

EDITORIAL

Conducting research in rural primary care medicine: do we need more experimental research or guidance?

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Introduction

Ecological evidence has suggested that health systems with a strong orientation towards primary care achieve lower overall costs, better satisfaction of their populations, and better health¹. Relevant research is essential to informing best practice in primary care settings, as this may be different to best practice in secondary or tertiary settings². However, several barriers have been described that impede the effort to provide quality evidence in primary care, including clinical leaders' reluctance to accept the problem, lack of skills for translational research, lack of funding for primary care related research questions, and lack of robust evidence from randomized controlled trials (RCTs) in primary care³. It is the latter barrier that this editorial seeks to address.

Similar barriers have been reported when rural primary care research is considered, as was discussed the second Rural Health Invitational Conference of the European Association of Remote and Isolated Physicians (EURIPA) forum at Sinaia, Romania in 2011 (<http://www.euripaforum2011.eu>). These barriers may be compromising clinical decisions in primary care, leading to primary care research being criticized as a lost cause⁴, which may have also had a negative impact on the development of academic rural practice.

Randomized controlled trials are considered the 'gold standard' for documenting the evidence for medical interventions, both in hospital and primary care, and therefore rural health research has been much criticized for its lack of RCT evidence. This editorial aims to describe why RCTs are difficult to conduct in rural health research, and to



suggest a set of key issues to be considered during the design and implementation of RCTs in rural communities.

Challenges of conducting RCTs in rural primary care settings

There is much discussion of whether RCTs are feasible in rural primary care because of characteristics that differ from those in hospital settings. Some of these differences are common to primary care in any setting, some are specific to rural research.

Typically, the patients recruited in primary care settings suffer from less severe clinical conditions and are more heterogeneous both in demographic and clinical characteristics than patients recruited in secondary care settings. They may have a lower probability of disease, or the disease may be diagnosed at a less severe stage, and they often report undifferentiated symptoms⁵. Thus, restrictive selection criteria may result in limited applicability of the trial in primary care.

Randomized controlled trials in primary care may need to evaluate therapeutic interventions that simultaneously include pharmacologic and non-pharmacologic therapies, such as physiotherapy, behavioral therapy, diet, or exercise. An RCT to assess a multifaceted intervention is more complex and costly.

Randomized controlled trials are often designed to compare individual agents with a placebo. This will not identify the most effective intervention in primary care where several clinical alternatives, known also as 'usual care', may have been offered to the population already. Usual care may also vary from practice to practice, adding further complexity and difficulty to generalizing results.

Randomized controlled trials in primary care often also need to focus on functional outcomes, including quality of life, symptom severity, satisfaction, and costs in addition to disease-specific end points, such as mortality and major

morbidity. However, these functional outcomes may be more related to health services utilization, referrals to other specialists, rates of hospital admissions, polypharmacy control, and the use of social facilities, rather than an intervention in a primary care medical practice.

A further issue that confronts those designing RCTs in primary care settings is the requirement for evidence of diagnostic, therapeutic and social impacts of interventions and diagnostic strategies, again all in comparison with usual care or practice^{6,7}.

An issue that is particularly pertinent for rural primary care research is the relationship of the researcher to the community being researched. This is often impossible to avoid in small rural communities and can influence the quality and results of the data. It should be noted that this influence is not always negative, for it is helpful if the researcher understands the nuances of local issues and relationships when approaching and interacting with participants. Local trust and respect can result in a better understanding of the subject and enhanced rapport with participants.

These challenges may be responsible for the scarcity of RCTs conducted in rural primary care settings³. Data presented pre-conference at the 2009 Rural WONCA conference in Crete confirmed the small number of RCTs in rural settings. Indeed, a search in this journal revealed only four original research publications since January 2007 that satisfied the criteria of an RCT.

Recommendations for conducting GP/ Family Medicine rural research

General guidance on conducting and reporting rural health research can be accessed on line⁸. An empirical model of 10 steps, developed and applied in Crete, has recently been reported for researchers in countries where limited resources are available⁹. For experimental studies, researchers in rural primary care need to formulate appropriate research questions for rural settings and collaborate with research



methodologists in the design and implementation of high quality RCTs. They are also encouraged in the *CONSORT Statement* (<http://www.consort-statement.org>) to report in parallel, crossover, cluster, or pragmatic RCTs¹⁰. Extensions of the *CONSORT Statement* (ie herbal medicinal interventions, non-pharmacological treatment interventions), based on the type of intervention, are included in the CONSORT website (<http://www.consort-statement.org/extensions/>) and are relevant to research in rural setting.

The following recommendations may assist the researchers and practitioners to design RCTs in rural settings.

The demographic diversity problem

The design of an RCT in primary care should explicitly consider diversity in factors such as age range, participants' levels of education, economic status, and multi-morbidity². Exclusion criteria should be kept to a minimum. Recruiting patients from a variety of primary care settings can assist in creating a valid sample.

The multifaceted intervention problem

Recruiting participants from a variety of settings may also be a useful approach in addressing this problem because it allows for variability in the way multifaceted interventions are provided. For internal validity, besides randomization, which is critical, cluster randomization is often needed to deal with contamination issues (eg when participants in the control group learn about the experimental intervention and adopt it themselves). It can be helpful to allow a variety of choices about the delivery of the intervention in order to keep it pragmatic and to ensure that patients are not harmed¹¹.

The problem with placebos

The use of comparative approaches as controls is more appropriate than placebo. Usual care must be explicitly defined in the rural setting. Since usual care may differ from practice to practice, recruiting patients from a variety of primary care settings can help to ensure validity of the

results. The use of cluster and pragmatic RCTs^{12,13} are appropriate strategies to overcome this problem, despite the fact that these approaches require larger sample sizes, longer follow up, and incur higher cost¹⁴.

The functional outcomes problem

Investigators in rural health need to select suitable functional outcomes relevant to clinical decisions. The period of follow up for RCTs in primary care often needs to be longer than in secondary care. A longer follow up may reflect the natural history of a disease better. It may also reveal different results in short-term than long-term treatment, a phenomenon that has been observed in non-pharmacologic interventions such as in weight loss behavioral strategies¹⁵. This was also considered as a priority at the Sinaia EURIPA forum mentioned above.

The multiple endpoints problem

While compliance is not considered as an outcome, researchers in primary care should also bear in mind that a lack of compliance in the 'real world' frequently renders an efficacious intervention ineffective¹¹, and they should address this issue in their study design. This will usually involve consideration of additional social and emotional endpoints.

The researcher relationship problem

Data collection and analysis must be blinded whenever possible in rural settings¹¹. With regard to data collected by interview, significant planning must occur prior to data collection in an attempt to identify any significant affiliations the researcher may have with research subjects. It may then be necessary to engage external data collection, and sometimes analysis, to overcome potential biases and conflicts in a resident researcher.

The multiple methods problem

It is acknowledged that rural research requires a plurality of methods and approaches. Using the best method requires



meticulous planning and methodological knowledge⁸. This is a challenge in itself for a researcher, because expertise is required in the various forms of empirical research and other approaches, such as metaethnography¹⁶. Using a team approach is one way to obtain the required breadth of expertise.

Concluding remarks

In conclusion, we believe that the conduct of a high quality rural primary care research is crucial to improving health outcomes in rural communities, and RCTs are a critical element in this evidence matrix.

The issues raised in this editorial should be considered as challenges in the rural primary care field, rather than reasons for criticizing RCTs as non-feasible in this setting. Primary care researchers need to develop and evaluate interventions at all levels of primary care: in process, at the physician and patient levels, as well as in health costs. The most recent European Forum for Rural Health on the island of Pag Croatia in 2012 (<http://www.3rd-euripa.conventuscredo.hr/>) called for more guidance and training through national and regional intensive courses on research methods, with the aim of creating a body of skilled researchers in rural health.

The journal *Rural and Remote Health* encourages rural practitioners and researchers to consider reporting the results of RCTs. We will strongly support their efforts by providing rigorous and timely review of their manuscript. Let the evidence continue to grow!

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