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E-RECRUITMENT: THE FUTURE FOR CLINICAL TRIALS IN A DIGITAL WORLD?

Hypothesis / aims of study

The efficient recruitment of trial participants is an ethical imperative for any effective study design (1). Recruitment in four centres of a pelvic organ prolapse physiotherapy trial using 'indirect' methods of recruitment, following the recruitment and study design of a similar trial conducted elsewhere, was slower than anticipated. To address this, 'direct' methods of recruitment were utilised. These included web-based sources of recruitment such as Facebook™, a social networking internet site. We propose these 'direct' methods are more efficient and provide a similar trial participant as the 'indirect' methods in the conduct of such trials. The aims of this study were to:

1. Compare the rates of recruitment and retention to the trial between the 'indirect' and the 'direct' methods,
2. Investigate the differences in a pelvic organ prolapse symptom score - POP-SS (2), POP-Q staging and age of participants who enquired and then consented to the trial, between the two methods of recruitment.

Study design, materials and methods

The comparison data were collected as part of the local trial, an on-going multi-centred randomised controlled trial of a pelvic floor muscle training intervention for women with pelvic organ prolapse. We defined the recruitment methods included as:

- 'indirect' – screening and referral to the trial by clinicians practising in public and private gynaecology clinics from three local recruiting sites, and distribution of pamphlets in clinic waiting rooms which referred to the participating hospitals.
- 'direct' – local public radio, publications (newspapers, newsletters), pamphlets to local clinics, and targeted Facebook™ advertisements, which were used at the fourth recruiting site. Responders to advertisements contacted the investigators and were screened verbally by telephone or via web-based screening of history and symptom status. Participants were assessed by a gynaecologist for clinical eligibility and POP-Q assessment, and entered the trial once eligibility status was confirmed. Symptom severity was measured using the POP-SS, range of scores 0 (no symptoms) – 28 (maximum severity).

Descriptive statistics were used to evaluate differences between recruitment methods in the number recruited, recruitment time and retention rates. Key characteristics of participants including POP-SS, POP-Q and age were compared using independent samples *t*-tests.

Results

Results of recruitment are shown in Table 1. The indirect method recruited 54.6% of the total cohort and this process took 27.5 months, compared with 45.4% of participants recruited using direct methods, which took 16 months, a 40% faster process.

Table 1: Recruitment methods and rate by site

	Site 1	**Site 2**	**Site 3**	**Site 4**	**Total**	**Time to recruit (months)**	**Recruitment rate (per month)**
Indirect methods							
Outpatients/Private	22	40	30	2	94	27.5	3
Direct methods						16	5
Facebook				39	39		
Radio	4			17	21		
Publications				10	10		
Pamphlets				4	4		
Total	26	40	30	72	168		

Regarding patient retention, of those recruited using indirect methods, 21 of 94 (22.3%) had withdrawn from the trial by 6 months. To date, 3/74 (4.1%) of the direct methods cohort have withdrawn, however this represents only 34.2% of this cohort completing the 6-month assessment. Assuming a steady rate of withdrawal, the projected total withdrawal for the direct methods cohort is 9 of 74 (12.1%), 46% lower than the rate of the indirect methods.

The results of the POP-SS, POP-Q and age measures for both methods of recruitment are shown in Table 2.

Table 2: POP-SS, POP-Q and age for both recruitment methods

Variables	**Indirect method (mean, 95%CI)**	**Direct method (mean, 95%CI)**	**Significance of difference between groups**
POP-SS	9.6 (8.5 – 10.7)	10.9 (9.6 – 12.3)	p=0.12
POP-Q stage	2.1 (2.0 – 2.2)	2.0 (1.8 – 2.1)	p=0.02
Age in years	57.9 (55.9 – 59.9)	52.4 (50.2 – 54.7)	p<0.001

Interpretation of results

In a clinical intervention study involving conservative treatment, the direct methods of recruitment used resulted in a 45% faster rate of recruitment, and retention to the trial to date appears substantially higher. Social media, in this case Facebook™, was the most efficient method of direct recruitment. Because social media advertisements can be tailored to specific demographics (gender, age group, geography) and are distributed widely, a large population can be accessed. Because of its voluntary nature, those participants engaged may be more compliant and have higher adherence to the trial. While there were significant

differences in the age and POP-Q stage of participants recruited by the two methods, POP symptom severity did not differ, therefore maintaining the desired specificity and homogeneity of participants on this key outcome measure. Caution may need to be exercised regarding the use of web-based recruitment for clinical trials if a population-representative sample of age groups is necessary for the particular trial, given the lower rates of social media usage with increasing age (3). A full health economic analysis is planned to explore comparative cost implications of both recruitment methods.

Concluding message

These findings highlight the challenges involved in traditional methods of recruitment to conservative therapy RCTs, and the potential difficulties replicating a method which may work in one health-care setting to another setting. These differences and challenges are best taken into consideration at trial design stage. Internet based recruitment, using social media as an example, may provide a more time efficient form of recruitment for these types of trials and lead to lower withdrawal rates from the study.

References

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Specify source of funding or grant	**National Health and Medical Research Council, Australia.**
Is this a clinical trial?	**Yes**
Is this study registered in a public clinical trials registry?	**Yes**
Specify Name of Public Registry, Registration Number	**Australian New Zealand Clinical Trials Registry (ANZCTR Number 12608000113358)**
Is this a Randomised Controlled Trial (RCT)?	**No**
What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**School of Health Sciences HREC, The University of Melbourne, Australia.**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**