

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

Hypothesis / aims of study

This study aims to show that continence promotion has potential to improve the care and quality of life of older community-dwelling women suffering from incontinence across different countries. The hypothesis is that women exposed to the continence promotion intervention will experience improvements in continence status and quality of life compared to women who experience a sham general health information workshop, regardless of their country and culture of origin.

For the first time a standardized continence promotion intervention for community-dwelling older women has been investigated internationally. The CACTUS-D project is an open-label cluster randomized controlled trial to test the effectiveness of an integrated, evidence-based continence promotion intervention for women age 65 and over across Canada, the UK and France.

Study design, materials and methods

This international study was conducted in Canada, the UK and France and the programme took place in English or French according to the locality. Community-dwelling women were recruited via community groups (lunch clubs, older people's groups, women's institutes, church groups etc.). Women were eligible to enrol in the trial if they were aged 65 years or older, reported urinary leakage of at least 2 to 3 times a week and were not treated for urinary incontinence in the previous year. Incontinence frequency was measured with the ICIQ-FLUTS. Two interactive workshops were developed; 1) An experimental continence promotion workshop that used constructivist learning and behaviour change techniques to encourage women with incontinence to initiate evidence-based self-management and/or consult for treatment. 2) A control sham general health information workshop. Each community group (cluster) was randomized 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 were provided with a falls diary and, in the case of the intervention group, a self-management booklet. Within one week of the workshop participants were phoned by an independent research assistant who was blinded to the intervention for a more detailed follow-up. Participants were re-contacted at three months and six months post-workshop. Self-reported improvements in incontinence were measured with the Global Impression of Improvement questionnaire. Quality of life at all time points was measured with the I-QOL. Healthcare resource use (hospitalization, treatment consultation) as well as falls were also measured by self-report. Recruitment is in progress and is 50% complete. A target sample size of 1000 is required in order to detect a clinically meaningful difference in urinary incontinence symptoms, falls incidence and quality of life between groups at 1 year. Comparison of changes in incontinence symptoms, belief on incontinence in ageing, hospitalization rates, falls rates at six months post-workshop between the intervention and control groups were determined by Chi-square analyses. Comparison of changes in quality of life between the two groups was determined by ANCOVA for repeated measures after correction for the group.

Results

Preliminary results on 174 women, representing almost 20% of the final sample size at six months stage are presented; compared to the control group, women exposed to the intervention workshop reported an overall significant improvement in self-reported incontinence symptoms six months post-workshop ($p=0.01$). Women reporting urine loss 2 to 3 times weekly at baseline showed the greatest improvement: 53% reported an improvement in their condition compared to 16% of the control group ($p=0.01$). Women in the intervention group reported significantly lower hospitalization rates than those in the control group (intervention group: 1% vs control group: 14%). No significant differences were observed among women with more severe incontinence, and no differences were detectable in rates of falls, change of quality of life or in rates of treatment consultation between the two groups in preliminary analyses. The continence promotion intervention was also successful in challenging the belief that incontinence is a normal part of ageing with 24% of women in the intervention group changing their mind about the inevitability of incontinence, compared to 9% number of women in the control group. Each country showed the same trends for all reported results.

Interpretation of results

Women with urine leakage 2-3 times weekly demonstrated the greatest rates of improvement in incontinence symptoms, compared to the control group at 6-months post-intervention. This could be due to the nature of the intervention which has a strong focus on self-management. Women are encouraged to try a number of different self-help strategies sequentially and to seek medical help if problems persist. It seems likely that the more severely affected women may take longer to benefit from the workshops as they may try a number of self-help strategies before consulting for treatment.

Concluding message

A single continence promotion intervention delivered to groups of older women by trained facilitators can significantly improve continence status in community-dwelling women aged 65 and over.

Disclosures

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de la recherche de l'Institut universitaire de gériatrie de Montréal Comité de protection des personnes de l'Institut National de la Santé et de la Recherche Médicale (INSERM) Human Research Ethics Board, University of Alberta. **Helsinki:** Yes **Informed Consent:** Yes