Clinical trial registration in physiotherapy research

Sir,

In India, prospective registration of clinical trials in the Clinical Trial Registry—India (CTRI) is a mandatory requirement of Drugs Controller General India (DCGI). For the purpose of registration, International Clinical Trials Registry Platform defines a clinical trial as “any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials”.[1] The web site of CTRI specifies that the term “intervention” not only includes drugs and surgical procedures, but also preventive measures, educational, or behavioral treatment and rehabilitation strategies.[2] Physiotherapy (PT), an integral component of modern healthcare system, is a growing profession in India that is beginning to place greater emphasis on research. This fact is highlighted by a positive trend towards increasing clinical trials in PT research.[3,4] Since PT research comes under the purview of DCGI guidelines on trial registration, it is imperative for physiotherapists in India to register their clinical trials in CTRI. However, not much is known about how this professional group has taken to clinical trial registration in India.

In an attempt to understand how this professional group has responded to the DCGI guidelines on trial registration, we searched the CTRI database for PT intervention trials. A search of the database using “Physiotherapy” and “Physical Therapy” as key words revealed 41 registered trials (after removal of one duplicate and eight non-PT intervention trials). There was also a progressive trend in registration of PT intervention trials since 2007. In addition to this search, we also conducted an online survey to understand the awareness and attitude of physiotherapists toward trial registration. Our survey showed that 39.3% (59/150) of physiotherapists with a postgraduate qualification were aware about trial registration and CTRI. The survey responders identified greater accountability, transparency, ethical standards, and quality of research; reduced duplication of research; increased scope for research funding, publication, developing research collaboration, and protection of intellectual property rights as advantages of prospectively registering clinical trials. Possibility of theft of research ideas, cumbersome, and time-consuming process were cited as disadvantages of prospective registration.

Research is a part of postgraduate PT education and yet the awareness about trial registration among this group of physiotherapist was low in our survey. In this era of evidence-based healthcare, DCGI has rightly made it mandatory for all healthcare professionals to prospectively register their clinical trials. With the stakeholders of CTRI attempting to encourage registration of research in medical colleges and as part of postgraduate dissertation,[5] it would be essential for them to take appropriate steps to improve awareness among all healthcare professionals involved in clinical trials. Clinical drug and surgical trials have received reasonable attention from stakeholders with regard to trial registration. We feel that it is time to reach out to healthcare professionals involved in non-drug clinical trials. This will not only ensure improved research quality and transparency in the overall healthcare research in our country, but also increase awareness about research in other healthcare disciplines and greatly increase the prospect of multidisciplinary collaborative research.

ACKNOWLEDGMENTS

Authors Sundar K. Veluswamy and Abraham S. Babu contributed equally toward conception, design, data collection, data analysis, and manuscript preparation. Ms. Prachi Shah contributed toward design, data collection, and manuscript preparation; and Dr. Arun G. Maiya contributed toward conception, design, manuscript preparation, and approval of the final manuscript.

Sundar K. Veluswamy is supported by a 3-year Ph. D. fellowship from Manipal University.

Sundar Kumar Veluswamy, Abraham Samuel Babu, Prachi Shah¹, Arun Gundmi Maiya

Departments of Physiotherapy, School of Allied Health Sciences, Manipal University, Manipal, Karnataka.
¹Physiotherapy and Sports Medicine, Dr. Balabhai Nanavati Hospital, Mumbai, Maharashtra, India

Address for correspondence: Mr. Abraham Samuel Babu, Department of Physiotherapy, School of Allied Health Sciences, Manipal University, Manipal - 576 104, Karnataka, India. E-mail: abrahambabu@gmail.com

REFERENCES

1. International Clinical Trials Registry Platform (ICTRP) [Internet]. Geneva: World Health Organization. Available from: http://www.
Qualitative research gives voice to the participants in the study. They have an active role in the study and can help modify the design of the clinical trial. In the study, the participants are empowered by sharing their experiences of the effects of the drug of interest. This can open our eyes to new aspects of the study. They have an active role in the study and can voice their individual benefits and harms of the study. The subjects also have an empowering experience in the study. The researcher works on the social parameters in addition to the quantitative measures in the study. The interpretation of results requires formal than in quantitative research.

In addition, with qualitative methods, the relationship between the researcher and the participant is often less pre-determined methods to nullify research bias. When the research design for the study is well-designed and the aims, procedures of the study are clearly described, the interpretation of results can be meticulously adjudicated. Study should have a great impact on data collection, its analysis and help modify the design of the clinical trial. Qualitative research can have a major contribution in health research. In clinical trials, qualitative research can be used to understand people’s beliefs, experiences, attitudes, and propagated by other researchers. Qualitative method is initially used in psychological studies when researchers found it tedious to evaluate human behavior in numeric. Since then, qualitative research is used in other research fields as well. In clinical research, qualitative approach can help view the data more extensively. It strengthens clinical trials by enhancing user involvement in it.

The integration of qualitative research into intervention studies is a research strategy that is gaining increased attention among researchers. Qualitative research as well as quantitative research are qualitative and quantitative research. The broad approaches of data collection and interpretation in the study. Two particular problem one can identify. There are various methods of formulating a research design for the study. Two elementary method of conducting research was quantitative, but recently, qualitative method of research has also gained momentum among researchers. Qualitative research focuses in understanding a research perspectives in clinical research should highlight advances in qualitative research as well, to optimize quality and utility of this method of research.

Qualitative research was initially used in psychological studies when researchers found it tedious to evaluate human behavior in numeric. Since then, qualitative research is used in other research fields as well. In clinical research, qualitative approach can help view the data more extensively. It strengthens clinical trials by enhancing user involvement in it.

Since then, qualitative research is used in other research fields as well. In clinical research, qualitative approach can help view the data more extensively. It strengthens clinical trials by enhancing user involvement in it.