Clinical research for older adults in rural areas: the MINDED study experience

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Abstract Due to the growing need to make clinical decisions based on valid and objective scientific evidence, the number of randomized controlled trials (RCTs) has increased over the last three decades. Nevertheless, evidence-based medicine has still limited applicability in older adults, because they are often excluded from clinical trials. Evidence-based medicine is even more challenging in rural areas, as its remote environment provides additional barriers. Nevertheless, given the high prevalence of older adults living in rural settings, research in this type of environment has become crucial. This can only be accomplished by considering the multiple additional challenges of these regions. In this paper,

we examine potential environmental, procedural, and participants' barriers to the management of a RCT in a rural area. Possible solutions and suggestions are provided based on our experience—from the Multidomain Intervention to prevent Disability in Elders (MINDED) project.

Keywords Older adult · Rural areas · Randomized controlled trial · MINDED

Introduction

Individuals aged ≥65 years and older constitute the most rapidly increasing age group (National Institute on Aging, National Institutes of Health, U.S. Department of Health and Human Services 2015). Older adults represent one third of health-care users, and more than half are hospital service recipients (Fried et al. 2001). Compared to older adults living in urban districts, epidemiological studies have reported that those who live in rural areas have poorer physical health and more chronic diseases. Lower incomes and a lack of medical resources are other factors that can increase their health problems (Cutler and Coward 1988; Rogers 2002). In addition, demonstration has been made that rural residents have more limited access to health-care services, lower rates of health insurance, and a poorer socioeconomic and educational level than urban residents; all of these considerations contribute to enhance health disparities (South Carolina Rural Health Research Center 2008; University of Pittsburgh Center for Rural Health

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Practice 2004). Therefore, the need to collect scientific evidence through the implementation of clinical research in older adults living in rural area has become a societal priority. Randomized controlled trials (RCTs) represent the best standard methodology to assess the efficacy of clinical interventions. However, the rate of enrolment in RCTs of older adults living in rural areas tends to be particularly low and quite challenging, leaving this population with unmet needs and being quite underrepresented in medical research (Cohen 2003; Maurer et al. 2001; Shavers et al. 2002).

In this paper, we describe the main issues that should be considered when carrying out successful RCTs in rural areas. More specifically, this paper will point out the potential barrier characteristic of rural areas and propose possible solutions on the basis of the experience obtained during the performance of the Multidomain Intervention to prevent Disability in Elders (MINDED) study. The MINDED project included a RCT that aimed to evaluate the efficacy of a comprehensive geriatric assessment and subsequent multidimensional and personalized plan of intervention to prevent dependency in community-dwelling older persons living in the rural area of Labastide-Murat, a small village located at about 150 km from Toulouse (France) (Cesari et al. 2014a).

Barriers to RCT participation in rural areas

Environmental barriers

One of main difficulties in rural areas is the access to an appropriate place to conduct research activities. The location needs to be properly equipped, have sufficient space, and be managed by qualified staff. Lastly, these facilities should be independent from the reference center where the RCT is performed. For example, in MINDED, a local rehabilitation center was used to support study development and management and to provide offices for clinical visits, a waiting room, and lab equipment. The implementation of these activities in an existing clinical facility allowed us to (National Institute on Aging, National Institutes of Health, U.S. Department of Health and Human Services 2015) avoid the implementation of a new research setting, requiring special administrative procedures for its certification and (Fried et al. 2001) benefit from onsite health-care

professionals already working in a remote geographical area, where they are particularly lacking.

The choice of the research site is important. The local population should have a positive image of the location; otherwise, the recruitment rate could be significantly impacted. For example, in MINDED, the rehabilitation center hosted some nursing home beds and services. The local population associated the center with the end of life and severe disabilities of relatives, family members, proxies.... Thus, it was important to correctly explain that the research activities (especially those focusing on prevention and/or community-dwelling individuals) are not related to the kind of clinical activities already hosted at the center.

Another important difficulty was to find qualified and interested staff willing to conduct research activities in the rural area. As mentioned, in MINDED, we largely relied upon the clinical staff already present at the rehabilitation center. However, we had to train them to respect good research practices and to become familiar with research protocol procedures. The person in charge of contacting/inviting potential participants should ideally live in the vicinity, thus breaking barriers, generating less concern, and overall facilitating the link with local residents.

Rural areas also have limited resources in transport, making it particularly difficult to perform research activities with elders who are already experiencing isolation and lack of mobility. It is therefore important to anticipate these inconveniences and develop a supporting network in order to ease enrollment and adherence (e.g., by solving transportation problems). In MINDED, a return trip by taxi was provided to subjects who reported poor functional status and limited mobility, enabling them to reach the local study center directly from home.

Procedural barriers

Overall, general practitioners have a great influence on the subject's decisions involving different aspects of health care. This is particularly true in rural areas where the limited number of health professionals makes general practitioners referent figures for a second advice. It is noteworthy that the relationship between a patient and his/her general practitioner affects recruitment/participation in research activities. In MINDED, a number of participants accepted to participate simply because the proposal was supported by their physician.

This implies that it is important to inform local general practitioners about the ongoing research work and to present to them regular feedback in order to optimize the procedures. Spreading information is not really a burden for the study staff, given the limited number of general practitioners in rural areas. However, this awareness may be extremely useful to successfully accomplish a study.

It is well established that the lack of knowledge about undergoing trials represents a major barrier to the participation of the population in scheduled activities (Cohen 2003; Advani et al. 2003). It is therefore essential that local authorities (e.g., mayor, health-care representatives), key local actors (e.g., pharmacists, homecare professionals), as well as general practitioners get together to raise awareness about the project. Furthermore, public conferences were organized with local authorities, and these events also helped promote the study. This approach was successfully achieved in the MINDED study. Given the geographical and social isolation of rural areas, the recruitment of community-dwelling older adults may need alternative strategies compared to those traditionally used (e.g., press releases in newspapers, magazines, church bulletins, newsletters, radio and television advertisements). We found them less efficient for the MINDED project. A direct contact with the potential candidates by e-mail, phone calls, or face-to-face meetings seemed to better encourage individuals to join research activities. In MINDED, we screened potential participants by e-mail and phone calls using a specially designed and validated questionnaire (Cesari et al. 2014b). The questionnaire was also handled over the phone by a trained investigator. Direct contact with individuals was privileged in order to avoid them transferring to the referenced study center (see paragraph about environmental barriers) and also to create a more open dialogue about issues and doubts. In this context, it is noteworthy that the MINDED team was dedicated to providing all necessary explanations. Staff was also available when study participants signed their consent forms related to the research activities, either at the center or at home. Such an approach may probably limit the number of contacts, but can bypass multiple issues (in particular misgivings about research) still nested in rural settings. In MINDED, we obtained a voters list from local public authorities in order to contact those who fitted age criteria. In other countries, this might not be possible and alternative lists of contacts (e.g., health-care beneficiaries) might be considered.

Participants' barriers

In general, residents in rural areas present lower levels of education and knowledge about clinical research practices than urban residents. This specificity will require that administrative documents, such as forms, questionnaires/tests, etc., be carefully designed in order to improve comprehension.

It might be difficult for older people living in rural areas to understand the necessity of implementing research work (especially if it has never been locally conducted) and to accept research staff from outside the community. In MINDED, the intervention of a local person was organized to gain the confidence of the older people. Being introduced by someone already known helped the research team improve the elderly's interest when presenting the study proposal.

Finally, one should consider the fact that during the cold season, part of the older population may leave the rural area to join relatives in more comfortable regions and big cities. This means that the recruitment in isolated and rural areas might be more complicated during part of the year. Furthermore, follow-up activities scheduled during that period should consider that participants could possibly be away from home. To avoid this problem in the MINDED study, most activities were performed during the spring-summer time.

Feasibility barriers

Overall, before conducting a RCT in rural areas, it is always better to drive a pilot study to test the feasibility of planned activities and potential barriers. Even the mere replication of a protocol already conducted with success in an urban setting may raise important and unforeseen challenges when translated in the rural settings. So, before starting the MINDED pilot study, preliminary experiences were conducted aiming at (National Institute on Aging, National Institutes of Health, U.S. Department of Health and Human Services 2015) obtaining a rough estimation of the target condition in the area (Matteo Cesari 2012), (Fried et al. 2001) validating a dedicated questionnaire to facilitate the screening/recruitment of participants, and (Cutler and Coward 1988) testing the feasibility of the planned intervention.

Conclusion

Clinical researchers need to develop educational strategies to raise awareness of rural residents on upcoming trials and RCTs. In the MINDED project, specific strategies were developed to directly enhance participation in the interventional study (RCTs) conducted among older adults living in rural areas.

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Compliance with ethical standards

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