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Shannon Morrison;Cathy Roche;Barbara Gower

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Aims: Explore the effects of BSN Honors student's face-to-face recruitment on clinical trial enrollment in an oncology clinic setting.

Methods: One-group pre/post design examined the efficacy face-to-face recruitment on enrollment in a nutrition-focused oncology clinical trial. Descriptive statistics summarized sample characteristics and t-tests/Man-Whitney U compared between-group differences. Enrollment percent change was calculated to determine intervention effectiveness.

Results: No between group differences were observed between individuals who enrolled versus those who declined. In-person BSN nursing student recruitment resulted in a 77% increase across six weeks.

Conclusions Nursing honors student recruitment was effective and well received by patients and clinical staff. Leveraging research application opportunities and undergraduate student nurse skill sets may provide a cost-effective strategy to reduce recruitment barriers and increase clinical trial target enrollment feasibility.

Keyword: BSN students, clinical trial recruitment, feasibility, resource leveraging

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Shannon Morrison (Corresponding author)
School of Nursing, University of Alabama at Birmingham 1720 2nd Ave South, UAB School of Nursing, Birmingham, AL 35294-1210 205-996-7841 | samorris@uab.edu

Cathy Roche
School of Nursing
University of Alabama at Birmingham
Birmingham, Alabama, USA

Barbara Gower
Department of Nutrition, University of Alabama at Birmingham
Birmingham, Alabama, USA

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Background*: Insufficient enrollment is a primary determinant of premature clinical trial closure. Nursing students enrolled in research-focused honors programs may be uniquely suited to address recruitment barriers.*

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Conclusions *Nursing honors student recruitment was effective and well received by patients and clinical staff. Leveraging research application opportunities and undergraduate student nurse skill sets may provide a cost-effective strategy to reduce recruitment barriers and increase clinical trial target enrollment feasibility.*

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1. Introduction

Clinical trials are the gold standard to validate safety and efficacy of health interventions in humans. Efficient and effective recruitment of eligible participants is critical to successful completion of clinical trials. Likewise, inadequate study accrual may negatively influence the accuracy of research findings (i.e., lack of power, Type II error) and reduce generalizability. Unfortunately, lack of sufficient accrual for clinical trial participation is a pervasive challenge across disease and population spectrums [1, 2] and is the primary predictor of early termination of human studies [3]. In fact, approximately 50% of prematurely discontinued clinical trials are due to insufficient accrual and 75% of all clinical trials never reach a priori recruitment targets [4].

Primary barriers to recruitment are fundamentally two-fold: individual and system. Individual factors related to study non-participation include a lack of awareness of the clinical trial, reluctance/mistrust of research/scientists, dissatisfaction of randomization and control group assignment, financial barriers and logistics (i.e., driving distance for data collection) and/or lack of interest in research participation [5]. System-related barriers consist of ambivalence towards study participation from clinicians and other stakeholders, inadequate office personnel to meet the demands of maintaining a clinical practice and staff or space necessary for recruitment, poor understanding of study aims by clinicians and staff, perceived conflicts of interest between research needs and patient-related clinical decision making autonomy, as well as a lack of systematic, efficient, eligibility screening mechanisms [6, 7].

Across human research domains, cancer clinical trials are particularly challenging. Despite consistent, positive associations between healthcare provider recommendation and an individual's decision to participate in research, oncology providers are sometimes hesitant to inform patients of research participation opportunities [8, 9]. Common themes among oncology providers regarding clinical trial referral hesitation include lack of time to provide study-related information in the context of the cancer treatment plan, random group assignment misgivings, apprehension related to conceivable cancer treatment protocol interference, as well as a concern that the patient and/or family may perceive that the research recommendation is simply a last-resort maneuver in regards to the patient's cancer prognosis [6, 10, 11].

To address these recruitment barriers, innovative, efficient, and cost-effective strategies are a high priority across research institutions. One such underexplored model includes strategic learning and research partnerships within academic science centers. For example, Bachelor of Science in Nursing (BSN) honors students may be uniquely well suited for clinical trial recruitment. Nursing honors students are academically motivated, high achieving, emerging professionals. These students demonstrate medical terminology proficiency, navigate electronic medical record systems efficiently, exhibit excellent interpersonal and professional skills within healthcare settings (i.e., outpatient clinics, acute care facilities, and community centers) as well as provide clear and compassionate communication to potential study participants and their families [12]. In addition, research-focused nurse honors programs provide students with the foundational research principles needed to meaningfully contribute to a research team (i.e., ethics, human protections, protocol adherence). Lastly, research-oriented practicum experiences are generally required for honors program completion. Thus, clinical trial activities, such as study recruitment, may support application of didactic research instruction while reducing staff time burden. However, little

evidence exists related to the effectiveness of such learning/research partnerships among nursing students enrolled in research-based honors programs.

2. Purpose

The purpose of this study is to evaluate the impact of BSN Honors student recruitment on study accrual in women diagnosed with gynecological (i.e., uterine and/or endometrial) cancer (i.e. newly diagnosed or recurrent) in a gynecology oncology outpatient clinic during a six-week research practicum experience.

3. Methodology

Four BSN students enrolled in a research-focused nursing honors program in an academic science healthcare center completed the Collaborative Institutional Training Initiative (CITI) Human Subjects Research Basic and the Responsible Conduct of Research (RCR) training as well Health Insurance Portability and Accountability Act (HIPPA)/confidentiality training. Institutional Review Board (IRB) approval was obtained for the addition of the student-led in-clinic recruitment initiative.

Support for student-led recruitment for the study was obtained from the clinic's healthcare providers and administrators. Emergency and Honors Program faculty contact information were made available to the clinic's administrative staff. In addition, students completed training led by the study's research coordinator that included a review of the clinical trial's specific aims, inclusion/exclusion criteria, group randomization procedures as well as intervention and control protocols.

3.1 Protocol

Medical records of scheduled patients were screened for eligibility at the beginning of each clinic day. Eligibility criteria for the study included 1) endometrial or ovarian cancer diagnosis, 2) measurable tumor(s) *or* elevated CA-125, 3) BMI > 18.5, 4) proficient in English (i.e., speaking and reading), and 5) agreeable to randomized group assignment. Healthcare providers queried eligible patients regarding research participation interest prior to discharge. Patients that indicated participation interest were provided verbal and written study-related information by a student in a private exam room prior to clinic discharge. Lastly, the name, medical record number, and preferred contact method were obtained from women requesting additional information. This information was placed in a sealed envelope and hand delivered to the research coordinator at the conclusion of each clinic day. Potential participants were contacted by the research coordinator within seven days to provide study-related information, verify participation interest, confirm eligibility, answer additional questions and schedule baseline data collection (as appropriate). Informed consent document was obtained by research staff prior to baseline data collection for all participants.

De-identified demographic (i.e., age, race, ethnicity, marital status, occupation, type of insurance) and descriptive (i.e., type and stage of cancer, body mass index, concurrent comorbidities) data were collected from the health record of the women that were counseled about the study by an Honors student.

Descriptive statistics were analyzed d to identify sample characteristics. Between-group comparisons were assessed via *t* (i.e., age, age at cancer diagnosis, and BMI) and Mann-Whitney U (i.e., cancer stage) test analyses to detect differences between the participants that enrolled in the study versus those who declined study participation. Percent change in study accrual from baseline to week 6 served as the proxy to assess effectiveness of the student-led recruitment initiative. Accrual increase of $\geq$ 25% across the 6-week practicum was determined a priori as the benchmark for success.

4. Results

Twenty-nine eligible women were eligible to participate. Of the 29 women, eight declined, ten enrolled, and 12 were pending enrollment (i.e. awaiting one or more of the following: final eligibility screening by research coordinator, informed consent, or baseline appointment scheduled) at the conclusion of the six-week student recruitment initiative (Table 1). There were no differences observed between women that enrolled in the study versus women that declined to participate on demographic (i.e., age, marital status, race/ethnicity, type of health insurance) or descriptive (i.e., cancer type and/or stage, existence and/or number of comorbidities) indicators. Overall, the sample primarily consisted of overweight or obese midlife to older women (M = 60.9, SD = 11.6), diagnosed with at least one additional comorbidity (i.e., hypertension, obesity, hyperlipidemia, and/or hypothyroidism). Of the women that declined participation, travel for study-related visits (n = 4) and uncertainty regarding effects of the intervention on cancer treatment (n = 3) were the most commonly cited reasons.

Table 1. Sample characteristics

	Enrolled (n = 10) (Mean/SD)	Declined (n = 8) (Mean/SD)	Pending Consent (n = 12) (Mean/SD)
Age in years	60.9 (9.3)	62.5 (13.0)	58.8 (13.7)
Age (years) at cancer diagnosis	60.9 (7.6)	57.2 (18.6)	56.9 (15.2)
Cancer stage (I – IV)	2.2 (1.2)	2.8 (0.9)	1.7 (1.4)
BMI	36.6 (11.2)	35.0 (12.0)	59.0 (13.7)
Private Insurance	5	6	9
Two or more comorbidities	8	6	7
Race (Caucasian)	9	7	9
Married/Partnership	4	3	6

Demographic variables of eligible women with face-to-face recruitment by enrollment status

Face-to-face recruitment significantly increased study enrollment (p < .001). In the prior ten-months utilizing traditional recruitment approaches (i.e., flier dissemination, word of mouth, and healthcare provider referral) 13 women were enrolled. During the 6-week student recruitment initiative, study accrual

increased from 13 to 23 participants, a 76.9% increase. In addition, 12 additional participants were scheduled to complete final screen and informed consent by the project coordinator at the project's conclusion.

5. Discussion

In this study, we found that onsite recruitment by BSN Honors students increased study enrollment by 76% in 6-weeks. Prior recruitment approaches included strategic advertisement (i.e., fliers), word of mouth, and physician/nursing staff referral. To set the stage for success, the primary investigator and research coordinator collaborated throughout the protocol development (i.e., grant application) and implementation stage with the clinic's medical, administrative, and nursing staff. These longitudinal collaborative efforts were aimed to ensure clarity of the study's purpose, recruitment goals, and research protocol as well as to identify potential clinic referral barriers, establish effective methods of communication and complete recruitment-specific staff training. To minimize clinic disruption, research funds were allocated to support additional staff during the recruitment period. However, in retrospect it seems that a specific time of day or number of hours per week dedicated to nurse recruitment endeavors weren't clearly delineated. Thus, it is plausible the nurse's day-to-day clinic responsibilities were not reduced proportionate to the research salary support provided. Consequently, time for study eligibility screening or providing eligible women with study-related information may not have been feasible given the time demands of caring for often acutely ill patients in a busy oncology clinic. As such, future research/practice partnerships may consider negotiating specific time designations for staff to complete research-related activities a-priori as appropriate.

Consistent with other studies, we found that reducing provider and clinical staff recruitment burden significantly increased study enrollment. Likewise, in a study of older, cognizant cancer patients, removing providers/staff from eligibility screening and informed consent procedures by having members of the research team in the clinic setting was more effective in comparison to a patient-centered approach (i.e., communication training of clinic staff members tailored to the older adult and allowing additional time for the participant to answer questions (81% versus 50% enrollment, respectively) [13]. Similarly, in a cancer trial of patient/caregiver dyads, Sygna and associates compared seven recruitment strategies: 1) on-site recruitment by research team member; 2) relying on providers at the hospital; 3) newspaper advertising; 4) internet and social media; 5) recruitment at a rehabilitation center; 6) flyers; and 7) opt-out with routine care letters in which patients who did not opt-out were contacted by telephone a few days later. The most effective recruitment method was the use of research team members to recruit at the clinic site (50%) followed by the opt-out option and follow up phone call by a member of the research team for patients that did not opt out (19.3%) [2]. Thus, human contact by a member of the research team appears to play an important role in recruitment success and may play an even greater role in cancer clinical trial recruitment. In our study, decreasing the screening burden as well as providing fundamental study-related information during the office visit to eligible, interested women resulted in more than a 75% rise in enrollment in 6-weeks.

It is well-established that physician recommendation for clinical trial participation is highly influential in research recruitment. Comis and colleagues conducted a cross-sectional study of N = 1,027 adults cancer survivors and/or diagnosis of another serious medical condition and found that nearly 60% relied either exclusively or primarily on their healthcare provider for all decisions impacting their health [14]. Of their sample, nine percent of cancer survivors reported that they were aware at the time of their diagnosis that they may be eligible to participate in a clinical trial. Of the ninety percent who were unaware of a clinical trial opportunity, 65% indicated they would have been receptive to learning more information about the study and/or enrollment. In this study, anecdotal observations suggested healthcare providers were willing to introduce women to the option of research participation and consistently did so for those women identified by the student team as eligible.

These observations underscore the importance of a thorough investigation of clinic resource availability when determining screening and recruitment procedures. Factors such as eligibility specificity may important to consider when determining whether screening is feasible among those providing care. Studies with more narrow requirements (e.g., nulliparous women, BMI > 24.9, prescribed at least one antidepressant, and received colposcopy with previous 12 months) may necessitate a more time-intensive, comprehensive review of the medical record, and thus less feasible in comparison to studies where the criteria is more broad (e.g.,, males at least 65 years). Likewise, clinical characteristics (e.g., type of practice (i.e., acute, primary, or chronic care; general versus specialty), population (i.e., age, level of overall health, and literacy of patients), and provider/clinic workload are also critical factors to consider when determining feasible provider and clinic staff participation regarding clinical trial recruitment.

5.1 Limitations

Small sample size, single-recruitment location, and a limited time frame (i.e., 6-weeks) due to the academic calendar parameters are noteworthy limitations. It is unclear as to how long a similar recruitment trend may have continued. It is also unclear whether the student's screening and identification of likely eligible participants for the healthcare providers or if the provision of basic study-related information by the student nurses was key. It is plausible that the mentioning of the clinical trial by the women's oncologists was largely responsible for the greater study enrollment. Alternatively, the inquiry by the oncologist as to whether the women may be interested in learning more about research participation followed by the onsite provision of study-related information by the nursing students worked synergistically to increase study enrollment.

6. Conclusion

Trust is a key component in clinical research. Trust between the research team and the clinic staff and more importantly trust must exist for patients and participants. Nursing students may be an ideal way to bridge the trust gap and overcome other barriers to research participation. Engaging nursing students in the process of educating clinic patients about research and providing the patients with opportunities to participate in clinical research is a win-win recruitment strategy. Patients win because they have a student devoted to thoroughly explaining the research and students win because by participating in the recruitment

process they gain insight to the research process. In addition, the clinic and the research study win because student effort is of no cost within the context of a learning environment. Lastly, the students win by gaining valuable research experience, increasing their professional network and being introduced to the academic nursing pathway, a career option often overlooked among new graduate BSN nurses.

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