

## CONSERVATIVE TREATMENT FOR URINARY INCONTINENCE IN WOMEN IN RESIDENTIAL CARE: OUTCOMES, QUALITY OF LIFE, AND COST

### Hypothesis / aims of study

To assess if conservative therapy can reduce the severity of leakage, and improve quality of life of elderly incontinent women in a rest home setting.

To assess benefits of this therapy in relation to costs

### Study design, materials and methods

Elderly women living in residential care, with urinary incontinence were identified by the rest home manager. Those with reasonable cognitive ability, defined as having a MiniMental Status score of >20/30, and ability to provide informed consent, were included. Those with other comorbidities were not excluded, as this was intended to be a 'real life' study. Signed informed consent was obtained. 26 resthomes participated.

Assessments by a specialist continence advisor nurse included clinical evaluation, bladder diary, 24-hour pad weigh test, and weekly pad usage. Quality of life questionnaires were administered by the continence advisor, and included: Functional Impairment Measure (FIM), Euroquol 5 dimension score (EQ-5D), and the International Consultation on Incontinence-Short Form (ICIQ-SF) [1]. Assessments were repeated after a 12-week course of conservative measures. The treatment package was tailored to the individual participant's needs by the continence advisor. It consisted basically of life style changes, pelvic floor muscle exercises and a medications review.

As each of the 26 rest homes had only a small number of participants, and a wide range of carers, randomization was not appropriate, and a 'before and after' study model was selected. The outcomes were a change from baseline. Differences of 0.5 of a standard deviation amount to about 1.5 leakages per day, 2.5 voids per day, and a change in score of 3 on the 0-18 ICIQ-SF scale. To detect a moderate difference of 0.5 of a standard deviation using a paired t-test, with alpha=0.05 with 90% power, 44 people studied before and after treatment, were needed. Because participants were clustered within rest homes a moderate design effect of 1.2 was used in the sample size calculation. This increased the numbers needed to 53.

Outcomes after 12 weeks of treatment were measured by repeating the above evaluations, and quality of life questionnaires. The costs of care involved in management as usual before the intervention were compared with those after it.

### Results

The research team visited 28 rest homes, of which only two did not wish to be involved. The Continence Advisor interviewed 119 women with urinary incontinence needing at least one pad per day, and 93 (78%) were suitable for and agreed to participate in the study. Twenty-five participants withdrew from the study at some stage after recruitment. Four participants died; six withdrew for health reasons, five for psychiatric reasons, and a further ten no longer wished to participate. 68 residents completed the study.

**Table 1. Bladder Storage symptoms**

	Week 1 (n=68)	Week12 (n=68)	Difference[95% CI]	p
Frequency	5.4 ± 1.9	5.2 ± 1.3	-0.22 [-0.61, 0.17]	0.266
Nocturia	2.0 ± 1.3	1.8 ± 1.1	-0.18 [-0.44 0.09]	0.190
Pad Weight (gms)	469 ± 469	408±455	-59.8 [-7.8, -111.8]	0.024
Pad Usage/week	24 ± 10.5	19.7 ± 9.6	-4.3 [-2.88, -5.74]	<0.0005
Post-void Residual Urine volume (cc)	34 ± 76.3	20 ± 42	-13.7 [-1.46, 26.00]	0.028

Paired analysis with adjustment for clustering within rest homes

**Table 2 Quality of life measures (mean ± SD)**

	Week 1 (n=68)	Week12 (n=68)	Difference [95% (CI)]	p
FIM	108.4 ± 8.7	109.6 ± 8.1	1.24 [0.28,2.20]	0.010
EQ-5D Score	0.58 ± 0.27	0.64 ± 0.26	0.05 [-0.01, 0.12]	0.094
EQ-5D VAS	61 ± 18	65.1 ± 18.1	4.06 [-0.04, 8.16]	0.052
ICIQ-SF	11.13 ± 3.12	8.29 ± 2.66	-2.84 [-1.96, -3.72]	<0.0005
ICIQ-SF Question #5	4.53±2.68	2.35±1.91	-2.18[-1.56, -2.79]	<0.0005

FIM Functional Impairment Measure

EQ-5D EuroQol quality of life 5 dimensional measure

ICIQ-SF International Consultation on Incontinence Questionnaire-Short Form

Note that a lower score in ICIQ-SF indicates an improvement.

**Table 3 Costs in 2013 NZ Dollars: Mean (SD)**

n=68	Week 1	Week 12	Difference [95% CI]	p
Pad Costs/week	14.90 ± 15.44	12.46 ± 13.60	-2.43 [-3.40,-1.46]	<0.0005
Carers' costs	10.42 ± 33.94	11.71 ± 33.72	-1.291[-6,103, 3.52]	0.5940
Costs/week Pads, Carers, Laundry	25.43 ± 38.50	24.28 ± 41.07	-1.17 [-3.29, 5.62]	0.608

Paired analysis with adjustment for clustering within rest homes. Advisor cost per participant was \$181.43 ( \$19.64). Pad costs are low because of a bulk purchasing arrangement for all resthomes.

#### Interpretation of results

Leakage was reduced by a mean of 60mls per 24 hours, and on average four fewer pads were required per week, as has been shown in other studies. [2]

Quality of life from the ICIQ-SF improved significantly ( $p < 0.0005$ ), but regression analysis showed no relation of this to reduced leakage or fewer pads being used. Quality of life in a resthome can improve due to a younger person visiting several times and showing an interest in their situation, quite apart from any benefit attributable to the intervention itself.

The EQ-5D, which is a key measure for estimation of Quality of Life Adjusted Year (QALY), did not demonstrate an improvement, so a cost-utility analysis could not be performed. Its sensitivity to change for this clinical problem in an elderly group of research participants has been questioned. [3].

The mean additional cost of the 12-week intervention including the advisor's costs, spread over a year plus pads, carers' time and additional laundry, was a modest \$NZ3.60 per resident per week above the cost of care as usual before the treatment.

#### Concluding message

Leakage was reduced by a statistically significant but modest mean of 60mls per 24 hours, and requiring on average four fewer pads per participant per week.

Quality of life from the ICIQ-SF improved significantly ( $p < 0.0005$ ) but regression analysis showed this was not related to reduced leakage or the fewer pads being used. The EQ-5D demonstrated no significant improvement so a cost-utility analysis could not be performed.

The mean additional cost of the 12-week intervention including the advisor's costs, spread over a year plus pads, carers' time and additional laundry, was a modest \$NZ3.60 per resident per week above the cost of care as usual before the treatment.

#### References

1. Wein AJ. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *JUrol* 2005; 173(3): 908-909
2. Vinsnes AG, Helbostad JL, Nyronning S, Harkless GE, Granbo R et al Effect of physical training on urinary incontinence: a randomised parallel group trial in nursing homes. *Clinical Interventions in Ageing* 2012 7: 45-50
3. Haywood KL, Garratt AM, Lall R, Smith JF, Lamb SE. EuroQol EQ-5D and condition-specific measures of health outcome in women with urinary incontinence: reliability, validity and responsiveness *Qual Life Res* 2008; 17:475–483

#### Disclosures

**Funding:** Canterbury District Health Board Urological Research Foundation **Clinical Trial:** Yes **Registration Number:** Australian and NZ Clinical Trials Registry ACTRN12614000087651 **RCT:** No **Subjects:** HUMAN **Ethics Committee:** The NZ Southern Health and Disability Ethics Committee (Upper Southern A Regional Ethics Committee) **Helsinki:** Yes **Informed Consent:** Yes