Effectiveness of continence promotion for older women via community organisations: a cluster randomised trial

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-004135
Article Type:	Research
Date Submitted by the Author:	27-Sep-2013
Complete List of Authors:	Tannenbaum, Cara; Université de Montréal, Faculty of Medicine Agnew, Rona; Glasgow Caledonian University, Benedetti, Andrea; McGill University, Departments of Medicine and of Epidemiology, Biostatistics & Occupational Health Thomas, Doneal; McGill University, Departments of Medicine and of Epidemiology, Biostatistics & Occupational Health van den Heuvel, Eleanor; Brunel University,
Primary Subject Heading:	Urology
Secondary Subject Heading:	Geriatric medicine
Keywords:	Urinary incontinences < UROLOGY, PUBLIC HEALTH, GERIATRIC MEDICINE

Effectiveness of continence promotion for older women via community organisations: a cluster randomised trial

Cara Tannenbaum, MD, MSc[1] Rona Agnew, PhD[2] Andrea Benedetti, PhD[3] Doneal Thomas, MSc[4] Eleanor van den Heuvel, PhD[5]

[1]Associate Professor, Faculty of Medicine, Université de Montréal, Quebec, Canada
[2]Clinical Research Fellow, Glasgow Caledonian University, Glasgow, UK
[3]Associate Professor, Departments of Medicine and of Epidemiology, Biostatistics & Occupational Health, McGill University, Quebec, Canada
[4]PhD candidate, Department of Epidemiology, Biostatistics & Occupational Health, McGill University, Quebec, Canada
[5]Director of Assistive Technology Programme, Brunel Institute for Ageing Studies, Brunel University, Uxbridge, UK

Word count : 3182

Key words: Continence promotion, cluster trial, community organisations, older women, urinary incontinence

Corresponding Author: Dr. Cara Tannenbaum, Centre de Recherche de l'Institut universitaire de gériatrie de Montréal, 4545 Queen Mary Road, Montreal, Quebec, Canada H3W 1W5. Tel (514) 340-2800. Fax : (514) 340-3530.
Email: cara.tannenbaum@umontreal.ca

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

The authors retained full independence from the study sponsors in the design, implementation, analysis, interpretation and reporting of the findings.

ABSTRACT

Objectives: The primary objective of this cluster randomised controlled trial was to compare the effectiveness of the three experimental continence promotion interventions against a control intervention on urinary symptom improvement in older women with untreated incontinence recruited from community organisations. A second objective was to determine whether changes in incontinence-related knowledge, new uptake of risk-modifying behaviours explained these improvements.

Setting: 71 community organisations across the United Kingdom

Participants: 259 women aged 60 years with untreated incontinence entered the trial; 88% completed the 3-month follow-up.

Interventions: The three active interventions consisted of a single 60-minute group workshop on 1) continence education (20 clusters, 64 women); 2) evidence-based self-management (17 clusters, 70 women); or 3) combined education and self-management (17 clusters, 61 women). The control intervention was a single 60-minute educational group workshop on memory loss, polypharmacy and osteoporosis (17 clusters, 64 women).

Primary and secondary outcome measures: The primary outcome was self-reported improvement in incontinence 3 months post-intervention at the level of the individual. Changes in incontinence-related knowledge and behaviours were also assessed.

Results: The highest rate of urinary symptom improvement occurred in the combined intervention group (66% vs 11% of the control group, prevalence difference 55%, 95% CI 43%-67%, intracluster correlation 0). Thirty percent versus 6% of participants reported significant improvement respectively (prevalence difference 23%, 95% CI 10%-36%, intracluster correlation 0). The number-needed-to-treat was 2 to achieve any improvement in incontinence symptoms, and 5 to attain significant improvement. Changes in knowledge and self-reported risk-reduction behaviours paralleled rates of improvement in all intervention arms.

Conclusion: Continence education combined with evidence-based self-management improves symptoms of incontinence among untreated older women. Community organisations represent an untapped vector for delivering effective continence promotion interventions.

Trial registration: ClinicalTrials.gov ID number NCT01239836

Article Summary : Strengths and limitations of this study

- First study to provide Level 1 evidence that continence promotion is an effective strategy for improving urinary symptoms among untreated community-dwelling older women
- Participants were recruited via community organisations with representation across diverse socio-economic strata
- Rates of knowledge acquisition and behaviour change provide an explanatory mechanism for the observed improvements in incontinence in participants receiving the education combined with the self-management strategy
- Only self-reported outcomes and crude dichotomous measures of behaviour change were collected so results must be interpreted with caution

Introduction

Urinary incontinence is more frequent than breast cancer, heart disease or diabetes among older women, but remains a stigmatized and untreated condition despite its high prevalence**.** [1-4] In the United States, Canada, the U.K. and other European countries, up to 40% of women aged 65 years and older experience involuntary urine leakage, but little more than 15-30% seek care.[1-4] Even fewer physicians feel competent evaluating or treating incontinence.[5-6] Urinary incontinence is associated with obesity, cardiovascular disease, diabetes, depression, social isolation, decline in function, falls, nursing home admission, and onerous out-of-pocket expenses.[6-10] In many cases incontinence can be improved, and even cured, when evidence-based diagnostic and treatment strategies are appropriately applied.[6,11-14]

It is a commonly held misconception that incontinence is a normal part of aging.[15] Not-for-profit organisations seek to raise continence awareness worldwide and promote treatment for incontinent individuals. Media campaigns, brochures and public awareness lectures attempt to de-stigmatise incontinence and increase help-seeking, but the effectiveness of these initiatives for reaching their target population remains unknown.[15] Transmission of public health education via community organisations is an unexplored strategy for improving urinary symptoms.[16] Data from randomised trials are needed to determine whether the delivery of an evidence-based, continence intervention via community organisations is an effective method for treating incontinence.

The primary objective of this cluster randomised controlled trial was to compare the effectiveness of the three experimental continence promotion interventions against a control intervention on urinary symptom improvement in older women with untreated incontinence recruited from community organisations. A second objective was to determine whether changes in incontinence-related knowledge, attitudes and new uptake of risk-modifying behaviours explained improvements in incontinence. We hypothesized that continence education combined with evidence-based self-management would yield the greatest improvement in incontinence symptoms, measured at the level of the individual, 3-months post-intervention.

METHODS

Study design and oversight

A 4 arm, parallel-group, controlled, cluster randomised trial was conducted. The study design, recruitment methods and interventions have been reported.[16] Clustering was at the level of the community organisation, from whence participants were recruited. The choice of a cluster design served to prevent contamination between participants in the same community organisation. The trial was designed by two of the authors and was overseen by the full investigator team, which had full access to the data. The data were collected at community organisations across the United Kingdom. All participants provided written informed consent. The protocol was approved by the Brunel University Research Ethics Committee.

Study population and recruitment

Inclusion criteria for community organisations included any organisation throughout the United Kingdom that consented to participate in the trial between November 2010 and September 2012. A community organisation was loosely defined as any not-for-profit group of individuals with a shared interest. These included interest and charity groups, seniors' housing groups, women's lobby groups and Asian caregiver associations.[16] Organisations were contacted strategically by convenience sampling, word of mouth and referral. A research coordinator approached community organisations to join the trial by telephone, email and newspaper advertising.

Inclusion criteria for participants were women aged 60 years and older who reported urinary incontinence at least once weekly on the International Consultation on Incontinence Questionnaire (ICIQ), and who were not under active treatment for incontinence. For privacy reasons, many community organisations were uncomfortable screening their members for incontinence in advance, so eligibility to participate in the trial could only be ascertained by the research coordinator on the day of delivery of the intervention.[16] Eligibility to participate in the trial was established by asking all attendees at the workshop to complete a baseline screening questionnaire upon arrival. At this time, a study information sheet and consent form were distributed to all participants. All women, regardless of eligibility or desire to enrol in

the trial, were permitted to stay for the workshop. Only those women who wished to enrol in the trial submitted the signed consent form to the workshop facilitator following delivery of the intervention, however all attendees were encouraged to submit the baseline screening questionnaire even if they were continent or did not want to participate in the trial.

Interventions

The interventions were applied at the level of each cluster. The three experimental interventions to be tested were continence education, self-management including the distribution of an evidence-based risk factor reduction tool for incontinence, and a combined intervention that included both components. The sham control intervention was a lecture on health promotion for older women that addressed topics other than incontinence. All interventions were delivered once in group format to 8-16 women by the same facilitator at a venue of the organisation's choosing, and lasted 60-90 minutes. A slide presentation with a pre-established script prepared for the facilitator was delivered at each workshop.

The continence promotion intervention incorporated elements of constructivist learning that challenged older adults' erroneous beliefs about accepting incontinence as a normal part of aging, and aimed to change attitudes and create new knowledge about the different types, etiology, risk factors and treatment options for urine loss.[16-17] The self-management workshop reviewed self-management theory in an interactive format, and provided a customised evidence-based self-management program for risk factor modification for incontinence to each participant.[18-19] The program targeted pelvic floor muscle weakness, obesity, consumption of caffeinated beverages, smoking, vision loss and constipation, with instructions on how to keep a bladder diary to help monitor symptoms. The content of the combined intervention condensed elements from the continence promotion workshop along with self-management theory, and provided the customized self-management tool to participants. The control intervention addressed other non-bladder related aspects of older women's health such as memory problems, polypharmacy, osteoporosis, nutrition, physical fitness and vision impairment.

Study Outcomes

The primary outcome was the participant's global impression of improvement in incontinence symptoms, measured at 3 months post-intervention by telephone interview using the patient's global impression of improvement (PGI-I) questionnaire. The PGI-I is a validated, single-item global rating of change scale that asks the patient to describe how their incontinence condition is now compared to how it was prior to the intervention (very much better, much better, a little bit better, no change, a little bit worse, much worse and very much worse).[20] The primary outcome, any improvement, was defined as a rating of a little bit better, much better or very much better. A secondary outcome, significant improvement, was defined as much better or very much better. The ICIQ, which measures the frequency, severity and bother from incontinence was used at baseline to screen participants for inclusion to the trial, and was repeated at follow-up.[21] The ICIQ diagnostic item was used by participants to describe the type of incontinence at baseline. A pre- and post-8-item questionnaire on knowledge and attitudes towards incontinence was administered at baseline and at 3-month follow-up, as were risk factors and behaviors related to incontinence.[17] Risk factors and behaviors included performance of pelvic floor muscle exercises three times weekly (yes, no), daily consumption of 1 cup or more of tea or coffee (yes, no), fluid intake > 1.5 L/day (yes, no), weight and height (self-report) and smoking status (yes, no). At three month follow-up participants were asked whether they had sought treatment for urine leakage during the past 3 months. All follow-up interviews were performed by the research coordinator, who was blinded to participant identification.

Randomisation and allocation concealment

Group allocation occurred by non-stratified randomisation in blocked groups of 4 of consenting organisations that agreed to host a workshop. An independent statistician at a distant study site was responsible for randomisation using computer-generated random digits. Community organisations were informed that one of four workshops would be delivered on health topics of interest to older women, but not which one. In this way, group allocation was concealed from both the clusters and the individual participants, who were invited by the host organisation to attend a "Women's Health Worshop". The research coordinator remained unaware of group allocation at the

time each community organisation was recruited to the trial because she was only informed which workshop to prepare for each organisation several days before each workshop. The trial is considered 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.

Sample Size

The trial was designed to detect a minimal 35% difference in the number of participants reporting any improvement (very much better, much better, a little bit better on the PGI-I) 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 anticipated maximum intracluster correlation (ICC) of 0.05 and unequal cluster size yielded a recruitment target of 56 participants per group.[22]

Statistical Methods

Differences in baseline characteristics between the four groups were determined. To assess the primary outcome we estimated the unadjusted risk difference (prevalence of the outcome) and 95% confidence intervals (CI) via generalized estimating equations (GEEs) for participants who reported any improvement on the PGI-I. We repeated the same analysis for those who reported significant improvement. GEEs with an identity link and an exchangeable correlation structure were used to account for possible correlation between women in the same organisation.[23] To adjust for the imbalance in potential confounders in the groups at baseline, additional analyses were conducted using multivariable logistic regression estimated via GEE with an exchangeable correlation structure. Potential confounders included age and baseline incontinence severity (ICIQ score) as continuous predictors, 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 (PP) analyses were performed. For the ITT analysis, participants with missing data were assumed to have no change in incontinence status at three-month follow-up. The number needed to treat was calculated as the inverse of the difference in absolute event rates between the experimental and control groups.[24] We report intra-cluster (intra-community organisation) correlation

coefficients (ICC) from the marginal model using GEE with assumed exchangeable correlation structure and robust standard errors.[25] To estimate adjusted mean group differences in ICIQ scores from baseline to 3-month follow up, we used GEE with a Gaussian regression model for continuous outcomes and followed the same procedure outlined above.

Improvements in incontinence-related knowledge by intervention type for proportions of individuals responding correctly to each knowledge questionnaire item at baseline compared to 3-month follow-up were estimated using McNemar's test for matched pair analysis. Rates of improvement in self-reported risk modifying behaviours for incontinence were calculated, along with 95% confidence intervals. Differences in improvement rates between the intervention and the control group were compared using Fisher's Exact test using a per protocol analysis. A difference in response for each health behavior item that indicated adoption of a new risk modifying behaviour was defined as a positive change at 3-month follow-up compared to baseline. Reduced coffee and tea intake refer to individuals who reduced their consumption to a single cup per day or less. Weight loss was determined by a positive response to the question, "Has your weight changed (yes, no) and if so, how much do you now weigh?" and evidence of self-reported current weight lower than self-reported weight at baseline. All statistical analyses were run using RStudio 0.97.310.0, an integrated development environment for R.

RESULTS

Study participants and follow-up

Four-hundred-and-twenty different community organisations were approached over an 18-month period to participate in the trial. Of these, 17% consented and succeeded in hosting an intervention, yielding 71 clusters that were randomised. Approximately one quarter of the groups contacted refused; 2% expressed interest but were unable to organise a workshop; and a little over half failed to give any response although most of them had been followed up and had received extra information on the project.[16] Figure 1 depicts the study flow of the clusters and participants through the trial. Seven-hundred-and-sixty three women attended the workshops, of whom 322 (42%) were known to be eligible for the trial. The mean number of participants recruited

from each cluster for the continence promotion group was 3 ± 2, whereas it was 4 ± 2 for the other 3 groups. Eighty-percent (259/322) of known eligible attendees to the workshops consented to take part in the trial. Two-hundred-and-twenty-eight of these (88%) were available for 3-month follow-up. Table 1 compares the baseline characteristics of participants in each trial arm.

Primary outcomes

The highest rate of improvement in incontinence occurred in the combined intervention group, 66% compared to 11% in the control group (prevalence difference 55%, 95% CI 43%-67%), yielding a number-needed-to-treat of 2. Thirty percent of the combined group reported significant improvement compared to 6% of controls (prevalence difference 23%, 95% CI10%-36%, number-needed-to-treat of 5). In adjusted analyses, the likelihood of achieving a significant improvement in urinary symptoms from exposure to the combined intervention was five times greater than exposure to the control intervention (OR 4.94, 95% CI 1.45-16.86). Compared to controls, the participants in the combined intervention reported an adjusted mean 2.05 point (95% CI 0.87-3.24) greater improvement on the ICIQ from baseline to 3-month follow up. The adjusted mean difference in ICIQ scores was also significantly higher for the continence education group compared to the control group (1.33 point greater improvement (95% CI 0.33-2.32)), but not for the self-management group. The per protocol analysis for the primary outcome and the intra-cluster correlation coefficients for each analysis are shown in Table 2.

Key secondary outcomes

Table 3 shows the changes in incontinence-related knowledge attributable to receipt of each intervention. Participants exposed to the combined intervention showed the greatest acquisition in knowledge, exhibiting significant within-group improvement on 6 out of 8 questionnaire items. Participants learned that incontinence is not an inevitable or irreversible part of aging, that losing weight, changing the type of fluid intake and performing pelvic floor muscle exercises can reduce urinary symptoms, and that wearing undergarment protection is not always the best way to manage incontinence.

The proportion of participants with modifiable risk factors for incontinence in each group at baseline is shown in Table 1. The adoption of various risk-modifying behaviours among participants occurred to a different degree as a result of exposure to all three experimental but not the control intervention (Figure 2). At three-month follow-up, the proportion of women reporting uptake of pelvic floor muscle exercises and weight loss was significantly higher in the continence education group (46% and 20% respectively), the self-management group (34% and 20%) and the combined intervention group (53% and 18%) compared to controls (8% and 3%). Many women additionally reduced their coffee intake and total fluid intake. The proportion of women who made an appointment to consult a health professional for urine leakage was 19% in the continence promotion group, 7% in the self-management group, 16% in the combined intervention group and 4% in the control group.

DISCUSSION

In this cluster-randomised trial testing the effectiveness of 3 different continence promotion interventions, we found that health education combined with the delivery of an evidence-based self-management tool via community organisations to untreated older women yielded the highest rate of urinary symptom improvement in 66% of recipients, half of whom reported significant improvements in incontinence. These outcomes translate into a number-needed-to-treat of 2 and 5 respectively, a magnitude of effect rarely achieved during public health interventions. Both new knowledge acquisition and the adoption of risk-modifying behaviours such as exercise and weight loss occurred as a result of community organisations' involvement in reaching untreated incontinent women outside the health care system.

Strengths and weaknesses of the study

This is the first randomised trial to test the effectiveness of continence promotion strategies through community outreach. Both explanatory mechanisms and final health outcomes were assessed, and the use of a cluster randomised design was chosen to avoid contamination of the control group.[26,27] Our choice of comparator controlled for the placebo effect of participating in a group intervention. Breaches in the fidelity and quality of implementation of the intervention were minimized by

having the same facilitator deliver each intervention. Improvements in urinary symptoms were shown with two validated measures, the PGI-I and the ICIQ. We believe the results have wide external validity as the community groups included women with varied educational levels and wide socioeconomic status.

The results of this study confirm findings from previous randomised trials suggesting a positive effect of continence education and self-monitoring strategies on urinary symptom improvement in untreated incontinent individuals.[28-33] However all previous trials invited participants for clinical assessments prior to the delivery of the intervention, or involved individualized education sessions. The current trial delivered group continence interventions without medical or nursing evaluations, in a true public health approach, to both continent and incontinent women as part of the regular activities offered by each community organisation. Rates of improvement reported in this trial on the PGI-I were similar to or exceeded those reported in other studies using self-help booklets, in the range of 50%. Because of the nature of recruitment and delivery of the intervention via community organisations, bladder diaries and pad tests could not be collected at baseline. The results of our trial can therefore not be directly compared to other trials that used more objective measures of symptom improvement.

Other limitations apply. Due to the nature of recruiting potential participants, individuals could not be screened and enrolled in the trial prior to randomisation of the clusters.[27] The result was an imbalance between groups, accounted for by analyses that took into account group differences in age, health status and baseline incontinence severity. The trial was not designed to measure the dose-response of knowledge acquisition and behaviour change on urinary symptom improvement. Thus only crude, dichotomous self-reported measures of behaviour change were collected and should be interpreted with caution.

Relevance to the discipline

The value of continence promotion interventions likely reflects the delivery method as well as the quality of the content. Group interventions that deliver continence education, self-management information, or a combination of the two will improve incontinence symptoms in 59%, 41% and 66% of recipients, respectively. It is surprising that the self-management intervention alone was not associated with

significant improvement compared to sham control in this trial. This can potentially be explained by the fact that continence education was completely omitted from the self-management workshop, whereas some information on bladder functioning was provided to participants during the initial work that tested the self-management tool.[19]

Implications for practice

Implementation of community-based programs that promote behavioural techniques as first-line management for incontinence support evidence for the superior efficacy and tolerability of conservative management approaches over pharmacological treatment for incontinence.[34] As "silent sufferers" become better informed that effective strategies exist for improving urinary symptoms, patient demand for care will likely increase. Almost 20% of women made an appointment to discuss urine leakage with a health professional in the three months following receipt of the continence education intervention. Evidence-based guidelines exist for physicians to evaluate and manage urinary incontinence when first-line behavioural strategies fail, and will need to be more frequently applied.[5,11]

In conclusion, continence education combined with self-management delivered via community organisations to untreated older women with incontinence leads to symptom improvement in 1 out of every 2 recipients. At the current time, the majority of older women with incontinence do not seek care, and either self-manage their symptoms inappropriately or use protection to palliate urine leakage.[1-4] As incontinence is associated with multimorbidity and other deleterious health effects, results from this trial provide strong justification for public health outreach via community organisations to reduce urine leakage among untreated individuals.

Acknowledgments

We wish to acknowledge the assistance of Mira Jabbour and Francine Giroux for their expert help with database management and the data analyses. Nikki Cotterill, Adele Long aided with recruitment in the Bristol area. The above-mentioned individuals received financial compensation for their contribution to this work. We express gratitude to all the participants who took part in this trial. Although not exhaustive, particular thanks are offered to the following organisations and groups for participating in the trial: the Women's Institute, AGE UK, the University of the Third Age, Queens Nursing Institute (Scotland), Kinship Carers, the Women's Guild, Hanover Housing Association, Good Neighbours, Asian Carers Groups, Older Peoples Forum throughout the UK.

Author Contribution Statement

Cara Tannenbaum designed the study and participated in the data analysis and interpretation. She wrote the first draft of the manuscript. Rona Agnew was responsible for data collection, participated in the data analysis and interpretation and critically reviewed the manuscript. Andrea Benedetti was responsible for the data analysis and interpretation and critically reviewed the manuscript. Doneal Thomas conducted the analyses and reviewed the manuscript. Eleanor van den Heuvel helped design the study, participated in the study implementation, helped interpret the findings and critically reviewed the manuscript.

Data Access and Sharing Statement

Cara Tannenbaum, Doneal Thomas and Andrea Benedetti had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Patient level data and the full dataset is available upon request from the authors. Consent for data sharing was not obtained but the presented data are anonymised and the risk of identification is low.

Competing interests

Cara Tannenbaum declares having been an advisory board member or received speaker honoraria from Pfizer, Watson, Astellas, Allergen and Ferring pharmaceuticals in the past 3 years, but not in relation to this work. All other authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

Funding and Sponsor's Role

The trial was funded by a joint collaboration between the Canadian Institutes of Health Research and the Economic and Social Research Council (UK). The authors retained full independence from the study sponsors in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, and approval of the manuscript; and decision to submit the manuscript for publication.

REFERENCES

1. Sexton CC, Coyne KS, Thompson C, Bavendam T, Chen CI, Markland A. Prevalence and effect on health-related quality of life of overactive bladder in older Americans: Results from the Epidemiology of Lower Urinary Tract Symptoms Study. J Am Geriatr Soc 2011;**59**:1465–1470.
2. Tannenbaum C, Corcos J, Assalian P. The relationship between sexual activity and urinary incontinence in older women. J Am Geriatr Soc 2006;**54**:1220-4.
3. O'Donnell M, Lose G, Sykes D, Voss S, Hunskaar S. Help-seeking behaviour and associated factors among women with urinary incontinence in France, Germany, Spain and the United Kingdom. Eur Urol 2005;**47**:385-92
4. Herschorn S, Gajewski J, Schulz J, Corcos J. A population-based study of urinary symptoms and incontinence: the Canadian Urinary Bladder Survey. BJU Int 2008;**101**:52-8.
5. Bland DR et al. The effects of implementation of the Agency for Health Care Policy and Research urinary incontinence guidelines in primary care. J Am Geriatr Soc 2003;**51**:979–984.
6. Subak LL, Wagner TH. Talking about incontinence: the first step toward prevention and treatment. JAMA 2010;**303**:2184-2185.
7. Tannenbaum C, Gray M, Hoffstetter S, Cardozo L. Comorbidities associated with bladder dysfunction. Int J Clin Pract 2013;**67**:105-13.
8. Farage MA, Miller KW, Berardesca E, Maibach HI. Psychosocial and societal burden of incontinence in the aged population. Arch Gynecol Obstet 2008;**277**:285-290.
9. Holroyd-Leduc JM, Mehta KM, Covinsky KE. Urinary incontinence and its association with death, nursing home admission, and functional decline. J Am Geriatr Soc 2004;**52**:712-8.
10. Chiarelli PE, Mackenzie LA, Osmotherly PG. Urinary incontinence is associated with an increase in falls: a systematic review. Aust J Physiother 2009;**55**:89-95.
11. Holroyd-Leduc JM, Tannenbaum C, Thorpe KE, Straus SE. What type of urinary incontinence does this woman have? JAMA 2008;**299**:1446-56.
12. Goode PS, Burgio KL, Richter HE, Markland AD. Incontinence in older women. JAMA 2010;**303**:2172-81.

13. Tannenbaum C, Bachand, G, DuBeau CE, Kuchel GA. Experience of an incontinence clinic for older women : no apparent age limit for potential physical and psychological benefits. J Women Health Gend Based Med 2001;**10**:751-56.
14. Tannenbaum C, Brouillette J, Corcos J. Rating improvements in urinary incontinence: do patients and physicians agree? Age Ageing 2008;**37**:1-5
15. Newman DK, Buckley B, Gordon D et al. Continence promotion, education and primary prevention. In Abrams P, Cardozo L, Khoury S, Wein A eds: Incontinence. 5th International Consultation on Incontinence, Paris, February 2012. Health Publication Ltd 2013.
16. Agnew R, van den Heuvel E, Tannenbaum C. Efficiency of using community organisations as catalysts for recruitment to continence promotion trials. Clin Trials 2013;**10**:151-9.
17. Tannenbaum C, Drali R, Holroyd-Leduc J Richard L. Lessons learned: Impact of a continence promotion activity for older community dwelling women. Neurourol Urodyn 2010;**29**:540-544.
18. Wilde MH, Bliss DZ, Booth J, Cheater F, Tannenbaum C. Self-Management of Urinary and Fecal Incontinence. AJN 2013 in press.
19. Holroyd-Leduc J, Strauss S, Thorpe K, Davis D, Schmaltz H, Tannenbaum C. Translation of evidence into a self-management tool for use by women with urinary incontinence. Age Ageing 2011;**40**:227-33.
20. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003;**189**: 98–101.
21. Avery K, Donovan J, Peters TJ et al. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn 2004; **23**: 322–30.
22. Eldridge SM; Ashby D; Kerry S. Sample size for cluster randomised trials: effect of coefficient of variation of cluster size and analysis method. Int J Epidemiol 2006;**35**:1292-1300.
23. Ukoumunne OC, Forbes AB, Carlin JB, Gulliford MC. Comparison of the risk difference, risk ratio and odds ratio scales for quantifying the unadjusted intervention effect in cluster randomised trials. Stat Med 2008;**27**: 5143-5155.
24. Users' guide to the medical literature. Integrating research evidence with the care of the individual patient. JAMA 2000;**283**;2829-2836.

25. Hanley JA, Negassa A, Edwardes MD. GEE analysis of negatively correlated binary responses: a caution. Stat Med 2000;**19**:715–722.
26. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;**337**:979-983.
27. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ 2012;**345**:e5661.
28. Kincade JE, Dougherty MC, Carlson JR, Hunter GS, Busby-Whitehead J. Randomised clinical trial of efficacy of self-monitoring techniques to treat urinary incontinence in women. Neurourol Urodyn 2007;**26**:507-11.
29. Wagg AR, Barron D, Kirby M, Stott D, Corlett K. A randomised partially controlled trial to assess the impact of self-help vs. structured help from a continence nurse specialist in women with undiagnosed urinary problems in primary care. Int J Clin Pract 2007;**61**:1863-73.
30. Dougherty MC, Dwyer JW, Pendergast JF et al. A randomised trial of behavioral management for continence with older rural women. Res Nurs Health 2002;**25**:3-13.
31. McFall SL, Yerkes AM, Cowan LD. Outcomes of a small group educational intervention for urinary incontinence: episodes of incontinence and other urinary symptoms. J Aging Health 2000;**12**:250-67.
32. Milne J. The impact of information on health behaviors of older adults with urinary incontinence. Clin Nurs Res 2000;**9**:161-76.
33. Goode PS, Burgio KL, Locher JL et al. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. JAMA 2003;**290**(3):345-52.
34. Shamliyan T, Wyman J, Kane RL. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Comparative Effectiveness Review No. 36. (Prepared by the University of Minnesota Evidence-based Practice Center under Contract No. HHSA 290-2007-10064-I.) AHRQ Publication No. 11(12)-EHC074-EF. Rockville, MD. Agency for Healthcare Research and Quality. April 2012. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Table 1: Baseline characteristics and distribution of modifiable risk factors of participants

	Continence education (n=64)	Self-management (n=70)	Combined intervention (n=61)	Control intervention (n=64)
	Mean ± SD			
Age	70.8 ± 7.9	71.0 ± 6.8	70.4 ± 6.7	74.1 ± 8.1
Mean ICIQ score*	8.5 ± 4.4	6.8 ± 3	7.3 ± 5.6	6.7 ± 3.4
	(% yes)			
Lives alone	48.4	40.0	37.7	59.4
Education				
University degree or equivalent	31.2	45.7	37.7	19.0
General health perception				
Good, very good, excellent	53.1	85.7	80.3	75.0
Fair/poor	45.3	14.3	16.4	25.0
Depression	48.4	35.7	32.8	20.3
Heart disease	35.9	25.7	16.4	21.0
Falls	45.3	31.4	18.0	18.8
Arthritis	78.1	52.9	44.3	57.8
Diabetes	39.1	24.3	18.0	20.3
High blood pressure	59.0	40.0	45.9	55.6
Type of incontinence				
Stress only	15.6	12.9	14.8	33.3
Urgency only	32.8	35.7	29.5	20.6
Mixed	45.3	42.9	55.7	39.7
Modifiable risk factors				
Performs pelvic floor muscle exercises 3 times per week	18.8	15.7	11.9	15.6
Self-reported body mass index $\geq$ 27 kg/m^2 **	53.2	53.0	42.4	49.2
Drinks more than 1.5 litres of fluid/day	43.8	44.3	54.1	37.5
Drinks one cup of tea or more/day	85.9	84.3	73.8	84.4
Drinks one cup of coffee or more/day	46.9	62.9	65.6	64.1
Smokes	6.3	4.3	4.9	6.2

*ICIQ = International Consultation on Incontinence Questionnaire, used to measure the severity and bother from urinary incontinence. Scores range from 0 to 21, with higher scores representing worse incontinence.

**Self-reported body mass index: calculated as weight (kg)/height^2 (m) based on participant's self-reported height and weight at baseline

Table 2: Prevalence, risk difference and odds ratios for self-reported improvements in incontinence at 3-months

	Prevalence at 3-month follow-up				Prevalence difference (95% CI)*			Odds ratio (95% CI)					
								Crude			Adjusted**		
	Conti-nence	SM	Combined	Control	Continence vs control	SM vs control	Combined vs control	Continence vs control	SM vs control	Combined vs control	Conti-nence 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)	11.72 (4.54-30.21)	5.16 (1.73-15.37)	15.51 (6.50-37.01)	9.14 (3.05-27.37)	2.71 (0.87-8.41)	17.63 (5.09-61.13)
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)	11.45 (4.27-30.67)	4.64 (1.48-14.56)	17.14 (6.51-45.11)	10.40 (3.05-35.48)	3.46 (1.08-11.03)	23.27 (5.91-91.59)
ICC Intention-to-treat	-	-	-	-	0.02	0.18	0	0.24	0.18	0	0	0.06	0
ICC per protocol	-	-	-	-	0.03	0.25	0	0.03	0.25	0	0	0.14	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)	4.2 (1.4-13.0)	3.8 (1.2-12.2)	6.3 (2.2-17.7)	2.83 (0.59-13.66)	1.81 (0.50-6.60)	4.94 (1.45-16.86)

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)	3.7 (1.2-11.3)	3.5 (1.06-11.31)	5.8 (2.0-17.4)	2.51 (0.48-13.18)	2.28 (0.63-8.24)	5.32 (1.39-20.34)
ICC Intention-to-treat	-	-	-	-	0.02	0.06	0	0.02	0.06	0	0	0	0
ICC per protocol	-	-	-	-	0.01	0.08	0.02	0.01	0.08	0	0	0.02	0

SM = Self-management; ICC = intra-cluster correlation correlation
*95% CI's were calculated using robust standard errors
**Adjusted for age, living alone, depression, heart disease, falls, arthritis, diabetes, high blood pressure, educational status, general health perception, and baseline incontinence severity score

Table 3: Change in incontinence-related knowledge

		Continence education n=64	Self-management n=70	Combined intervention n=61	Control n=64
1. Urinary incontinence is a normal part of ageing	Baseline % agreement	73.0	79.7	77.0	79.7
	3 month follow up % agreement	36.2	63.9	38.2	82.7
	p value for change*	**<0.001**	**0.02**	**<0.001**	0.73
2. Once people start to leak urine, they are never able to control their urine again	Baseline % agreement	41.9	32.9	36.1	50.8
	3 month follow up % agreement	29.3	17.7	7.3	51.9
	p value for change	0.12	0.06	**<0.001**	1
3. Urine leakage can be caused by many different things	Baseline % agreement	88.9	92.8	88.3	86.9
	3 month follow up % agreement	93.1	88.7	92.7	90.4
	p value for change	1	0.77	0.73	0.63
4. Wearing pads or diapers is the best way to manage urinary incontinence	Baseline % agreement	57.1	40.6	52.5	67.2
	3 month follow up % agreement	36.8	33.9	27.3	69.2
	p value for change	**0.03**	0.11	**0.001**	1
5. What you drink can contribute to urine leakage	Baseline % agreement	64.5	66.7	68.3	66.1
	3 month follow up % agreement	77.6	75.8	89.1	68.6

		Continence education n=64	Self-management n=70	Combined intervention n=61	Control n=64
	p value for change	0.26	0.36	**0.01**	0.77
6. How much you drink can contribute to urine leakage	Baseline % agreement	72.6	65.2	67.2	71.4
	3 month follow up % agreement	77.6	71	76.4	65.4
	p value for change	0.63	0.65	0.36	0.79
7. Losing weight can lead to improvement in incontinence	Baseline % agreement	61.3	74.3	66.1	75
	3 month follow up % agreement	77.6	77.4	90.9	80.8
	p value for change	0.08	0.69	**<0.001**	0.48
8. Exercising pelvic floor muscles can help control urine leakage	Baseline % agreement	85.5	88.6	85.2	96.9
	3 month follow up % agreement	96.5	96.7	98.2	98.1
	p value for change	**0.04**	0.13	**0.02**	1.0

** McNemar's test for matched-pairs data*

Figure 1: Flow of participants through the trial

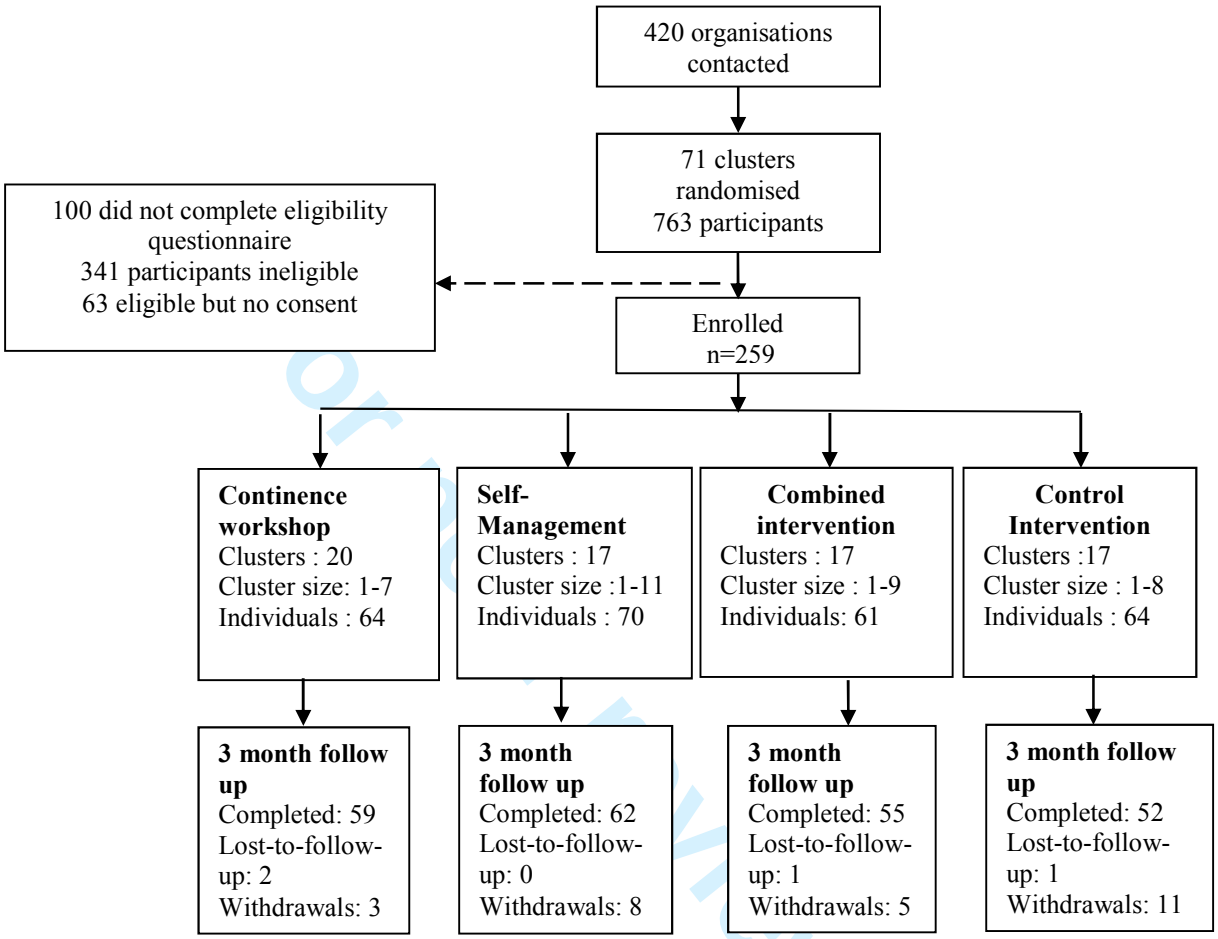
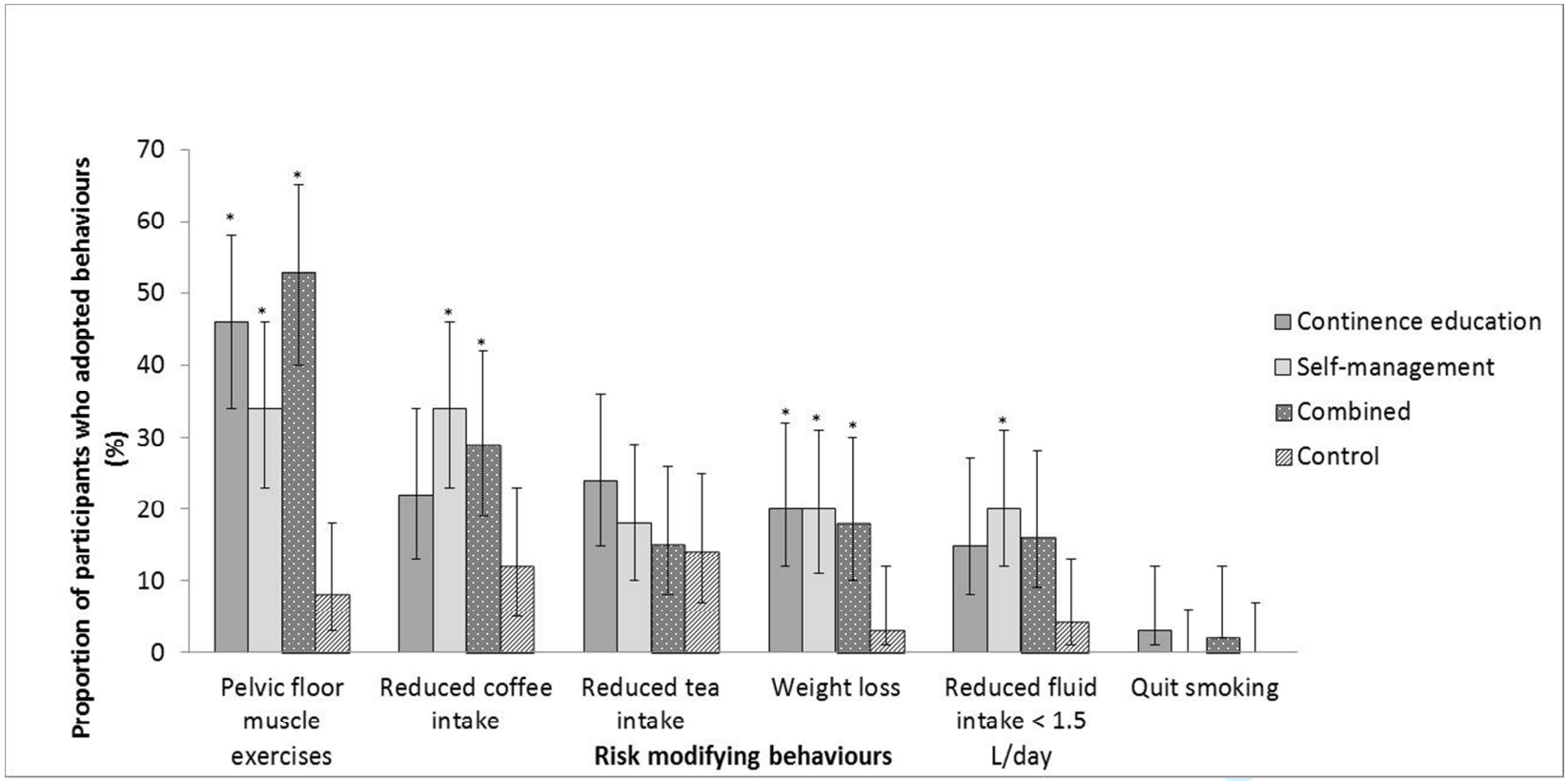


Figure 2: Change in risk-modifying behaviours at 3-month follow-up



*Significantly different from the control group ($p<0.05$) using Fisher's Exact test in per protocol analysis
Error bars represent 95% confidence intervals

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	3-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		-
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	6-7
	4b	Settings and locations where the data were collected		6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	8

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		-
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	9,26
	7b	When applicable, explanation of any interim analyses and stopping guidelines		-
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	-
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	8
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		8
	11b	If relevant, description of the similarity of interventions		8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		9-10
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	26
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	26
Recruitment	14a	Dates defining the periods of recruitment and follow-up		6
	14b	Why the trial ended or was stopped		-
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	20

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	26
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	11,22-25
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		11,22-25
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		11,22-25
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		-
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	13-14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		13-14
Other information				
Registration	23	Registration number and		4

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4,16

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.

BMJ open

Effectiveness of continence promotion for older women via community organisations: a cluster randomised trial

Journal:	*BMJ Open*
Manuscript ID:	bmjopen-2013-004135.R1
Article Type:	Research
Date Submitted by the Author:	05-Nov-2013
Complete List of Authors:	Tannenbaum, Cara; Université de Montréal, Faculty of Medicine Agnew, Rona; Glasgow Caledonian University, Benedetti, Andrea; McGill University, Departments of Medicine and of Epidemiology, Biostatistics & Occupational Health Thomas, Doneal; McGill University, Departments of Medicine and of Epidemiology, Biostatistics & Occupational Health van den Heuvel, Eleanor; Brunel University,
Primary Subject Heading:	Urology
Secondary Subject Heading:	Geriatric medicine
Keywords:	Urinary incontinences < UROLOGY, PUBLIC HEALTH, GERIATRIC MEDICINE

Effectiveness of continence promotion for older women via community organisations: a cluster randomised trial

Cara Tannenbaum, MD, MSc[1] Rona Agnew, PhD[2] Andrea Benedetti, PhD[3] Doneal Thomas, MSc[4] Eleanor van den Heuvel, PhD[5]

[1]Associate Professor, Faculty of Medicine, Université de Montréal, Quebec, Canada
[2]Clinical Research Fellow, Glasgow Caledonian University, Glasgow, UK
[3]Associate Professor, Departments of Medicine and of Epidemiology, Biostatistics & Occupational Health, McGill University, Quebec, Canada
[4]PhD candidate, Department of Epidemiology, Biostatistics & Occupational Health, McGill University, Quebec, Canada
[5]Director of Assistive Technology Programme, Brunel Institute for Ageing Studies, Brunel University, Uxbridge, UK

Word count : 3182

Key words: Continence promotion, cluster trial, community organisations, older women, urinary incontinence

Corresponding Author: Dr. Cara Tannenbaum, Centre de Recherche de l'Institut universitaire de gériatrie de Montréal, 4545 Queen Mary Road, Montreal, Quebec, Canada H3W 1W5. Tel (514) 340-2800. Fax : (514) 340-3530.
Email: cara.tannenbaum@umontreal.ca

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

The authors retained full independence from the study sponsors in the design, implementation, analysis, interpretation and reporting of the findings.

ABSTRACT

Objectives: The primary objective of this cluster randomised controlled trial was to compare the effectiveness of the three experimental continence promotion interventions against a control intervention on urinary symptom improvement in older women with untreated incontinence recruited from community organisations. A second objective was to determine whether changes in incontinence-related knowledge and new uptake of risk-modifying behaviours explain these improvements.

Setting: 71 community organisations across the United Kingdom

Participants: 259 women aged 60 years and older with untreated incontinence entered the trial; 88% completed the 3-month follow-up.

Interventions: The three active interventions consisted of a single 60-minute group workshop on 1) continence education (20 clusters, 64 women); 2) evidence-based self-management (17 clusters, 70 women); or 3) combined continence education and self-management (17 clusters, 61 women). The control intervention was a single 60-minute educational group workshop on memory loss, polypharmacy and osteoporosis (17 clusters, 64 women).

Primary and secondary outcome measures: The primary outcome was self-reported improvement in incontinence 3 months post-intervention at the level of the individual. The secondary outcome was change in the International Consultation on Incontinence Questionnaire (ICIQ) from baseline to 3-month follow-up. Changes in incontinence-related knowledge and behaviours were also assessed.

Results: The highest rate of urinary symptom improvement occurred in the combined intervention group (66% vs 11% of the control group, prevalence difference 55%, 95% CI 43%-67%, intracluster correlation 0). Thirty percent versus 6% of participants reported significant improvement respectively (prevalence difference 23%, 95% CI 10%-36%, intracluster correlation 0). The number-needed-to-treat was 2 to achieve any improvement in incontinence symptoms, and 5 to attain significant improvement. Compared to controls, participants in the combined intervention reported an adjusted

mean 2.05 point (95% CI 0.87-3.24) greater improvement on the ICIQ from baseline to 3-month follow up. Changes in knowledge and self-reported risk-reduction behaviours paralleled rates of improvement in all intervention arms.

Conclusion: Continence education combined with evidence-based self-management improves symptoms of incontinence among untreated older women. Community organisations represent an untapped vector for delivering effective continence promotion interventions.

Trial registration: ClinicalTrials.gov ID number NCT01239836

Article Summary : Strengths and limitations of this study

- First study to provide Level 1 evidence that continence promotion is an effective strategy for improving urinary symptoms among untreated community-dwelling older women
- Participants were recruited via community organisations with representation across diverse socio-economic strata
- Rates of knowledge acquisition and behaviour change provide an explanatory mechanism for the observed improvements in incontinence in participants receiving the combined education plus self-management strategy
- Only self-reported outcomes and crude dichotomous measures of behaviour change were collected so results must be interpreted with caution

Introduction

Urinary incontinence is more frequent than breast cancer, heart disease or diabetes among older women, but remains a stigmatized and untreated condition despite its high prevalence**.** [1-4] In the United States, Canada, the U.K. and other European countries, up to 40% of women aged 65 years and older experience involuntary urine leakage, but little more than 15-30% seek care.[1-4] Even fewer physicians feel competent evaluating or treating incontinence.[5-6] Urinary incontinence is associated with obesity, cardiovascular disease, diabetes, depression, social isolation, decline in function, falls, nursing home admission, and onerous out-of-pocket expenses.[6-10] In many cases incontinence can be improved, and even cured, when evidence-based diagnostic and treatment strategies are appropriately applied.[6,11-14]

It is a commonly held misconception that incontinence is a normal part of aging.[15] Not-for-profit organisations seek to raise continence awareness worldwide and promote treatment for incontinent individuals. Media campaigns, brochures and public awareness lectures attempt to de-stigmatise incontinence and increase help-seeking, but the effectiveness of these initiatives for reaching their target population remains unknown.[15] Transmission of public health education via community organisations is an unexplored strategy for improving urinary symptoms.[16] Data from randomised trials are needed to determine whether the delivery of an evidence-based continence intervention via community organisations is an effective method for treating incontinence.

The primary objective of this cluster randomised controlled trial was to compare the effectiveness of the three experimental continence promotion interventions against a control intervention on urinary symptom improvement in older women with untreated incontinence recruited from community organisations. A second objective was to determine whether changes in incontinence-related knowledge, attitudes and new uptake of risk-modifying behaviours explain improvements in incontinence. We hypothesized that continence education combined with evidence-based self-management would yield the greatest improvement in incontinence symptoms, measured at the level of the individual, 3-months post-intervention.

METHODS

Study design and oversight

A 4 arm, parallel-group, controlled, cluster randomised trial was conducted. The study design, recruitment methods and interventions have been reported.[16] Clustering was at the level of the community organisation, from whence participants were recruited. The choice of a cluster design served to prevent contamination between participants in the same community organisation. The trial was designed by two of the authors and was overseen by the full investigator team, which had full access to the data. The data were collected at community organisations across the United Kingdom. All participants provided written informed consent. The protocol was approved by the Brunel University Research Ethics Committee.

Study population and recruitment

Inclusion criteria for community organisations included any organisation throughout the United Kingdom that consented to participate in the trial between November 2010 and September 2012. A community organisation was loosely defined as any not-for-profit group of individuals with a shared interest. These included interest and charity groups, seniors' housing groups, women's lobby groups and Asian caregiver associations.[16] Organisations were contacted strategically by convenience sampling, word of mouth and referral. A research coordinator approached community organisations to join the trial by telephone, email and newspaper advertising.

Inclusion criteria for participants were women aged 60 years and older who reported urinary incontinence at least once weekly on the International Consultation on Incontinence Questionnaire (ICIQ), and who were not under active treatment for incontinence. For privacy reasons, many community organisations were uncomfortable screening their members for incontinence in advance, so eligibility to participate in the trial could only be ascertained by the research coordinator on the day of delivery of the intervention.[16] Eligibility to participate in the trial was established by asking all attendees at the workshop to complete a baseline screening questionnaire upon arrival. At this time, a study information sheet and consent form were distributed to all participants. All women, regardless of eligibility or desire to enrol in

the trial, were permitted to stay for the workshop. Only those women who wished to enrol in the trial submitted the signed consent form to the workshop facilitator following delivery of the intervention, however all attendees were encouraged to submit the baseline screening questionnaire even if they were continent or did not wish to participate in the trial.

Interventions

The interventions were applied at the level of each cluster. The three experimental interventions to be tested were continence education, self-management including the distribution of an evidence-based risk factor reduction tool for incontinence, and a combined intervention that included both components. The sham control intervention was a lecture on health promotion for older women that addressed topics other than incontinence. All interventions were delivered once in group format to 8-16 women by the same facilitator at a venue of the organisation's choosing, and lasted 60-90 minutes. A slide presentation with a pre-established script prepared for the facilitator was delivered at each workshop.

The continence promotion intervention incorporated elements of constructivist learning that challenged older adults' erroneous beliefs about accepting incontinence as a normal part of aging, and aimed to change attitudes and create new knowledge about the different types, etiology, risk factors and treatment options for urine loss.[16-17] The self-management workshop reviewed self-management theory in an interactive format, and provided a customised evidence-based self-management program for risk factor modification for incontinence to each participant.[18-19] The program targeted pelvic floor muscle weakness, obesity, consumption of caffeinated beverages, smoking, vision loss and constipation, with instructions on how to keep a bladder diary to help monitor symptoms. The content of the combined intervention condensed elements from the continence promotion workshop along with self-management theory, and provided the customized self-management tool to participants. The control intervention addressed other non-bladder related aspects of older women's health such as memory problems, polypharmacy, osteoporosis, nutrition, physical fitness and vision impairment.

Study Outcomes

The primary outcome was the participant's global impression of improvement in incontinence symptoms, measured at 3 months post-intervention by telephone interview using the patient's global impression of improvement (PGI-I) questionnaire. The PGI-I is a validated, single-item global rating of change scale that asks the patient to describe how their incontinence condition is now compared to how it was prior to the intervention (very much better, much better, a little bit better, no change, a little bit worse, much worse and very much worse).[20] The primary outcome, any improvement, was defined as a rating of a little bit better, much better or very much better. A secondary outcome, significant improvement, was defined as much better or very much better. The ICIQ, which measures the frequency, severity and bother from incontinence was used at baseline to screen participants for inclusion to the trial, and was repeated at follow-up.[21] The ICIQ diagnostic item was used by participants to describe the type of incontinence at baseline. A pre- and post-8-item questionnaire on knowledge and attitudes towards incontinence was administered at baseline and at 3-month follow-up, as were risk factors and behaviors related to incontinence.[17] Risk factors and behaviors included performance of pelvic floor muscle exercises three times weekly (yes, no), daily consumption of 1 cup or more of tea or coffee (yes, no), fluid intake > 1.5 L/day (yes, no), weight and height (self-report) and smoking status (yes, no). At three month follow-up participants were asked whether they had sought treatment for urine leakage during the past 3 months. All follow-up interviews were performed by the research coordinator, who was blinded to participant identification.

The original study protocol sought to examine reductions in urinary frequency as measured on a bladder diary and reductions in the cost of pad use as primary and secondary outcomes respectively. However as soon as recruitment for the trial commenced it became apparent that distribution of bladder diaries and objective measurement of pad use pre-intervention would not be possible. This occurred as a result of privacy concerns expressed by participating community organisations for revealing and sharing their members' names and contact information with the research team prior to the delivery of the workshops.[16] The PGI-I was therefore used as the revised primary measure of effectiveness from the onset of the trial. Data on self-efficacy for managing incontinence was also collected, but is not reported in

this paper due to problems with comprehension of the visual analogue response scale during the 3-month telephone follow-up that occurred non-differentially among participants in all arms of the study.

Randomisation and allocation concealment

Group allocation occurred by non-stratified randomisation in blocked groups of 4 of consenting organisations that agreed to host a workshop. An independent statistician at a distant study site was responsible for randomisation using computer-generated random digits. Community organisations were informed that one of four workshops would be delivered on health topics of interest to older women, but not which one. In this way, group allocation was concealed from both the clusters and the individual participants, who were invited by the host organisation to attend a "Women's Health Worshop". The research coordinator remained unaware of group allocation at the time each community organisation was recruited to the trial because she was only informed which workshop to prepare for each organisation several days before each workshop. The trial is considered 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.

Sample Size

The trial was designed to detect a minimal 35% difference in the number of participants reporting any improvement (very much better, much better, a little bit better on the PGI-I) 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 anticipated maximum intracluster correlation (ICC) of 0.05 and unequal cluster size yielded a recruitment target of 56 participants per group.[22]

Statistical Methods

Differences in baseline characteristics between the four groups were determined. To assess the primary outcome we estimated the unadjusted risk difference (prevalence of the outcome) and 95% confidence intervals (CI) via generalized estimating equations (GEEs) for participants who reported any improvement on the PGI-I. We repeated the same analysis for those who reported significant improvement. GEEs

with an identity link and an exchangeable correlation structure were used to account for possible correlation between women in the same organisation.[23] To adjust for the imbalance in potential confounders in the groups at baseline, additional analyses were conducted using multivariable logistic regression estimated via GEE with an exchangeable correlation structure. Potential confounders included age and baseline incontinence severity (ICIQ score) as continuous predictors, 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 (PP) analyses were performed. For the ITT analysis, participants with missing data were assumed to have no change in incontinence status at three-month follow-up. The number needed to treat was calculated as the inverse of the difference in absolute event rates between the experimental and control groups.[24] We report intra-cluster (intra-community organisation) correlation coefficients (ICC) from the marginal model using GEE with assumed exchangeable correlation structure and robust standard errors.[25] In cases where an ICC<0 was detected, we assumed a correlation structure of independence, but still used the robust variance estimator. The robust variance estimator is robust to misspecification of the correlation structure, so standard errors, confidence intervals and p values are still correct. To estimate adjusted mean group differences in ICIQ scores from baseline to 3-month follow up, we used GEE with a Gaussian regression model for continuous outcomes and followed the same procedure outlined above.

Improvements in incontinence-related knowledge by intervention type for proportions of individuals responding correctly to each knowledge questionnaire item at baseline compared to 3-month follow-up were estimated using McNemar's test for matched pair analysis. Rates of improvement in self-reported risk modifying behaviours for incontinence were calculated, along with 95% confidence intervals. Differences in improvement rates between the intervention and the control group were compared using Fisher's Exact test using a per protocol analysis. A difference in response for each health behavior item that indicated adoption of a new risk modifying behaviour was defined as a positive change at 3-month follow-up compared to baseline. Reduced coffee and tea intake refer to individuals who reduced their consumption to a single cup per day or less. Weight loss was determined by a positive response to the question, "Has your weight changed (yes, no) and if so, how much do you now

weigh?" and evidence of self-reported current weight lower than self-reported weight at baseline. All statistical analyses were run using RStudio 0.97.310.0, an integrated development environment for R.

RESULTS

Study participants and follow-up

Four-hundred-and-twenty different community organisations were approached over an 18-month period to participate in the trial. Of these, 17% consented and succeeded in hosting an intervention, yielding 71 clusters that were randomised. Approximately one quarter of the groups contacted refused; 2% expressed interest but were unable to organise a workshop; and a little over half failed to give any response although most of them had been followed up and had received extra information on the project.[16] Figure 1 depicts the study flow of the clusters and participants through the trial. Seven-hundred-and-sixty three women attended the workshops, of whom 322 (42%) were known to be eligible for the trial. The mean number of participants recruited from each cluster for the continence promotion group was 3 ± 2, whereas it was 4 ± 2 for the other 3 groups. Eighty-percent (259/322) of known eligible attendees to the workshops consented to take part in the trial. Two-hundred-and-twenty-eight of these (88%) were available for 3-month follow-up. Table 1 compares the baseline characteristics of participants in each trial arm.

Primary and secondary outcomes

The highest rate of improvement in incontinence occurred in the combined intervention group, 66% compared to 11% in the control group (prevalence difference 55%, 95% CI 43%-67%), yielding a number-needed-to-treat of 2. Thirty percent of the combined group reported significant improvement compared to 6% of controls (prevalence difference 23%, 95% CI10%-36%, number-needed-to-treat of 5). In adjusted analyses, the likelihood of achieving a significant improvement in urinary symptoms from exposure to the combined intervention was five times greater than exposure to the control intervention (OR 4.94, 95% CI 1.45-16.86). Compared to controls, the participants in the combined intervention reported an adjusted mean 2.05 point (95% CI 0.87-3.24) greater improvement on the ICIQ from baseline to 3-month follow up. The adjusted mean difference in ICIQ scores was also significantly higher

for the continence education group compared to the control group (1.33 point greater improvement (95% CI 0.33-2.32)), but not for the self-management group. The per protocol analysis for the primary outcome and the intra-cluster correlation coefficients for each analysis are shown in Table 2.

Other outcomes

Table 3 shows the changes in incontinence-related knowledge attributable to receipt of each intervention. Participants exposed to the combined intervention showed the greatest acquisition in knowledge, exhibiting significant within-group improvement on 6 out of 8 questionnaire items. Participants learned that incontinence is not an inevitable or irreversible part of aging, that losing weight, changing the type of fluid intake and performing pelvic floor muscle exercises can reduce urinary symptoms, and that wearing undergarment protection is not always the best way to manage incontinence.

The proportion of participants with modifiable risk factors for incontinence in each group at baseline is shown in Table 1. The adoption of various risk-modifying behaviours among participants occurred to a different degree as a result of exposure to all three experimental but not the control intervention (Figure 2). At three-month follow-up, the proportion of women reporting uptake of pelvic floor muscle exercises and weight loss was significantly higher in the continence education group (46% and 20% respectively), the self-management group (34% and 20%) and the combined intervention group (53% and 18%) compared to controls (8% and 3%). Many women additionally reduced their coffee intake and total fluid intake. The proportion of women who made an appointment to consult a health professional for urine leakage was 19% in the continence promotion group, 7% in the self-management group, 16% in the combined intervention group and 4% in the control group.

DISCUSSION

In this cluster-randomised trial testing the effectiveness of 3 different continence promotion interventions, we found that health education combined with the delivery of an evidence-based self-management tool via community organisations to untreated older women yielded the highest rate of urinary symptom improvement in 66% of

recipients, half of whom reported significant improvements in incontinence. These outcomes translate into a number-needed-to-treat of 2 and 5 respectively, a magnitude of effect rarely achieved during public health interventions. Both new knowledge acquisition and the adoption of risk-modifying behaviours such as exercise and weight loss occurred as a result of community organisations' involvement in reaching untreated incontinent women outside the health care system.

Strengths and weaknesses of the study

This is the first randomised trial to test the effectiveness of continence promotion strategies through community outreach. Both explanatory mechanisms and final health outcomes were assessed, and the use of a cluster randomised design was chosen to avoid contamination of the control group.[26,27] Our choice of comparator controlled for the placebo effect of participating in a group intervention. Breaches in the fidelity and quality of implementation of the intervention were minimized by having the same facilitator deliver each intervention. Improvements in urinary symptoms were shown with two validated measures, the PGI-I and the ICIQ. We believe the results have wide external validity as the community groups included women with varied educational levels and wide socioeconomic status.

The results of this study confirm findings from previous randomised trials suggesting a positive effect of continence education and self-monitoring strategies on urinary symptom improvement in untreated incontinent individuals.[28-33] However all previous trials invited participants for clinical assessments prior to the delivery of the intervention, or involved individualized education sessions. The current trial delivered group continence interventions without medical or nursing evaluations, in a true public health approach, to both continent and incontinent women as part of the regular activities offered by each community organisation. Rates of improvement reported in this trial on the PGI-I were similar to or exceeded those reported in other studies using self-help booklets, in the range of 50%. Because of the nature of recruitment and delivery of the intervention via community organisations, bladder diaries and pad tests could not be collected pre-intervention. The results of our trial can therefore not be directly compared to other trials that used more objective measures of symptom improvement.

Other limitations apply. Due to the nature of recruiting potential participants, individuals could not be screened and enrolled in the trial prior to randomisation of the clusters.[27] The result was an imbalance between groups, accounted for by analyses that took into account group differences in age, health status and baseline incontinence severity. The trial was not designed to measure the dose-response of knowledge acquisition and behaviour change on urinary symptom improvement. Thus only crude, dichotomous self-reported measures of behaviour change were collected and should be interpreted with caution.

Relevance to the discipline

The value of continence promotion interventions likely reflects the delivery method as well as the quality of the content. Group interventions that deliver continence education, self-management information, or a combination of the two will improve incontinence symptoms in 59%, 41% and 66% of recipients, respectively. It is surprising that the self-management intervention alone was not associated with significant improvement compared to sham control in this trial. This can potentially be explained by the fact that continence education was completely omitted from the self-management workshop, whereas some information on bladder functioning was provided to participants during the initial work that tested the self-management tool.[19]

Implications for practice

Implementation of community-based programs that promote behavioural techniques as first-line management for incontinence support evidence for the superior efficacy and tolerability of conservative management approaches over pharmacological treatment for incontinence.[34] As “silent sufferers” become better informed that effective strategies exist for improving urinary symptoms, patient demand for care will likely increase. Almost 20% of women made an appointment to discuss urine leakage with a health professional in the three months following receipt of the continence education intervention. Evidence-based guidelines exist for physicians to evaluate and manage urinary incontinence when first-line behavioural strategies fail, and will need to be more frequently applied.[5,11]

In conclusion, continence education combined with self-management delivered via community organisations to untreated older women with incontinence leads to symptom improvement in 1 out of every 2 recipients. At the current time, the majority of older women with incontinence do not seek care, and either self-manage their symptoms inappropriately or use protection to palliate urine leakage.[1-4] As incontinence is associated with multimorbidity and other deleterious health effects, results from this trial provide strong justification for public health outreach via community organisations to reduce urine leakage among untreated individuals.

Acknowledgments

We wish to acknowledge the assistance of Mira Jabbour and Francine Giroux for their expert help with database management and the data analyses. Nikki Cotterill, Adele Long aided with recruitment in the Bristol area. The above-mentioned individuals received financial compensation for their contribution to this work. We express gratitude to all the participants who took part in this trial. Although not exhaustive, particular thanks are offered to the following organisations and groups for participating in the trial: the Women's Institute, AGE UK, the University of the Third Age, Queens Nursing Institute (Scotland), Kinship Carers, the Women's Guild, Hanover Housing Association, Good Neighbours, Asian Carers Groups, Older Peoples Forum throughout the UK.

Author Contribution Statement

Cara Tannenbaum designed the study and participated in the data analysis and interpretation. She wrote the first draft of the manuscript. Rona Agnew was responsible for data collection, participated in the data analysis and interpretation and critically reviewed the manuscript. Andrea Benedetti was responsible for the data analysis and interpretation and critically reviewed the manuscript. Doneal Thomas conducted the analyses and reviewed the manuscript. Eleanor van den Heuvel helped design the study, participated in the study implementation, helped interpret the findings and critically reviewed the manuscript.

Data Access and Sharing Statement

Cara Tannenbaum, Doneal Thomas and Andrea Benedetti had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Patient level data and the full dataset is available upon request from the authors. Consent for data sharing was not obtained but the presented data are anonymised and the risk of identification is low.

Competing interests

Cara Tannenbaum declares having been an advisory board member or received speaker honoraria from Pfizer, Watson, Astellas, Allergen and Ferring pharmaceuticals in the past 3 years, but not in relation to this work. All other authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

Funding and Sponsor's Role

The trial was funded by a joint collaboration between the Canadian Institutes of Health Research and the Economic and Social Research Council (UK). The authors retained full independence from the study sponsors in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, and approval of the manuscript; and decision to submit the manuscript for publication.

REFERENCES

1. Sexton CC, Coyne KS, Thompson C, et al. Prevalence and effect on health-related quality of life of overactive bladder in older Americans: Results from the Epidemiology of Lower Urinary Tract Symptoms Study. J Am Geriatr Soc 2011;**59**:1465–1470.
2. Tannenbaum C, Corcos J, Assalian P. The relationship between sexual activity and urinary incontinence in older women. J Am Geriatr Soc 2006;**54**:1220-4.
3. O'Donnell M, Lose G, Sykes D, et al. Help-seeking behaviour and associated factors among women with urinary incontinence in France, Germany, Spain and the United Kingdom. Eur Urol 2005;**47**:385-92
4. Herschorn S, Gajewski J, Schulz J, et al. A population-based study of urinary symptoms and incontinence: the Canadian Urinary Bladder Survey. BJU Int 2008;**101**:52-8.
5. Bland DR et al. The effects of implementation of the Agency for Health Care Policy and Research urinary incontinence guidelines in primary care. J Am Geriatr Soc 2003;**51**:979–984.
6. Subak LL, Wagner TH. Talking about incontinence: the first step toward prevention and treatment. JAMA 2010;**303**:2184-2185.
7. Tannenbaum C, Gray M, Hoffstetter S, et al. Comorbidities associated with bladder dysfunction. Int J Clin Pract 2013;**67**:105-13.
8. Farage MA, Miller KW, Berardesca E, et al. Psychosocial and societal burden of incontinence in the aged population. Arch Gynecol Obstet 2008;**277**:285-290.
9. Holroyd-Leduc JM, Mehta KM, Covinsky KE. Urinary incontinence and its association with death, nursing home admission, and functional decline. J Am Geriatr Soc 2004;**52**:712-8.
10. Chiarelli PE, Mackenzie LA, Osmotherly PG. Urinary incontinence is associated with an increase in falls: a systematic review. Aust J Physiother 2009;**55**:89-95.
11. Holroyd-Leduc JM, Tannenbaum C, Thorpe KE, et al. What type of urinary incontinence does this woman have? JAMA 2008;**299**:1446-56.
12. Goode PS, Burgio KL, Richter HE, et al. Incontinence in older women. JAMA 2010;**303**:2172-81.

13. Tannenbaum C, Bachand, G, DuBeau CE, et al. Experience of an incontinence clinic for older women : no apparent age limit for potential physical and psychological benefits. J Women Health Gend Based Med 2001;**10**:751-56.
14. Tannenbaum C, Brouillette J, Corcos J. Rating improvements in urinary incontinence: do patients and physicians agree? Age Ageing 2008;**37**:1-5
15. Newman DK, Buckley B, Gordon D et al. Continence promotion, education and primary prevention. In Abrams P, Cardozo L, Khoury S, Wein A eds: Incontinence. 5th International Consultation on Incontinence, Paris, February 2012. Health Publication Ltd 2013.
16. Agnew R, van den Heuvel E, Tannenbaum C. Efficiency of using community organisations as catalysts for recruitment to continence promotion trials. Clin Trials 2013;**10**:151-9.
17. Tannenbaum C, Drali R, Holroyd-Leduc J Richard L. Lessons learned: Impact of a continence promotion activity for older community dwelling women. Neurourol Urodyn 2010;**29**:540-544.
18. Wilde MH, Bliss DZ, Booth J, et al. Self-Management of Urinary and Fecal Incontinence. AJN 2013 in press.
19. Holroyd-Leduc J, Strauss S, Thorpe K, et al. Translation of evidence into a self-management tool for use by women with urinary incontinence. Age Ageing 2011;**40**:227-33.
20. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003;**189**: 98–101.
21. Avery K, Donovan J, Peters TJ et al. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn 2004; **23**: 322–30.
22. Eldridge SM; Ashby D; Kerry S. Sample size for cluster randomised trials: effect of coefficient of variation of cluster size and analysis method. Int J Epidemiol 2006;**35**:1292-1300.
23. Ukoumunne OC, Forbes AB, Carlin JB, et al. Comparison of the risk difference, risk ratio and odds ratio scales for quantifying the unadjusted intervention effect in cluster randomised trials. Stat Med 2008;**27**: 5143-5155.
24. Users' guide to the medical literature. Integrating research evidence with the care of the individual patient. JAMA 2000;**283**;2829-2836.

25. Hanley JA, Negassa A, Edwardes MD. GEE analysis of negatively correlated binary responses: a caution. Stat Med 2000;**19**:715–722.
26. Craig P, Dieppe P, Macintyre S, et al. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;**337**:979-983.
27. Campbell MK, Piaggio G, Elbourne DR, et al. Consort 2010 statement: extension to cluster randomised trials. BMJ 2012;**345**:e5661.
28. Kincade JE, Dougherty MC, Carlson JR, et al. Randomised clinical trial of efficacy of self-monitoring techniques to treat urinary incontinence in women. Neurourol Urodyn 2007;**26**:507-11.
29. Wagg AR, Barron D, Kirby M, et al. A randomised partially controlled trial to assess the impact of self-help vs. structured help from a continence nurse specialist in women with undiagnosed urinary problems in primary care. Int J Clin Pract 2007;**61**:1863-73.
30. Dougherty MC, Dwyer JW, Pendergast JF et al. A randomised trial of behavioral management for continence with older rural women. Res Nurs Health 2002;**25**:3-13.
31. McFall SL, Yerkes AM, Cowan LD. Outcomes of a small group educational intervention for urinary incontinence: episodes of incontinence and other urinary symptoms. J Aging Health 2000;**12**:250-67.
32. Milne J. The impact of information on health behaviors of older adults with urinary incontinence. Clin Nurs Res 2000;**9**:161-76.
33. Goode PS, Burgio KL, Locher JL et al. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. JAMA 2003;**290**(3):345-52.
34. Shamliyan T, Wyman J, Kane RL. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Comparative Effectiveness Review No. 36. (Prepared by the University of Minnesota Evidence-based Practice Center under Contract No. HHSA 290-2007-10064-I.) AHRQ Publication No. 11(12)-EHC074-EF. Rockville, MD. Agency for Healthcare Research and Quality. April 2012. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Table 1: Baseline characteristics and distribution of modifiable risk factors of participants

	Continence education (n=64)	Self-management (n=70)	Combined intervention (n=61)	Control intervention (n=64)
	Mean ± SD			
Age	70.8 ± 7.9	71.0 ± 6.8	70.4 ± 6.7	74.1 ± 8.1
Mean ICIQ score*	8.5 ± 4.4	6.8 ± 3	7.3 ± 5.6	6.7 ± 3.4
	(% yes)			
Lives alone	48.4	40.0	37.7	59.4
Education				
University degree or equivalent	31.2	45.7	37.7	19.0
General health perception				
Good, very good, excellent	53.1	85.7	80.3	75.0
Fair/poor	45.3	14.3	16.4	25.0
Depression	48.4	35.7	32.8	20.3
Heart disease	35.9	25.7	16.4	21.0
Falls	45.3	31.4	18.0	18.8
Arthritis	78.1	52.9	44.3	57.8
Diabetes	39.1	24.3	18.0	20.3
High blood pressure	59.0	40.0	45.9	55.6
Type of incontinence				
Stress only	15.6	12.9	14.8	33.3
Urgency only	32.8	35.7	29.5	20.6
Mixed	45.3	42.9	55.7	39.7
Modifiable risk factors				
Performs pelvic floor muscle exercises 3 times per week	18.8	15.7	11.9	15.6
Self-reported body mass index $\geq$ 27 kg/m^2 **	53.2	53.0	42.4	49.2
Drinks more than 1.5 litres of fluid/day	43.8	44.3	54.1	37.5
Drinks one cup of tea or more/day	85.9	84.3	73.8	84.4
Drinks one cup of coffee or more/day	46.9	62.9	65.6	64.1
Smokes	6.3	4.3	4.9	6.2

*ICIQ = International Consultation on Incontinence Questionnaire, used to measure the severity and bother from urinary incontinence. Scores range from 0 to 21, with higher scores representing worse incontinence.

**Self-reported body mass index: calculated as weight (kg)/height^2 (m) based on participant's self-reported height and weight at baseline

Table 2: Prevalence, risk difference and odds ratios for self-reported improvements in incontinence at 3-months

	Prevalence at 3-month follow-up				Prevalence difference (95% CI)*			Odds ratio (95% CI)					
								Crude			Adjusted**		
	Conti-nence	SM	Combined	Control	Continence vs control	SM vs control	Combined vs control	Continence vs control	SM vs control	Combined vs control	Conti-nence 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)	11.72 (4.54-30.21)	5.16 (1.73-15.37)	15.51 (6.50-37.01)	9.14 (3.05-27.37)	2.71 (0.87-8.41)	17.63 (5.09-61.13)
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)	11.45 (4.27-30.67)	4.64 (1.48-14.56)	17.14 (6.51-45.11)	10.40 (3.05-35.48)	3.46 (1.08-11.03)	23.27 (5.91-91.59)
ICC Intention-to-treat	-	-	-	-	0.02	0.18	0	0.24	0.18	0	0	0.06	0
ICC per protocol	-	-	-	-	0.03	0.25	0	0.03	0.25	0	0	0.14	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)	4.2 (1.4-13.0)	3.8 (1.2-12.2)	6.3 (2.2-17.7)	2.83 (0.59-13.66)	1.81 (0.50-6.60)	4.94 (1.45-16.86)

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)	3.7 (1.2-11.3)	3.5 (1.06-11.31)	5.8 (2.0-17.4)	2.51 (0.48-13.18)	2.28 (0.63-8.24)	5.32 (1.39-20.34)
ICC Intention-to-treat	-	-	-	-	0.02	0.06	0	0.02	0.06	0	0	0	0
ICC per protocol	-	-	-	-	0.01	0.08	0.02	0.01	0.08	0	0	0.02	0

SM = Self-management; ICC = intra-cluster correlation correlation
*95% CI's were calculated using robust standard errors
**Adjusted for age, living alone, depression, heart disease, falls, arthritis, diabetes, high blood pressure, educational status, general health perception, and baseline incontinence severity score

Table 3: Change in incontinence-related knowledge

		Continence education n=64	Self-management n=70	Combined intervention n=61	Control n=64
1. Urinary incontinence is a normal part of ageing	Baseline % agreement	73.0	79.7	77.0	79.7
	3 month follow up % agreement	36.2	63.9	38.2	82.7
	p value for change*	**<0.001**	**0.02**	**<0.001**	0.73
2. Once people start to leak urine, they are never able to control their urine again	Baseline % agreement	41.9	32.9	36.1	50.8
	3 month follow up % agreement	29.3	17.7	7.3	51.9
	p value for change	0.12	0.06	**<0.001**	1
3. Urine leakage can be caused by many different things	Baseline % agreement	88.9	92.8	88.3	86.9
	3 month follow up % agreement	93.1	88.7	92.7	90.4
	p value for change	1	0.77	0.73	0.63
4. Wearing pads or diapers is the best way to manage urinary incontinence	Baseline % agreement	57.1	40.6	52.5	67.2
	3 month follow up % agreement	36.8	33.9	27.3	69.2
	p value for change	**0.03**	0.11	**0.001**	1
5. What you drink can contribute to urine leakage	Baseline % agreement	64.5	66.7	68.3	66.1
	3 month follow up % agreement	77.6	75.8	89.1	68.6

		Continence education n=64	Self-management n=70	Combined intervention n=61	Control n=64
	p value for change	0.26	0.36	**0.01**	0.77
6. How much you drink can contribute to urine leakage	Baseline % agreement	72.6	65.2	67.2	71.4
	3 month follow up % agreement	77.6	71	76.4	65.4
	p value for change	0.63	0.65	0.36	0.79
7. Losing weight can lead to improvement in incontinence	Baseline % agreement	61.3	74.3	66.1	75
	3 month follow up % agreement	77.6	77.4	90.9	80.8
	p value for change	0.08	0.69	**<0.001**	0.48
8. Exercising pelvic floor muscles can help control urine leakage	Baseline % agreement	85.5	88.6	85.2	96.9
	3 month follow up % agreement	96.5	96.7	98.2	98.1
	p value for change	**0.04**	0.13	**0.02**	1.0

** McNemar's test for matched-pairs data*

Effectiveness of continence promotion for older women via community organisations: a cluster randomised trial

Cara Tannenbaum, MD, MSc[1] Rona Agnew, PhD[2] Andrea Benedetti, PhD[3] Doneal Thomas, MSc[4] Eleanor van den Heuvel, PhD[5]

[1]Associate Professor, Faculty of Medicine, Université de Montréal, Quebec, Canada
[2]Clinical Research Fellow, Glasgow Caledonian University, Glasgow, UK
[3]Associate Professor, Departments of Medicine and of Epidemiology, Biostatistics & Occupational Health, McGill University, Quebec, Canada
[4]PhD candidate, Department of Epidemiology, Biostatistics & Occupational Health, McGill University, Quebec, Canada
[5]Director of Assistive Technology Programme, Brunel Institute for Ageing Studies, Brunel University, Uxbridge, UK

Word count : 3182

Key words: Continence promotion, cluster trial, community organisations, older women, urinary incontinence

Corresponding Author: Dr. Cara Tannenbaum, Centre de Recherche de l'Institut universitaire de gériatrie de Montréal, 4545 Queen Mary Road, Montreal, Quebec, Canada H3W 1W5. Tel (514) 340-2800. Fax : (514) 340-3530.
Email: cara.tannenbaum@umontreal.ca

All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

The authors retained full independence from the study sponsors in the design, implementation, analysis, interpretation and reporting of the findings.

ABSTRACT

Objectives: The primary objective of this cluster randomised controlled trial was to compare the effectiveness of the three experimental continence promotion interventions against a control intervention on urinary symptom improvement in older women with untreated incontinence recruited from community organisations. A second objective was to determine whether changes in incontinence-related knowledge and new uptake of risk-modifying behaviours explain these improvements.

Setting: 71 community organisations across the United Kingdom

Participants: 259 women aged 60 years and older with untreated incontinence entered the trial; 88% completed the 3-month follow-up.

Interventions: The three active interventions consisted of a single 60-minute group workshop on 1) continence education (20 clusters, 64 women); 2) evidence-based self-management (17 clusters, 70 women); or 3) combined continence education and self-management (17 clusters, 61 women). The control intervention was a single 60-minute educational group workshop on memory loss, polypharmacy and osteoporosis (17 clusters, 64 women).

Primary and secondary outcome measures: The primary outcome was self-reported improvement in incontinence 3 months post-intervention at the level of the individual. The secondary outcome was change in the International Consultation on Incontinence Questionnaire (ICIQ) from baseline to 3-month follow-up. Changes in incontinence-related knowledge and behaviours were also assessed.

Results: The highest rate of urinary symptom improvement occurred in the combined intervention group (66% vs 11% of the control group, prevalence difference 55%, 95% CI 43%-67%, intracluster correlation 0). Thirty percent versus 6% of participants reported significant improvement respectively (prevalence difference 23%, 95% CI 10%-36%, intracluster correlation 0). The number-needed-to-treat was 2 to achieve any improvement in incontinence symptoms, and 5 to attain significant improvement. Compared to controls, participants in the combined intervention reported an adjusted

mean 2.05 point (95% CI 0.87-3.24) greater improvement on the ICIQ from baseline to 3-month follow up. Changes in knowledge and self-reported risk-reduction behaviours paralleled rates of improvement in all intervention arms.

Conclusion: Continence education combined with evidence-based self-management improves symptoms of incontinence among untreated older women. Community organisations represent an untapped vector for delivering effective continence promotion interventions.

Trial registration: ClinicalTrials.gov ID number NCT01239836

Article Summary : Strengths and limitations of this study

- First study to provide Level 1 evidence that continence promotion is an effective strategy for improving urinary symptoms among untreated community-dwelling older women
- Participants were recruited via community organisations with representation across diverse socio-economic strata
- Rates of knowledge acquisition and behaviour change provide an explanatory mechanism for the observed improvements in incontinence in participants receiving the combined education plus self-management strategy
- Only self-reported outcomes and crude dichotomous measures of behaviour change were collected so results must be interpreted with caution

Introduction

Urinary incontinence is more frequent than breast cancer, heart disease or diabetes among older women, but remains a stigmatized and untreated condition despite its high prevalence. [1-4] In the United States, Canada, the U.K. and other European countries, up to 40% of women aged 65 years and older experience involuntary urine leakage, but little more than 15-30% seek care.[1-4] Even fewer physicians feel competent evaluating or treating incontinence.[5-6] Urinary incontinence is associated with obesity, cardiovascular disease, diabetes, depression, social isolation, decline in function, falls, nursing home admission, and onerous out-of-pocket expenses.[6-10] In many cases incontinence can be improved, and even cured, when evidence-based diagnostic and treatment strategies are appropriately applied.[6,11-14]

It is a commonly held misconception that incontinence is a normal part of aging.[15] Not-for-profit organisations seek to raise continence awareness worldwide and promote treatment for incontinent individuals. Media campaigns, brochures and public awareness lectures attempt to de-stigmatise incontinence and increase help-seeking, but the effectiveness of these initiatives for reaching their target population remains unknown.[15] Transmission of public health education via community organisations is an unexplored strategy for improving urinary symptoms.[16] Data from randomised trials are needed to determine whether the delivery of an evidence-based continence intervention via community organisations is an effective method for treating incontinence.

The primary objective of this cluster randomised controlled trial was to compare the effectiveness of the three experimental continence promotion interventions against a control intervention on urinary symptom improvement in older women with untreated incontinence recruited from community organisations. A second objective was to determine whether changes in incontinence-related knowledge, attitudes and new uptake of risk-modifying behaviours explain improvements in incontinence. We hypothesized that continence education combined with evidence-based self-management would yield the greatest improvement in incontinence symptoms, measured at the level of the individual, 3-months post-intervention.

METHODS

Study design and oversight

A 4 arm, parallel-group, controlled, cluster randomised trial was conducted. The study design, recruitment methods and interventions have been reported.[16] Clustering was at the level of the community organisation, from whence participants were recruited. The choice of a cluster design served to prevent contamination between participants in the same community organisation. The trial was designed by two of the authors and was overseen by the full investigator team, which had full access to the data. The data were collected at community organisations across the United Kingdom. All participants provided written informed consent. The protocol was approved by the Brunel University Research Ethics Committee.

Study population and recruitment

Inclusion criteria for community organisations included any organisation throughout the United Kingdom that consented to participate in the trial between November 2010 and September 2012. A community organisation was loosely defined as any not-for-profit group of individuals with a shared interest. These included interest and charity groups, seniors' housing groups, women's lobby groups and Asian caregiver associations.[16] Organisations were contacted strategically by convenience sampling, word of mouth and referral. A research coordinator approached community organisations to join the trial by telephone, email and newspaper advertising.

Inclusion criteria for participants were women aged 60 years and older who reported urinary incontinence at least once weekly on the International Consultation on Incontinence Questionnaire (ICIQ), and who were not under active treatment for incontinence. For privacy reasons, many community organisations were uncomfortable screening their members for incontinence in advance, so eligibility to participate in the trial could only be ascertained by the research coordinator on the day of delivery of the intervention.[16] Eligibility to participate in the trial was established by asking all attendees at the workshop to complete a baseline screening questionnaire upon arrival. At this time, a study information sheet and consent form were distributed to all participants. All women, regardless of eligibility or desire to enrol in

the trial, were permitted to stay for the workshop. Only those women who wished to enrol in the trial submitted the signed consent form to the workshop facilitator following delivery of the intervention, however all attendees were encouraged to submit the baseline screening questionnaire even if they were continent or did not wish to participate in the trial.

Interventions

The interventions were applied at the level of each cluster. The three experimental interventions to be tested were continence education, self-management including the distribution of an evidence-based risk factor reduction tool for incontinence, and a combined intervention that included both components. The sham control intervention was a lecture on health promotion for older women that addressed topics other than incontinence. All interventions were delivered once in group format to 8-16 women by the same facilitator at a venue of the organisation's choosing, and lasted 60-90 minutes. A slide presentation with a pre-established script prepared for the facilitator was delivered at each workshop.

The continence promotion intervention incorporated elements of constructivist learning that challenged older adults' erroneous beliefs about accepting incontinence as a normal part of aging, and aimed to change attitudes and create new knowledge about the different types, etiology, risk factors and treatment options for urine loss.[16-17] The self-management workshop reviewed self-management theory in an interactive format, and provided a customised evidence-based self-management program for risk factor modification for incontinence to each participant.[18-19] The program targeted pelvic floor muscle weakness, obesity, consumption of caffeinated beverages, smoking, vision loss and constipation, with instructions on how to keep a bladder diary to help monitor symptoms. The content of the combined intervention condensed elements from the continence promotion workshop along with self-management theory, and provided the customized self-management tool to participants. The control intervention addressed other non-bladder related aspects of older women's health such as memory problems, polypharmacy, osteoporosis, nutrition, physical fitness and vision impairment.

Study Outcomes

The primary outcome was the participant's global impression of improvement in incontinence symptoms, measured at 3 months post-intervention by telephone interview using the patient's global impression of improvement (PGI-I) questionnaire. The PGI-I is a validated, single-item global rating of change scale that asks the patient to describe how their incontinence condition is now compared to how it was prior to the intervention (very much better, much better, a little bit better, no change, a little bit worse, much worse and very much worse).[20] The primary outcome, any improvement, was defined as a rating of a little bit better, much better or very much better. A secondary outcome, significant improvement, was defined as much better or very much better. The ICIQ, which measures the frequency, severity and bother from incontinence was used at baseline to screen participants for inclusion to the trial, and was repeated at follow-up.[21] The ICIQ diagnostic item was used by participants to describe the type of incontinence at baseline. A pre- and post-8-item questionnaire on knowledge and attitudes towards incontinence was administered at baseline and at 3-month follow-up, as were risk factors and behaviors related to incontinence.[17] Risk factors and behaviors included performance of pelvic floor muscle exercises three times weekly (yes, no), daily consumption of 1 cup or more of tea or coffee (yes, no), fluid intake > 1.5 L/day (yes, no), weight and height (self-report) and smoking status (yes, no). At three month follow-up participants were asked whether they had sought treatment for urine leakage during the past 3 months. All follow-up interviews were performed by the research coordinator, who was blinded to participant identification.

The original study protocol sought to examine reductions in urinary frequency as measured on a bladder diary and reductions in the cost of pad use as primary and secondary outcomes respectively. However as soon as recruitment for the trial commenced it became apparent that distribution of bladder diaries and objective measurement of pad use pre-intervention would not be possible. This occurred as a result of privacy concerns expressed by participating community organisations for revealing and sharing their members' names and contact information with the research team prior to the delivery of the workshops.[16] The PGI-I was therefore used as the revised primary measure of effectiveness from the onset of the trial. Data on self-efficacy for managing incontinence was also collected, but is not reported in

this paper due to problems with comprehension of the visual analogue response scale during the 3-month telephone follow-up that occurred non-differentially among participants in all arms of the study.

Randomisation and allocation concealment

Group allocation occurred by non-stratified randomisation in blocked groups of 4 of consenting organisations that agreed to host a workshop. An independent statistician at a distant study site was responsible for randomisation using computer-generated random digits. Community organisations were informed that one of four workshops would be delivered on health topics of interest to older women, but not which one. In this way, group allocation was concealed from both the clusters and the individual participants, who were invited by the host organisation to attend a "Women's Health Worshop". The research coordinator remained unaware of group allocation at the time each community organisation was recruited to the trial because she was only informed which workshop to prepare for each organisation several days before each workshop. The trial is considered 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.

Sample Size

The trial was designed to detect a minimal 35% difference in the number of participants reporting any improvement (very much better, much better, a little bit better on the PGI-I) 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 anticipated maximum intracluster correlation (ICC) of 0.05 and unequal cluster size yielded a recruitment target of 56 participants per group.[22]

Statistical Methods

Differences in baseline characteristics between the four groups were determined. To assess the primary outcome we estimated the unadjusted risk difference (prevalence of the outcome) and 95% confidence intervals (CI) via generalized estimating equations (GEEs) for participants who reported any improvement on the PGI-I. We repeated the same analysis for those who reported significant improvement. GEEs

with an identity link and an exchangeable correlation structure were used to account for possible correlation between women in the same organisation.[23] To adjust for the imbalance in potential confounders in the groups at baseline, additional analyses were conducted using multivariable logistic regression estimated via GEE with an exchangeable correlation structure. Potential confounders included age and baseline incontinence severity (ICIQ score) as continuous predictors, 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 (PP) analyses were performed. For the ITT analysis, participants with missing data were assumed to have no change in incontinence status at three-month follow-up. The number needed to treat was calculated as the inverse of the difference in absolute event rates between the experimental and control groups.[24] We report intra-cluster (intra-community organisation) correlation coefficients (ICC) from the marginal model using GEE with assumed exchangeable correlation structure and robust standard errors.[25] In cases where an ICC<0 was detected, we assumed a correlation structure of independence, but still used the robust variance estimator. The robust variance estimator is robust to misspecification of the correlation structure, so standard errors, confidence intervals and p values are still correct. To estimate adjusted mean group differences in ICIQ scores from baseline to 3-month follow up, we used GEE with a Gaussian regression model for continuous outcomes and followed the same procedure outlined above.

Improvements in incontinence-related knowledge by intervention type for proportions of individuals responding correctly to each knowledge questionnaire item at baseline compared to 3-month follow-up were estimated using McNemar's test for matched pair analysis. Rates of improvement in self-reported risk modifying behaviours for incontinence were calculated, along with 95% confidence intervals. Differences in improvement rates between the intervention and the control group were compared using Fisher's Exact test using a per protocol analysis. A difference in response for each health behavior item that indicated adoption of a new risk modifying behaviour was defined as a positive change at 3-month follow-up compared to baseline. Reduced coffee and tea intake refer to individuals who reduced their consumption to a single cup per day or less. Weight loss was determined by a positive response to the question, "Has your weight changed (yes, no) and if so, how much do you now

weigh?" and evidence of self-reported current weight lower than self-reported weight at baseline. All statistical analyses were run using RStudio 0.97.310.0, an integrated development environment for R.

RESULTS

Study participants and follow-up

Four-hundred-and-twenty different community organisations were approached over an 18-month period to participate in the trial. Of these, 17% consented and succeeded in hosting an intervention, yielding 71 clusters that were randomised. Approximately one quarter of the groups contacted refused; 2% expressed interest but were unable to organise a workshop; and a little over half failed to give any response although most of them had been followed up and had received extra information on the project.[16] Figure 1 depicts the study flow of the clusters and participants through the trial. Seven-hundred-and-sixty three women attended the workshops, of whom 322 (42%) were known to be eligible for the trial. The mean number of participants recruited from each cluster for the continence promotion group was 3 ± 2, whereas it was 4 ± 2 for the other 3 groups. Eighty-percent (259/322) of known eligible attendees to the workshops consented to take part in the trial. Two-hundred-and-twenty-eight of these (88%) were available for 3-month follow-up. Table 1 compares the baseline characteristics of participants in each trial arm.

Primary and secondary outcomes

The highest rate of improvement in incontinence occurred in the combined intervention group, 66% compared to 11% in the control group (prevalence difference 55%, 95% CI 43%-67%), yielding a number-needed-to-treat of 2. Thirty percent of the combined group reported significant improvement compared to 6% of controls (prevalence difference 23%, 95% CI10%-36%, number-needed-to-treat of 5). In adjusted analyses, the likelihood of achieving a significant improvement in urinary symptoms from exposure to the combined intervention was five times greater than exposure to the control intervention (OR 4.94, 95% CI 1.45-16.86). Compared to controls, the participants in the combined intervention reported an adjusted mean 2.05 point (95% CI 0.87-3.24) greater improvement on the ICIQ from baseline to 3-month follow up. The adjusted mean difference in ICIQ scores was also significantly higher

for the continence education group compared to the control group (1.33 point greater improvement (95% CI 0.33-2.32)), but not for the self-management group. The per protocol analysis for the primary outcome and the intra-cluster correlation coefficients for each analysis are shown in Table 2.

Other outcomes

Table 3 shows the changes in incontinence-related knowledge attributable to receipt of each intervention. Participants exposed to the combined intervention showed the greatest acquisition in knowledge, exhibiting significant within-group improvement on 6 out of 8 questionnaire items. Participants learned that incontinence is not an inevitable or irreversible part of aging, that losing weight, changing the type of fluid intake and performing pelvic floor muscle exercises can reduce urinary symptoms, and that wearing undergarment protection is not always the best way to manage incontinence.

The proportion of participants with modifiable risk factors for incontinence in each group at baseline is shown in Table 1. The adoption of various risk-modifying behaviours among participants occurred to a different degree as a result of exposure to all three experimental but not the control intervention (Figure 2). At three-month follow-up, the proportion of women reporting uptake of pelvic floor muscle exercises and weight loss was significantly higher in the continence education group (46% and 20% respectively), the self-management group (34% and 20%) and the combined intervention group (53% and 18%) compared to controls (8% and 3%). Many women additionally reduced their coffee intake and total fluid intake. The proportion of women who made an appointment to consult a health professional for urine leakage was 19% in the continence promotion group, 7% in the self-management group, 16% in the combined intervention group and 4% in the control group.

DISCUSSION

In this cluster-randomised trial testing the effectiveness of 3 different continence promotion interventions, we found that health education combined with the delivery of an evidence-based self-management tool via community organisations to untreated older women yielded the highest rate of urinary symptom improvement in 66% of

recipients, half of whom reported significant improvements in incontinence. These outcomes translate into a number-needed-to-treat of 2 and 5 respectively, a magnitude of effect rarely achieved during public health interventions. Both new knowledge acquisition and the adoption of risk-modifying behaviours such as exercise and weight loss occurred as a result of community organisations' involvement in reaching untreated incontinent women outside the health care system.

Strengths and weaknesses of the study

This is the first randomised trial to test the effectiveness of continence promotion strategies through community outreach. Both explanatory mechanisms and final health outcomes were assessed, and the use of a cluster randomised design was chosen to avoid contamination of the control group.[26,27] Our choice of comparator controlled for the placebo effect of participating in a group intervention. Breaches in the fidelity and quality of implementation of the intervention were minimized by having the same facilitator deliver each intervention. Improvements in urinary symptoms were shown with two validated measures, the PGI-I and the ICIQ. We believe the results have wide external validity as the community groups included women with varied educational levels and wide socioeconomic status.

The results of this study confirm findings from previous randomised trials suggesting a positive effect of continence education and self-monitoring strategies on urinary symptom improvement in untreated incontinent individuals.[28-33] However all previous trials invited participants for clinical assessments prior to the delivery of the intervention, or involved individualized education sessions. The current trial delivered group continence interventions without medical or nursing evaluations, in a true public health approach, to both continent and incontinent women as part of the regular activities offered by each community organisation. Rates of improvement reported in this trial on the PGI-I were similar to or exceeded those reported in other studies using self-help booklets, in the range of 50%. Because of the nature of recruitment and delivery of the intervention via community organisations, bladder diaries and pad tests could not be collected pre-intervention. The results of our trial can therefore not be directly compared to other trials that used more objective measures of symptom improvement.

Other limitations apply. Due to the nature of recruiting potential participants, individuals could not be screened and enrolled in the trial prior to randomisation of the clusters.[27] The result was an imbalance between groups, accounted for by analyses that took into account group differences in age, health status and baseline incontinence severity. The trial was not designed to measure the dose-response of knowledge acquisition and behaviour change on urinary symptom improvement. Thus only crude, dichotomous self-reported measures of behaviour change were collected and should be interpreted with caution.

Relevance to the discipline

The value of continence promotion interventions likely reflects the delivery method as well as the quality of the content. Group interventions that deliver continence education, self-management information, or a combination of the two will improve incontinence symptoms in 59%, 41% and 66% of recipients, respectively. It is surprising that the self-management intervention alone was not associated with significant improvement compared to sham control in this trial. This can potentially be explained by the fact that continence education was completely omitted from the self-management workshop, whereas some information on bladder functioning was provided to participants during the initial work that tested the self-management tool.[19]

Implications for practice

Implementation of community-based programs that promote behavioural techniques as first-line management for incontinence support evidence for the superior efficacy and tolerability of conservative management approaches over pharmacological treatment for incontinence.[34] As “silent sufferers” become better informed that effective strategies exist for improving urinary symptoms, patient demand for care will likely increase. Almost 20% of women made an appointment to discuss urine leakage with a health professional in the three months following receipt of the continence education intervention. Evidence-based guidelines exist for physicians to evaluate and manage urinary incontinence when first-line behavioural strategies fail, and will need to be more frequently applied.[5,11]

In conclusion, continence education combined with self-management delivered via community organisations to untreated older women with incontinence leads to symptom improvement in 1 out of every 2 recipients. At the current time, the majority of older women with incontinence do not seek care, and either self-manage their symptoms inappropriately or use protection to palliate urine leakage.[1-4] As incontinence is associated with multimorbidity and other deleterious health effects, results from this trial provide strong justification for public health outreach via community organisations to reduce urine leakage among untreated individuals.

Acknowledgments

We wish to acknowledge the assistance of Mira Jabbour and Francine Giroux for their expert help with database management and the data analyses. Nikki Cotterill, Adele Long aided with recruitment in the Bristol area. The above-mentioned individuals received financial compensation for their contribution to this work. We express gratitude to all the participants who took part in this trial. Although not exhaustive, particular thanks are offered to the following organisations and groups for participating in the trial: the Women's Institute, AGE UK, the University of the Third Age, Queens Nursing Institute (Scotland), Kinship Carers, the Women's Guild, Hanover Housing Association, Good Neighbours, Asian Carers Groups, Older Peoples Forum throughout the UK.

Author Contribution Statement

Cara Tannenbaum designed the study and participated in the data analysis and interpretation. She wrote the first draft of the manuscript. Rona Agnew was responsible for data collection, participated in the data analysis and interpretation and critically reviewed the manuscript. Andrea Benedetti was responsible for the data analysis and interpretation and critically reviewed the manuscript. Doneal Thomas conducted the analyses and reviewed the manuscript. Eleanor van den Heuvel helped design the study, participated in the study implementation, helped interpret the findings and critically reviewed the manuscript.

Data Access and Sharing Statement

Cara Tannenbaum, Doneal Thomas and Andrea Benedetti had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis. Patient level data and the full dataset is available upon request from the authors. Consent for data sharing was not obtained but the presented data are anonymised and the risk of identification is low.

Competing interests

Cara Tannenbaum declares having been an advisory board member or received speaker honoraria from Pfizer, Watson, Astellas, Allergen and Ferring pharmaceuticals in the past 3 years, but not in relation to this work. All other authors declare: no support from any organisation for the submitted work; no financial relationships with any organisations that might have an interest in the submitted work in the previous three years, and no other relationships or activities that could appear to have influenced the submitted work.

Funding and Sponsor's Role

The trial was funded by a joint collaboration between the Canadian Institutes of Health Research and the Economic and Social Research Council (UK). The authors retained full independence from the study sponsors in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, and approval of the manuscript; and decision to submit the manuscript for publication.

REFERENCES

1. Sexton CC, Coyne KS, Thompson C, Bavendam T, Chen CI, Markland A. Prevalence and effect on health-related quality of life of overactive bladder in older Americans: Results from the Epidemiology of Lower Urinary Tract Symptoms Study. J Am Geriatr Soc 2011;**59**:1465–1470.
2. Tannenbaum C, Corcos J, Assalian P. The relationship between sexual activity and urinary incontinence in older women. J Am Geriatr Soc 2006;**54**:1220-4.
3. O'Donnell M, Lose G, Sykes D, Voss S, Hunskaar S. Help-seeking behaviour and associated factors among women with urinary incontinence in France, Germany, Spain and the United Kingdom. Eur Urol 2005;**47**:385-92
4. Herschorn S, Gajewski J, Schulz J, Corcos J. A population-based study of urinary symptoms and incontinence: the Canadian Urinary Bladder Survey. BJU Int 2008;**101**:52-8.
5. Bland DR et al. The effects of implementation of the Agency for Health Care Policy and Research urinary incontinence guidelines in primary care. J Am Geriatr Soc 2003;**51**:979–984.
6. Subak LL, Wagner TH. Talking about incontinence: the first step toward prevention and treatment. JAMA 2010;**303**:2184-2185.
7. Tannenbaum C, Gray M, Hoffstetter S, Cardozo L. Comorbidities associated with bladder dysfunction. Int J Clin Pract 2013;**67**:105-13.
8. Farage MA, Miller KW, Berardesca E, Maibach HI. Psychosocial and societal burden of incontinence in the aged population. Arch Gynecol Obstet 2008;**277**:285-290.
9. Holroyd-Leduc JM, Mehta KM, Covinsky KE. Urinary incontinence and its association with death, nursing home admission, and functional decline. J Am Geriatr Soc 2004;**52**:712-8.
10. Chiarelli PE, Mackenzie LA, Osmotherly PG. Urinary incontinence is associated with an increase in falls: a systematic review. Aust J Physiother 2009;**55**:89-95.
11. Holroyd-Leduc JM, Tannenbaum C, Thorpe KE, Straus SE. What type of urinary incontinence does this woman have? JAMA 2008;**299**:1446-56.
12. Goode PS, Burgio KL, Richter HE, Markland AD. Incontinence in older women. JAMA 2010;**303**:2172-81.

13. Tannenbaum C, Bachand, G, DuBeau CE, Kuchel GA. Experience of an incontinence clinic for older women : no apparent age limit for potential physical and psychological benefits. J Women Health Gend Based Med 2001;**10**:751-56.
14. Tannenbaum C, Brouillette J, Corcos J. Rating improvements in urinary incontinence: do patients and physicians agree? Age Ageing 2008;**37**:1-5
15. Newman DK, Buckley B, Gordon D et al. Continence promotion, education and primary prevention. In Abrams P, Cardozo L, Khoury S, Wein A eds: Incontinence. 5th International Consultation on Incontinence, Paris, February 2012. Health Publication Ltd 2013.
16. Agnew R, van den Heuvel E, Tannenbaum C. Efficiency of using community organisations as catalysts for recruitment to continence promotion trials. Clin Trials 2013;**10**:151-9.
17. Tannenbaum C, Drali R, Holroyd-Leduc J Richard L. Lessons learned: Impact of a continence promotion activity for older community dwelling women. Neurourol Urodyn 2010;**29**:540-544.
18. Wilde MH, Bliss DZ, Booth J, Cheater F, Tannenbaum C. Self-Management of Urinary and Fecal Incontinence. AJN 2013 in press.
19. Holroyd-Leduc J, Strauss S, Thorpe K, Davis D, Schmaltz H, Tannenbaum C. Translation of evidence into a self-management tool for use by women with urinary incontinence. Age Ageing 2011;**40**:227-33.
20. Yalcin I, Bump RC. Validation of two global impression questionnaires for incontinence. Am J Obstet Gynecol 2003;**189**: 98–101.
21. Avery K, Donovan J, Peters TJ et al. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn 2004; **23**: 322–30.
22. Eldridge SM; Ashby D; Kerry S. Sample size for cluster randomised trials: effect of coefficient of variation of cluster size and analysis method. Int J Epidemiol 2006;**35**:1292-1300.
23. Ukoumunne OC, Forbes AB, Carlin JB, Gulliford MC. Comparison of the risk difference, risk ratio and odds ratio scales for quantifying the unadjusted intervention effect in cluster randomised trials. Stat Med 2008;**27**: 5143-5155.
24. Users' guide to the medical literature. Integrating research evidence with the care of the individual patient. JAMA 2000;**283**;2829-2836.

25. Hanley JA, Negassa A, Edwardes MD. GEE analysis of negatively correlated binary responses: a caution. Stat Med 2000;**19**:715–722.
26. Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M. Developing and evaluating complex interventions: the new Medical Research Council guidance. BMJ 2008;**337**:979-983.
27. Campbell MK, Piaggio G, Elbourne DR, Altman DG. Consort 2010 statement: extension to cluster randomised trials. BMJ 2012;**345**:e5661.
28. Kincade JE, Dougherty MC, Carlson JR, Hunter GS, Busby-Whitehead J. Randomised clinical trial of efficacy of self-monitoring techniques to treat urinary incontinence in women. Neurourol Urodyn 2007;**26**:507-11.
29. Wagg AR, Barron D, Kirby M, Stott D, Corlett K. A randomised partially controlled trial to assess the impact of self-help vs. structured help from a continence nurse specialist in women with undiagnosed urinary problems in primary care. Int J Clin Pract 2007;**61**:1863-73.
30. Dougherty MC, Dwyer JW, Pendergast JF et al. A randomised trial of behavioral management for continence with older rural women. Res Nurs Health 2002;**25**:3-13.
31. McFall SL, Yerkes AM, Cowan LD. Outcomes of a small group educational intervention for urinary incontinence: episodes of incontinence and other urinary symptoms. J Aging Health 2000;**12**:250-67.
32. Milne J. The impact of information on health behaviors of older adults with urinary incontinence. Clin Nurs Res 2000;**9**:161-76.
33. Goode PS, Burgio KL, Locher JL et al. Effect of behavioral training with or without pelvic floor electrical stimulation on stress incontinence in women: a randomized controlled trial. JAMA 2003;**290**(3):345-52.
34. Shamliyan T, Wyman J, Kane RL. Nonsurgical treatments for urinary incontinence in adult women: diagnosis and comparative effectiveness. Comparative Effectiveness Review No. 36. (Prepared by the University of Minnesota Evidence-based Practice Center under Contract No. HHSA 290-2007-10064-I.) AHRQ Publication No. 11(12)-EHC074-EF. Rockville, MD. Agency for Healthcare Research and Quality. April 2012. Available at: www.effectivehealthcare.ahrq.gov/reports/final.cfm.

Table 1: Baseline characteristics and distribution of modifiable risk factors of participants

	Continence education (n=64)	Self-management (n=70)	Combined intervention (n=61)	Control intervention (n=64)
	Mean ± SD			
Age	70.8 ± 7.9	71.0 ± 6.8	70.4 ± 6.7	74.1 ± 8.1
Mean ICIQ score*	8.5 ± 4.4	6.8 ± 3	7.3 ± 5.6	6.7 ± 3.4
	(% yes)			
Lives alone	48.4	40.0	37.7	59.4
Education				
University degree or equivalent	31.2	45.7	37.7	19.0
General health perception				
Good, very good, excellent	53.1	85.7	80.3	75.0
Fair/poor	45.3	14.3	16.4	25.0
Depression	48.4	35.7	32.8	20.3
Heart disease	35.9	25.7	16.4	21.0
Falls	45.3	31.4	18.0	18.8
Arthritis	78.1	52.9	44.3	57.8
Diabetes	39.1	24.3	18.0	20.3
High blood pressure	59.0	40.0	45.9	55.6
Type of incontinence				
Stress only	15.6	12.9	14.8	33.3
Urgency only	32.8	35.7	29.5	20.6
Mixed	45.3	42.9	55.7	39.7
Modifiable risk factors				
Performs pelvic floor muscle exercises 3 times per week	18.8	15.7	11.9	15.6
Self-reported body mass index $\geq$ 27 kg/m^2 **	53.2	53.0	42.4	49.2
Drinks more than 1.5 litres of fluid/day	43.8	44.3	54.1	37.5
Drinks one cup of tea or more/day	85.9	84.3	73.8	84.4
Drinks one cup of coffee or more/day	46.9	62.9	65.6	64.1
Smokes	6.3	4.3	4.9	6.2

*ICIQ = International Consultation on Incontinence Questionnaire, used to measure the severity and bother from urinary incontinence. Scores range from 0 to 21, with higher scores representing worse incontinence.

**Self-reported body mass index: calculated as weight (kg)/height^2 (m) based on participant's self-reported height and weight at baseline

Table 2: Prevalence, risk difference and odds ratios for self-reported improvements in incontinence at 3-months

	Prevalence at 3-month follow-up				Prevalence difference (95% CI)*			Odds ratio (95% CI)					
								Crude			Adjusted**		
	Conti-nence	SM	Combined	Control	Continence vs control	SM vs control	Combined vs control	Continence vs control	SM vs control	Combined vs control	Conti-nence 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)	11.72 (4.54-30.21)	5.16 (1.73-15.37)	15.51 (6.50-37.01)	9.14 (3.05-27.37)	2.71 (0.87-8.41)	17.63 (5.09-61.13)
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)	11.45 (4.27-30.67)	4.64 (1.48-14.56)	17.14 (6.51-45.11)	10.40 (3.05-35.48)	3.46 (1.08-11.03)	23.27 (5.91-91.59)
ICC Intention-to-treat	-	-	-	-	0.02	0.18	0	0.24	0.18	0	0	0.06	0
ICC per protocol	-	-	-	-	0.03	0.25	0	0.03	0.25	0	0	0.14	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)	4.2 (1.4-13.0)	3.8 (1.2-12.2)	6.3 (2.2-17.7)	2.83 (0.59-13.66)	1.81 (0.50-6.60)	4.94 (1.45-16.86)

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)	3.7 (1.2-11.3)	3.5 (1.06-11.31)	5.8 (2.0-17.4)	2.51 (0.48-13.18)	2.28 (0.63-8.24)	5.32 (1.39-20.34)
ICC Intention-to-treat	-	-	-	-	0.02	0.06	0	0.02	0.06	0	0	0	0
ICC per protocol	-	-	-	-	0.01	0.08	0.02	0.01	0.08	0	0	0.02	0

SM = Self-management; ICC = intra-cluster correlation correlation
*95% CI's were calculated using robust standard errors
**Adjusted for age, living alone, depression, heart disease, falls, arthritis, diabetes, high blood pressure, educational status, general health perception, and baseline incontinence severity score

Table 3: Change in incontinence-related knowledge

		Continence education n=64	Self-management n=70	Combined intervention n=61	Control n=64
1. Urinary incontinence is a normal part of ageing	Baseline % agreement	73.0	79.7	77.0	79.7
	3 month follow up % agreement	36.2	63.9	38.2	82.7
	p value for change*	**<0.001**	**0.02**	**<0.001**	0.73
2. Once people start to leak urine, they are never able to control their urine again	Baseline % agreement	41.9	32.9	36.1	50.8
	3 month follow up % agreement	29.3	17.7	7.3	51.9
	p value for change	0.12	0.06	**<0.001**	1
3. Urine leakage can be caused by many different things	Baseline % agreement	88.9	92.8	88.3	86.9
	3 month follow up % agreement	93.1	88.7	92.7	90.4
	p value for change	1	0.77	0.73	0.63
4. Wearing pads or diapers is the best way to manage urinary incontinence	Baseline % agreement	57.1	40.6	52.5	67.2
	3 month follow up % agreement	36.8	33.9	27.3	69.2
	p value for change	**0.03**	0.11	**0.001**	1
5. What you drink can contribute to urine leakage	Baseline % agreement	64.5	66.7	68.3	66.1
	3 month follow up % agreement	77.6	75.8	89.1	68.6

		Continence education n=64	Self-management n=70	Combined intervention n=61	Control n=64
	p value for change	0.26	0.36	**0.01**	0.77
6. How much you drink can contribute to urine leakage	Baseline % agreement	72.6	65.2	67.2	71.4
	3 month follow up % agreement	77.6	71	76.4	65.4
	p value for change	0.63	0.65	0.36	0.79
7. Losing weight can lead to improvement in incontinence	Baseline % agreement	61.3	74.3	66.1	75
	3 month follow up % agreement	77.6	77.4	90.9	80.8
	p value for change	0.08	0.69	**<0.001**	0.48
8. Exercising pelvic floor muscles can help control urine leakage	Baseline % agreement	85.5	88.6	85.2	96.9
	3 month follow up % agreement	96.5	96.7	98.2	98.1
	p value for change	**0.04**	0.13	**0.02**	1.0

** McNemar's test for matched-pairs data*

Figure 1: Flow of participants through the trial

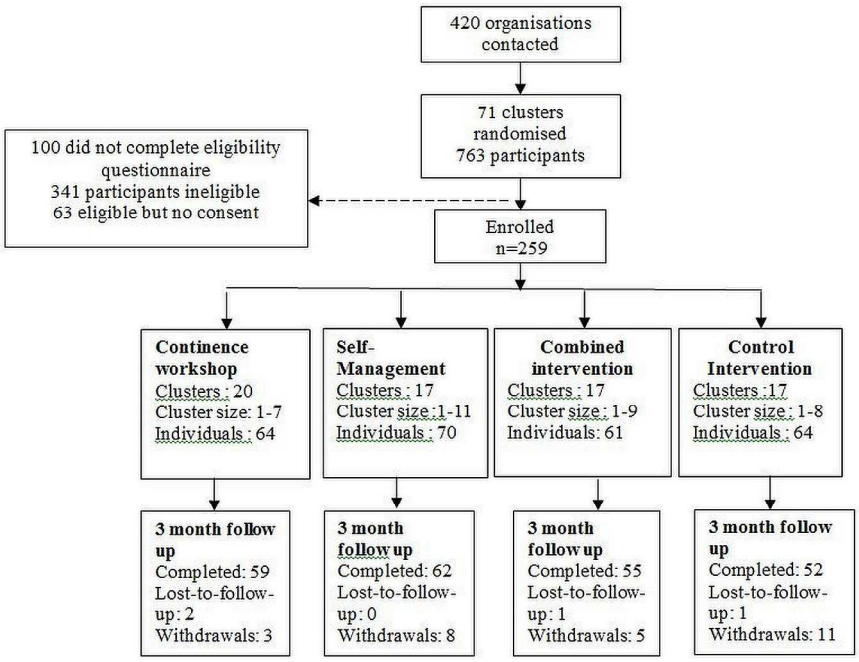
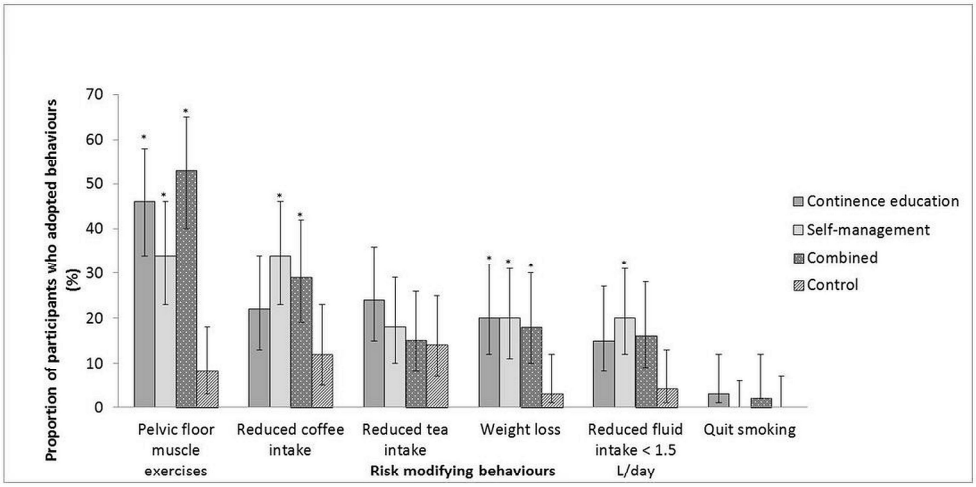


Figure 1: Flow of participants through the trial
235x186mm (300 x 300 DPI)

Figure 2: Change in risk-modifying behaviours at 3-month follow-up



*Significantly different from the control group ($p<0.05$) using Fisher's Exact test in per protocol analysis
Error bars represent 95% confidence intervals

Figure 2: Change in risk-modifying behaviours at 3-month follow-up
297x186mm (300 x 300 DPI)

Table 1: CONSORT 2010 checklist of information to include when reporting a cluster randomised trial

Section/Topic	Item No	Standard Checklist item	Extension for cluster designs	Page No *
Title and abstract				
	1a	Identification as a randomised trial in the title	Identification as a cluster randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)[1,2]	See table 2	3-4
Introduction				
Background and objectives	2a	Scientific background and explanation of rationale	Rationale for using a cluster design	6
	2b	Specific objectives or hypotheses	Whether objectives pertain to the the cluster level, the individual participant level or both	5
Methods				
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	Definition of cluster and description of how the design features apply to the clusters	6
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons		-
Participants	4a	Eligibility criteria for participants	Eligibility criteria for clusters	6-7
	4b	Settings and locations where the data were collected		6
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Whether interventions pertain to the cluster level, the individual participant level or both	7
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and	Whether outcome measures pertain to the cluster level, the individual participant level or both	8

		when they were assessed		
	6b	Any changes to trial outcomes after the trial commenced, with reasons		-
Sample size	7a	How sample size was determined	Method of calculation, number of clusters(s) (and whether equal or unequal cluster sizes are assumed), cluster size, a coefficient of intracluster correlation (ICC or *k*), and an indication of its uncertainty	9,26
	7b	When applicable, explanation of any interim analyses and stopping guidelines		-
Randomisation:				
Sequence generation	8a	Method used to generate the random allocation sequence		8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	Details of stratification or matching if used	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	Specification that allocation was based on clusters rather than individuals and whether allocation concealment (if any) was at the cluster level, the individual participant level or both	8
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	Replace by 10a, 10b and 10c	-
	10a		Who generated the random allocation sequence, who enrolled clusters, and who assigned clusters to interventions	8
	10b		Mechanism by which individual participants were included in clusters for the purposes of the trial (such as complete	6

			enumeration, random sampling)	
	10c		From whom consent was sought (representatives of the cluster, or individual cluster members, or both), and whether consent was sought before or after randomisation	6
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how		8
	11b	If relevant, description of the similarity of interventions		8
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	How clustering was taken into account	9-10
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses		9-10
Results				
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	For each group, the numbers of clusters that were randomly assigned, received intended treatment, and were analysed for the primary outcome	26
	13b	For each group, losses and exclusions after randomisation, together with reasons	For each group, losses and exclusions for both clusters and individual cluster members	26
Recruitment	14a	Dates defining the periods of recruitment and follow-up		6
	14b	Why the trial ended or was stopped		-
Baseline data	15	A table showing baseline demographic and clinical	Baseline characteristics for the individual and cluster levels as	20

		characteristics for each group	applicable for each group	
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	For each group, number of clusters included in each analysis	26
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	Results at the individual or cluster level as applicable and a coefficient of intracluster correlation (ICC or k) for each primary outcome	11,22-25
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended		11,22-25
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory		11,22-25
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms[3])		-
Discussion				
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses		12
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	Generalisability to clusters and/or individual participants (as relevant)	13-14
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence		13-14
Other information				
Registration	23	Registration number and		4

		name of trial registry	
Protocol	24	Where the full trial protocol can be accessed, if available	-
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	4,16

** Note: page numbers optional depending on journal requirements*

Table 2: Extension of CONSORT for abstracts[1,2] to reports of cluster randomised trials

Item	Standard Checklist item	Extension for cluster trials
Title	Identification of study as randomised	**Identification of study as cluster randomised**
Trial design	Description of the trial design (e.g. parallel, cluster, non-inferiority)	
Methods		
Participants	Eligibility criteria for participants and the settings where the data were collected	**Eligibility criteria for clusters**
Interventions	Interventions intended for each group	
Objective	Specific objective or hypothesis	**Whether objective or hypothesis pertains to the cluster level, the individual participant level or both**
Outcome	Clearly defined primary outcome for this report	**Whether the primary outcome pertains to the cluster level, the individual participant level or both**
Randomization	How participants were allocated to interventions	**How clusters were allocated to interventions**
Blinding (masking)	Whether or not participants, care givers, and those assessing the outcomes were blinded to group assignment	
Results		
Numbers randomized	Number of participants randomized to each group	**Number of clusters randomized to each group**
Recruitment	Trial status[1]	
Numbers analysed	Number of participants analysed in each group	**Number of clusters analysed in each group**
Outcome	For the primary outcome, a result for each group and the estimated effect size and its precision	**Results at the cluster or individual participant level as applicable for each primary outcome**
Harms	Important adverse events or side effects	
Conclusions	General interpretation of the results	
Trial registration	Registration number and name of trial register	
Funding	Source of funding	

[1] Relevant to Conference Abstracts

REFERENCES

1 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG, et al. CONSORT for reporting randomised trials in journal and conference abstracts. *Lancet* 2008, 371:281-283

2 Hopewell S, Clarke M, Moher D, Wager E, Middleton P, Altman DG at al (2008) CONSORT for reporting randomized controlled trials in journal and conference abstracts: explanation and elaboration. *PLoS Med* 5(1): e20

3 Ioannidis JP, Evans SJ, Gotzsche PC, O'Neill RT, Altman DG, Schulz K, Moher D. Better reporting of harms in randomized trials: an extension of the CONSORT statement. *Ann Intern Med* 2004; 141(10):781-788.