

RECRUITMENT STRATEGIES IN A PELVIC PAIN TRIAL: IS E-RECRUITMENT A PROMISING METHOD ?

Hypothesis / aims of study

Recruitment is a major challenge in successfully completing any randomized control trial (RCT) as difficulties in recruitment can have an important impact on the duration of the study, its costs and more critically, can be related to trial failure [1]. Investigators are increasingly using new e-recruitment initiatives, such as Facebook advertisement. However, no studies in urogynecology have investigated or compared recruitment strategies regarding efficiency, retention, clinical characteristics and cost. The aim of this study was to compare three recruitment methods (conventional methods (ads, poster, leaflets), professional referrals and e-recruitment,) for the number of patients screened/enrolled, the efficiency rate, the retention rate, the baseline characteristics of participants, and the average cost per enrolled participant.

Study design, materials and methods

We conducted a bi-centric, parallel group RCT evaluating the efficacy of physiotherapy in comparison to topical lidocaine in women diagnosed with provoked vestibulodynia. The three recruitment methods included: 1) conventional methods (ads in local newspapers/scholar planners, word of mouth, posters and leaflets in clinics, universities, professional schools, restaurants, gyms, etc.); 2) health professional referrals (physicians, gynecologists, psychologists and physiotherapists who received email reminders, newsletters and conferences) and 3) e-recruitment (Facebook ads and Web pages). Recruitment occurred over a period of 33 months in two university hospital centers. Women interested in participating were screened and were assessed by a study gynecologist to confirm their diagnosis. Participants were assessed at baseline, after a 12-week treatment and at 6-month follow-up. The numbers of screened and enrolled patients were defined as the number of women having made the initial contact and those who were randomized, respectively. After randomization, structured interviews were undertaken by a blinded evaluator to describe their baseline characteristics (age, pain intensity, duration of symptoms, frequency of intercourse, pain at first intercourse and use of oral contraceptives). Cost related to recruitment methods was determined considering professional fees (e.g., for sending emails, posting ads, etc.) as well as the recruitment materials (e.g., leaflets, Facebook and newsletter adds) [2]. The average cost was also calculated per enrolled participant for each recruitment method (total cost for a recruitment method / number of patient enrolled for this method) [2]. Chi-square and one-way analysis of variances were used to compare the participants according to the recruitment methods.

Results

A total of 521 women contacted us to participate and 212 were enrolled in the study. A total of 201 women completed the post-treatment assessment (n=201) and 195 women, the 6-month follow-up (n=195).

As shown in **Table 1**, most of the participants screened came from conventional methods (56%) followed by the e-recruitment methods (28%) and health professional referrals (16%). The number of enrolled participants was statistically different between the three methods, in favor of the conventional methods ($p=0.012$). The efficiency rate (percentage of women enrolled/screened) was similar in the professional health referrals and e-recruitment methods ($p=1.000$) but significantly differed from the conventional methods ($p<0.05$). The retention rate was similar for all three recruitment methods ($p=0.798$). In regards to baseline characteristics (**Table 2**), no significant differences were found between the three groups ($p\geq 0.189$).

The budget total expenses were distributed as follow: e-recruitment \$7,071, professional referrals \$1,964 and conventional methods \$11,026. The average cost per enrolled participant was higher for e-recruitment \$118, followed by the conventional methods \$93 and health professional referrals \$60.

Table 1. Efficiency of recruitment and retention across recruitment methods

		Conventional methods N (%)	Health professional referrals N (%)	E-recruitment N (%)	Total N
Patient screened for eligibility		332 (64%)	67 (13%)	122 (23%)	521
Patients enrolled		119 (56%)	33 (16%)	60 (28%)	212
Retention rate at 6-month follow-up		110 (92%)	30 (91%)	55 (91%)	195
Efficiency (enrolled/screened)	rate	119/332 (36%)	33/67 (49%)	60/122 (49%)	

Table 2. Baseline characteristics according to recruitment methods

	Conventional methods (N=119) Mean (SD) or N (%)	Health professional referrals (N=33) Mean (SD) or N (%)	E-recruitment (N=60) Mean (SD) or N (%)	P-value
Age (years)	24 (4)	22 (4)	24 (5)	0.389
Pain intensity (NRS/10)	6.9 (1.7)	7.5 (1.7)	7.4 (1.5)	0.224
Duration of symptoms (years)	4.2 (3.4)	3.8 (3.7)	4.0 (3.3)	0.922
Frequency of intercourse (per year)	5.6 (6.1)	4.4 (4.6)	5.0 (5.2)	0.707
Primary vestibulodynia	48 (40%)	11 (33%)	16 (27%)	0.189
Use of oral contraceptive	97 (82%)	28 (88%)	44 (73%)	0.226

Interpretation of results

The conventional methods resulted in higher numbers of screened and enrolled participants, followed by e-recruitment and health professional referrals. Health professional referrals were the cheapest method and e-recruitment was the most expensive. It should be underlined that this disparity may increase in the upcoming years given the constant cost augmentation for Facebook advertisement. The efficiency rate of both health professional referrals and e-recruitment was greater than the conventional methods. The superiority of these two methods may be explained by the fact that the health professionals knew the inclusion/exclusion criteria and may have been more likely to refer eligible women and that the website included some information on the eligibility criteria which may have discouraged non-eligible women to contact us. Interestingly, participant characteristics and retention rate were not influenced by recruitment method.

Concluding message

Our findings revealed the advantages and limitations related to each method that should be considered when planning a RCT. Multiplication of recruitment methods appears the most beneficial in promoting clinical trial recruitment. As the recruitment methods influenced neither retention rate nor patient baseline characteristics, the use of e-recruitment is a useful recruitment strategies in a pelvic pain trial but its higher cost should be taken into account.

References

1. McDonald, A., Knight, R., Campbell et al. (2006). What influences recruitment to randomized controlled trials? A review of trials funded by two UK funding agencies. *Trials*, 7(1), 9.
2. Krusche, A. et al. An evaluation of the effectiveness of recruitment methods: the staying well after depression randomized controlled trial. *Clinical trials* 2014; 11:141-149.

Disclosures

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