation procedures) receiving nurse
32
33 specialist care with UI patients receiving care-as-usual in general practice in four Dutch
34
35 regions (Maastricht, Nijmegen, Helmond, The Hague). A detailed study protocol and
36
37 description of the intervention is reported elsewhere.[17] In short, adult patients with stress,
38
39 urgency or mixed UI, already known or newly diagnosed by their GP, were eligible and
40
41 actively recruited by their GP to participate in the study and followed during one year. To
42
43 identify patients known to suffer from UI, GPs searched in their electronic medical record
44
45 system using the International Classification of Primary Care (ICPC) coding system and
46
47 obtained a list with pad users from the local pharmacies. Patients who met the in- and
48
49 exclusion criteria were invited to participate in the trial (Table 1). Randomisation was

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1
2 computer-generated, with allocation concealment by sealed envelopes. Blinding patients and
3
4 health care providers was obviously not possible.

5
6 Based on a mean UI severity sum score on our primary outcome, the International
7
8 Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF),[18] of 7.18 (sd 6.64),
9
10 an expected clinical important improvement of two points on the outcome scale (delta value
11
12 of $2/6.64 = 0.301$), a power of 80% and a two-sided significance level of 0.05, we needed 175
13
14 patients per arm, 350 in total.

15 16 17 Intervention

18
19 Six nurse specialists provided the intervention (Figure 1). The nurse specialists received
20
21 special training in tasks related to diagnostics, intervention and monitoring of incontinence
22
23 based on guidelines and protocols and proved their competencies afterwards in an assessment.
24
25 After the initial medical UI diagnosis by the GP, the nurse specialists, further specified the
26
27 diagnosis, registered problems in pelvic floor/bladder function (impairment), activities
28
29 (disability), participation problems and the influence of personal and external factors
30
31 following the International Classification of Functioning, Disability and Health (ICF).[19]
32
33 The nurses used micturition diaries and advised on lifestyle, toilet habits, bladder- and pelvic
34
35 floor muscle training and, when appropriate, the choice of incontinence pads. Patients were
36
37 treated during one year, with five to seven visits during the first three months, followed by
38
39 consultations at six and 12 months to monitor effect and adherence. Details of the training of
40
41 the nurse specialists and the intervention are described and free full text available elsewhere.

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Care-as-usual

Patients randomised to care-as-usual could not get a referral to the nurse specialist. We assumed that GPs would not change their care-as-usual, which is mostly restricted to pads prescription, where only a minority of UI patients gets active treatment or a referral to either physical therapist or specialist.[8, 10, 11, 20]

Outcome measures

The primary outcome was the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF) severity sum score of self-reported UI frequency, perceived UI quantity (weighted items) and the UI impact on health-related quality of life (Visual Analogue Scale (VAS)).[18] Overall score ranges from zero (no UI) to 21 (most severe UI). UI definitions followed International Continence Society (ICS) standards.[21]

Effects were controlled for accepted baseline effect modifiers (conditions or risk factors that may influence the effects, such as age, UI type, parity, type of delivery, BMI, restricted mobility, anxiety/depression).[1]

The self-completed EuroQol health-related quality of life questionnaire (EQ-5D), provided a five dimensional descriptive profile of mobility, self-care, usual activities, pain/discomfort and anxiety/depression for general health status.[22] Each dimension had three levels: no, some or severe problems.

Deleted: General health (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) was measured with t

Data collection and statistical analysis

Data was collected through postal questionnaires at baseline and for the two study end-points, three and 12 months. Non-responders were reminded by telephone two to three weeks later.

Kolmogorov-Smirnov tests were used to test normality of distributions in metric variables.

Comparability of groups at baseline was checked for demographics, medical history, and

1
2 general health. To test the overall effects in outcome at three months paired t-tests of
3
4 differences with baseline were used by summing results over both groups. Repeated measures
5
6 ANOVA was used to test outcome time differences from baseline between both groups, both
7
8 at three months and for the duration of the total follow-up. Repeated measures ANCOVA was
9
10 used to adjust for baseline outcome measurements, UI type, age, BMI, parity, complications
11
12 at delivery and baseline EuroQol scales mobility and anxiety/depression. Dummy regression
13
14 analysis was used on both the three months difference in outcome and on the linear-weighted
15
16 trend over all outcome measurements in time. To test overall one-year follow-up results for
17
18 both groups a one-sample t-test was done on the linear weighted trend. Missing data were
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20 imputed by using the mean of observed scores for both groups. A p-value of less than 0.05
21
22 was assumed to be statistically significant. Data analysis was done according intention-to-
23
24 treat principles, using SPSS-pc 15.0 and 16.0.
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28 Results

29
30 109 GPs in 65 practices participated. They identified 4055 UI patients. As expected because
31
32 of the broad recruitment strategy 47% (n = 1889) had exclusion criteria (mostly co-
33
34 morbidities) for the study. The remaining 2166 patients were invited to participate. 667
35
36 Patients were interested and wished to be informed; 206 then refused and 77 were excluded
37
38 due to co-morbidities.
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40 Finally, 384 patients met the study criteria; 186 were randomly allocated to the intervention
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42 and 198 to care-as-usual (Figure 2).
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44 Over the study period 40 (10.4%) (19 intervention, 21 control) patients dropped out.
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Both groups were comparable for factors such as age, gender, parity etc (Table 2). No separate analysis could be performed for gender since only very few males participated in the study.

Of the 186 patients randomised to the nurse specialist, 137 (73.6%) had seven to nine consultations (mean time spent 3.1 hours). Fewer consultations were related to poor health (n = 14) or no motivation/too much burden (n = 15). Adverse events were unrelated to the nurse intervention.

Main results

Overall, both the difference between both groups in ICIQ score at three months and the one-year linear trend was not significant (p = 0.06 and p = 0.15 respectively) (Table 3). In contrast to our expectations, patients in both groups improved on the ICIQ score at three months and on the one-year linear trend (both endpoints p < 0.001). However, when controlling for the accepted effect modifiers UI type, BMI and baseline ICIQ score we found that, compared to the care-as-usual group, the ICIQ score differences at three months significantly improved in the intervention group (B = -0.56, p = 0.04; n = 381) (Table 3).

Neither BMI, nor UI type was significantly related to the one-year linear trend of the ICIQ score.

Relation with general health

As suggested in literature, we checked the influence of aspects of general health on improvements of the ICIQ sum scores, but found no influences, except for anxiety/depression. Although no differences after three months were found, after one year anxiety/depression was responsible for less improvement of the ICIQ sum score (interactive effect B = 1.02, p = 0.03; n

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= 381; B effect for patients without baseline anxiety/depression = -.63, p = 0.03; n = 272) (Table 3).

Discussion

Summary of main findings

Significant differences between groups in favour of the intervention group were found after correction for known effect modifiers (UI type and BMI) after three months intervention. Surprisingly, both study groups improved in ICIQ sum score at three months and the one-year linear trend. Also, after one year of intervention we found effects in specific situations (anxiety/depression). Before drawing any conclusion a few remarks must be made.

Strengths and limitations of the study

The choice for a pragmatic design ensured that the intervention was as close as possible to treatment options in daily practice. This will facilitate future implementation. We enrolled patients in our study who were typical for the normal GP-caseload. Nevertheless, in terms of external validity, our results may only be valid for patients with a more than mild UI or who are prepared to play an active role towards their UI. As already mentioned, our study population had a higher mean baseline ICIQ sum score (11) as compared to the mean sum-score of 7 for a primary care UI population as used in our power calculation, [23] It is generally assumed that mild UI forms do profit most from bladder and pelvic floor muscle training. Our results however, show that also UI patients with severe or complex UI can profit from this intervention.[24-26] In patients with mild UI, the effects of our intervention may be higher.

The assumption prior to the study was that the care-as-usual group -as in many years before- would stay unchanged during the one-year study period.[27, 28] Given this assumption, the

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3 current recruitment numbers should have been sufficient to trace a significant difference.
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5 However, reality was different. Unexpectedly, the care-as-usual group also improved on the
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7 main outcome parameter. Consequently, the difference between both groups on the outcome
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9 became lower than expected. This would signify an unforeseen study effect that might be caused
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11 by several factors. GPs may have changed their care-as-usual policy, now being aware their UI
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13 approach is monitored (Hawthorne-effect). Theoretically, contamination might have occurred,
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15 but from our data we have no indication that this indeed occurred. A learning effect in GPs is in
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17 our view unlikely as the average GP included (only) 6 patients in the trial. Next to this, patients
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19 in the care-as-usual group may be influenced by being actively recruited for the study. An
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21 increased awareness about possible solutions for their UI problem may have occurred by extra
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23 contact with the GP for enrolment, the informed consent procedure and by repeatedly completing
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25 voiding diaries and questionnaires.[29, 30] Finally, the general mean imputation of missing items
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27 for the intention-to-treat-analysis leads to a regression to the mean in effects.
28
29 Altogether, when any improvement in the care-as-usual group was to be factored in for the
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31 power calculation, more patients would have been needed. As a result, our findings may be quite
32
33 conservative.

34 *Comparison with existing literature*

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36 This is one of few pragmatic RCTs comparing nurse involvement for UI patients supplementary
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38 to care-as-usual by GPs with a long term follow-up of one year.[15, 16] Our findings are in line
39
40 with RCTs of nurse interventions for incontinent community-dwelling patients.[15, 16]
41
42 However, comparability of results is limited due to varying populations, settings, outcome
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44 measurements, controls, nurse education level and duration of follow-up (often less than one
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46 year). Also, our finding that baseline reported anxiety/depression was associated with less UI
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2 improvement is in line in literature.[31-33] Lack of motivation, especially in those suffering
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4 from depression, might explain the lack of effect of our intervention on the one-year linear trend.
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6
7 *Implications for clinical practice and future research*

8 UI is a chronic dynamic disorder and often complicated by comorbidities.[1] The positive effect
9
10 of the nurse specialist intervention on the short term would argue in favour of a repeated
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12 intervention by trained health care professionals to monitor the condition and achieve long term
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14 effects.[34]
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16 Further research should focus on tailoring the intervention to patients characteristics which are
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18 prognostic and predictive for UI and changeable (depression[1, 31, 33], overweight[1, 35]). Also,
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20 research into the cost-effectiveness of involving nurse specialists for UI patients in general
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22 practice is needed.[36]
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Author contributions

All authors have approved the final draft for submission and had access to the study data. Specific contributions were made in the following area's: Pytha Albers-Heitner was involved in the conception and design of the study, data collection, statistical analysis and interpretation. In addition, she was responsible for the preparation, drafting and critical revision and approval of the manuscript. Toine Lagro-Jansen was helpful in the conception and design of the study, facilitated data collection, supervised the project, participated in the data interpretation, preparation and critical revision of the manuscript for important intellectual content and approval. Manuela Joore assisted in the conception and design of the study, supervised the project and critically revised the drafts of the manuscript for important intellectual content and approval. Bary Berghmans was responsible for the conception and design of the study, facilitated

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1
2 data collection, supervised the project, participated in the data interpretation, preparation and
3
4 critical revision and approval of the manuscript for important intellectual content. Fred Nieman
5
6 was helpful in the conception and design of the study, was responsible for methodology and the
7
8 statistical analysis and interpretation, and was involved in revising and approval of the
9
10 manuscript for important intellectual content. Pieter Venema was helpful in the conception and
11
12 design of the study, facilitated data collection and critically revised and approved the final drafts
13
14 of the manuscript for important intellectual content.

15
16 Johan Severens gave advice regarding the conception and design of the study,
17
18 supervised the project, advised in data analysis and interpretation and was involved in revising
19
20 and approval of the manuscript for important intellectual content. Ron Winkens (project leader)
21
22 was responsible for the conception and design of the study, supervised the project, facilitated
23
24 data collection, participated in the data interpretation, preparation and critical revision and
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26 approval of the manuscript for important intellectual content.
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Figure 1. Flow chart intervention nurse specialist for patients with UI

PFM (T)= Pelvic Floor Muscle (Training); GP = general practitioner; PPT = pelvic physiotherapist; NS = nurse specialist
 Definitions following International Continence Society (ICS) standards.

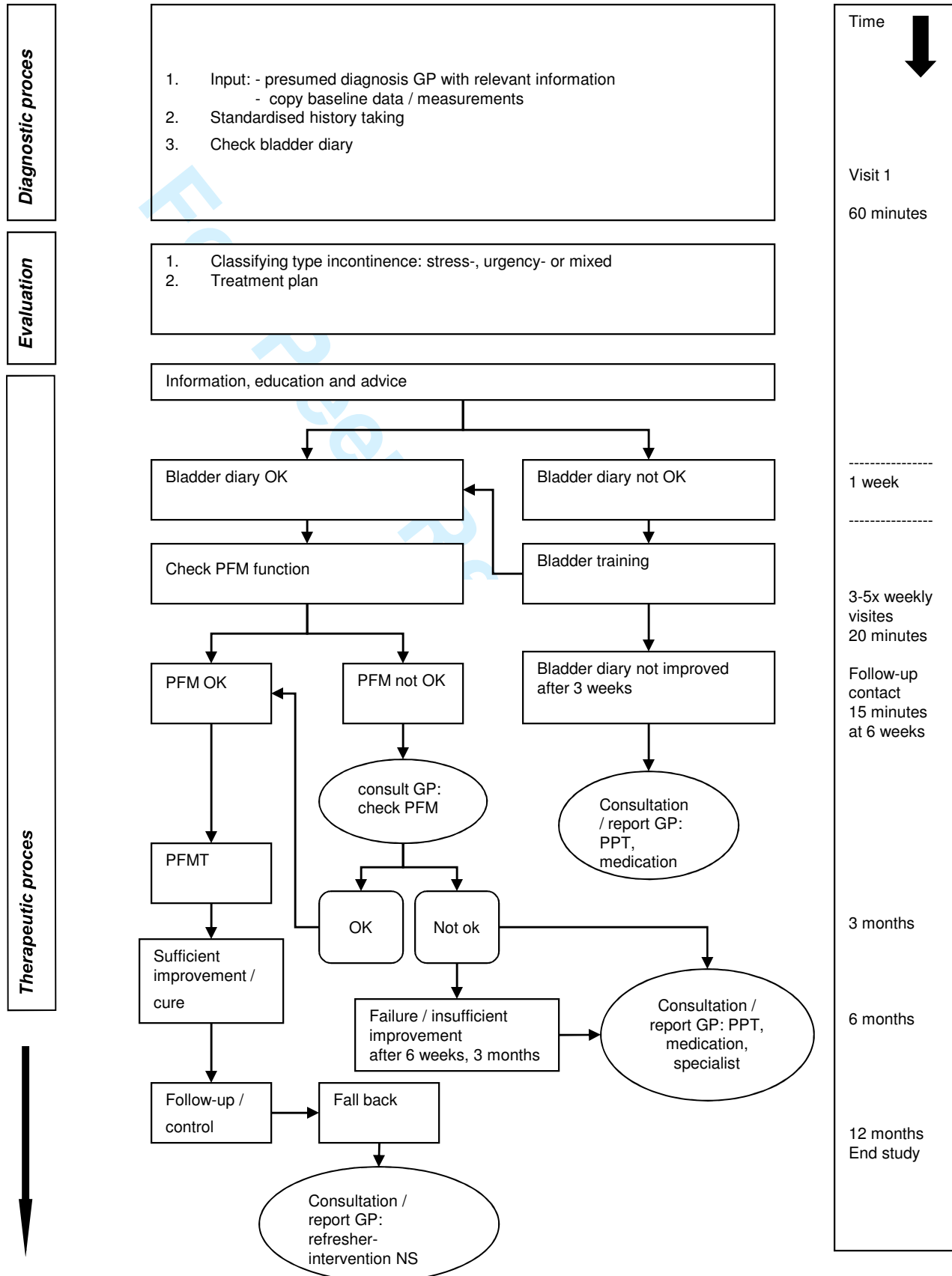


Figure 2. Flow of participants through each stage of the randomised trial and analysed for primary outcome

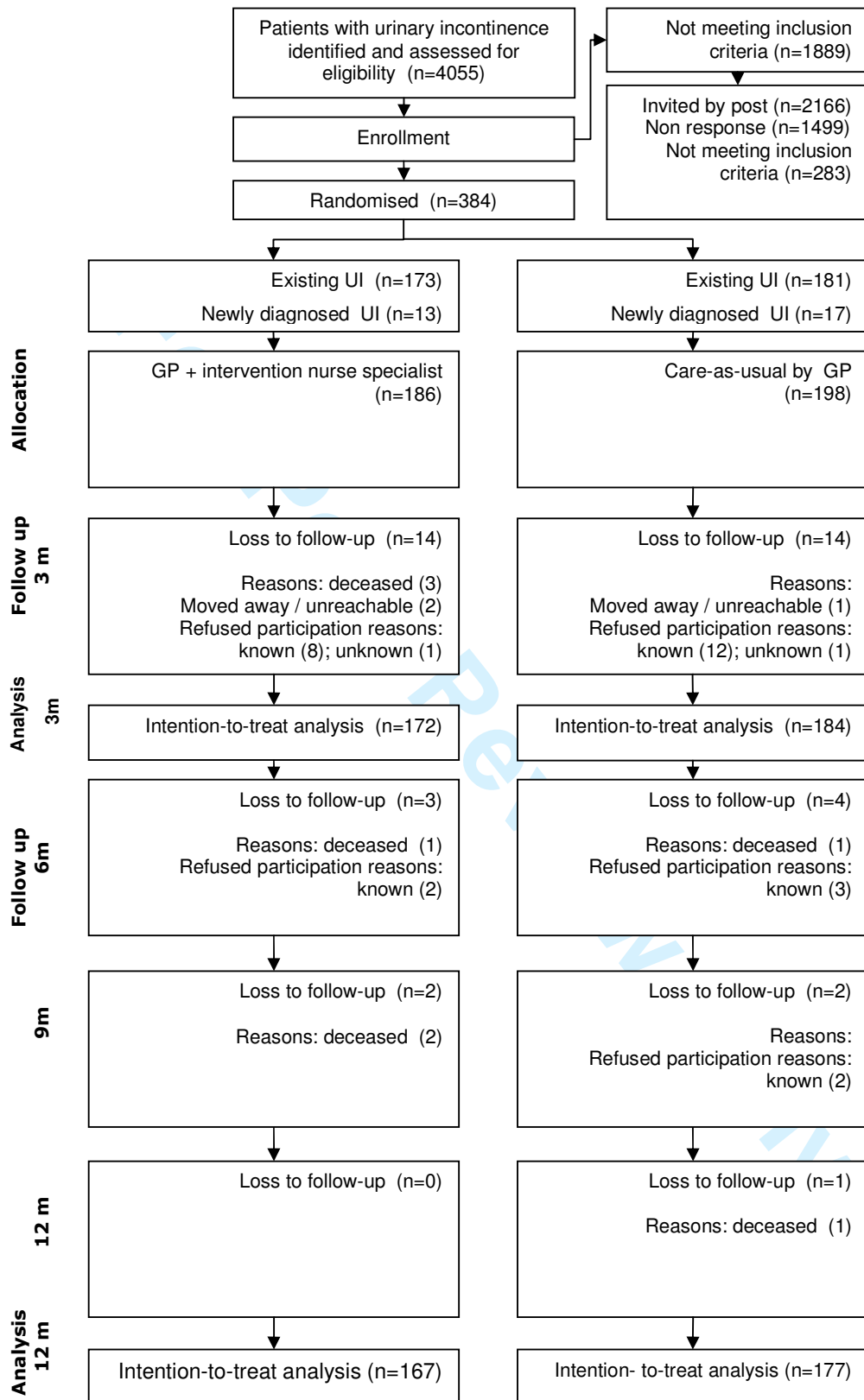


Table 1. In- and exclusion criteria**Inclusion criteria**

- age \geq 18 years
- SUI, UUI or MUI already or newly diagnosed by GP (according to the guidelines of the Dutch College of General Practitioners on UI)

Exclusion criteria

- women with prolapse degree III or more
- pregnancy or delivery < 6 months ago
- patients with
 - other types of UI than SUI, UUI or MUI / signs of reflex- or overflow UI
 - abdominal tumors
 - neurological diseases associated with UI (multiple sclerosis, stroke, diabetes, cauda equina syndrome)
 - urinary tract infection, hematuria without urinary tract infection
 - male < 65 years with unclear reason for UI
 - ongoing other treatment for UI
 - failure after surgery for UI or failure of conservative therapy
 - severe cognitive problems
 - living in nursing home
 - otherwise severe medical or psychiatric diseases
 - comprehension of Dutch language not good enough to fill in questionnaires

Abbreviation: SUI=stress urinary incontinence; UUI=urgency urinary incontinence; MUI=mixed urinary incontinence; UI=urinary incontinence; GP=general practitioner

Table 2. Demographics and baseline characteristics of patients. N = 384 (100%)

CHARACTERISTIC			INTERVENTION group N = 186 (48.4%)	USUAL CARE group N = 198 (51.6%)
Female n (%)			171 (91.9)	184 (92.9)
Age mean \pm sd			64.5 (14.1)	64.9 (11.6)
BMI mean \pm sd kg/m ²			28.3 (6.5)	28.1 (5.8)
			6 mv	7 mv
Type UI n (%)		SUI	68 (36.6)	67 (34.4)
		UUI	30 (16.1)	34 (17.4)
		Mixed	71 (38.2)	78 (40.0)
		NOS	17 (9.1)	16 (8.2)
				3 mv
Prolapse problems n (%)			24 (12.9)	26 (13.1)
Constipation n (%)			52 (28.0)	42 (21.2)
FI n (%)			33 (17.7)	38 (19.2)
EuroQol 5-D:	MOBILITY (%)	No problems	59.1	57.6
		Problems*	40.9	42.4
	SELF-CARE (%)	No problems	89.2	93.4
		Problems	10.8	6.6
	USUAL ACTIVITIES (%)	No problems	69.4	61.1
		Problems	30.7	38.9
	PAIN/DISCOMFORT (%)	No problems	48.8	46.5
		Problems	55.8	53.5
	ANXIETY/DEPRESSION (%)	No problems	71.5	74.2
		Problems	28.5	25.7

Abbreviation: mv=missing value; BMI=body mass index, calculated as weight in kilograms divided by height in meters squared; UI=urinary incontinence; SUI=stress urinary incontinence; UUI=urgency urinary incontinence; MUI=mixed urinary incontinence; NOS=not otherwise specified; FI=fecal incontinence

*problems=sum of moderate and severe problems

Table 3. Results intention-to-treat repeated measures Ancova /regression analysis on ICIQ-UI SF sum score;
a higher score means more severity and impact of urinary incontinence

	Intervention (n=186)	Care-as-usual (n=198)	Between Group Unstandardized B Effect size (CI 95%)	P value	Overall within Group Effect size (CI 95%)	P value
<i>Sum score ICIQ-UI SF (0-21)</i>						
<i>mean ± sd</i>						
<i>(weighted frequency/volume (0-11)</i>						
<i>plus impact (0-10))</i>						
baseline	11.1 ± 4.3	11.3 ± 3.7				
3 mo ¹	9.1 ± 2.9	9.7 ± 2.9	-0.51 (-1.03 to +0.01)	0.06	-1.79 (-2.18 to -1.41)	< 0.001*
3 mo ²			-0.56 (-1.08 to -0.04)	0.04*		
12 mo ¹	9.6 ± 3.7	10.3 ± 3.3	-0.34 (-0.80 to +0.12)	0.15	-0.64 (-0.93 to -0.36)	< 0.001*
12 mo ²			-0.34 (-0.81 to +0.14)	0.16		
12 mo ³			-0.63 (-1.20 to -0.06)	0.03*		

¹ Model = stimulus effect adjusted for baseline differences

² Model = stimulus effect controlled for BMI, type UI, baseline sum score, and type UI*baseline sumscore (n = 381)

³ Model = same model as under 2, but for patients without baseline mental health problems anxiety/depression (n = 272)

Abbreviations: ICIQ-UI SF=International Consultation Incontinence Questionnaire Short Form; mo=month(s); yr=year;

BMI=body mass index, calculated as weight in kilograms divided by height in meters squared; typeUI=type of urinary incontinence

*statistically significant improvement