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Towards a new generation of clinical trials: participatory action research in health

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The participatory action research in health (PaPS) approach is a promising proposal for a new generation of clinical trials, especially in community-based studies. Therefore, we will reflect on its relevance and how to increase the use of PaPS in academia and other contexts.

It is widely recognized that efficient and effective clinical trials (experimental design) are the main means of providing scientific evidence to support health and social interventions. However, it appears that controlled and randomized clinical trials (RCT) seem not to be ineffective for this purpose, especially in contexts such as: communities, schools or impoverished populations (Rootman et al., 2001). The most common weaknesses in these RCT studies were: failure of true random assignment, lack of double concealment and scarcity in the analysis of abandonment of the study. In order for their results to be valid, RCTs must employ rigorous methods that can achieve and preserve the comparability of intervention and control groups and avoid potential threats to validity. The allocation concealment process keeps researchers, participants and outcome assessors unaware of the future assignment. This as-

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sumption is impossible to guarantee when it comes to community groups such as schools or neighborhoods. Another dimension is the utility and transferability of knowledge. The RCT proposals are made by the researchers and benefit only the experimental group while the control group is monitored with few or no interventions. And, after the end of the research, in general, there are no funds or resources to expand the intervention, causing disappointments in the target population and researchers. Several researches are already studying the effects of the study's characteristics on different interventions, configurations and results and may provide more evidence on the theme of RCT.

PaPS is being disseminated worldwide and is considered as a means to achieve and produce evidence about positive changes in society, in the interests of people's health: For example, changing the way health professionals are trained, the way institutions care providers work, or how policies that affect the health of communities are designed. It is considered an alternative to new experimental research methodologies as they address current challenges such as: the use of emerging health technologies and patient/ community involvement strategies to co-create useful products; data management; the emergence of participatory epidemiology. The main assumption of PaPS is that the participation of those whose life or work is the subject of the study, which affects all aspects of the research. The involvement of these people in the study is an end in itself as it recognizes the value of each person's contribution to the co-creation of knowledge, in a process that is not only practical, but also collaborative and empowering (Onwuegbuzie et al., 2009). PaPS involves people whose life experience is the topic of the research and, therefore, participate in the study design, analysis, implementation of action research and dissemination of results (ICPHR, 2013). Thus, PaPS produces knowledge and action that can make a unique contribution by addressing growing issues related to the usefulness of research, health inequity and increased impact on different types of experimental research. PaPS incorporates qualitative and quantitative methods, depending on the type of data required, which generally means non-compliance with traditional methodological standards, established for clinical trials of health research. However, the adherence to specific validity criteria of participatory approaches is observed in PaPS:

- Participative Validity. The extent to which all interested persons are able to take an active part in the investigation process to the fullest extent possible;
- Intersubjective validity. The extent to which research is viewed as being credible and meaningful by stakeholders from a variety of perspectives;
- Contextual Validity. The extent to which the research relates to the local situation;
- Catalytic Validity. The extent to which research is useful in terms of presenting new possibilities for social action;
- Ethical Validity. The extent to which the results of the investigation and the changes exerted on people by the survey are solid and fair;
- Empathic Validity. The extent to which research has increased empathy among participants.[1]

Innovative experimental projects can be developed by applying PaPS to the production of scientific evidence. PaPS clinical trials assume studies on performance and better control of complex health problems or conditions, assuming the involvement and maximizing the participation of those whose life or work is the object of the research. Together, they map problems or conditions and initiate participatory data collection processes to co-create and validate useful products and/or reorganize health/social services. They also measure the effect of these interventions and discuss the results obtained. Steeped wedge studies can provide evidence on: people-centered interventions and involvement in data management; sustainable impact on lifestyle and health/social indicators; sustainable impact on health/social services; rapid and sustainable knowledge transfer; scientific evidence to ensure optimal health interventions. But the most important thing is that

Research is not done "on" people as taxpayers who provide "data", but "with" them to provide relevant information in order to improve their lives. The research process is seen as a partnership between interested parties, which may include academic researchers; professionals in the areas of health, education and social welfare; members of civil society; policy makers and others. To be called participatory, people whose life or work is the subject of the research must actively participate in the research process.[1]

Increasing the participation of people affected by health problems has led to improvements, for example, in relation to the recruitment and retention of participants (less loss of subjects in successive measurements), more data quality, in the analysis and interpretation of results and in dissemination of evidence. By increasing the number of PaPS projects, we hope to establish a new community-based clinical trial methodology and improve the relevance, quality and efficiency of participatory research. The International Collaboration for Participatory Action Research in Health (ICPHR) has been operating since 2009 and supports PaPS researchers to ensure the sustainability of their projects. Since then, the ICPHR has also addressed the challenge of recognizing PaPS so that it is used more in the academia and beyond.

Participatory research is not a research method, but a research approach that includes a relational process through which new knowledge is produced collectively, and not by just a team of researchers. The purpose of this new knowledge is to bring about changes or actions, while the process of doing so is a continuum of learning, reflection and action. It means involving people whose lives or work are on the topic of research, in making key decisions to bring about change or action. Thus, they define what the focus of the research should be, what the research questions are, how to answer these questions, what information to collect, how to analyze that information, how to share it and what change or action should be taken as a result of this process. The research design is developed in conversation with people. Although it is possible to identify main stages of a participatory research process in a linear way, these stages are not developed in this way. This is what makes this type of research so rich, exciting and comprehensive, and recognizing the validity of this flow will allow the establishment of new methodologies for clinical trials (experimental design) with special relevance for community-based research.

To prove this, we consider the case of people living with chronic illness because they represent a group of pathologies with intensive use of resources and high cost for the health system. The continuous gaps in the management of chronic diseases and the persistent fragmentation in the health system, generates the need for new strategies to promote models of care in partnership. Many programs address this issue, but disintegrated and isolated approaches are found, with high variability in contexts and cultures, often focusing on a specific context or disease. This multitude of activities are not evaluated and demonstrate unclear value, effects and security. By applying PaPS with the objective of creating evidence on participatory interventions, better control of problems or chronic conditions can be obtained, in addition to also other results. The participation of people living with chronic illness will allow: mapping needs and resources (participatory epidemiology), prioritizing problems to solve, co-creating and validating interventions that mobilize people and resources to implement behavioral and organizational changes. This mobilization can increase the awareness and positive attitudes of these patients, their families and health professionals regarding healthy lifestyle, management of the health/disease process and control of acute incidents related to chronic diseases. At the same time, it could increase the sustainable relationship between patients and health/social professionals to avoid crisis situations and promote integrated care. The replication of PaPS projects in different contexts will produce robust data and universal approaches, converging to safer interventions in the self-management of chronic conditions, for example.

PaPS brings the concept of participatory epidemiology as a new methodology that simplifies the measurement of quantifiable indicators, guaranteed by the participation of patients and family members and health professionals in all phases of the study. In intervention studies, this participatory approach is consistent with patient-centered care, ensuring voluntary adherence, reducing operational complexity, ensuring transparency and trust, following the sense of relevance from the patient’s perspective.

By applying the participatory approach, we will bring together all stakeholders that, being supported by digital solutions, can lead to the production of metadata and eliminate communication barriers at different levels of care (hospital, primary health care and community).

To assure the comparability of the data collected in different clusters, a common standard must be defined, with which all participants agree. This standard should be based on a consensus for data collection and analysis of results. And that is the main challenge for the PaPS researcher: ensuring participation. By increasing cultural competence or, as stated by Campinha Bacote (1991), intercultural mediation or cultural competitiveness, the researcher enables the co-creation of useful products, their immediate validation and the sustainable transfer of knowledge. In addition to involving people and their families, often considered marginalized, it involves people with problems in research on these topics, it involves health professionals in the search for improvements in practices or conditions, it involves local citizens in the search for safer and healthier environments for people. Therefore, participation becomes the main research method and means that existing qualitative and quantitative research methods need to be adapted in order to promote participation.

This innovative work will largely contribute to a better understanding of health/social problems, but it may contain several important limitations, most of which are methodological and ethical. That is why research competence and interdisciplinary considerations must be taken into account, when it becomes relevant to apply PaPS to move from interventions focused on health services to interventions focused on people whose life/work is the focus of research and development of products.

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