

027 - Enrolment fraud in online shared decision-making research: lessons learned in an Internet-based randomised controlled trial

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Background and Aims: Studies that recruit participants, deploy interventions, collect data, and compensate participants via the Internet have been enabled by technological advancements. Such studies represent a low-cost approach to research, may be more inclusive than those adopting conventional recruitment methods, and, where interventions are intended to be deployed electronically, may also be highly ecologically valid. However, they are also vulnerable to enrolment fraud. In this paper, we will describe the enrolment fraud we encountered in a recent study and share lessons learned relevant to others conducting Internet-based research.

Methods: We conducted an Internet-based randomised controlled trial of a patient decision aid on postpartum contraception [ClinicalTrials.gov Identifier: NCT03500952]. Eligible to enrol were people who were pregnant, lived in the United States, and met other criteria. A range of recruitment methods was employed including paid Facebook and YouTube advertisements, Facebook and Twitter posts, and outreach to relevant communities with an online presence. Recruitment materials directed individuals to a website at which they could become informed about the study, consent, be screened for eligibility, and complete an initial survey. Participants were offered \$20 and \$30 Amazon.com gift cards for completing a second and third survey, respectively. The target sample size was 392 participants.

Results and Conclusions: We discontinued recruitment efforts after significant and persisting incidents of enrolment fraud. Altogether, 1290 of the 1331 people who passed eligibility screening and were randomized were determined to be ineligible for the study. We detected the enrolment fraud via large volumes of enrolment in concentrated periods of time, patterns and duplication in the email clients and email addresses of consecutive enrollees, participant IP addresses originating outside of the United States and in regions different from reported state of residence, and other unusual item responses and patterns. Informed by our experiences and our subsequent consultation of the literature and with others, we developed a set of strategies for preventing enrolment fraud in Internet-based research (e.g., provision of compensation by mail only), as well as strategies for detecting, responding to, and minimizing the negative impact of enrolment fraud.