**PRIZE AWARD: Best Clinical Abstract**

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# CLUSTER RANDOMIZATION TRIAL OF THREE DIFFERENT COMMUNITY-BASED CONTINENCE PROMOTION INTERVENTIONS TO IMPROVE URINARY INCONTINENCE AMONG UNTREATED OLDER WOMEN

Hypothesis / aims of study

Continence organizations worldwide use media campaigns, information brochures and public awareness lectures to de-stigmatize incontinence and promote symptom improvement among untreated individuals. The effectiveness of these strategies to improve incontinence remains unknown. The impact of continence promotion efforts could be maximized if data from randomized trials were available to better inform the delivery of evidence-based, effective interventions. The aim of this study was to use the rigour of a randomized controlled trial to compare the effects of three continence promotion interventions against a control condition on urinary symptom improvement in untreated community-dwelling older women with incontinence. We hypothesized that a strategy combining constructivist learning theory with distribution of an evidence-based self-management tool would yield the greatest improvement in incontinence symptoms, measured at the level of the individual, 3-months post-intervention.

Study design:

An open-label cluster-randomized controlled trial comparing three continence promotion interventions and one control condition was conducted. Randomization was at the level of each community organisation, from whence participants were recruited. Randomization was conducted according to computer-generated random digits at a distant study site, balanced in non-stratified blocks of four. Although allocation of the intervention was blinded at the time of randomization, the study is open-label because both the research facilitator who delivered the intervention and the participants who received it were aware of which intervention was being delivered.

Setting: Seventy-one seniors' or women's community organisations throughout the UK.

Participants: Inclusion criteria for clusters included any community-based seniors' or women's organization throughout the UK that consented to participate. All members of the organization were welcome to attend the intervention. Only women aged 60+ with urinary incontinence (UI) at least once weekly on the International Consultation on Incontinence Questionnaire (ICIQ) and who had never sought care were eligible to enrol in the trial.

Interventions: The three interventions to be tested were a constructivist learning workshop on incontinence, the delivery of an evidence-based risk factor reduction self-management (SM) tool for incontinence, and a combined intervention that included both components. The control intervention was a lecture on health promotion for older women that addressed topics other than incontinence. All interventions were delivered in group format and lasted 60 minutes.

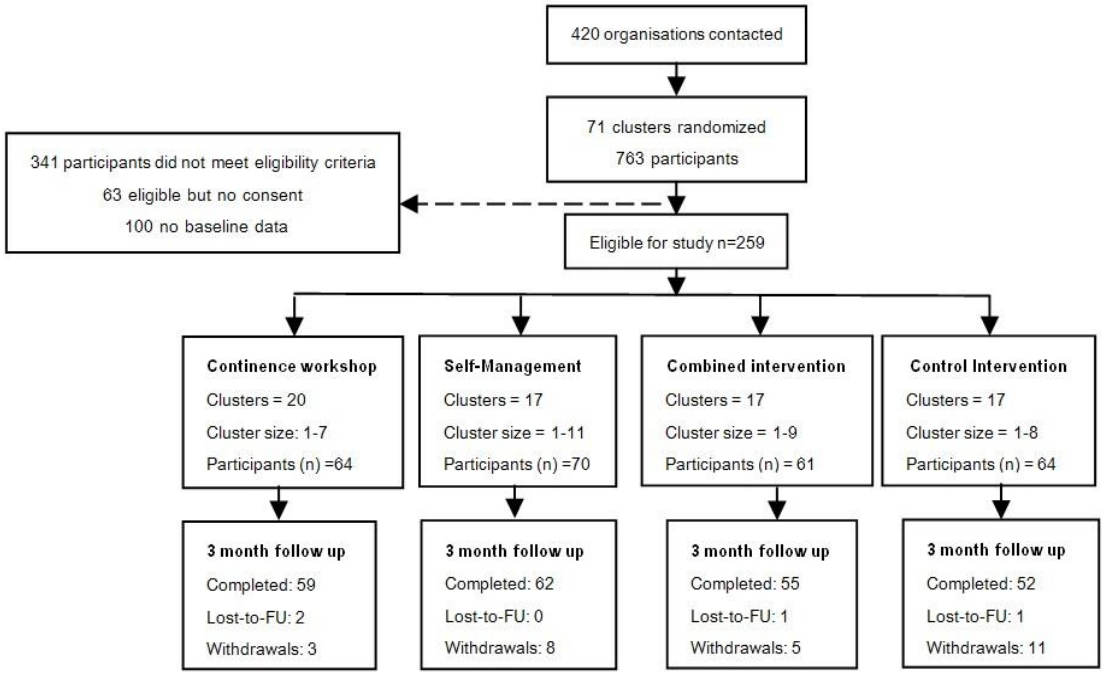
Main outcome measures: The primary outcome was the participant's global impression of improvement (PGI-I) in UI 3 months post-intervention.

Sample size and analysis: The trial was designed to detect a minimal 35% difference in the number of participants reporting any improvement between the experimental and control conditions, assuming a rate of improvement in the control condition as high as 20%, with 80% power and alpha 0.05 two-sided (n=34). Using an inflation factor of 1.65 to account for an intracluster correlation (ICC) of 0.05 and unequal cluster size yielded a recruitment target of 56 participants per group. Two analyses were performed. In the first we estimated the unadjusted risk difference (prevalence of the outcome) with 95% confidence intervals (CI) for patients who reported any improvement on the PGI-I, as well as for those who reported being very much better or much better (defined as a significant improvement). Generalized estimating equations (GEE) with an identity link and an exchangeable correlation structure were used to account for correlation between women in the same organization. To adjust for the imbalance in potential confounders in the groups at baseline, analyses were conducted using logistic regression estimated via GEE with an exchangeable correlation structure, and controlled for age as a continuous predictor, and living alone, depression, heart disease, falls, arthritis, diabetes, high blood pressure, educational status and general health perception as dichotomous predictors. Both intent-to-treat (ITT) and per protocol analyses were performed. For the ITT analysis, participants with missing data were assumed to have no change in UI.

Results

Two-hundred and fifty-nine women participated in the trial (Figure 1). Participants had a mean age of 72.6 $\pm$ 7.5 years (range 60-95), and a mean ICIQ score of 7.3 $\pm$ 3.7.

**Figure 1:** Study flow




The combined intervention was most effective for reducing urinary symptoms with a 55% and a 23% prevalence difference for any or significant improvement respectively compared to controls at 3 months post-intervention (Table 1). The likelihood of reporting significant improvement was 6.27 times higher (95% CI 2.23-17.67) among participants who received the combined intervention compared to controls in adjusted logistic regression analyses.

**Table 1:** Prevalence of participants who reported improvements in incontinence by group

| | **Prevalence at 3-month follow-up** | | | | **Prevalence difference (95% CI)** | | |
|---|---|---|---|---|---|---|---|
| | Workshop | SM | Combined | Control | Workshop vs control | SM vs control | Combined vs control |
| **Any improvement** | | | | | | | |
| Intention-to-treat | 0.59 | 0.41 | 0.66 | 0.11 | 0.48 (0.33-0.64 | 0.28 (0.08-0.48) | .55 (0.43-0.67) |
| Per protocol | 0.64 | 0.47 | 0.73 | 0.13 | 0.51 (0.34-0.67) | 0.29 (0.07-0.51) | 0.59 (0.45-0.74) |
| Number needed to treat ITT (n) | - | - | - | - | 3 | 4 | 2 |
| ICC | - | - | - | - | 0.025 | 0.25 | 0 |
| **Very much better or much better** | | | | | | | |
| Intention-to-treat | 0.22 | 0.21 | 0.30 | 0.06 | 0.16 (0.03-0.29) | 0.14 (0.01-0.27) | 0.23 (0.10-0.36) |
| Per protocol | 0.24 | 0.24 | 0.33 | 0.08 | 0.16 0.02-0.30) | 0.15 (0.00-0.29) | 0.26 (0.10-0.42) |
| Number needed to treat ITT (n) | - | - | - | - | 7 | 8 | 5 |
| ICC | - | - | - | - | 0.009 | 0.084 | 0.024 |

Interpretation of results: A community intervention that combines constructivist learning for incontinence and self-management techniques for risk factor reduction yields a number-needed-to-treat of 2 and 5 for any or significant improvements in incontinence respectively.

Concluding message: Level 1 evidence now exists to inform the effective delivery of continence promotion interventions to untreated older women with incontinence.

Disclosures
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