

Albers-Heitner, MSc, PPT C<sup>1</sup>, Berghmans, PhD, PPT L<sup>2</sup>, Lagro-Janssen, Prof, PhD, MD A<sup>3</sup>, Joore, PhD M<sup>4</sup>, Nieman, PhD F<sup>4</sup>, Venema, PhD, urologist P<sup>5</sup>, Severens, Prof. PhD J<sup>6</sup>, Winkens, PhD, MD R<sup>7</sup>

1. Integrated Care Unit & School for Public Health and Primary Care (CAPHRI), MUMC+ (Maastricht University Medical Centre), Maastricht, The Netherlands, 2. Pelvic care Centre Maastricht (PcCM), MUMC+, 3. Department of General Practice, Women Studies Medicine, University Medical Centre St. Radboud, Nijmegen, The Netherlands, 4. Department of Clinical Epidemiology and Medical Technology Assessment & School for Public Health and Primary Care (CAPHRI), MUMC+, 5. Poliklinisch Continente Centrum, Haga Hospital, The Hague, The Netherlands, 6. Department of Clinical Epidemiology and Medical Technology Assessment; Department of Health Organisation, Policy, and Economics & School for Public Health and Primary Care (CAPHRI), MUMC+, 7. Integrated Care Unit; Department of General Practice & School for Public Health and Primary Care (CAPHRI), MUMC+

## EFFECTIVENESS OF INVOLVING A NURSE SPECIALIST FOR PATIENTS WITH URINARY INCONTINENCE IN PRIMARY CARE: RESULTS OF A PRAGMATIC MULTICENTRE RANDOMISED CONTROLLED TRIAL

### Hypothesis / aims of study

Treatment of urinary incontinence in primary care proves to be suboptimal.(1) We studied whether shifting care from general practitioner to nurse specialist for people with urinary incontinence improves severity and impact of urinary incontinence.(2)

### Study design, materials and methods

In a randomised controlled trial on patients of 18 years and up with urinary incontinence in the Netherlands we compared an intervention by the nurse specialist with care as usual by the general practitioner. The nurse specialist took over tasks from the general practitioner related to diagnostics, treatment and monitoring of patients.

The primary outcome is a severity sum score of urinary incontinence as validated by the International Consultation on Incontinence Questionnaire Short Form (ICIQ-UI SF).(3)

Based on a mean score on the ICIQ-UI SF of 7.18 (sd 6.64), and an expected improvement of two on the outcome scale from zero to 21 (which gives a delta value of  $2/6.64 = 0.301$ ), a power of 80% and a significance level of 0.05, and given the two-sided H1-hypothesis, that the new professional improves the effect, the needed number of patients per arm was 175.

Randomisation was computer-generated with allocation concealment. Blinding patients and health care providers was not possible. Statistical analysis was by intention-to-treat.

### Results

186 patients followed the intervention of the nurse specialist and 198 patients received care as usual. Overall, all patients improved significantly after three and 12 months ( $p < 0.001$ ), but the difference in ICIQ sum score between both groups after three and 12 months is not statistically significant (respectively  $p = 0.056$  and  $p = 0.151$ ). Controlling for type of urinary incontinence and baseline scores showed that compared to the control group the ICIQ sum score after three months significantly improved in the intervention group ( $p = 0.037$ ).

### Interpretation of results

An important finding of our study is that also the severe forms of urinary incontinence can profit from these interventions notwithstanding the generally accepted idea that especially the mild forms of urinary incontinence do profit most from bladder training and pelvic floor muscle training. Based on the fact that the nurse specialist fills a gap in the care for patients with urinary incontinence due to suboptimal care of general practitioners for this problem, that overall quality of urinary incontinence care has improved and that care by the nurse specialist was at least equal to care by general practitioners, also for severe forms of urinary incontinence, introduction of this new professional is feasible.

### Concluding message

Shifting of relevant care from general practitioners to nurse specialists reduces the severity and impact of urinary incontinence. Long term research on costs, barriers and facilitators for further implementation is needed.

### References

- Albers-Heitner P, Berghmans B, Nieman F, Lagro-Janssen T, Winkens R. Adherence to professional guidelines for patients with urinary incontinence by general practitioners: a cross-sectional study. *J Eval Clin Pract* 2008;14(5):807-811
- Laurant M, Reeves D, Hermens R, Braspenning J, Grol R, Sibbald B. Substitution of doctors by nurses in primary care: *Cochrane Database of Systematic Reviews*, 2004
- Avery K, Donovan J, Peters T, Shaw C, Gotoh M, Abrams P. ICI-Q: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol Urodyn* 2004;23(4):322-30

<b>Specify source of funding or grant</b>	<b>Funding</b> The Netherlands Organisation for Health Research and Development (ZonMw) funded this study, grant number 945-04-224.
<b>Is this a clinical trial?</b>	Yes
<b>Is this study registered in a public clinical trials registry?</b>	Yes
<b>Specify Name of Public Registry, Registration Number</b>	Current Controlled Trials ISRCTN62722772.
<b>What were the subjects in the study?</b>	HUMAN
<b>Was this study approved by an ethics committee?</b>	Yes
<b>Specify Name of Ethics Committee</b>	This study protocol was approved by the Medical Ethical Commission (MEC) of the University Maastricht and the University Hospital Maastricht, The Netherlands, by the MEC of UMCN Radboud, Nijmegen, The Netherlands, by the METC-ZWH The Hague, The Netherlands and by the MEC of QUARTZ, Elkerliek Hospital, Helmond, The Netherlands.
<b>Was the Declaration of Helsinki followed?</b>	Yes
<b>Was informed consent obtained from the patients?</b>	Yes