

Assessing Efficacy of Complementary Medicine: Adding Qualitative Research Methods to the “Gold Standard”

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ABSTRACT

Randomized controlled trials (RCTs) have an important place in the assessment of the efficacy of complementary and alternative medicine (CAM). However, they address only one, limited, question, namely whether an intervention has—statistically—an effect. They do not address why the intervention works, how participants are experiencing the intervention, and/or how they give meaning to these experiences. Therefore, we argue that the addition of qualitative research methods to RCTs can greatly enhance understanding of CAM interventions. Qualitative research can assist in understanding the meaning of an intervention to patients as well as patients’ beliefs about the treatment and expectations of the outcome. Qualitative research also assists in understanding the impact of the context and the process of the intervention. Finally, qualitative research is helpful in developing appropriate outcome measures for CAM interventions. Greater understanding of CAM interventions has the potential to improve health care delivery.

INTRODUCTION

The strengths and limitations of the use of randomized controlled trials (RCTs) to assess the efficacy of complementary and alternative medicine (CAM) have been widely debated in the literature (e.g., Nahin and Straus, 2001; Vickers et al., 1997) and this debate continues. Adaptations to RCTs that have been suggested (see below) increase the potential of RCTs to assess the efficacy of CAM. However, despite these adaptations to RCTs, many questions remain regarding the usefulness and effectiveness of CAM that are not easily addressed using these strategies.

In this paper we argue that although RCTs have an important place in the assessment of the efficacy of CAM, the addition of qualitative research methods to RCTs can greatly enhance

the understanding of CAM. Such additions have the potential to improve CAM interventions, and, thus, health care delivery.

LIMITATIONS OF RCTs

An RCT is a study design in which individuals are randomly allocated to at least two groups, usually called the “study” and the “control” group. One group is subject to a standardized experimental intervention, while the other group receives placebo or standard treatment. The results are assessed by rigorous comparison of the outcome(s) in the study and control groups respectively. In order to limit bias, group allocation maybe concealed to participants (i.e., blinding). RCTs are generally considered as the most scientifically rigorous

method of assessing the efficacy of an intervention and, thus, represent the "gold standard."

Challenges to RCTs of CAM interventions are various and include the following. First, CAM interventions are often complex and use multiple modalities (e.g., naturopathy and Traditional Chinese Medicine). Second, CAM treatments are frequently not standardized, but individualized and flexible, adjusting treatment as needed for the individual patient. In addition, there are wide variations in practice. Third, CAM interventions often apply to non-specific, multifactorial conditions (e.g., stress, lack of energy) or patients with complex, chronic conditions (Walach et al., 2002). Thus, defining clinical problems (and treatment) may be very difficult. In addition, the focus is often on restoring balance rather than treating specific symptoms. Fourth, recruitment and randomization can be problematic because of participants' beliefs, practices, and preferences. Fifth, identification of appropriate placebo treatment (e.g., acupuncture, massage therapy) is often difficult or impossible, which results in difficulty blinding patients and practitioners. Finally, RCTs generally try to minimize or exclude the impact of the patient-provider relationship (nonspecific effects) on the outcomes, while in CAM the therapeutic effect of the patient-provider relationship is considered a crucial part of the intervention. It is important to understand that many of these challenges are not unique to CAM and apply equally to several conventional interventions, such as physiotherapy, psychotherapy, surgery, and nursing care.

Several adaptations of RCTs have been suggested to address these issues, such as the conduct of pragmatic trials in which whole systems are assessed in their proper context so that both the diagnosis and treatment may be highly individualized (e.g., Stephenson and Imrie, 1998; Vickers, 1996). This solution addresses the first three challenges. Preference trials, which take into account patients' preferences as a separate variable, deal with the fourth challenge (e.g., Brewin and Bradley, 1989; Torgerson et al., 1996). The difficulty is that such trials are not always possible, in particular if potential participants have strong

preferences for the intervention. Vickers (1996) has pointed out that blinding and placebo control are not integral parts of the RCT design and, thus, if not appropriate can be deleted. However, this may be considered as weakening the design, and thus, the evidence provided. The last challenge is not easy to resolve. Because of interactions between the diagnostic process, the therapist, and the patients, RCTs will not be able to explain the specific effects of the patient-provider relationship.

A challenge of a different nature is related to limitations to the type of information that can be generated from RCTs. Mostly knowledge generated from RCTs is general and in aggregate form and answers questions about frequencies and strength of association. Qualitative research, however, is designed to generate specific information regarding the why and how of individual experiences and, therefore, should be considered as an addition to RCTs.

QUALITATIVE RESEARCH AND ITS PURPOSES

Qualitative research consists of the investigation of phenomena in their natural context, in an in-depth holistic fashion through the collection of rich narrative data. As such it does not seek quantified answers. Its goal is the development of concepts, which helps us to understand social phenomena in natural (rather than experimental) settings, giving due emphasis to the meanings, experiences, and views of all the participants (Pope and Mays, 1995). Research purposes for which qualitative studies are especially suited include the following. (Green & Britten, 1998; Maxwell, 1996). The first purpose is gaining an understanding of an intervention by identifying the meaning of the intervention for participants in the study, of the events, situations, and actions in which they are involved. The second purpose involves understanding the particular (natural) context within which the participants act, and the influence that this context has on their actions. An important part of this is identifying the role of patient-provider interaction in the intervention. The third purpose is understanding the process by which events and actions take place, and the

fourth, assessing how perspectives of reality of different stakeholders (patients, practitioners, and researchers) on interventions differ. In the process of conducting qualitative research it is common that unanticipated phenomena and influences emerge that have the potential to formulate new research questions and to improve health care practice.

As in quantitative research, there are multiple strategies to ensure rigor in qualitative research (Mays and Pope, 1995). Although these strategies are different, there is no reason to assume that qualitative research in itself is not rigorous.

RELEVANCE OF ADDING QUALITATIVE METHODS TO RCTS

Understanding the meaning of the intervention

RCTs can establish whether an intervention works by means of a strong, highly controlled design in which two or more groups are randomized to rule out confounding variables. However, just as there are intervention studies that generate statistical significant results that have no clinical significance or substantive or real-life importance either to patients or to their caregivers, it is also possible to find nonstatistically significant results that have important implications for individual patients. If an RCT shows no treatment effect, it cannot tell us whether the intervention worked in ways other than expected or whether some specific individuals benefited from the intervention. Although less dramatic, this may also apply to RCTs that do show a treatment effect.

Although such issues have been addressed in disciplines such as nursing and education, medicine is slower to follow, and information has appeared in abstracts and/or is as yet unpublished. Becker et al. (2001) conducted a controlled intervention study aimed at evaluating the effects of *qigong* lessons on performance, social behavior, and health in school children. While improvements were found with respect to several outcomes, no significant differences were found between the two groups in quality of life using a validated quality-of-life scale. However, data collected in qualitative inter-

views with teachers illustrated a calming and relaxing effect of *qigong*, as well as a decrease in complaints for some children. These elements were not part of the quality of life scale. Pope found several significant outcomes following an RCT of a mind-body intervention for patients with a chronic disease, however no improvement was found in the amount of personal stress (cited in Verhoef et al., 2001). In qualitative interviews, participants described a personal growth process, which they felt was moving them toward improved well-being. They spoke about gaining self-awareness, which they viewed as a positive outcome, even though their reaction to this awareness was not always positive. How an intervention works has also been addressed by Alraek and Baerheim (2001) who qualitatively assessed participants' subjective experiences in a trial of acupuncture in the prevention of recurrent cystitis. This trial has not yet been published. The qualitative study was based on the investigators' experiences in their practice that patients often described changes in their health in addition to curing the problem they came for, which seemed to reflect going from disharmony to harmony. The results demonstrated experiences related to changes in urinary habits, more energy, reduced stress level, better sleep, better digestion, and reduced pain from headaches, back pain and joint pain.

Weinholtz et al. (1995) report a dramatic example of a combined study in the education literature. They describe how qualitative data helped them find significance from the statistically insignificant findings of a study they conducted on the impact of small group instruction. These data showed that one of their outcome measures was insensitive to a certain learning outcome.

These examples show that an intervention may result in meaningful and desirable changes to patients that may not be apparent as improvement on instrumental measures designed with a specific conceptualization of normal, average, or optimal functioning. In order to assess such changes, research needs to address the individual experiences of people receiving the intervention. Qualitative research as opposed to quantitative research is case-oriented rather than variable-oriented and is more

suitable to detecting subtleties in the intervention process that account for the research findings (Sandelowski, 1996).

Outcomes of an intervention

The above examples illustrate that available outcome measurements do not always address all potential benefits of CAM interventions. Cohen and Mount (1992) found that the tendency of most instruments to weigh their questions toward the physical while ignoring issues related to meaning, purpose, and spirituality renders them invalid in the palliative care setting. We would argue that this also applies to many CAM interventions that frequently are holistic in nature and are based on a strong belief in the mind-body connection. In addition, the previous examples identified that we do not always know what potential benefits of interventions are. Levin et al. (1997) describe that according to the literature on Bach Flower remedies, treatment with the water violet formula is said to restore serenity. Most likely, available outcome measurements will not assess this quality, and thus, may conclude that this remedy has no effect. In such cases it is useful to conduct qualitative research before the start of the trial, to assess what relevant outcomes are, in order to develop appropriate measures.

While availability of appropriate measures is an issue, the study conducted by Weinholtz et al. (1995) has shown that lack of sensitivity of existing measures to assess important qualitative between- and within-person differences is another issue. To increase sensitivity, outcome measures need to be valid, reliable, specific, amenable to change (long- or short-term) and have a range of scores that allow detection of change (Stewart and Archbold, 1992, 1993).

Context

For the purposes of research and analysis, interventions in RCTs are studied in isolation, whereas in clinical practice any intervention is but a part of a treatment approach. van Weel (2001) indicated that "nonspecific effects work through their integration into the overall treatment approach, which is an essential way into

which context effects differ from specific effects." The value of context effects is in their enhancement of specific interventions, so that efficacy is maximized. RCTs are not the ideal design for assessing context effects. Therefore, exploring the unique physical and psychosocial context in which an intervention takes place is an important added value of qualitative research.

One of the most frequently discussed non-specific effects is the patient-physician relationship, which is often seen as an integral part of treatment by complementary practitioners. Di Blasi et al. (2001) have conducted a systematic review to examine whether there was any empirical evidence to support the therapeutic effects of the doctor-patient relationship. Their results showed much inconsistency regarding these effects and the only relatively consistent finding was that physicians who adopt a warm, friendly, and reassuring manner are more effective than those who keep consultations formal and do not offer reassurance. Systematically and rigorously conducted qualitative research might lead to deeper insight and, thus, allow building theoretical models that can be tested in quantitative research. Similarly, Jobst (2001) comments that "while it may be well said that good bedside manners work, the question nevertheless remains: 'How?'"

Process

How interventions fit within the process of participants' lives is important for future applications of the intervention. Research has shown that people often experiment with different types of complementary treatments and use "trial and error" in making their disease management decisions. (Verhoef et al., 1998). This practice results in frequent changes in treatment. How patients integrate symptoms and management of symptoms with the practicalities of their lives is an important area of exploration. Information about participants' circumstances will increase understanding of the feasibility of the intervention in real life and real time and will identify the burdens of the intervention.

The process of the intervention itself is im-

portant as well. Weaver et al. (1996) describe how they complemented their study of case management for people with serious mental illness with a qualitative study of process designed to identify aspects of case management associated with positive or negative outcomes. The results of this study have not yet been published. Qualitative research could also provide profound insight in what flexibility and adjustment within an intervention involve. Last, implementation of an intervention is often very different from the way it was planned (Rabeneck et al., 1992). In such cases, qualitative methods can be used to assess how the intervention is actually enacted as well as the actors' responses to it (Sandelowski, 1996).

Multiple realities

Qualitative sociologists have long recognized the existence of multiple realities. Yerxa (1991) has contended that the experimental method does not represent the patient's reality because it excludes the patient's subjective experience and natural environment. Around CAM, patients and practitioners may have different beliefs about healing (holism versus biomedicine) and about evidence. While researchers, and to a lesser degree practitioners, find scientific evidence crucial, many patients tend to believe that CAM is natural, and thus, safe, and find scientific evidence of less importance than personal evidence. Patients' beliefs are closely related to their expectations and may have a major impact on trial results. Exploring how such expectations are related to the process of the intervention is of great importance.

The role and importance of patients' beliefs have been described in several qualitative studies. For example, the factors that Chinese immigrants with arthritis perceived as contributory to the disease as well as the perceived severity of the disease were major factors in treatment preferences and choices (Zhang and Verhoef, 2002). Holman (1993) describes how patients who benefited from an arthritis self-management program did not view their disease as irretrievably damaging their lives and believed that they could do things to better their situation.

DISCUSSION

RCTs are important in assessing the efficacy of CAM. Many adjustments to RCTs have been suggested that facilitate their conduct with respect to CAM. However, RCTs address only one, limited, question, namely whether the intervention has—statistically—an effect. They do not address why the intervention works, how participants are experiencing the intervention and/or how they give meaning to these experiences. These are different questions, that require a different design, so it would be wrong to fault RCTs for not being able to address these questions, just as it would be wrong to fault qualitative research for its lack of "statistical significance." We argue that both are needed to evaluate fully the usefulness of CAM interventions provided that both are conducted rigorously, meticulously, and with great attention to validity and interpretation of the data. When such methods are combined, the potential for increased validity of the results is enhanced by numerical as well as conceptual generalizability.

Combining quantitative and qualitative methods is especially relevant with respect to CAM. In conventional medicine, randomized clinical trials are frequently conducted after extensive pretrial studies, such as *in vitro* and animal studies to assess the mechanism of the intervention. With respect to CAM, RCTs are often conducted based on prevalence and popular demand. The use of qualitative methods to identify why an intervention works, is more suitable to interventions that are complex, and that are based on mind-body, spiritual, and energy paradigms, than those that are focused and based on a body paradigm, such as herbal treatments.

Qualitative methods may be used before starting an RCT, to assist in the development of appropriate outcome measures or they may be embedded in the trial to assist in understanding the measuring context and process of the intervention. Third, qualitative methods can be used after the trial is completed to explain the trial results.

The discussion of the use of combined methods is directly relevant to the tension between patient-centered care and the use of evidence

in clinical practice. As Holman (1993) states, "the practice of medicine, with its focus on the individual, lives an unrelieved tension between knowledge of the average effects of a disease or treatment upon a group and the individual effects upon a single patient." Practitioners are interested in improving individual patient outcomes in specific situations, and, therefore, in understanding as much as they can about the application, operation, and outcomes of an intervention in particular cases. Accordingly, emphasizing individual variation as idiosyncrasies in responses to interventions over time may be more clinically relevant than group means per se, from which individuals will often deviate in subtle, but clinically important ways.

Methods other than qualitative methods can provide such information as well, for example, comparing all patients who improved with those who did not, disregarding the group they were in, or collecting survey data looking at patients' beliefs and experiences. However, in such methods it is still the investigator who identifies what data need to be collected or analyzed and thus, still the investigator's reality that is being tested or explored. This prespecified perspective is avoided by qualitative methods. We argue that the best way to assess the advantages of combined methods research is to conduct such studies and to demonstrate the potential to contribute to improved health care delivery and ultimately health status.

REFERENCES

- Alraek T, Baerheim A. Subjective experiences following acupuncture treatment—Expected or not? [abstract]. *FACT* 2001;6:69–100.
- Becker M, Witt C, Bandelin K, Willich SN. Qigong for school children [abstract]. *Altern Ther Health Med* 2001;7:S4.
- Brewin CR, Bradley C. Patient preferences and randomised clinical trials. *BMJ* 1989;299:313–315.
- Cohen SR, Mount BM. Quality of life in terminal illness: Defining and measuring subjective well-being in the dying. *J Palliat Care* 1992;8:40–45.
- Di Blasi ZD, Harkness E, Ernst E, Georgiou A, Kleijnen J. Influence of context effects on health outcomes: A systematic review. *Lancet* 2001;357:757–762.
- Green J, Britten N. Qualitative research and evidence based medicine. *BMJ* 1998;316:1230–1232.
- Holman HR. Qualitative inquiry in medical research. *J Clin Epidemiol* 1993;46:29–36.
- Jobst KA. Rigor and compassion: The paradoxical challenge of peer review. *J Altern Complement Med* 2001;7:1–3.
- Levin JS, Glass TA, Kushi LH, Schuck JR, Steele L, Jonas WB. Quantitative methods in research on complementary and alternative medicine: A methodological manifesto. *Med Care* 1997;35:1079–1094.
- Maxwell JA. *Qualitative Research Design: An Interactive Approach*. Thousand Oaks, CA: Sage Publications, 1996.
- Mays N, Pope C. Rigour and qualitative research. *BMJ* 1995;311:109–112.
- Nahin RL, Straus SE. Research into complementary and alternative medicine: Problems and potential. *BMJ* 2001;322:161–164.
- Pope C, Mays N. Reaching the parts other methods cannot reach: An introduction to qualitative methods in health and health services research. *BMJ* 1995;311:42–45.
- Rabeneck L, Viscoli CM, Horwitz RI. Problems in the conduct and analysis of randomized clinical trials: Are we getting the right answers to the wrong questions? *Arch Intern Med* 1992;152:507–512.
- Sandelowski M. Focus on qualitative methods: Using qualitative methods in intervention studies. *Res Nurs Health* 1996;19:359–364.
- Stephenson J, Imrie J. Why do we need randomised controlled trials to assess behavioural interventions? *BMJ* 1998;316:611–613.
- Stewart BJ, Archbold PG. Focus on psychometrics: Nursing intervention studies require outcome measures that are sensitive to change: Part One. *Res Nurs Health* 1992;15:477–481.
- Stewart BJ, Archbold PG. Focus on psychometrics: Nursing intervention studies require outcome measures that are sensitive to change: Part Two. *Res Nurs Health* 1993;16:77–81.
- Torgerson DA, Klaber-Moffett J, Russell IT. Patient preferences in randomised trials: Threat or opportunity? *J Health Serv Res Policy* 1996;1:194–197.
- van Weel C. Examination of context of medicine [letter]. *Lancet* 2001;357:733–734.
- Verhoef MJ, Pope A, Hilsden RJ. Combining randomized controlled trials and qualitative methods to assess the efficacy of complementary medicine [poster]. *Art & Science of Healing II: Integration of Conventional & Complementary Medicine Conference*, Vancouver, Canada, November 2001.
- Verhoef MJ, Scott CM, Hilsden RJ. A multimethod research study on the use of complementary therapies among patients with inflammatory bowel disease. *Altern Ther Health Med* 1998;4:68–71.
- Vickers A, Cassileth B, Ernst E, Fisher P, Goldman P, Jonas W, Kang SK, Lewith G, Schultz K, Silagy C. How should we research unconventional therapies? *Int J Technol Assess Health Care* 1997;13:111–121.
- Vickers A. Methodological issues in complementary and alternative medicine research: A personal reflection on

- 10 years of debate in the United Kingdom. *J Altern Complement Med* 1996;2:515–524.
- Walach H, Jonas WB, Lewith G. The role of outcomes research in evaluating complementary and alternative medicine. In: Lewith G, Jonas WB, Walach H, eds. *Clinical Research in Complementary Therapies. Principles, Problems and Solutions*. Toronto: Harcourt Publishers Limited, 2002:29–45.
- Weaver T, Renton A, Tyrer P, Ritchie J. Combining qualitative studies with randomised controlled trials is often useful [letter]. *BMJ* 1996;313:629.
- Weinholtz D, Kacer B, Rocklin T. Salvaging quantitative research with qualitative data. *Qual Health Res* 1995; 5:388–397.
- Yerxa EJ. Nationally speaking—Seeking a relevant, ethical, and realistic way of knowing for occupational therapy. *Am J Occup Ther* 1991;45:199–204.
- Zhang J, Verhoef MJ. Illness management among Chinese Immigrants living with arthritis. *Soc Sci Med* 2002 (in press).

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