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RANDOMISED CONTROLLED TRIAL OF THE CLINICAL EFFECTIVENESS OF SERVICES FOR URINARY SYMPTOMS: SIX YEAR FOLLOW-UP

Hypothesis / aims of study

We undertook a randomised controlled trial (RCT) of a new continence nurse practitioner (CNP)-led service for urinary symptoms, with outcomes at 3 months and 6 months. The new CNP led service proved to be more effective with a 10% higher cure rate than standard care (SC) and showed statistically and clinically significant reductions in urgency, frequency and nocturia as well as incontinence. This presentation reports the long-term outcomes from this trial.

Study design, materials and methods

This study is a follow-up study of a 2-arm, non-blinded randomised controlled trial that recruited from a community based population between 1998-2000. All individuals were recruited to the original trial with one of more of the following symptoms: *incontinence* several times per month or more, *frequency*, hourly or more, *nocturia*, three times per nightor *urgency*, very strong or overwhelming. Randomisation to the trial was undertaken by household at a ratio of 4:1 (CNP:GP) The statistical programme SAS was used to generate the random allocation sequence and was implemented using sealed envelopes, numbered sequentially. The participants were randomised to receive either: a continence service provided by specially trained nurses delivering evidence-based interventions using pre-determined care pathways or standard care which comprised usual access to GP and existing continence services. Full details of study methods, interventions and 3 and 6 month outcomes have been reported previously. We followed-up the original participants using a postal questionnaire (with two reminders) between 5-7 years later (participants had been recruited over a 3 year period, mean time to follow-up was 6 years). The primary outcome was improvement in one or more symptoms of which cure (no symptoms) is a subset which was assessed using validated symptom severity questions, comprising the symptoms of incontinence, urgency, frequency and nocturia, obtained by postal questionnaire. Secondary outcome measures included: number of symptoms alleviated, a validated impact on quality of life scale, patient perception of problem, satisfaction with current symptoms and resource use.

Results

Of the 3746 individuals who took part in the original trial and therefore comprised our sample, 335 had died, 99 requested no further contact on completion of the original trial and 185 had migrated out of county, of the 3127 remaining a response rate of 87% (n=2728) was achieved following 3 mailings. There were no significant baseline differences in those originally recruited (n=3746) and those who were followed up (n=2728) in terms of age, gender, ethnicity, long term health or urinary symptoms. The randomised groups were also similar. The mean length of follow-up from baseline was 6 years. Overall at follow-up, significantly more individuals were improved (had fewer symptoms) in the CNP group (72%) than in the SC group (67%) (difference of 5% 95% CI=0.6 to 9;p=0.02) (Table 1). Positive changes in individual urinary symptoms (leakage, frequency, urgency and nocturia) that had been observed at 3 and 6 months, however were no longer significantly different between the two groups.

Table 1: Numbers of individuals with each symptom, no symptoms and improvement at 6 year follow-up.

	CNP		**SC**		**Diff 95%CI and p value**
	N total responder	**N with symptom**	**N total responder**	**N with symptom**	
Leakage	2093	1166 (56%)	580	334 (58%)	-2% (-6 to3;p=0.4)
Frequency	2098	290 (14%)	576	85 (15%)	-1% (-4 to2;p=0.6)
Urgency	2108	482 (23%)	583	153 (26%)	-3% (-7 to 0.6; p=0.09)
Nocturia	2106	437 (21%)	585	135 (23%)	-2% (-6 to 2; p=0.2)
Improved	2045	1530 (72%)	567	380 (67%)	**5% (0.6 to 9: p=0.02)**
Cure	2069	643 (31%)	571	156 (27%)	4% (-0.4 to 8;p=0.08)

Interpretation of results

The improvements in the CNP group shown immediately post treatment were maintained at 6 year follow-up, although the magnitude of the difference had decreased.

Concluding message

This is the first study to show the long term outcomes of nursing services on urinary storage symptoms. These findings may indicate that in order to maintain improvements within the new service an inexpensive 'top-up' intervention could be explored.

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HUMAN SUBJECTS: This study was approved by the Leicestershire Ethics Committee and followed the Declaration of Helsinki Informed consent was obtained from the patients.