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Effective Recruitment of Schools for Randomized Clinical Trials: Role of School Nurses

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Abstract

In school settings, nurses lead efforts to improve the student health and well-being to support academic success. Nurses are guided by evidenced-based practice and data to inform care decisions. The randomized controlled trial (RCT) is considered the gold standard of scientific rigor for clinical trials. RCTs are critical to the development of evidence-based health promotion programs in schools. The purpose of this article is to present practical solutions to implementing principles of randomization to RCT trials conducted in school settings. Randomization is a powerful sampling method used to build internal and external validity. The school's daily organization and educational mission provide several barriers to randomization. Based on the authors' experience in conducting school-based RCTs, they offer a host of practical solutions to working with schools to successfully implement randomization procedures. Nurses play a critical role in implementing RCTs in schools to promote rigorous science in support of evidence-based practice.

Keywords

best practices/practice guidelines; leadership; program development/evaluation; school nurse characteristics; evidence-based practice

Schools are an important community setting for reaching the majority of school-aged youth or families with health promotion and prevention programming. The school setting is the second most influential environment in a child's life. School nurses address educational and health needs of students (National Association of School Nurses [NASN], 2016). As such, school nurses are able to communicate effectively with teachers, health professionals, community stakeholders, and parents to advocate for health promotion programs (Wolfe, 2013). The ongoing relationship between school nurses, parents, students, teachers, and schools provides an ideal setting in which student health behaviors can be fostered and

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maintained. The school setting is essential for implementation of child and adolescent health promotion and risk reduction research.

Evidenced-based nursing is an approach of providing nursing care based on the most current, relevant research available on the topic to improve health outcomes (Melnik & Fineout-Overholt, 2015). Evidenced-based nursing relies on the collection, interpretation, and application of research findings into practice settings including schools (Melnik & Fineout-Overholt, 2015). Evidenced-based nursing enables school nurses to provide the highest quality of care based on the best evidence available (Adams & McCarthy, 2007). School nurses may lack the resources or skills to critically evaluate the quality of prevention research programs needed to guide evidenced-based practice (Adams & McCarthy, 2007; Pravikoff, Tanner, & Pierce, 2005). At the same time, school nurses lead in the development of school-based health promotion and risk reduction programs to advance the health and well-being of students (NASN, 2016).

School nurses encounter guidelines on school health-related websites. These guidelines may vary from expert opinions to systematically developed evidenced-based practice guidelines (Adams & McCarthy, 2007; Melnik & Fineout-Overholt, 2015). When making decisions regarding best practice, nursing practice guidelines and health curricula delivered in school settings should be guided by the evidence generated from randomized controlled trials (RCTs). RCTs are experimental studies; participants are randomly assigned to an intervention group or control group and followed over time to determine whether the intervention impacts a specific health outcome (Plichta & Kelvin, 2013). Rigorous RCTs and systematic reviews produce the “best evidence” for nursing practice in school settings (U.S. Preventive Services Task Force, 2014).

The purpose of this article is to present practical solutions to implementing principles of randomization to RCT trials conducted in the school setting. The authors will share their practical experience implementing RCTs in rural schools. The challenge is to apply rigorous design principles to maintain internal and external validity while not disrupting the daily operations of schools. As leaders in planning, implementing, and evaluating health promotion and risk reduction efforts in schools, the implications for the school nurse are discussed.

In their seminal work, Flay and Collins (2005) have provided an historical overview of school-based health promotion research, suggesting that four generations of study have made progress in improving program efficacy. They suggest this progress in school health research has generated interest in evidence-based programs and drawn the attention of funding agencies. The National Institutes of Health (NIH), the “gold standard” for extramural research funding, has increased funding for school-based prevention trials. Along with increased interest among funding agencies has come demands for increased scientific rigor. The NIH (2016) competitive grant review process conducted by scientific experts has encouraged the use of RCTs. Methods to codify attributes of high-quality research now include the U.S. Preventive Services Task Force (2014), Task Force on Community Preventive Services (2005), Cochrane Collaboration (2008), and the Campbell Collaboration (2004). These organizations have produced review criteria that place a premium on RCT

methods to review the literature supporting formulation of recommendations for evidence-based practice.

The foundation of RCTs is randomization of participants. In school-based studies, to improve the rigor and reduce concerns about similarities among students with the school, the school itself is most often the focus of analysis while controlling for differences among individuals (Murray, Varnell, & Blitstein, 2004; Turner, Li, Gallis, Prague, & Murray, 2017). The implication of this analysis strategy is that the school is the unit of randomization (Murray et al., 2004; Turner et al., 2017). Within each school, it is important to have a sufficient number of participating students to be representative of the school or target school subsample. The process of randomization presents a host of challenges to school organization and everyday functions.

Before Recruitment Begins

Fisher's (1935) theory of design states that the unit randomized is the unit of statistical analysis. In school health, promotion research randomization could occur at the individual student, classroom, or school level. The nature of the intervention will dictate the randomization level. Most often school health promotion programs are delivered to multiple, intact classrooms in each school. Further, most health promotion programs seek to enhance the school environment as part of the intervention. It is also generally assumed that students interact across classrooms to further enhance a program's impact. For these reasons, most health promotion studies consider the school as the unit of intervention to be randomized. As a result, to uncover meaningful effects on health outcomes, school-based RCTs usually require a considerable number of schools (up to 30). The number of schools needed for adequate statistical power will depend on the variables of interest and intraclass correlations within the school (Murray, 1998; Murray, Hannan, & Baker, 1996; Murray et al., 2004; Turner et al., 2017). Before recruitment begins, it is important to determine how many schools must be recruited and what the critical inclusion and exclusion criteria are for participation.

Study Eligibility Criteria

School-based RCTs define clear eligibility criteria for schools to be considered for recruitment to the study. School-level eligibility criteria serve to reduce between school variability and determine the population of schools you can generalize study findings. School-level eligibility criteria may include geographical location such as rural or urban, school size, poverty levels, and the types of programs the schools offer. Other criteria may also include rates of student health behaviors of interest to a particular study or health status. Examples include rates of student physical activity, participation in athletic programs, or routinely collected health measures such as body mass index. Researchers may also consider the county or community specific data such as population density and percentage of adults in the counties with specific health outcomes. Key considerations are specific to the purpose of the study, as it relates to target populations and ultimately the population you wish to generalize the findings. Inclusion and exclusion criteria should be established at the school level as well as the student participant level.

Control Group Conditions

In early health promotion, research control group subjects often received no intervention. Researchers often found that schools that were initially interested in study participation lose interest when informed that they were randomized to no treatment control group (Peter et al., 2008). In some designs, the control group received a delayed treatment after the study was completed. Often the delayed treatment was provided to reduce study refusals to participate. For school-based health promotion studies, a “no treatment” control is not recommended for several reasons.

First, schools are in the business of educating youth. School nurses advance the academic mission by striving to keep students healthy. For many youth, the school may be the primary resource for health information, health-related resources, and health care. School administration, teachers, and parents are often resistant to participate in a study in which students receive no program or a delayed treatment. No treatment control groups may disproportionately refuse to participate in studies during the recruitment phase creating sampling bias. No treatment control groups can also suffer from disproportionate attrition. These refusals and dropouts can have negative effects on both internal and external validity. An important scientific rationale against no intervention control groups is preventing the Hawthorne effect. Ideally, the control group schools receive equal attention and resources when compared to the treatment group. If control condition schools do not receive equal attention, it is difficult to maintain enthusiasm for the research project. Failure to provide a credible standard program can lead to overestimation of treatment group effects. Finally, ethical considerations arise if schools located in underserved or underresourced areas are allocated to a no treatment control. Failure to provide programming or delayed programming may be perceived as withholding the limited health information or health programming available to other schools.

Generally, health promotion and risk reduction researchers want to compare the treatment group to an established contemporary program in which effects are known. For these reasons, control schools should receive an established program to serve as the control condition. To draw credible inferences about intervention effects, a widely accepted program should serve as the control condition. Ideally, treatment and control schools receive equal attention and are blinded to the comparisons being tested in the study.

Timing of Study Events

Timing of Recruitment

By necessity, most schools plan at least one academic year into the future. Organizing students into classes; ensuring that needed courses, classroom space, and school-related resources to conduct a study; and teacher commitment to the project take considerable time. Research staff should respect the complexity of these tasks by conducting recruitment at least one academic year in advance. This allows school administration to incorporate the study requirements into planning with a minimum of disruption. School nurses and teachers also need time to adjust their schedules to accommodate the requirements of the study. Providing adequate time to accommodate the requirements of the study will increase the

likelihood of school participation. School staff has voiced their appreciation for having adequate time to prepare for the study. With adequate time for collaboration, the research team and school health team often can articulate how participation in the study assists the school in meeting its health-related mission, goals, and standards. For example, in our physical activity intervention, we were able to help the school health teachers and school nursing personnel map out how the intervention meets state standards for annual fitness, physical education, and health assessment.

As the health experts, school nurses develop policies, programs, and procedures to deliver school health services (NASN, 2016). As an advocate for the students' health, school nurses provide leadership and act as agents of change when prevention research is proposed. The school nurse should be involved in the study planning from the earliest stages. By involving school nurses in the earliest planning phases, researchers have a greater chance of having a strong study advocate at the school. The school nurse's advocacy can help secure school and student participation and ensure quality implementation of the project.

Timing of Randomization

The order in which schools are recruited, randomized, and notified of study condition can affect the school's decision to participate. One goal in recruitment of schools is to keep participation refusal and attrition to a minimum. Participation refusal and attrition can have serious negative effects on both internal and external validity of the study. Losing schools during the project can result in an under-powered and possibly biased study if the school cannot be replaced.

There are two general approaches to randomization of schools to treatment/control conditions that are equivalent but could have an important effect on a school participation in a study. The first approach is to identify schools that meet study criteria. Schools are contacted to discuss the requirements for participation in the study and study protocols (including randomization). Using this approach, schools make a tentative decision regarding the feasibility of participation after being informed of the requirements of both the treatment and control conditions. Once an adequate number of tentative school commitments have been secured (usually by a letter of support), randomization of schools to treatment or control groups is completed. Schools are then informed of their study condition assignment. It is at this point that schools often need to reassess their commitment. Our experience suggests that some schools will refuse to participate after this assignment is made. Reasons cited may include feasibility of participation in one condition but not the other or a concern about withholding quality programs by being in the control group.

A second approach for recruitment is to identify schools that meet eligibility criteria and apply random assignment procedures before school contact. In this recruitment approach, only the study protocol randomly assigned to a particular school is discussed. The uncertainty of being assigned to treatment or control groups is removed. School personnel and stakeholders can make informed decisions knowing specifically what is required for participation in the study. The schools do not need to know the details of the other study condition. This randomization approach reduces confusion and uncertainty about study

expectations. If the control group receives a quality prevention program, staff at both treatment and control schools can be blinded to condition, thus strengthening the study.

In our experience, school personnel and stakeholders prefer the second approach. The clear message about study expectations allows for an immediate assessment of feasibility. It also reduces the uncertainty about the research conditions they are committing to. This recruitment approach has resulted in reduced school attrition. School staff's enthusiasm and intervention fidelity have been improved by this randomization first followed by recruitment approach.

School Perspective Regarding Recruitment

It is important for researchers to approach schools with a clear and concise recruitment plan. In their seminal work, Petosa and Goodman (1991) developed taxonomy of school decision-making that can be used to develop a sound recruitment approach. This taxonomy describes five distinct phases of decision-making among school districts: legitimacy, information-seeking, expression of limitations, engagement, and commitment. First, schools are concerned with two types of legitimacy. The credibility of study personnel including their expertise, experience, funding history, and alignment with appropriate research agencies (i.e., universities) is one source of legitimacy.

A second form of legitimacy is the research project's relative importance in the context of local school needs. Does the study align with school: mission, curriculum, and district initiatives? The information-seeking phase of recruitment focuses on the demands the study would place on school. These requirements would include class/student time, measurement protocols, disruption of daily school activities, and other project-specific school responsibilities. Next, it is important to engage school staff in a discussion of perceived limitations. School staff considers situational factors that could affect participation including school policies, teacher schedules, classroom organization, curriculum demands, and local political concerns. The research team needs to be resourceful and creative in adapting to school concerns without compromising the integrity of the research design.

During the engagement phase, the research project staff and school representatives are working together toward mutual problem-solving. Incentives and benefits to the school for study participation should be discussed. Commitment to the project is strengthened with school staff believe that the benefits of study participation outweigh perceived costs. This framework can help research staff develop tailored, refined recruitment strategies that meet the needs of the schools. The tailored strategies developed through this process assure better recruitment of school administrators and teachers leading to stronger implementation fidelity at each school. To implement this recruitment process, sufficient time and staff resources are needed for the recruitment phase. In our experience, we have found that these tasks are not ones to be delegated to others but rather the responsibility of the researchers.

Importance to School Nursing

The school nurse of today is charged with providing care based on the best scientific evidence (NASN, 2016). More than ever before, evidence-based research is being conducted

in school settings. While initial decisions to participate in health promotion and risk reduction research may originate with school administrators, health promotion research provides both opportunities and challenges to school nurses. As health experts, school nurses lead advocacy efforts for health promotion and risk reduction research within schools while at the same time being at the forefront of evaluating the evidence for practice. School nurses should lead efforts on behalf of their school(s) to evaluate any proposed research project for appropriateness, feasibility, strength of the study design, reliability and validity of the measures, and implementation recruitment plans at the school level. Given these logistics, conducting health promotion and risk reduction research within school settings may be disruptive to daily operations. School administrators, parents, and community members often consult with the nurse in deciding on the value of participation in a research study. Because of their expertise, school nurses are best suited to bridge the needs of administrators, students, parents, and the research team to ensure the successful planning, implementation, and completion of a rigorous RCT in a school setting.

School nursing practice is based on the best evidence. Evidence for nursing practice, nursing guidelines, school-based health services, and health curricula are generated from rigorous scientific studies. As the health expert in the school, the school nurse serves as a leader in health promotion and risk reduction efforts in schools (Council on School Health, 2008; NASN, 2016). Efforts to strengthen evidenced-based practice targeting children and adolescents have led to more rigorous research studies being conducted in school settings. The gold standard for clinical research is the RCT. Randomization is a key component of a rigorous controlled trial. As more health promotion and risk reduction research move into school settings, school nurses must be fully prepared to evaluate the rigor, feasibility, and appropriateness of the proposed research studies for their administrators, families, and student populations. Assessing the quality of a research project and making recommendations to school administrators are tasks often held exclusively by school nurses. Establishing workable partnerships with research teams is an essential role of the nurse as advocate, health leader, and consumer of school-based research.

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