

Abstract Title:

CONTINENCE ACROSS CONTINENTS TO UPEND STIGMA AND DEPENDENCY (CACTUS-D): PRELIMINARY RESULTS OF AN INTERNATIONAL RANDOMIZED CONTROLLED TRIAL OF A CONTINENCE PROMOTION INTERVENTION.

Abstract Text:

Hypothesis / aims of study

Continence problems affect one in two women over 65 but only a minority either seek care or implement evidence-based conservative, pharmaceutical or surgical treatments [1]. Many believe that incontinence is a normal part of ageing and fail to realize that simple treatments and self-help improve urinary symptoms.

The CACTUS-D trial aimed to test the effectiveness of an integrated, evidence-based continence promotion intervention on urinary symptom improvement, quality of life, and care seeking among community-dwelling women aged 65 years and older suffering from incontinence in France, the UK, and Canada [2]. We hypothesized that women exposed to a community-based continence promotion intervention would experience improvements in urinary symptoms and incontinence-related quality of life, more frequently compared to women who were exposed to a general health information workshop. We planned to monitor the demand for care (GP visit and hospitalization).

Study design, materials and methods

CACTUS-D was an open-label cluster randomised controlled trial conducted across Canada, the UK, and France. Community-dwelling women were recruited via community groups (lunch clubs, older people's groups, women's institutes, church groups, etc.) or health insurance databases. Women were eligible if they were aged 65 years or older, reported urinary leakage of at least 2 times a week and were not treated for urinary incontinence in the previous year.

The experimental intervention was an integrated evidence-based continence promotion workshop that used constructivist learning and behaviour change techniques to encourage women with incontinence to initiate evidence-based self-management. The control was a general health information workshop that mentioned the prevalence of incontinence, but did not direct participants towards self-management options. Each community group (cluster) was randomized 1:1 with blinded group allocation to receive either the control or experimental intervention. The workshop (intervention or control) was delivered to groups of 6-30 women as a single 45-minute interactive session. Women were asked to fill in a questionnaire covering risk factors and continence status prior to the workshop. Participants in the intervention group received a self-management booklet. Within one week of the workshop participants were phoned by a research assistant, blinded to the intervention, for a more detailed follow-up. Participants were contacted at three and six months after the workshop. Self-reported improvements in incontinence were measured with the Global Impression of Improvement questionnaire. Urinary symptoms were measured with the ICIQ-FLUTS questionnaire (F-score for OAB symptoms and I-score for urinary incontinence symptoms). Urinary specific quality of life at all time points was measured with the I-QOL. Healthcare resource use (hospitalisation, treatment consultation) as well as falls were measured by self-report.

A target sample size of 1000 was required in order to detect a 20% clinically meaningful difference in urinary incontinence symptoms and quality of life between groups (improvement by 4,74 points). Enrollment ended December 2016. Comparison of changes in incontinence symptoms, Quality of life, and hospitalisation rates at six-month post-workshop between the intervention and control groups were determined by Mann-Whitney or Fisher's Exact Test. Risk differences between the intervention and control groups were calculated, along with 95% CI. Results were disaggregated by center.

Results

Preliminary results on 810 women at the six-month endpoint are included. There were 406 women in the intervention group and 404 in the control group. There was no significant difference between the 2 groups at baseline; the mean age and ranges of the women in each

group were 77.3 and 78.7 respectively; severity of incontinence was comparable with 36% and 40% of women leaking urine once per day or more in the intervention group and control group, respectively.

At 6-month follow-up, compared to the control group, more women exposed to the intervention reported an impression of improvement of their continence [38% (n= 154) improved versus 19% for controls (n= 78), RR= 2.0, 95% CI: 1.5/2.3, p< 0.0001]. ICIQ-FLUTS scores improved significantly in both groups, for F-score -1.0 [95% CI: -1.3/-0.8] and -1.0 [-1.2/-0.7] respectively, and for I-score -1.7 [-2.0/1.5] and -1.6 [-1.8/-1.3] respectively. The difference between groups was not significant for changes in OAB symptoms (difference in F-score: -0.07 point, 95% CI: -0.4 to +0.3, p= 0.80), and for changes in incontinence symptoms (difference in I-score: -0.1 point, 95% CI: -0.5 to +0.2, p= 0.34) between the intervention and control groups.

Urinary specific quality of life (I-QOL) was significantly improved at 6 months in both groups: +9.3 [+7.8/+10.9], and +9.6 points [+7.9/+11.3] respectively. Changes were similar in the intervention and control group (difference = -0.3 points, 95% CI: -2.5 to +2.0, p= 0.61).

Changes at 6 months	Overall	Alberta	Montréal Intervention vs. Control	London	Poitiers
Impression of improvement	38 vs. 19%*	29 vs. 11%*	41 vs. 23%*	42 vs. 23%*	27 vs. 10%*
Urinary specific QoL (I-QOL)	+9.3 vs.+9.6	+11.9 vs. +8.5	+11.2 vs. +10.4	+9.9 vs. +11.0	+1.2 vs. +5.8
OAB symptoms (F-score)	-1.0 vs. -1.0	-1.2 vs. -1.2	-1.0 vs. -1.0	-1.2 vs. -1.3	-1.0 vs. -0.5
UI symptoms (I-score)	-1.7 vs. -1.6	-1.9 vs. -1.5	-1.9 vs. -2.0	-1.5 vs. -1.2	-1.4 vs.-0.7
Hospitalization rate	5 vs. 10%*	4 vs. 2%	7 vs. 8%	5 vs. 18%*	3 vs. 12%

Table: Changes in the intervention and control groups (% or mean, * if p< 0.05)

Women in the intervention group reported significantly lower hospitalization rates in the last 3 months than those in the control group (intervention group: 5% (n= 22) versus control group: 10% (n= 39, RR= 0.6, 95% CI 0.3/0.9, p= 0.02).

No differences were detectable in GP visits for UI [7% (n= 27) in the intervention group versus 7% (n= 27) in the control group; RR = 1.0, 95% CI: 0.6/1.6, p= 0.92].

Interpretation of results

The self-management tools delivered during the promotion workshop may explain that more women in the intervention group reported an impression of improvement despite no significant difference on symptoms.

Concluding message

A single continence promotion intervention delivered to groups of older women significantly induced an impression of improvement.

There was no difference between the continence promotion and general health workshop's effect on urinary incontinence severity.