FOR DEBATE . . .

The scope for qualitative methods in research and clinical trials in dementia

GRANT GIBSON, ALISON TIMLIN, STEPHEN CURRAN, JOHN WATTIS

Ageing and Mental Health Research Group, University of Huddersfield, Queensgate, Huddersfield HD1 3DH, UK

Abstract

In the evaluation of drugs, the randomised double-blind placebo controlled trial is the ‘gold standard’. This method, based on a positivist paradigm, answers questions about efficacy and side-effects of treatments that are accepted as valid, reliable and generalisable, provided the study is well designed and properly conducted. In contrast, qualitative research methodologies, originating from the social sciences, embrace a variety of approaches, including phenomenological and other paradigms. Within clinical and health services research, qualitative approaches view the world more subjectively, acknowledging that the researcher is part of what is researched, focusing on meanings and understanding of experience, rather than on what can be reduced to quantitative measures. They can develop new ideas through induction from data, rather than confirming or refuting hypotheses. Qualitative methods have improved our understanding of the experiences of people with dementia and, if used alongside clinical trials, could be used to improve the relevance of outcomes to patients, compliance and user involvement. They could also possibly generate new measures of efficacy and effectiveness in severe dementia.

Keywords: qualitative research, dementia, clinical trials, Alzheimer’s Disease, elderly

Introduction

The randomised controlled trial is the most commonly used tool within clinical research, and provides a range of benefits in the formulation of scientific knowledge. For studies into pharmacological and other clinical interventions, the randomised controlled trial is unparalleled. However, to rely solely upon this method restricts the areas that are open to research and narrows access to useful knowledge even in the area of drug efficacy and effectiveness. If used within well-designed research projects, qualitative methods can strengthen clinical trials by enhancing user involvement, and by revealing new areas of research that would remain hidden within wholly quantitative studies. This paper seeks to illustrate some of the differences between the two methodologies, and to show how within dementia research, including clinical trials, qualitative and quantitative approaches can be complementary.

Differences between quantitative and qualitative methods in health services research

The positivist framework enables questions to be answered in a highly specific way by controlling extraneous variables. This framework provides the basis of the double blind placebo controlled clinical trial. Reliability, validity, generalisability and objectivity are the bywords of the clinical trial, deriving a clear answer from a precise question of fact. Through appropriate statistical techniques, results are recognised as generalisable. That is they can be applied to the wider population from whom the trial sample was drawn.

Within the context of health services research, qualitative research has an alternative philosophical underpinning, approaching different questions in different ways with different purposes [1]. For example, phenomenological approaches may challenge the ‘independence’ of the observer. They recognise that in research the observer is a participant whose own views and values impinge on outcomes; they explore experience and meaning rather than causality; they inductively look for patterns, themes and meanings; they reject reductionist approaches, claiming that topics must be studied within the complexity of real life. Concepts such as validity and reliability have to be approached in a different way in qualitative research, such as through triangulation [2, 3]. The main differences between the qualitative and quantitative methods, and the philosophical underpinnings upon which they are based within health services and related research are summarised in Table 1 [2].

For many health service professionals qualitative research has been erroneously defined as being ‘what quantitative research is not’ [4], leading to the creation of a false
dichotomy between the two methods, with extreme views on both sides of the divide. Extremes include the claim that qualitative research is not ‘real’ research or, on the other side of the divide, that dementia should not be considered as a disease, being mainly a social construction [5]. Within health services research this divide has been reinforced by many badly designed and validated qualitative research designs, giving the use of qualitative methods an undeserved ‘bad press’. Similarly, a lack of training for medical staff on the application of qualitative methodologies within health services research has led to a lack of knowledge on the possibilities that arise from the use of these methods. However, over recent years, an increasing number of scientists and researchers within each ‘camp’ are coming to the view that qualitative and quantitative methods are complementary and that using both approaches enables us to obtain a more complete understanding of the issues and outcomes of clinical and health services research [6].

### Types of qualitative research and their applications

Generally, three broad categories of qualitative research exist of interest to health service researchers; observational studies, interview studies and documentary/textual analysis of various written records [1, 7]. Rather than robustly confirming existing hypotheses, qualitative approaches can often generate new ideas for further research and provide insights into the experiences of service users and carers not immediately accessible to quantitative methods.

Qualitative methods have a wide scope of use within clinical trials. They can address issues such as informed consent and randomisation [8]. They can allow those undertaking treatments and their carers to share their own experiences of the benefits and impacts that drug treatments bring, perhaps particularly relevant in severe dementia. Beyond the clinical trial, they can explore reasons for inequity of access to treatment [9]. Because of the respect shown to the participants views, qualitative research can be useful in improving the design of randomised controlled trials, and in improving recruitment [8]. Because they do not have to decide in advance which rating scales to use, qualitative methods in drug evaluation can increase the likelihood of discovering new kinds of information about the experiences of patients and those who care for them (including benefits and impacts that may not be discovered using quantitative methods). To date qualitative methods have not been widely used in clinical trials to evaluate the use of psychoactive drugs in older or younger people, or more specifically in people with dementia. They could help us to understand the perspective of people with dementia and their carers, and the meanings they attach to treatment and treatment response. When combined with quantitative approaches, this could significantly enhance our understanding of anti-dementia drugs.

### Characteristics of qualitative research

Within clinical trials specifically and clinical research more generally, qualitative methods have the following characteristics and benefits:

i. **Qualitative research as participatory:** participants feel valued as more than subjects/objects.

ii. **Qualitative research as reflexive:** reflection is encouraged, opening up new lines of enquiry.

iii. **Qualitative research as complementary:** the ‘objective’ results of quantitative research are complemented by the subjective accounts of participants.

### Qualitative research as participatory

One of the most significant aspects of much qualitative research work is its participatory nature. Those taking part in research are given value as participants, rather than being research subjects [10]. Many forms of qualitative research have the ability to create a two-way learning process, within which knowledge is gained and transferred between researcher and participant. In this respect, for participants research can be an empowering experience [11]. Some people, particularly old people and those with dementia, may feel lonely, irrelevant or marginalised. Qualitative research can allow such people to feel that they have a ‘voice’, that others are listening to their concerns and are interested in their opinions and experiences. Participants in this type of research may be ‘amazed that someone was taking an interest in their situation’ [12]. Similarly, with suitable levels of familiarity and trust, detailed sources of data can be accessed that would remain hidden in quantitative research. Participants may also be able to voice concerns they would not be able to raise within the context of other research methods. When combined with a clinical trial, improved researcher understanding and user feeling of involvement may enhance compliance.

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<th>Basic beliefs</th>
<th>Positivist ‘quantitative’ paradigm</th>
<th>Phenomenological ‘qualitative’ paradigm</th>
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<tr>
<td>The world is external and objective</td>
<td>Focus on facts</td>
<td>Focus upon meaning/interpretation</td>
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<td>Observer is independent</td>
<td>Look for causality and fundamental laws</td>
<td>Try to understand what is happening</td>
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<td>Science is value free</td>
<td>Reduce phenomena to simplest elements</td>
<td>Look at the totality of each situation</td>
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<td>Formulation and testing of hypotheses</td>
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<td>Operationalising &amp; measuring concepts</td>
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<td>Taking large samples</td>
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<th>Preferred methods include</th>
<th>Positivist ‘quantitative’ paradigm</th>
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Table 1. Differences between quantitative and qualitative methodology within health services research (modified from [2])

**For debate . . .**
Qualitative research as reflexive

Thoughtful reflection on outcomes can be a powerful tool in developing research and clinical practice. Qualitative methods lend themselves to this kind of reflection. This reflexivity is often identified as a criticism of qualitative methods, in that they lack ‘objectivity’ and external ‘validity’. From the qualitative viewpoint, researchers, and the act of research, are rooted within the interactions and relationships that occur within the social world [12]. Qualitative research cannot exist outside of the social world, and is involved in constructing and negotiating this world. There is no one universal experience for people with dementia, but each person has an individual account of the illness and its past, current and future effects. From these accounts common themes will emerge linking the experiences of different individuals, helping them feel less isolated, and helping the researcher better understand these experiences. This can then lead to improved practice through a better understanding of the subjective and individual experiences of people with dementia and those who care for them. Qualitative research allows us to recognise, investigate, and challenge how our positions as clinicians and researchers affect outcomes. Within clinical trials, it can impact upon the data collected, its subsequent analysis, the results gained and their interpretation, and their usefulness in clinical practice.

Qualitative methods as complementary

As noted earlier, a common (mis)conception in research is the existence of a qualitative–quantitative divide based upon fundamentally different philosophical underpinnings irreversibly distanced from each other [2, 13]. However, this dichotomy, based on ideology rather than theory is commonly detrimental to the research process [1, 4, 14]. Qualitative research methods provide a powerful tool in complementing statistical forms of research. Indeed a good quality piece of quantitative research is often dependent on the findings of descriptive studies based upon qualitative techniques [1]. If utilised correctly, the ability of qualitative methods to analyse micro-scale phenomena can be perfectly complemented by quantitative methods and their ability to examine phenomena at larger scales. Furthermore qualitative studies can often suggest new ideas that can be further evaluated using quantitative techniques with larger samples. This is one example of the ways in which qualitative and quantitative methods, when combined, provide a fuller picture of a population than either method can separately.

Qualitative research and research into dementia

Qualitative methods are more often used in management research. They are probably under used in clinical research, including dementia research. However, there has been an encouraging growth in the number of qualitative research studies in dementia. Qualitative methods have been well used in investigating the phenomenology of dementia, illustrating the experiences and perspectives of people with dementia and their carers [15–19]. Phenomenological, psychoanalytical and feminist studies on the notion of selfhood have led to the development of alternative theories on the impact of dementia upon individuals’ quality of life [4, 20, 21]. Further qualitative work has examined and evaluated the healthcare and wider support provided to people with dementia and their carers, often concentrating on evaluating forms of care provision and highlighting new systems for the benefit of people with dementia and their caregivers [22–24].

However, within clinical trials qualitative methods remain underused. This can in part be attributed to the dominance of the randomised controlled trial, a highly successful quantitative design. Here the person with dementia may have little input or involvement beyond being the subject of various tests, measures and other procedures. Put simply, the person with dementia is little more than a passive vessel of answers [14]. Clearly this is an important and necessary part of the research and development process, however the legitimacy of this approach as the only way to conduct research into the effectiveness of drug treatments can be challenged. The effectiveness of utilising qualitative methods within randomised clinical trials has been demonstrated, for example showing how these methods are useful in improving recruitment rates by increasing researcher awareness of how medical terms may be misinterpreted by patients, and the impact of these misinterpretations [10].

Clinical trials and other clinical research studies do not seek to measure social phenomena; rather they seek to understand the impact of drug treatments on clinical conditions. However, qualitative methods are not in conflict with traditional quantitative methods, instead they can widen and complement the knowledge generated in such studies and elsewhere in dementia research. The adoption of qualitative methods within clinical research on dementia drug treatments would acknowledge that dementia is not simply a biological process characterised by cognitive and functional decline, but is also a socially constructed experience of the individual patient. In including and further developing qualitative research within psychopharmacological studies we gain a deeper understanding, not only of the psychosocial and experiential concerns arising for individual patients, but also the relationships and conflicts that may occur when the social worlds of people with dementia meet the clinical world of dementia research. If we broaden our research into the experiences of people undertaking drug treatments, we must consider their social worlds and how they interact with being prescribed anti-dementia medication. By undertaking qualitative research in conjunction with clinical trials, we may gain an understanding of the effectiveness of these drugs through the lived experiences of people with dementia, complementary to their psychometric effectiveness.

Specific ethical and methodological issues arise when conducting research with people suffering from cognitive impairment. However, within a relevant and well thought out research design, using well trained and sympathetic researchers, qualitative methods can be particularly suited to conducting research with people with mild to moderate forms of dementia [14]. Downs [20] describes a study where ethnographic methods such as participant observation were
used to good effect in investigating the opinions of people with dementia regarding the quality of home-based day care provided. Clearly in this respect there is scope for investigating the opinions, experiences and practices of people taking anti-dementia drugs during trials. The use of qualitative methods within dementia treatment studies allows researchers to more fully investigate issues surrounding the disease that, because of their nature, may not be picked up during the use of standardised tests for cognitive ability.

Qualitative research is also well suited to investigating services for the provision of anti-dementia treatments. Qualitative methods with service users can be used to illustrate in detail particular strengths and weaknesses that may not be as readily apparent using statistical and other records. While a clinic may be successful in terms of managerial efficiency, service users may evaluate services using very different measures of success. A statistical analysis using sources such as patient records may not be able to differentiate between these different judgements. Of course a purely qualitative project based upon patient experiences and opinions can not be relied upon in isolation, but when the two methods are combined, we are able to provide a fuller analysis of services and treatments based upon the experiences and practices of all involved and analysing a variety of seemingly different trends and data sources.

**Conclusion**

Interest in qualitative methods in researching dementia and dementia care is growing. However little consideration has been given on how these methods may complement quantitative studies into drug treatments for Alzheimer’s and other forms of dementia. An adoption of qualitative methods within this area, when combined effectively with quantitative measures would allow both researchers and practitioners to gain a fuller understanding of the improvements these drugs provide, and crucially how these improvements are experienced by people with dementia themselves. Of course, and as with quantitative research, qualitative studies must be well designed and rigorous according to their aims, objectives and outcomes. In this regard, qualitative methods can provide interesting and valuable case studies or ‘snapshots’ on the effectiveness of drug treatment, rooting the benefits of these treatments within the context of patient’s experiences, and providing a powerful tool for encouraging further development for research into drug treatments in the future [5].

**Key points**

Qualitative methods:
- Can enhance clinical trials in a variety of ways.
- Have a different philosophical foundation to the quantitative methods that dominate clinical trials.
- Supplement but do not replace quantitative methods.
- Allow patients and carers to share their experiences of treatment and its effects on their own terms.
- Can allow patients and carers to be more actively engaged in research rather than simply being its objects.
- Can be used to generate new areas of enquiry, rather than to prove or disprove hypotheses.

**Conflict of interest**

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