Research and diabetes nursing. Part 3: Quantitative designs

Vivien Coates

This article is the third in a series that aims to assist nurses working in diabetes to understand research from a broad perspective, to help them critically appraise research publications and develop research protocols. This article focuses on quantitative research designs and the different types of experimental and descriptive studies that come under that banner. Five studies are explored as examples to illustrate the principles that underpin quantitative design with regard to diabetes nursing. Where possible, studies relating to the impact of DSNs are used.

Article points

1. Quantitative research is based on the need for "precise measurement, replicability, prediction, and control".
2. Across the spectrum of quantitative research there are a variety of research designs. The design is the overall plan for the type of study to be conducted and includes "how, when and where data are to be collected and analysed".
3. Research results are only as dependable as the rigor with which the study was designed and executed.

Key words

- Design
- Quantitative
- RCT
- Research

This series of articles is designed to help nurses working in diabetes care understand research and how it relates to their role and scope of practice. In the first article, Dunning (2011) illustrated that there were two broad approaches to research: quantitative and qualitative, plus a related third category, not defined as research, that includes audit and service evaluation. All three approaches are explored in this series with quantitative research being the focus of this third article.

Five studies are used to illustrate the principles underpinning quantitative research designs. Where possible, articles have been selected with the editorial by Hicks (2010) in mind as research can supply the most valuable evidence when DSNs need to "prove their worth".

Background: Quantitative research

Quantitative research is based on the need for "precise measurement, replicability, prediction, and control" (Powers and Knapp, 2006). Across the spectrum of quantitative research there are a variety of research designs. The design is the overall plan for the type of study to be conducted and includes "how, when and where data are to be collected and analysed" (Parahoo, 2006).

Selecting a research design is dictated initially by the research question to be addressed. So, if the question was: "Is the new DSN inpatient service more effective compared with usual diabetes care?", then a quantitative design would be deemed most appropriate, measuring outcomes such as length of stay and change in HbA_{1c} over time. However, if the question was: "What do the staff on the acute wards think should be the scope and remit of a new DSN service?", then a qualitative design that allows for exploration and description would be more suitable.

In this article several experimental and descriptive studies are outlined to illustrate different issues about the design and how this influences the evidence produced by the study. While the research question drives the selection of research designs, the study will also be influenced by the context in which the research is to be conducted and the resources available to the researchers, including their own skills and, to some extent, by their values and beliefs. Once a design is selected there are a wide variety of methods by which the data may be collected, but this is only one part of the design.

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Page points

1. Experiments in health care are usually referred to as clinical trials; they can be designed in a variety of ways and the most well known are randomised controlled trials (RCTs), cluster RCTs, pilot RCTs, explanatory and pragmatic trials, crossover trials, and pre- and post-intervention trials.
2. An RCT is a full experimental test of an intervention in which participants are randomly assigned to different groups (arms) and in which all variables are controlled. RCTs are considered by many to be the "gold standard" when seeking evidence upon which to base care.
3. Pragmatic trials involve large samples representative of the wider clinical population.
4. In a crossover trial an individual would cross from one arm of the study to another, each for the same length of time. Then the results would be compared in each participant.

Experimental design

Experiments in health care are usually referred to as clinical trials; they can be designed in a variety of ways and the most well known are randomised controlled trials (RCTs), cluster RCTs, pilot RCTs, explanatory and pragmatic trials, crossover trials, and pre- and post-intervention trials.

RCT

An RCT is a full experimental test of an intervention in which participants are randomly assigned to different groups (arms) and in which all variables are controlled. RCTs are considered by many to be the "gold standard" when seeking evidence upon which to base care (Torgerson and Torgerson, 2008). They are based on the following three principles:

- An intervention to be tested.
- Randomisation of participants to groups.
- Control of all known and unknown variables.

While these requirements might be achieved when testing a medication under laboratory conditions, in clinical practice all three principles can be very difficult to achieve.

Cluster RCT

Instead of allocating individuals, cluster RCTs randomly allocate groups of individuals to either the intervention or control arms of the experiment. For example, all patients admitted to Hospital A will be in the intervention arm, while all those in Hospital B will be in the control arm. The randomisation was at the hospital level rather than an individual level.

Pilot RCT

A pilot RCT is a study that is too small to produce definitive results or is evaluating an intervention that in not fully developed (Torgerson and Torgerson, 2008).

Explanatory and pragmatic trials

A clinical trial that achieves high levels of control is known as an explanatory trial. However, it may be so tightly controlled that it would be difficult to translate to routine practice. For example, the inclusion criteria might be such that only a small percentage of people with diabetes would be eligible to participate. If the intervention is found to be effective it may be difficult to decide whether it would be applicable to the general population of people with diabetes. Pragmatic trials involve large samples representative of the wider clinical population.

Crossover trials

In crossover trials each individual would be in either the control group or the intervention group and the results are compared across groups. In such a trial an individual would cross from one arm of the study to another, each for the same length of time. Then the results would be compared in each participant.

Pre- and post-intervention trial

Also known as "before and after studies", pre- and post-intervention studies measure relevant variables during a pre-test phase, then an intervention is introduced and the variables are measured again. Differences between the pre- and post-measurements are attributed to the intervention. As this design lacks the rigor of a full experiment it is known as a quasi-experimental approach.

Examples of experimental design

RCT

Hicks (2010) urged DSNs to "prove their worth" and the most robust way to achieve this would be with evidence from an RCT.

There are relatively few RCTs to establish the effectiveness of DSNs; however, one such study is that by New et al (2003), which aimed to determine the effectiveness of specialist nurse-led clinics for hypertension and hyperlipidaemia provided for people with diabetes receiving hospital-based care. The premise of the study was that there are guidelines and targets available to guide this care but that a substantial number of people with diabetes do not achieve these targets through usual services – therefore, a specialist nurse-led approach may be more effective. Thus the intervention was the nurse-led service, which was compared with usual care.

This study recruited people with diabetes who were not achieving target levels for either

blood pressure or lipids; once they agreed to participate, participants were randomly assigned to either the nurse-led service or to usual care. As is required in a trial, the number of participants is calculated in advance. This is to ensure that there are enough participants to identify a difference in the outcomes (if one exists) that can be attributed to the intervention rather than to chance, while also ensuring that resources are not wasted by recruiting a larger sample than is required. In this study the primary outcome measure was based on the number of participants who subsequently achieved target levels for hypertension and hyperlipidaemia.

All participants in this study were randomly assigned to either the intervention or control groups by a remote, concealed process designed to minimise bias. The third requirement for a trial – control of all known and unknown variables – is challenging in a trial based in clinical practice. In this study it was achieved through a number of design features, such as:

- Involving a sufficient sample size.
- The use of protocols for both experimental and control groups.
- The gathering of clinical data from the routine diabetes database by staff who were blinded (unaware) of the group to which the participants belonged.
- Running the hypertension and the hyperlipidaemia clinics independently so that there was no contamination of protocols within one clinic visit.
- Ensuring full agreement with the whole diabetes team, including those in primary care.

All these design features were important to minimise bias from uncontrolled variables. This study is a good example of an RCT. While the results are not presented here in any detail, the RCT generated evidence that the nurse-led intervention was effective, had been evaluated through a robust study design and, therefore, can be considered to provide robust evidence to support specialist nurse-led clinics in the management of people with diabetes.

Pilot RCT

An example of a pilot trial is the research by Charlton et al (2004), which was also designed to explore the effects of a DSN working in a nurse-led clinic structure.

This study was set up like a trial, in which people with type 1 diabetes were randomly recruited from the diabetes clinic database. Once they agreed to participate they were randomly assigned to either the nurse-led clinic or to usual care. A protocol in the form of guidelines for the consultations with the DSN was agreed in advance. Feedback about the clinics was by means of an anonymously completed participant questionnaire.

This design included an intervention and randomisation, but as a pilot study there was no pre-determined sample size to establish whether there were significant differences in the outcomes between the groups. From a research perspective the importance of this study was under the heading "Lessons learnt". The design enabled the identification of areas that worked well and those that did not.

This would be an important step prior to conducting a full RCT as it provides an opportunity to revise aspects of the intervention and study design that were found to be problematic. As the study had not been designed to produce definitive results about the effect of the nurse-led clinic, the results can only be used with caution, and would not be considered strong evidence.

Cluster RCT

Research into the impact of DSNs using a cluster trial methodology were not identified, however the principles underlying cluster trial design can be illustrated with reference to the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) programme (Davies et al, 2008). This study was designed to evaluate the effectiveness of a structured group education programme in people with newly diagnosed type 2 diabetes.

To fulfil this objective an experimental approach was needed. However, rather than randomise each individual to either the intervention group (DESMOND) or to usual care, randomisation was at the general practice level. Thirteen primary care sites in England and Scotland were involved in the study and,

Page points

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2. The third requirement for a trial – control of all known and unknown variables – is challenging in a trial based in clinical practice.
3. An example of a pilot trial is the research by Charlton et al (2004), which was designed to explore the effects of a DSN working in a nurse-led clinic structure.

Page points

1. A power calculation is an important issue in experimental studies. The experiment is not run for a length of time in the hope that enough people will be involved to enable robust results to be calculated; rather, the number is pre-determined, the likely rate of recruitment is estimated and then the number of study sites and the duration estimated.
2. The results of the DESMOND (Diabetes Education and Self-Management for Ongoing and Newly Diagnosed) study were that those in the intervention group demonstrated greater improvements in weight loss and smoking cessation and positive improvements in beliefs about illness but no difference in HbA_{1c} levels up to 12 months after diagnosis.
3. Courtenay et al (2007) undertook a study to evaluate the impact of a "specialist nurse prescriber on diabetes inpatient service delivery" using a quasi-experimental design.

from these, 207 general practices participated. These practices were randomised to either the intervention or the control arm of the study.

As people attending these centres were diagnosed with type 2 diabetes and agreed to participate in the study they would be either in the intervention or the control arm according to group to which their practice had been allocated. This method overcomes the problem of contamination within groups. For example, if within one practice patients were randomised to either the intervention or the control group it is quite possible that patients would know each other, information across groups could be shared and thus there could be people allocated to the control arm but who were actually getting access to the intervention informally. The use of a cluster design avoids this problem.

A power calculation was used to determine that 315 people were needed for each group to enable a difference in HbA_{1c} level of 1% to be detected. As this was the number needed for the final analysis, allowance was made for those who decline to take part, or who do not complete the study. Thus it was calculated that 500 participants for each group should be recruited. This type of calculation is an important issue in experimental studies. The experiment is not run for a length of time in the hope that enough people will be involved to enable robust results to be calculated; rather, the number is pre-determined, the likely rate of recruitment is estimated and then the number of study sites and the duration estimated. This estimation of sample size and strategies to attain it are all part of the study design. In other respects the trial is then run in a similar way to other RCTs with delivery of the intervention, measurement of outcomes and comparison of results across groups.

In this study the intervention group demonstrated greater improvements in weight loss and smoking cessation and positive improvements in beliefs about illness but no difference in HbA_{1c} levels up to 12 months after diagnosis (Davies et al, 2008).

This study was designed as a full experiment and contained the essential elements of an intervention and randomisation. However, the third criterion – control of all known and unknown variables likely to influence the results – proved hard to achieve. One of the likely reasons why no difference in HbA_{1c} was achieved is that at the same time as this study was being conducted the UK government also launched a Quality Improvement Framework to improve the outcomes for the management of a range of chronic conditions, including diabetes (Tahrani et al, 2007). It is thought that the improvements achieved by the introduction of this policy masked improvements that could have been achieved by the study (Dineen, 2008). Thus, even in the most robust of studies it can be difficult to control all variables in a clinical care setting.

Pre- and post-intervention trial

Courtenay et al (2007) undertook a study to evaluate the impact of a "specialist nurse prescriber on diabetes inpatient service delivery" using a quasi-experimental design.

All people with diabetes admitted to any of six wards within a district general hospital, and who were treated with insulin or oral antidiabetes drugs (OADs) during the time of the study, were included. A 3-month pre-intervention phase was conducted in which participants received usual care. In addition to demographic information, data were gathered relating to the primary outcomes of insulin and OAD medication errors and diabetes patients' length of stay. Secondary outcome data relating to patients' views regarding self-management using a self-report questionnaire were also gathered.

An intervention was then introduced in the form of a DSN prescriber whose role and remit was defined; this included patient assessment, review of medication, patient and ward staff education, and ongoing review of the medication by the DSN prescriber. If medical prescribing was delayed or not available, the nurse prescriber could also instigate supplementary nurse prescribing. Primary and secondary outcome data were then gathered following the intervention phase.

This is an example of a quasi-experiment; a pre-determined intervention was tested, a sample of 452 participants was involved but they were

not randomised. Furthermore, variables that might have influenced the results between the pre- and post-intervention phases could not be controlled. This study provides evidence about the impact of this intervention but evidence from this design would not be regarded as robust as that gained from a full experiment.

Descriptive design

Descriptive research provides a completely contrasting quantitative design to that of experiments and is often used to provide a knowledge base on a topic about which little is known, to add clarity to a subject, or to describe a situation. This information may be useful in its own right or may be the preliminary phase of an experiment or in a correlational study to explore relationships between the described variables (Powers and Knapp, 2006).

Descriptive research designs are usually in the form of surveys or observations and may be conducted at one time point (cross-sectional) or over time (longitudinal). Data gathering may be by database analysis, questionnaire, interview or by a combination of methods. Although regarded as a less robust form of evidence than that from an experiment, descriptive research must use precise measurement, be able to be replicated, take place in a controlled way and generate results that can form the basis for prediction of future trends.

Example of descriptive design

A survey by James et al (2009) will be presented to elaborate on some of the features of a descriptive design. The aim of the survey was to review the working practices and roles of DSNs across the UK. This study was designed as a cross-sectional survey using a postal questionnaire sent to all lead DSNs in the UK. To ensure that the data could be precisely measured it was vital that the research instrument – a questionnaire designed specifically for this study – was both valid (measures what it is supposed to measure) and reliable (can consistently measure the attributes of interest).

In this study the questionnaire was designed by a study group of diabetes specialists. The questionnaire was piloted with DSNs who were asked to comment on the clarity of the questions and questionnaire and then was amended to enhance the face validity of the instrument. If the questionnaire was to gather data on unseen or abstract concepts, such as attitudes or beliefs about the role, then a form of factor analysis would be required to establish the construct validity of the instrument.

It is important that the process of a quantitative study can be replicated. Therefore, details of the sample population, the method of recruitment, the use of reminders and the response rate are all vital. Such information is available in the study by James et al (2009) and, therefore, if the study was to be repeated it would be possible to follow a similar process.

The methods by which the data were collated, entered into a statistical database and then analysed are also provided both to enable readers to follow the process of the study and also for future use if the study were to be replicated. The results of this study, based on a 44% response rate, describe the role of DSNs in hospital and community, the way in which the role has evolved since the 2000 survey (Winocour et al, 2002) and gaps in service provision.

This survey presents an accurate, nationwide description of the DSNs and their roles. Through a robust design and accurate methods of data gathering the results can be regarded as evidence of the current situation. Potential problems have been identified and can serve as an early warning of situations that could be addressed to remedy some of the issues before they become a real problem.

Conclusion

Evidence-based practice is a key element in the role of DSNs and in this article the designs of studies that produce quantitative evidence have been discussed and illustrated. The essential elements of quantitative designs depend upon accurate measurement, replicability, control. Research results are only as dependable as the rigor with which the study was designed and executed. Good-quality quantitative research will produce robust results that can be used to guide practice and may also be used to demonstrate the worth and impact of DSNs. ■

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