Gynecologic Oncology xxx (2016) xxx–xxx

Contents lists available at ScienceDirect

Gynecologic Oncology

journal homepage: www.elsevier.com/locate/ygyno

# Recruitment challenges in clinical research: Survey of potential participants in a diagnostic study of ovarian cancer

Zhuoyu Sun [a,*,1], Lucy Gilbert [b,c], Antonio Ciampi [a], Olga Basso [a,b]

[a] Department of Epidemiology, Biostatistics and Occupational Health, Faculty of Medicine, McGill University, Montreal, Quebec, Canada
[b] Department of Obstetrics and Gynecology, Research Institute of the McGill University Health Centre, Montreal, Quebec, Canada
[c] Department of Oncology, McGill University Health Centre, Montreal, Quebec, Canada

## HIGHLIGHTS

- Self-selection of participants in clinical studies can compromise validity.
- Certain groups are typically more difficult to recruit.
- Seeking the views of potential participants can help improve recruitment strategies.
- Involvement of primary care physicians is crucial to successful recruitment.

## ARTICLE INFO

*Article history:*
Received 6 May 2017
Received in revised form 14 June 2017
Accepted 17 June 2017
Available online xxxx

*Keywords:*
Clinical research
Underrepresented populations
Motivators and barriers to participation

## ABSTRACT

*Objective.* Recruiting participants in clinical research is challenging. Certain groups, such as older adults, rural residents, and individuals with lower socio-economic status, are typically underrepresented. Here, we explore perceived motivators and barriers among potential participants in a diagnostic study of ovarian cancer.

*Methods.* Women aged 50 and older who answered a mail survey in Montreal, Canada, were asked to assess their eligibility to participate in the ongoing Diagnosing Ovarian cancer Early (DOvE) Study. If 'eligible', they were asked whether they planned to participate in DOvE. Using modified Poisson regression, we examined responders' self-assessment of eligibility, intention to participate, and reasons for why or why not, as a function of socio-demographic and health indicators.

*Results.* Of 826 responders, 33.1% misclassified themselves with respect to eligibility. Among 532 self-assessed eligible women, 56.4% planned to participate in the study. The majority of women not planning to participate preferred to be assessed by their physicians (a reason more commonly reported by those with lower education or income) or believed they were not at risk of ovarian cancer (despite having no fewer risk factors). "Inconvenience" was also a commonly reported reason, especially among rural residents. Women who planned to participate often perceived a benefit (e.g. to rule out ovarian cancer, or to receive a quick check-up).

*Conclusions.* Recruitment, particularly of underrepresented groups, in clinical studies may be enhanced by involving primary care providers, facilitating access to study sites, and providing clear information about the disease under study (including risk factors) and eligibility criteria.



## 1. Introduction

Recruiting participants is a major challenge in clinical cancer research; older adults, rural residents, and individuals with lower socio-economic status are particularly difficult to reach [1–3], despite the fact that these groups tend to experience higher rates of cancer and worse outcomes [4–6]. Failure to recruit a sufficient number of participants can affect a study in different ways, from reducing statistical power to compromising external and, potentially, internal validity. While knowledge of the factors that promote and hinder participation would help in developing recruitment strategies, directly seeking the views of non-participants in any given study is challenging. Information on potentially eligible individuals is often not available in studies relying on volunteers and, even in instances when they are known, they cannot be easily reached, due to their own reluctance, as well as obstacles in obtaining ethics approval to pursue them beyond a certain point.

* Corresponding author at: Department of Epidemiology, Biostatistics and Occupational Health, Faculty of Medicine, McGill University, 1020 Pine Avenue West, Montreal, Quebec H3A 1A2, Canada.
*E-mail address:* zhuoyu.sun@mail.mcgill.ca (Z. Sun).
[1] This author is now based at the following address: Department of Epidemiology and Biostatistics, School of Public Health, Tianjin Medical University, Tianjin, China.

http://dx.doi.org/10.1016/j.ygyno.2017.06.021
0090-8258/

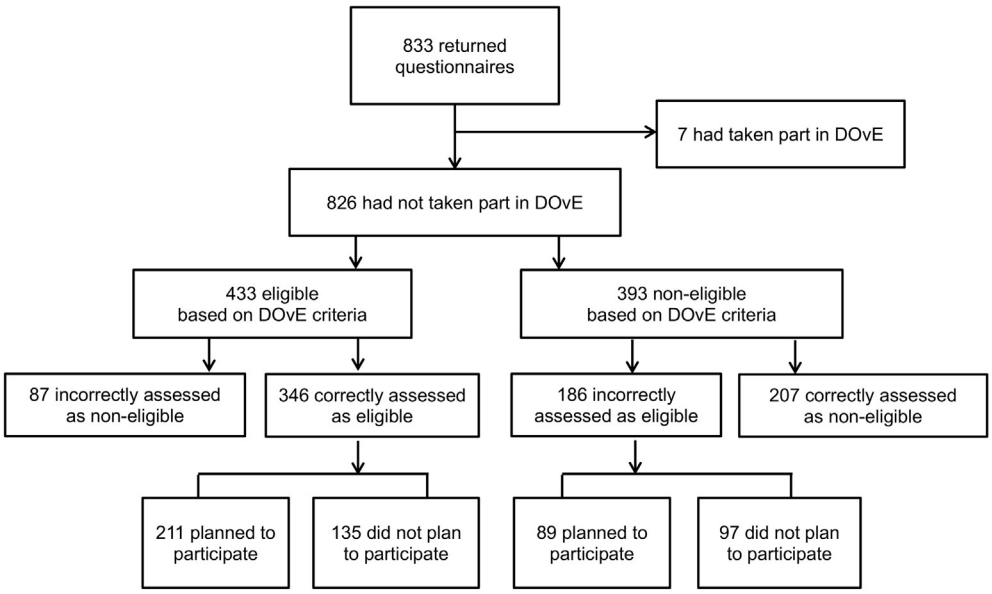


**Fig. 1.** Study population flow chart.

The Diagnosing Ovarian cancer Early Study (DOvE) is an ongoing project in Montreal (Canada) with the aim of evaluating whether prompt assessment of symptomatic women aged 50 and older results in earlier diagnosis of ovarian cancer and, ultimately, better prognosis [7]. Results from the pilot phase suggested a "high" prevalence of ovarian cancer in this population, as well as a tendency for women diagnosed through DOvE to more frequently have low-volume, completely resectable disease, compared with patients diagnosed through routine clinical practice in the same hospital [7]. (Both tendencies persist in the ongoing study (unpublished data)). However, these promising findings were based on a somewhat selected study population, consisting of predominantly younger (50–55 years), highly educated and Anglophone women, which raised the concern of volunteer bias. Those who volunteer to participate in cancer prevention and screening trials are overall healthier than the general population [8–10]. The DOvE Study has no control group, given that all participants have symptoms. Thus, benefits of the intervention could be overestimated if a high proportion of participants would have been diagnosed earlier even without DOvE. A better understanding of motivators and barriers to participation is useful in developing strategies to improve recruitment of underrepresented groups, which would lead to broader generalizability of the findings. Furthermore, this knowledge may help to address differences in access to potential beneficial interventions among more vulnerable subgroups [5,6,11–13].

While in-depth exploration of the reasons for participation in a specific study may be best achieved by means of qualitative research, such an approach generally allows for small groups being studied. In many volunteer-based studies, including DOvE, the eligible population is unknown, which makes it even more challenging to study determinants of non-participation. For this reason, we took advantage of a survey aimed at estimating the prevalence of "ovarian cancer symptoms" in the Montreal general population [14] to ask women who classified themselves as eligible whether they planned or not to take part in DOvE, and the reasons why or why not. In this paper, we report on the perceived motivators and barriers among responders to the survey. These findings may prove useful in developing strategies to improve

**Table 1**
Characteristics of study participants according to correct or incorrect self-assessment of eligibility.

| Characteristics | Eligible based on DOvE[a] | | | | Non-eligible based on DOvE[a] | | | |
|---|---|---|---|---|---|---|---|---|
| | Correct self-assessment $N = 346$ | | Incorrect self-assessment $N = 87$ | | Correct self-assessment $N = 207$ | | Incorrect self-assessment $N = 186$ | |
| | % | 95%CI | % | 95%CI | % | 95%CI | % | 95%CI |
| Health related factors (yes vs. no) | | | | | | | | |
| Family/personal cancer history[b] | 52.0 | 46.8–57.3 | 55.2 | 44.7–65.6 | 45.9 | 39.1–52.7 | 52.7 | 45.5–59.9 |
| Cancer screening in prior 5 years[c] | 88.4 | 85.1–91.8 | 82.8 | 74.8–90.7 | 78.7 | 73.2–84.3 | 88.7 | 84.2–93.3 |
| Not having a family doctor | 9.5 | 6.4–12.6 | 12.6 | 5.7–19.6 | 13.5 | 8.9–18.2 | 10.8 | 6.3–15.2 |
| Prior awareness of DOvE | 11.9 | 8.4–15.3 | 6.9 | 1.6–12.2 | 4.4 | 1.6–7.1 | 9.1 | 5.0–13.3 |
| Self-perceived health | | | | | | | | |
| Excellent/very good | 51.0 | 45.7–56.3 | 69.0 | 59.2–78.7 | 73.8 | 67.8–79.8 | 61.3 | 54.3–68.3 |
| Good | 36.4 | 31.3–41.5 | 25.3 | 16.2–34.4 | 21.4 | 15.8–27.0 | 31.7 | 25.0–38.4 |
| Fair/poor | 12.6 | 9.1–16.1 | 5.8 | 0.9–10.6 | 4.9 | 1.9–7.8 | 7.0 | 3.3–10.7 |

CI: confidence intervals.
[a] DOvE eligibility criteria: having at least one ovary, no previous diagnosis of ovarian cancer, and at least one symptom lasting ≥2 weeks and ≤1 year.
[b] This category includes family or personal history of ovarian, uterine, cervical, vulvar and breast cancer.
[c] Any one of four screenings (Pap test, mammogram, colonoscopy or fecal occult blood test) in the previous 5 years.

Please cite this article as: Z. Sun, et al., Recruitment challenges in clinical research: Survey of potential participants in a diagnostic study of ovarian cancer, Gynecol Oncol (2016), http://dx.doi.org/10.1016/j.ygyno.2017.06.021