OUTCOMES AND COST-EFFECTIVENESS OF MASS MAILING RECRUITMENT FOR A URINARY INCONTINENCE PRIMARY PREVENTION STUDY

Hypothesis / aims of study
The Translating Unique Learning for Incontinence Prevention (TULIP) study enrolled women from diverse backgrounds to determine whether a group class or a take-home DVD of behavioural techniques for bladder health is more effective in preventing urinary incontinence (UI). A reactive mass mailing recruitment was used for cost-effectiveness [1]. Aims of the study were to examine the success of a telephone pre-screening method for potential enrollment in a primary prevention study, to determine the cost-effectiveness of mailings in Southeast Michigan and Philadelphia, Pennsylvania, United States and to examine potential barriers to enrollment.

Study design, materials and methods
Recruitment was via mass mailings broadly distributed using a commercial mailing list (50,000/site). A targeted letter of invitation method [2] was mailed to zip codes with ethnically and racially diverse residents [3]. A reactive approach, where participants are asked to follow-up with an action leading to recruitment initiation, was used to prevent “cold-calling.” This approach included a letter that defined UI and noted that there are proven “bladder control” strategies for prevention. If women were willing to receive further information, they were asked to return a tear-off notice that included their contact information. The woman was subsequently contacted by telephone for pre-screening.

Results
Nine mass mailings of at least 8000 pieces (N=83,500) were sent; 1975 respondents were screened by telephone. Participants were women 55 yo with no UI or mild UI symptoms, had to score <5 on the ICIQ-SF, had no previous bladder problems or treatments, no persistent pelvic pain, no past or current neurological conditions, and no more than 2 UTIs within 6 months of the pre-screening date. Forty-nine percent (n=959) of respondents passed the pre-screen survey (see Table 1) and 555 participants met the physical examination screening criteria. The primary reason for pre-screening exclusion was UI symptoms.

Table 1: Five top reasons for Telephone Pre-screening Failure

<table>
<thead>
<tr>
<th>Reason for Pre-screen Failure</th>
<th>Frequency (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICIQ too high (Questions 1 + 2 = &lt;5)</td>
<td>191 (34)</td>
</tr>
<tr>
<td>No longer interested - Transportation</td>
<td>107 (19)</td>
</tr>
<tr>
<td>No longer Interested in participating</td>
<td>93 (17)</td>
</tr>
<tr>
<td>Previous treatment for UI</td>
<td>70 (12)</td>
</tr>
<tr>
<td>Bladder control medications</td>
<td>27 (5)</td>
</tr>
</tbody>
</table>

Compared to literature, expected recruitment response is 1% to 3% and both sites were at the highest end (see Table 2).

Table 2: Mailing Costs Per Participant

<table>
<thead>
<tr>
<th></th>
<th>Southeast Michigan</th>
<th>Philadelphia</th>
</tr>
</thead>
<tbody>
<tr>
<td># Mailed</td>
<td>42,000 (5 mailings)</td>
<td>41,500 (4 mailings)</td>
</tr>
<tr>
<td>Mailing Costs</td>
<td>USD16,500</td>
<td>$20,412</td>
</tr>
<tr>
<td># Responses</td>
<td>1,314*</td>
<td>1,134*</td>
</tr>
<tr>
<td>Cost/participant</td>
<td>USD11.68</td>
<td>USD18.00/USD15.86**</td>
</tr>
</tbody>
</table>
**Expected return was 1-3%: ** Michigan 3.1%; Philadelphia 2.7%

**Participant cost including correction of postage error**

**Interpretation of results**

The mailing produced a diverse sample of women (see Figure 1) that were screened at a baseline evaluation visit. Mass mailings were found to be a cost-effective manner in which to recruit women for this primary prevention study. As the study endpoint (n=600) nears, the study team will assess how to better maintain enrollment, decrease study attrition, and increase study accessibility.

Figure 1: Total Subjects Evaluated

(Includes Screen Failures)

Concluding message

There is strong motivation from community-dwelling women to seek bladder self-care strategies, both for primary and secondary prevention of UI. If this program is successful, it will be a model of how the distribution of awareness information (e.g. invitational mailing) and the provision of self-managed bladder control instruction can cost-effectively assist women who are appropriate for primary prevention (49%). This model will also be beneficial for the other 51% who are highly motivated, but would require secondary prevention.

References


Disclosures

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**Clinical Trial:** Yes

**Registration Number:** National Institute of Nursing Research, National Institute of Health, R01NR012011 ClinicalTrials.gov Identifier: NCT01599715

**RCT:** No

**Subjects:** HUMAN

**Ethics Committee:** University of Pennsylvania Institutional Review Board Approval # 811370

**Helsinki:** Yes

**Informed Consent:** Yes