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Clinical Methods

Challenges of conducting experimental studies within a clinical nursing context

M. Gustafsson, RN, PhD student *, D.M. Bohman, RN, PhD, G. Borglin, RN, PhD

Department of Health Science, Blekinge Institute of Technology, SE-379 71 Blekinge, Sweden

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ABSTRACT

In recent years, several distinguished scholars have advocated for nursing research that may carry strong evidence for practice. Their advocacy have highlighted that nursing science has reached a point where as nurse researchers we need to develop the questions we ask and design studies that have the power to produce solid, translational, evidence-based knowledge. To do so, we need to carry out experimental tests on complex, everyday nursing interventions and activities. We also need to create public space to present accounts of our endeavours pursuing this type of design in clinical practice. This paper will discuss some of the most important insights gained from conducting a quasi-experimental study in which the aim was to investigate the effect of a theory-based intervention, targeting knowledge and attitudes among registered nurses regarding cancer pain management. The importance of careful practical and methodological planning is emphasised, and the need for participation-friendly interventions is discussed.

1. Introduction

This paper will highlight the challenges and experiences of conducting an experimental study that aims to implement and evaluate a theory-based educational intervention where the target group are registered nurses in clinical practice (Gustafsson & Borglin, 2013). What are these challenges and how do they affect the practicality of experimental designs? We identify with the idea that experimental designs in nursing research can further improve patient care as they offer a different approach and open up potential to test a hypothesis in an actual care situation. According to Polit and Beck (2012), the use of experimental studies is regarded as a valid method for evaluating healthcare interventions. However, as Brink and Wood (1998) state when performing experimental research in nursing science, there are many aspects that need to be taken into account, partly for ethical reasons but also in the light of the discrepancy between a controlled environment and the actual nursing context (Brink & Wood, 1998). There is a call nowadays for implementation of evidence-based care that involves applying knowledge in the clinical nursing context in order to raise the quality of nursing care. Our standpoint is that nursing science can benefit from experimental designs. The barriers are nonetheless numerous and diverse and, in line with Richards and Hamers (2009), these barriers must be dealt with through careful practical and methodological planning. In many cases the use of a theoretical framework can help us to better understand and deal with pre-existing barriers (Craig et al., 2008). Stark, Craig, and Miller (2011) acknowledge the importance of building a nursing intervention on top of a model in order to evaluate and refine the design of the intervention. However, we must also bear in mind that some barriers and facilitators may only become apparent during the implementation process (Grol, Wensing, & Eccles, 2004). The nursing environment is a unique setting, where the nurse researcher must take into account numerous influencing factors that can make or break the intervention. In this paper we will discuss the importance of experimental designs as well as the challenge of conducting them.

2. Experimental studies within the clinical nursing context

The use of experimental studies is seen as a valid method for evaluating healthcare interventions (Polit & Beck, 2012), and the practice of conducting experimental studies in nursing science has increased over the years (Smith et al., 2008). True experimental studies offer the most convincing evidence about the relationship between cause and effect and consist of three elements: manipulation, control and randomisation. Manipulation is the researcher's ability to influence the independent variable; control is the researcher's control over the study environment and confounding factors; randomisation refers to how the study participants are divided into study groups (Polit & Beck, 2012). According to Brink and Wood (1998), there is no more suitable design when accounting for control of extraneous variables and maximising the effect of the independent variable (Brink & Wood, 1998). The manner in which the experimental studies are reported is also important in order to ensure a high level of quality. The nurse researcher can use a set of recommendations, named the CONSORT, for reporting randomised controlled trials (RCTs), which is a requirement laid down by several high-quality, peer-reviewed

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* Corresponding author. Tel.: +46 455 385 485.
E-mail address: markus.gustafsson@bth.se (M. Gustafsson).

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journals when reporting results from experimental studies (Lindsay, 2004). The CONSORT extension for pragmatic RCTs is an attempt to help researchers involved in pragmatic experimental research in a healthcare context (Zwarenstein et al., 2008). According to Borglin and Richards (2010), the pragmatic extension can be used to improve the experimental design, make it better suited to the clinical nursing context and generally improve the way in which experimental studies are reported within nursing research. However, when designing an experimental study, the researcher is obliged to appraise scientific rigour in relation to the context and available resources (Thompson & Panacek, 2006). As resources are frequently scarce within healthcare management, the use of a true experimental design can lead to financial problems. We therefore believe that the research design must also be suitable for the nursing environment, and by only using the 'gold standard', i.e. RCT, the progress of nursing care can be impeded and can slow down implementation of knowledge, which needs to be continuous.

Nowadays, there is a call for implementation of evidence-based care and to help initiate and evaluate new knowledge systematically; an experimental design that can be adopted for the organisation would be of great value. According to Brink and Wood (1998), a quasi-experimental design has less scientific rigour but is more cost-efficient and easier to adapt to the clinical nursing context. Depending on the research issue, a true experimental design might not always be the most suitable, for ethical or legal reasons, to answer the question, and in such cases a quasi-experimental design could be of interest (Brink & Wood, 1998). Quasi-experimental studies often lack the randomisation element but still have the control and manipulation elements (Thompson & Panacek, 2006). Randomisation, however, only helps to check for selection bias, which is just one of the four biases within clinical research. Consequently, randomisation has no direct impact on detection, attrition and performance biases (Borglin & Richards, 2010). In those instances that randomisation is not possible, conducting research that checks for remaining biases is still far more preferable in relation to randomised research, where none of the biases is assessed accurately (Hill, 1962). Hence, this kind of experimental design could prove suitable for the implementation of different improvement projects since the randomisation element can be removed, which allows for more pragmatic considerations that are better suited to the clinical nursing context.

3. Challenges when conducting experimental research within nursing

Experiences from the field confirm numerous factors that have the potential to influence the outcomes measured in an intervention within a clinical nursing context. According to Grol et al. (2004), when planning an experimental study in a healthcare context it is recommended that it be checked carefully first for possible influencing, context-specific elements although certain barriers and facilitators may only appear during the actual implementation process (Grol et al., 2004). According to Rycroft-Malone (2012), many evidence-based practice projects produce more questions than answers (Rycroft-Malone, 2012). This could be a result of the practical difficulties of working in an organisational context where full control over influencing factors cannot be achieved and every situation is unique in its own setting. Rycroft-Malone also highlights the difficulties that arise in improving nursing practice that involves numerous interactions. These difficulties will ultimately govern the outcome of the study (Rycroft-Malone, 2012). In an attempt to design and evaluate these kinds of multifaceted interventions systematically, the United Kingdom Medical Research Council (MRC) has created a framework for managing complex interventions that consists of five phases. The first three phases are related to preparation for the RCT, and the two following phases make up the intervention and implementation process. The first phase establishes the theoretical basis for the intervention, and the second phase, the modelling phase, recommends pilot testing in an attempt to increase knowledge of the components that make up the intervention. The third phase is the exploratory trial, where the feasibility of the intervention is explored. These preparation phases aim to provide a solid methodological framework for interventions within a medical setting (Craig et al., 2008). In accordance with the recommendations from the MRC, we regard the first three phases as essential when planning for upcoming practical difficulties, and the use of pilot testing can help discover practical and methodological difficulties that may only become apparent when working in the actual context. This plan should also involve an assessment of how to effectively monitor the adherence and competent delivery of the intervention as this otherwise will affect the validity of the intervention.

Richards and Hamers (2009) suggest that the complexity of nursing and the artificial state of experimental research can be accommodated by means of methodology that has been carefully thought out. However, in a commentary response to the paper by Richards and Hamers, Rolfe (2009) argues that the complexity of nursing cannot be based on the assumption that this complexity can be broken down into different elements that can be identified and measured through RCTs. A complex nursing intervention is unique, and the same intervention in another setting might yield different outcomes (Rolfe, 2009). Forbes (2009) agrees that the nursing intervention is performed within a complex nursing context but emphasises that the intervention is a specific activity that requires its impact to be tested to ensure its usefulness to the patient (Forbes, 2009). We stress that this could prove to be a problem with regard to the transferability of experimental studies in different clinical nursing contexts. Nevertheless, it also depends on the research issue. If our research aims to implement evidence-based nursing knowledge in the clinical nursing context, this might not be as important. Consequently, this would require extensive testing whenever new knowledge is to be implemented and if any generalisability is to be achieved.

Providing external validity is one the difficulties in experimental nursing research. This is exemplified in a multifactorial interventional RCT study that examines prevention of falls among psychogeriatric nursing home patients and where the majority of nursing homes declined to take part due to merger procedures and internal reorganisation of the care process (Neyens et al., 2009). Drop-outs of this nature are a significant problem for the nurse researcher since the organisational structure does not allow easy access and does not put enough effort into connecting nursing research with organisational development. If the healthcare organisation does not allow access, this clearly affects the practicality of experimental research and inhibits the progress of nursing care. We can see a distancing between nursing research and the healthcare organisation, where nursing research is not seen as something that is incorporated naturally and performed on a daily basis. Instead, it is viewed as a time-consuming activity that detracts from the nurses' care of the patients. Consequently, this could affect the response rate and adherence to the purpose of the experimental study. This is illustrated in a quasi-experimental study, where the aim was to evaluate the impact of a computerised educational module on nurses' diabetes knowledge and confidence levels. Both the pre-test and the post-test survey had a low response rate, 44% and 9% respectively. The authors discussed the possibility of frequent interruptions when the nurses filled in the surveys as being an important barrier although the introduction of a new electronic system could also have interrupted the process of completing the surveys (Eaton-Spiva & Day, 2011). However, occurrences of this nature are common in a clinical nursing context and should not influence adherence so strongly. If the organisation cannot work with implementation of evidence-based care because of a lack of integration into the structures and resources, how can we improve care for our patients?

The experiences of working closely with experimental nursing research, both as researchers and as participating nurses, have led us