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Efficiency and Cost: E-Recruitment Is a Promising Method in Gynecological Trials

Justine Benoit-Piau, MPT,[1] Chantale Dumoulin, PT, PhD,[2] Marie-Soleil Carroll, MSc,[3] Marie-Hélène Mayrand, MD, PhD,[4] Sophie Bergeron, PhD,[5] Samir Khalifé, MD,[6] Guy Waddell, MD,[7] and Mélanie Morin, PT, PhD,[8] On behalf of the Provoked Vestibulodynia (PVD) Study Group*

ABSTRACT

Background: Recruitment of participants is crucial to the success of any trial as it can have a major impact on study costs, the duration of the study itself, and, more critically, trial failure. Given that vulvodynia particularly affects young women, the use of social media and e-recruitment could prove efficient for enrollment.

Aim: To compare the efficiency, effectiveness, and cost-effectiveness of three different recruitment methods.

Methods: The comparison data were collected as part of a bicentric randomized controlled trial evaluating the efficacy of physiotherapy in comparison with topical lidocaine in 212 women suffering from provoked vestibulodynia. The recruitment methods included: (i) conventional methods (eg, posters, leaflets, business cards, newspaper ads); (ii) health professional referrals, and (iii) e-recruitment (eg, Facebook ads and web initiatives). Women interested in participating were screened by telephone for eligibility criteria and were assessed by a gynecologist to confirm their diagnosis. Once included, structured interviews were undertaken to describe their baseline characteristics.

Main Outcome Measures: The outcomes of this study were the recruitment efficiency (the number of patients screened/enrolled), recruitment effectiveness (the number of participants enrolled), cost-effectiveness (cost per enrolled participant), and retention rate, and baseline characteristics of participants were monitored for each method.

Results: The conventional methods (n = 101, 48%) were more effective as they allowed for greater enrollment of participants, followed by e-recruitment (n = 60, 28%) and health professional referrals (n = 33, 16%) ($P < 0.007$). Recruitment efficiency was found to be similar for e-recruitment and referrals (60/122 and 33/67, 49%, $P = 0.055$) but lower for conventional methods (101/314, 32%, $P < 0.011$). Nonsignificant differences were found between the three groups for baseline characteristics ($P \geq 0.189$) and retention rate (91%, $P \geq 0.588$). The average cost per enrolled participant was fairly similar for e-recruitment ($117) and conventional methods ($110) and lower for referrals ($60).

Clinical Implications: Our results suggest that having a variety of recruitment methods is beneficial in promoting clinical trial recruitment without affecting participant characteristics and retention rates.

Strength & Limitations: Although recruitment methods were used concomitantly, this study gives an excellent insight into the advantages and limitations of recruitment methods owing to a large sample size.

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[1]School of Rehabilitation, Faculty of Medicine and Health Sciences, Université de Sherbrooke, and Research Center, Centre hospitalier de l'Université de Sherbrooke (CHUS), Sherbrooke, QC, Canada;

[2]School of Rehabilitation, Faculty of Medicine, Université de Montréal, and Research Center, Institut universitaire de gériatrie de Montréal, Montréal, QC, Canada;

[3]Faculty of Medicine and Health Sciences, Université de Sherbrooke, and Research Center, Centre hospitalier de l'Université de Sherbrooke (CHUS), Sherbrooke, QC, Canada;

[4]Departments of Obstetrics and Gynecology and Social and Preventive Medicine, Université de Montréal, and Research Center, Centre hospitalier de l'Université de Montréal, Montréal, QC, Canada;

[5]Department of Psychology, Université de Montréal, Montréal, QC, Canada;

[6]Jewish General Hospital and Royal Victoria Hospital, McGill University Health Center, Montréal, QC, Canada;

[7]Department of Obstetrics and Gynecology, CHUS and Université de Sherbrooke, Sherbrooke, QC, Canada;

[8]School of Rehabilitation, Faculty of Medicine and Health Sciences, Université de Sherbrooke, Research Center, Centre hospitalier de l'Université de Sherbrooke (CHUS), Sherbrooke, QC, Canada

*The PVD Study Group comprises authors and clinical collaborators Dr Isabelle Girard and Dr Yves-André Bureau from the Université de Sherbrooke and the Centre hospitalier de l'Université de Sherbrooke, as well as Dr Stéphane Ouellet, Dr Barbara Reichetzer, Dr Laurence Simard-Émond, and Dr Ian Brochu from the Université de Montréal, Centre hospitalier de l'Université de Montréal.

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Conclusion: The study findings revealed that e-recruitment is a valuable recruitment method because of its comparable efficiency and cost-effectiveness to health professional referrals and conventional methods, respectively.

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Key Words: Recruitment; Provoked Vestibulodynia; Facebook; Randomized Controlled Trial

INTRODUCTION

Recruitment is a major challenge in conducting a clinical study. Recruitment difficulties have been reported as being the cause of 45% of study delays, potentially leading to significant consequences.[1] These difficulties can result in longer study duration[2,3] and cause much of the funding to be quickly squandered on material and human resources. Delays can also lead to a failure to meet recruitment goals and thus limit the ability to test scientific hypotheses.[4] To reach their objectives, researchers are sometimes forced to extend the recruitment period, add new enrollment sites, or modify inclusion criteria.[5] In an attempt to avoid additional costs or ensure the success of studies, experts have highlighted the importance of carefully identifying the target population and planning recruitment efforts accordingly.[6]

Many recruitment strategies are described in the literature. However, few studies to date have considered the technological shift in the last decade and the new generation of participants. In fact, print advertising, flyers, direct mail, and referrals represent the strategies that are most commonly used in gynecology and other fields of medicine.[5−10] Conducting a randomized controlled trial (RCT) in gynecology or sexual health can be even more challenging considering the stigma related to several conditions.[11] Provoked vestibulodynia (PVD) is a sexual health condition related to painful intercourse. Pain is located to the vestibule area (eg, entry of the vagina) and elicited by an application of pressure such as the insertion of a tampon or intercourse. It affects women of all ages but is more prevalent among younger women.[12,13] Despite increased awareness in the community, pain during intercourse remains a taboo topic of discussion.[14] Women often feel dismissed and stigmatized by health care professionals and remain reluctant to discuss this problem with others, making clinical trial recruitment efforts especially challenging.[15,16] Moreover, gynecologists do not routinely ask if patients have pain during intercourse. No study thus far has investigated the efficiency of e-recruitment in women with vulvar pain. However, clicking on an ad from the comfort of home provides anonymity that posters and leaflets simply cannot. In addition, 67% of all Internet users use Facebook, which is especially appealing to women aged 18 to 29 years.[17] Supporting the relevance of e-recruitment initiatives, Bull et al[18] have suggested, in a study investigating AIDS, that ads displayed on Web pages specific to the study population greatly help recruitment. In a study investigating depression, Krusche et al[19] underlined that the ability to target the audience according to some background information (eg, location, Internet browsing history) is a significant advantage of Web-based advertising over other methods. These findings are interesting but it is unclear to what extent they could translate to gynecological and sexual health studies.

Despite the increase in e-recruitment, the available studies in various fields of medicine have focused mainly on conventional recruitment methods (direct mail, physician referral, flyers, newspaper, and radio advertisement).[5,6,8,20] Conflicting results have been reported: some studies show that mailing is a more efficient approach,[3,5,11] whereas others suggest that referrals by health professionals or flyers yielded more favorable outcomes.[8,21] There is therefore a paucity of data concerning the influence of recruitment strategies on participant screening, enrollment, characteristics, and retention as well as the cost related to each initiative, which provides crucial information for guiding trialists on the design and implementation of large RCTs.[9,11,18,19]

Given that e-recruitment could help researchers overcome recruitment difficulties in women with provoked vestibulodynia and that the available evidence relies only on scarce non-gynecological research, this study aimed to investigate and compare the recruitment efficiency (number of patients enrolled/screened), the recruitment effectiveness (number of participants enrolled), the retention rate, and the baseline characteristics of participants as well as the cost-effectiveness of 3 recruitment methods in women with provoked vestibulodynia: (1) conventional methods, (2) health-professional referrals, and (3) e-recruitment.

MATERIALS AND METHODS

Study Overview

Women were recruited for a large RCT investigating the efficacy of physical therapy and topical lidocaine (50 mg/g, Lidocan, Odan Lab, 35g) to reduce pain intensity during intercourse. Recruitment covered a period of 40 months between May 2012 and August 2015 in Sherbrooke and Montréal university hospital centers. Details of the RCT design and methods are reported elsewhere.[22] The study was approved by the respective institutional ethics committees.

Figure 1. Example of a Facebook ad. Figure 1 is available in color online at www.jsm.jsexmed.org.

Procedures

Women interested in participating were screened verbally for eligibility criteria via telephone by a research coordinator and had thereafter an appointment with a gynecologist to confirm their diagnosis. Once their diagnosis had been established, the women were asked to attend a baseline assessment session and were randomized to receive either physiotherapy or topical lidocaine. During the baseline assessment, the physiotherapist, blinded to group allocation, performed a physical examination and collected the participants' baseline characteristics, including demographic variables and pain characteristics. The assessments were repeated after treatment and at a 6-month follow-up visit.

Conventional Methods

Conventional methods entailed the distribution of colored posters and leaflets in hospitals, clinics, universities, professional schools, gyms, restaurants, and pubs. Posters were designed by a research assistant and included detachable phone numbers and email addresses. They were regularly verified to ensure they were still posted and still had contact information available. Business cards featuring the study objectives and contact information were distributed at the community mail center, gyms, universities, and festivals. 20 ads also appeared in the local newspapers of Sherbrooke and Montreal. An advertisement was published in university and college calendars. Word of mouth was also included in the conventional recruitment strategies.

Health Professional Referrals

We provided detailed trial information to family physicians, gynecologists, physiotherapists, and psychologists/sexologists located in Sherbrooke and Montréal. 5 lectures were given to 9 gynecologists and family physicians at the beginning of the study explaining the aim of the study as well as the inclusion and exclusion criteria. Every 4 to 6 months, a reminder was emailed to all collaborators, inviting them to refer their patients with PVD. These reminders included the number of women to be recruited, the inclusion criteria, and the contact information. The health professionals were also given prescription pads with information about this study and other studies conducted by our team. After distributing the patient information about the study, physicians could contact the team directly or invite the women to contact the research team on their own. Newsletters were also emailed during the study to provide information on the progress of ongoing projects in the laboratory and recruitment activities. No compensation was offered for referrals.

E-Recruitment Methods

E-recruitment included 12 ad campaigns on Facebook (Figure 1), Kijiji (classifieds site), and an advertising Web page for all Sherbrooke clinical research studies. A Facebook advertisement was created as a "Click to Website" ad and was displayed to women aged 18 to 45 years who lived in Sherbrooke and Montréal. These ads referred to the laboratory Web page, which included contact information and a brief summary of the study. The eligibility questionnaire was available online allowing women to complete it and return it by email. The inclusion and exclusion criteria were also reviewed over the phone by the research coordinator.

Recruitment Efficiency and Effectiveness

Recruitment efficiency was determined for each method by dividing the number of participants enrolled by the number of patients screened.[11] Recruitment effectiveness was defined as the number of participants enrolled for each method.[11]

Recruitment Costs

To determine the recruitment costs associated with this study, all activities required for recruitment were included. The costs for conventional methods included the amount spent on newspaper ads, leaflets, business cards, and honorarium fees related to the preparation and distribution of recruitment materials by the research coordinator. A few newspaper ads were offered to the team free of charge, thus reducing the total cost for conventional methods. It should also be noted that several students

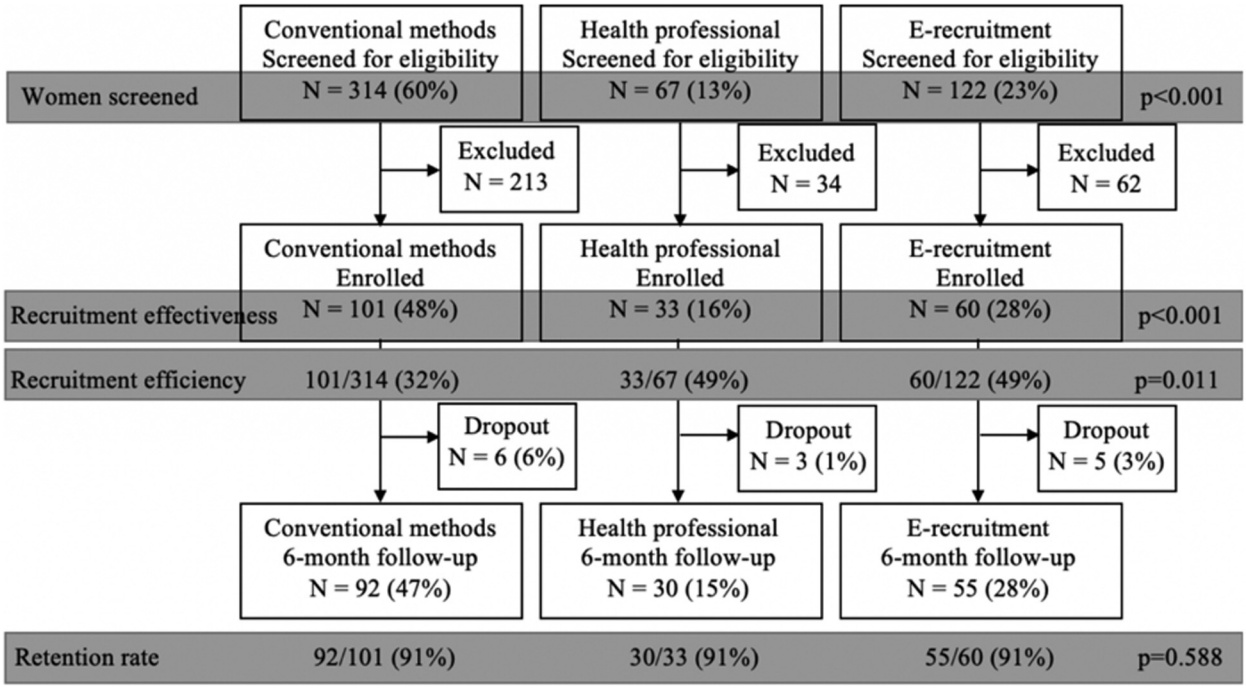

Figure 2. Participant enrollment.

volunteered to help with the distribution and upkeep of recruitment materials. An average salary of CAD$22.59 per hour plus 26% in benefits was considered for research assistants. The cost for health professional referrals included the time spent on the preparation and presentation of lectures, the cost of prescription pads, as well as the time spent to email reminders to health professionals. Costs related to e-recruitment included the time a research assistant spent on designing the ads and purchasing images, and the Facebook fee related to the ads. The cost-effectiveness for each method was calculated per enrolled participant by dividing the total cost for a recruitment method by the number of participants enrolled by this method.

Statistical Analyses

Statistical analyses were conducted using SPSS 24.0 (Statistical Package for the Social Sciences, IBM). Chi-square and one-way analysis of variance tests were used to compare the baseline characteristics of the participants according to the recruitment method used. Data were also compared for recruitment efficiency and effectiveness, as well as retention rate using chi-square tests for overall differences. When significant, additional chi-square analyses were used to evaluate between-groups differences (eg, conventional methods vs e-recruitment, conventional methods vs health professional referrals, and e-recruitment vs health professional referrals). Multinomial logistic regression was used to examine which characteristics increased the likelihood of a participant being enrolled by conventional methods, health professional referrals, or e-recruitment. The level of significance was set at $P < .05$.

RESULTS

A total of 521 women were screened and 212 were enrolled, as seen in Figure 2. Recruitment spanned 40 months. There were 18 women enrolled with missing data concerning the method of recruitment used.

Recruitment Effectiveness, Efficiency, and Retention Rate

As shown in Figure 2, screened participants were mainly recruited by conventional methods (314/503, 60%), followed by e-recruitment (122/503, 23%) and health professional referrals (67/503, 13%) ($P < .001$). At the very initial stage, the study was launched progressively using selected conventional methods (posters) and health professional referrals to slowly implement the study. Thereafter, promotion and recruitment were rapidly intensified using the 3 methods concomitantly to reach the cruising speed. Recruitment effectiveness (number of participants enrolled) was significantly different between the 3 groups ($P < .001$). Between-group analyses revealed that conventional methods yielded a higher number of participants enrolled compared to health professional referrals ($P < .001$) and e-recruitment ($P = .002$). As for recruitment efficiency (number of participants enrolled/screened), the 3 methods were significantly different ($P = .032$). Between-group analyses showed that e-recruitment and health professional referrals had similar efficiency ($P \geq .055$), while conventional methods were significantly lower ($P \leq .011$). No difference was found in terms of the retention rate at the 6-month follow-up regarding the recruitment method used ($P = .588$).

Table 1. Baseline characteristics according to recruitment methods

Characteristic	Conventional methods (N = 101), 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)	.389
Ethnicity				
North America	89 (88)	29 (88)	55 (91)	.655
South and Central America	5 (5)	0 (0)	1(2)	
Europe	3 (3)	1(3)	1 (2)	
Other	4 (4)	3 (9)	3(5)	
Education				
< College	16 (16)	14 (43)	11 (18)	.069
College	47 (47)	9 (27)	30 (50)	
University graduate	25 (25)	8 (24)	16 (27)	
Post-graduate	13 (12)	2 (6)	3 (5)	
Annual income				
$0-29,999	80 (79)	22 (67)	46 (77)	.434
$30,000+	21 (21)	11 (33)	14 (23)	
Marital status				
Single	64 (63)	22 (67)	37 (62)	.725
Marriage/common-law	37 (37)	11 (33)	23 (38)	
Pain intensity (NRS/10)	6.9 (1.7)	7.5 (1.7)	7.4 (1.5)	.224
Duration of symptoms (years)	4.2 (3.4)	3.8 (3.7)	4.0 (3.3)	.922
Frequency of intercourse (per month)	5.6 (6.1)	4.4 (4.6)	5.0 (5.2)	.707
Primary vestibulodynia	48 (40)	11 (33)	16 (27)	.189
Use of oral contraceptives	97 (82)	28 (88)	44 (73)	.226

NRS = Numerical Rating Scale.

Participant Characteristics

As depicted in Table 1, no significant differences were found between the 3 groups with regard to baseline characteristics ($P \leq .069$). Moreover, multinomial logistic regression revealed that none of the baseline characteristics were associated with any of the recruitment methods.

Recruitment Costs

The total budget for recruitment activities was CAD$20,061. The conventional methods involved the use of over 3000 business cards and 22 newspaper ads. As part of the health professional referrals effort, 5 presentations were given, 5 newsletters were used for ads, and 9 reminders were sent. In terms of e-recruitment, 12 ad campaigns were run on Facebook and had to be paid, while Kijiji ads were free. The costs related to these strategies are presented in Table 2. The conventional methods were found to be the most expensive in terms of total budget spent, followed by e-recruitment and referrals from health professionals. As for cost-effectiveness, e-recruitment was fairly similar to the conventional methods in terms of cost and health professional referrals showed the lowest cost per enrolled participant.

DISCUSSION

This study compared 3 methods frequently used in RCTs and, more specifically, investigated whether e-recruitment could be a possible successful recruitment option in gynecological trials. Our results indicate that recruitment effectiveness (number of patients enrolled) was greater for conventional methods, whereas recruitment efficiency (number of participants enrolled/screened) was higher for e-recruitment and health professional referrals. Moreover, no differences were found between the 3 methods in terms of retention rate and baseline characteristics. Finally, the cost-effectiveness for e-recruitment and conventional methods was similar, whereas health professional referrals cost less.

Recruitment effectiveness was found to be far greater using conventional methods as the number of participants enrolled was higher than health professional referrals and e-recruitment. This is in line with the findings of Butt et al (2012)[9] evaluating the use of gabapentin for hot flashes among postmenopausal women. They found that newspaper ads and leaflets were the most effective recruitment method compared to referrals, community outreach, and direct mailing. Similarly, Krusche et al (2014)[19] found that the combined use of posters and media advertisements yielded a higher number of enrolled participants than Web initiatives and health professional referrals among adults overcoming depression. Overall, the superiority of conventional methods found in a population of adults and older women was also confirmed in the present study targeting a much younger population of nulliparous women with a mean age of 23 years.

Table 2. Cost comparison of recruitment methods

Cost details	Conventional methods (CAD)	Health professional referrals (CAD)	E-recruitment (CAD)	Total cost (CAD)
Budget spent on each method	11,106 (55%)	2,062 (10%)	6,991 (35%)	20,061
Ads	6,712	0	6,026	
Purchase of pictures	80	0	80	
Fees	2,590	1,964	341	
Printing	1,724	0	0	
Web site	0	0	544	
Prescription pads	0	98	0	
Average cost per screened participant	35	31	57	
Average cost per enrolled participant	110	69	117	

For recruitment efficiency, that is, the number of women enrolled/screened, it was found to be significantly higher for e-recruitment and health professional referrals. This is in contrast to the findings of Bachour et al,[11] the only other study available in a gynecological population. Bachour et al[11] found no significant differences in recruitment efficiency between mass mailing, media, clinician referrals, and community outreach in women suffering from PVD. The difference in efficiency rates between recruitment methods in the present study could be explained by the different strategies used in each method. In the present study, mass mailing and community outreach were not used, while Bachour et al (2017) did not use multiple conventional methods or e-recruitment. The greater efficiency in e-recruitment could be explained by the fact that women who saw the ad on Facebook could consult the eligibility criteria on the laboratory's web site, whereas women recruited through posters and leaflets had to call the research coordinator for further details. Similarly, health professionals knew the eligibility criteria, which could explain the higher recruitment efficiency rate.

We found that there were no statistically significant differences between the 3 recruitment methods with respect to the baseline characteristics of participants and retention rates. Another study found that the baseline characteristics could be influenced by the method used to recruit participants, which conflicts with our findings.[11] It could be expected that e-recruitment would yield younger participants, but no differences were found in the age of women between recruitment groups. Another study found differences in ethnicity between recruitment methods showing that African-American women were more likely to get recruited via mass mailing. This was however not found in the present study with nonsignificant differences between recruitment methods.[11] It could also have been expected that women recruited through health professional referrals would present higher pain intensity and a longer duration of symptoms, which was not observed in the study. Participants in the present study were mostly young Caucasian women reporting a low income given that they were still full-time students. Although these characteristics portray the usual population involved in RCTs among women with provoked vestibulodynia,[23] this homogenous sample could explain why no differences were found between the recruitment methods. With respect to retention rate, no studies thus far have investigated the influence of recruitment methods on dropout. It could be hypothesized that e-recruitment would result in a higher dropout rate as it does not involve close contact with the research team. However, this was refuted in our study as the dropout rate among participants recruited via Web initiatives was no greater than that for women recruited via conventional methods or by health professional referrals.

As for cost-effectiveness, the cost per enrolled participant was fairly similar for e-recruitment and conventional methods and was significantly lower for health professional referrals. This differs with the results of Krusche et al[19] in a study on depression and those obtained by Butt et al[9] studying hot flashes in postmenopausal women who found that health professional referrals were among the most expensive recruitment methods. These higher costs could be explained by the fact that health professionals were paid for attending study information sessions and received patient recruitment incentives, which was not the case in the present study. Despite this monetary compensation, Butt et al[9] reported that only 30% of family practitioners participated actively in study recruitment. Although the present study did not collect this information, it should be emphasized that it is common for most professionals to play a minor role in recruitment in nonsurgical and nonpharmacological studies.[9] As previously mentioned, many women will not discuss their vulvar pain with their doctor, making it more difficult for physician to refer them to clinical trials. Furthermore, the comparable costs per enrolled participant found in the present study for e-recruitment and conventional methods are in line with the findings of Krusche et al.[19] However, it should be noted that the distribution of costs varied. Our study confirmed that the conventional methods involved larger sums in honorarium fees for the research professional who conceived the ads and distributed them to all participating locations, whereas with e-recruitment, the budget was mainly allotted to advertisements and the minimal human resources required.

It should be underlined that there are benefits and limitations to each recruitment method. Conventional methods yielded a higher number of participants (high efficacy) but had a lower efficiency than e-recruitment and health professional referrals and cost more than health referrals. The health professional referrals were cost-effective, but this method had the lowest number of participants screened. Finally, e-recruitment had a similar recruitment efficiency to conventional methods but was more expensive than health professional referrals.

Some limitations should be acknowledged. Given that the recruitment methods were used concomitantly, assessment of the relative contribution of each method may be challenging as women could have seen the study via many different media but identified only one when asked. Moreover, the contribution of each component included in the conventional methods could have been assessed separately. However, this would have increased the likelihood of a type II error due to the lack of statistical power. To isolate the distinct contribution of each recruitment method, it would have been optimal to randomize or assess each method independently. This is however not feasible in a context of an RCT where the recruitment should be quick and efficient, using multiple concomitant methods, to ensure a timely completion of the study. Despite these minor limitations, the present study has several important strengths. The large sample size gives an excellent insight into the advantages and limitations of e-recruitment for RCTs aimed at recruiting young women suffering from gynecological conditions. This study is also one of the few detailing the tremendous costs incurred to recruit participants for an RCT and the cost-effectiveness of different methods.

CONCLUSION

Our findings support the high effectiveness of conventional methods and the lower cost of health professional referrals. They also support the use of e-recruitment in RCTs because the efficiency rate is as high as that of health professional referral. The costs involved with e-recruitment are also comparable to those of conventional methods. The costs involved also do not influence participants' characteristics or retention rate. Because recruitment techniques influenced neither the retention rate nor the participant's baseline characteristics, all 3 methods can contribute to the recruitment effort. Because each method has its own benefits and limitations, the 3 methods should be equally used. Moreover, since time is of the essence in the recruitment of an RCT, it is believed that these methods should be used simultaneously. The advent of new recruitment techniques such as e-recruitment offers an anonymity that other methods do not. In a condition such as provoked vestibulodynia, this could help overcome the barrier of taboo and help recruit more women, faster. Using a variety of recruitment methods should therefore be the privileged strategy.

Corresponding Author: Mélanie Morin, PT, PhD, School of Rehabilitation, Faculty of Medicine and Health Sciences, Université de Sherbrooke, 3001, 12e avenue Nord, Sherbrooke, QC, Canada, J1H 5N4. Tel: 819-346-1110, #13818; E-mail: melanie.m.morin@usherbrooke.ca

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STATEMENT OF AUTHORSHIP

Category 1

(a) Conception and Design
Mélanie Morin; Chantale Dumoulin; Marie-Hélène Mayrand; Sophie Bergeron; Samir Khalifé; Guy Waddell

(b) Acquisition of Data
Mélanie Morin; Chantale Dumoulin

(c) Analysis and Interpretation of Data
Justine Benoit-Piau; Marie-Soleil Carroll; Mélanie Morin

Category 2

(a) Drafting the Article
Justine Benoit-Piau; Marie-Soleil Carroll

(b) Revising It for Intellectual Content
Mélanie Morin; Chantale Dumoulin; Marie-Hélène Mayrand; Sophie Bergeron; Samir Khalifé; Guy Waddell

Category 3

(a) Final Approval of the Completed Article
Justine Benoit-Piau; Mélanie Morin; Marie-Soleil Carroll; Chantale Dumoulin; Marie-Hélène Mayrand; Sophie Bergeron; Samir Khalifé; Guy Waddell

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