264

Agnew R[1], van den Heuvel E[2], Tannenbaum C[1]
1. *Montreal University,* ***2.*** *Brunel University*

RECRUITING FOR CONTINENCE PROMOTION TRIALS: BARRIERS AND SOLUTIONS FOR OPTIMIZING EFFICIENCY

Hypothesis / aims of study

More than half of women with urinary incontinence do not seek care for their symptoms. Continence promotion involves educating people that evidence-based therapeutic options exist, and that improvements and cures can be achieved at all ages. Although worldwide continence awareness campaigns have been launched to reduce the stigma and negative beliefs associated with incontinence, few studies have documented the effectiveness of these programs for reaching untreated incontinence sufferers, engaging them in proactive management behaviours, and ultimately reducing incontinence symptoms. The first ever randomized controlled trial has been launched in the United Kingdom to compare the impact of different continence promotion strategies on senior women with incontinence. The target population is community-dwelling women with incontinence who have not talked to a health care professional about their condition. *Ipso facto,* potential recruits are women who have been uninterested or unmotivated to seek care for various reasons. Randomised control trials are notorious for failing to be efficient in recruitment with 50% of studies not meeting their recruitment target or needing to extend the study[1]. Given the anticipated challenges with recruitment for the current continence promotion trial, a preliminary evaluation of recruitment efficiency was carried out following 4 months of collecting data[2]. The aim of this report is to describe the efficiency of early recruitment efforts for a continence promotion trial in the United Kingdom. Barriers and possible solutions for increasing recruitment are discussed.

Study design, materials and methods

A randomised controlled trial using open label clustering in a 2 x 2 factorial design was conducted. Each cluster was randomly allocated to participate in a workshop using constructivist learning theory, a workshop that distributed evidence-based self-management (self-mgt) tools for incontinence, a combination of the two, or a control intervention on general women's health. Target participants were women aged 60 years and older with weekly incontinence who had not sought treatment for their urinary symptoms. Initial recruitment strategies to host the group interventions were via invitations to local community organisations in conjunction with Age UK, the Women's Institute and other such organisations. To provide an intimate environment the continence promotion activities were designed to be delivered to groups of 10-20 women, free of cost to the participants and organising institution. Phone calls, word of mouth, and targeted advertisements featured in online or paper newsletters aimed to secure buy-in for the project. Women were personally invited through their community organisation to participate in information sessions on reducing urinary incontinence and bladder problems that can occur with age. Invitations were sent with a 3 day bladder journal to be completed prior to the workshop. For reasons of confidentiality, women could not be screened for eligibility prior to the continence promotion sessions, resulting in a mixed group of attendees. Attendees were then informed of the opportunity to participate in the research study, and were asked to decide after the session if they wished to sign the consent form and submit the baseline assessment questionnaire. Women who did not meet the inclusion criteria or who did not wish to take part in the research were free to leave without enrolling in the study. Recruitment efficiency was defined as the number of participants recruited/number of attendees at each workshop.

Results

165 organisations were contacted during the first four months of the study, with 19 groups agreeing to host a workshop (11 % uptake). Table 1 details the number of completed workshops and the characteristics of the participants recruited.

Table 1. Workshops and participant characteristics.

Type of Intervention	Total No. of Workshops	No. of attendees	No. of Recruits	Mean Age (yrs)	% no formal education	% good health
Constructivist workshop	5	59	16	71±6.7	36%	66%
Self Mgt Tool	4	37	22			
Mixed	4	39	10			
Control	4	29	3			
Total	17	164	51			

Recruitment efficiency during the initial stage of this trial was low (30%, range 25-42%). Efforts were made to increase attendance at the workshops, which resulted in a greater number of attendees at each workshop, but did not improve overall efficiency (Table 2).

Table 2. Trends in Recruitment Efficiency Over Time

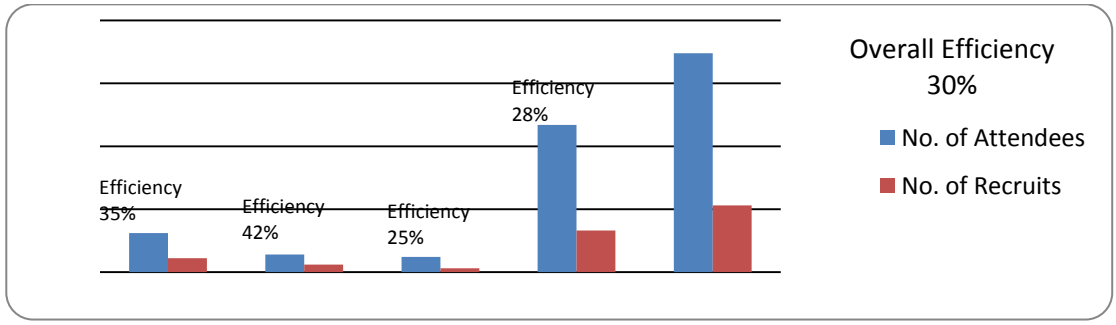

Table 3. Barriers and Solutions for optimizing recruitment to continence promotion trials

Barrier to participation	Solution
Lack of willingness to host a workshop	Telephone calls to organisations to personally introduce the study. Use of testimony of previous participants
Reluctance to attend a bladder health workshop	Introduced workshops as women`s health education rather than solely as bladder health workshops
Bladder diary not completed prior to attending workshop	Incorporated frequency of incontinence episodes into the questionnaire. Will not use bladder diary as outcome
Poor overall attendance at each workshop	Increased attendance maximum to 30
Concern about confidentiality and anonymity if attendees agree to participate in front of their peers at the workshop	Eligibility to participate in research confirmed by telephone after the workshop. All ethical principles are met as before.
Questionnaire not completed /don't attend due to having to complete paperwork	Questionnaire completion presentation done so that participants work through the completion together
Consent form not completed properly therefore unable to recruit to study.	This is worked through in the group with particular attention to the signature aspect of the form.
Goal attainment not fully understood	Discussed while completing the questionnaire as a group

Table 3 shows a qualitative evaluation of various barriers to recruitment for the continence promotion trial as reported by potential community organizers, or volunteered by the attendees at the workshops. Alongside each barrier is listed a possible solution.

Interpretation of results

There remains significant reluctance among community organizations to host events on bladder health, a seemingly "taboo" topic in the UK. All attendees at such events will not necessarily be women with incontinence, which reflects reality but also limits the potential pool of recruits to a continence promotion trial. To ensure that recruitment targets are met and to successfully complete the trial it will be essential to continually evaluate the recruitment process, both prior to and during the continence promotion interventions.

Concluding message

Based on the present recruitment efficiency of 30%, more innovative strategies are needed to find ways to increase uptake if the power of the study is to be maintained. Alternatives to traditional recruitment strategies are required to maximise recruitment efficiency for continence promotion trials.

References

1. 1.Treweek,s., Pitkethly,M., Kjeldstrom, M., Taskila, T., Johansen, M. Sullivan, F., Wilson, S. Jackson,C., Jones, R., Mitchell, E,. (2009) Strategies to improve recruitment to randomised controlled trails (Review), The Cochrane Collaboration, Wiley: London
2. 2.McDonald, A.M., Knight, R.C., Campbell, M.K., Entwistle, V.A., Grant, A.M., Cook, J.A., Elbourne, D.R., Francis, D. Garcia, J., Roberts, I. (2006) What influences recruitment to randomised controlled trials? A review of trials funded by two UK funding agencies. Trials 2006; 7:9.

Specify source of funding or grant	**The Canadian Institutes of Health Research**
Is this a clinical trial?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**Brunel University**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**