PanAfrican Medical Journal

Open Access

Workshop report

Setting the stage for randomized controlled trials in Cameroon: a workshop report

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Key words: Clinical trials, capacity building, Cameroon, workshop

Received: 23/07/2013 - Accepted: 06/08/2013 - Published: 21/08/2013

Abstract

In order to improve the generation and use of high quality health research evidence among Cameroonian researchers, the Centre for Development of Best Practices in Health (CDBPH) located in the Yaounde Central Hospital organised a three day workshop on clinical trials from the 29th April to the 1st May 2013. Sixteen participants form the Faculty of Medicine and Biomedical Science of the University of Yaounde 1 and the Ministry of Health attended this workshop. This report includes the material covered in the workshop, the readings and supplementary resources for clinical trials. The workshop was well received by the participants and resulted in significant gains in knowledge on clinical trials.

Pan African Medical Journal. 2013; 15:144. doi:10.11604/pamj.2013.15.144.313

This article is available online at: http://www.panafrican-med-journal.com/content/article/15/144/full

Introduction

Randomized controlled trials (RCTs) are often regarded as the most rigorous method available for hypothesis testing about the effects of therapies, interventions or treatments in epidemiology and medicine [1]. In its simplest form, participants are randomly allocated to one of two interventions and followed up for a predefined duration over which to measure specific outcomes [1]. Since randomized controlled trials are experimental studies involving human subjects, specific design, ethical, administrative and organisational issues must be understood by health researchers. The Centre for Development of Best Practices in Health (CDBPH; www.cdbph.org) is a knowledge translation institution located in the Yaounde Central Hospital, Yaounde, Cameroon, that supports decision-makers, members of civil society organisations, journalist and health researchers in the collection, use and generation of health research evidence.

In December 2010, the CDBPH organised a workshop on systematic reviews which involved appraising RCTs [2]. Systematic reviews of RCTs (and other studies) inform evidence-based health care and are used to develop health care practice and policies. During this workshop, we noted significant limitations in understanding the concepts related to RCTs. For this reason, we organised another workshop introducing Cameroonian medical research scientists to clinical trials. The number of clinical trials conducted in Cameroon is relatively low, with only 34 registered trials on the www.clinicaltrials.gov website (search conducted 22nd June 2013), compared to other countries like Ghana (81 trials) or Malawi (99 trials) with similar population sizes [3]. This workshop responds to the urgent needs for health research capacity building in developing countries to promote evidence based health care [4, 5]. This lack of research capacity is often seen in the considerably small number of African-led trials within the continent [6].

The purpose of this report is to provide a detailed account of the activities and the material covered during the workshop, such that it can be replicated and adapted to suit other trainer's needs.

Workshop report

Location

The CDBPH arranged and supported the workshop, which took place from the 29th April to the 1st May 2013, at the Laurence Vergne Room of the Yaounde Central Hospital, Yaounde, Cameroon.

Aims

The aims of this workshop were to build clinical trials skills in Cameroon by enabling participants to 1) distinguish clinical trials from other forms of clinical research, 2) describe the different phases of clinical trials, 3) list the steps involved in conducting a clinical trial, 4) understand key concepts in design, analysis and reporting of clinical trials, 5) understand the limitations of clinical trials and 6) describe variants in clinical trial design. These concepts were introduced at a basic level and followed-up in-depth according to participant interest.

Participants

The CDBPH invited lecturers from the Faculty of Medicine and Biomedical Sciences, of the University of Yaounde 1 and staff from the Division of Health Operations Research of the Ministry of Health.

Facilitators

The facilitators where chosen based on their methods expertise and experience with clinical trials in resource limited settings: a Canadian professor of biostatistics and epidemiology, originally from Lesotho, with extensive experience conducting international trials; a Cameroonian professor of radiology and epidemiology, with vast experience in evidence-based policy development and a Cameroonian doctor and epidemiologist with a strong background and experience in heath research methodology and clinical trials.

Pre-workshop tasks

Prior to the workshop, participants were expected to 1) complete one introductory reading on clinical trials [7], 2) prepare one research question for which a randomized clinical trial would be appropriate and 3) find one randomized clinical trial in their respective fields for appraisal.

Program

Over three days participants were introduced to the role of clinical trials in clinical research and how to set-up and run a clinical trial in Cameroon, using practical examples. Their clinical trial topics were discussed and revised according to standard recommendations for question formulation[8]. **Table 1** is a list of trial topics proposed by the participants. The sessions were interactive, with engaging discussions between the staff from the Ministry of Health and individual researchers. Participants were also expected to take a pre- and post-workshop multiple choice questionnaire to evaluate their clinical trial knowledge. The questionnaire was tailored to assess if the objectives of the workshop were met.

During the workshop, participants described the challenges they faced in conducting clinical research in Cameroon. As a compliment to the new material provided to participants during the workshop, discussions were held upon the difficulties they encountered in their own clinical research and solutions were proposed. For example, issues related to high drop-out rates were addressed during the session on attrition. The following challenges were identified:

1. Lengthy and complex consent forms
2. Lengthy ethics approval procedures
3. Difficulties in securing funding
4. Poor access to high quality medical archives
5. High drop-out rates
6. Stigma preventing participants from taking part in research
7. Difficulties in obtaining adequate comparators (placebos)
8. Limited statistical competency
9. Limited access to information regarding the regulation of research in Cameroon

Course material and readings

The participants were provided with reading material relevant to each topic addressed. **Table 2** is a summary of the topics covered in the workshop, the readings and other electronic resources. We sought to make the training relevant to the country by using some local readings and examples as often as possible.

Evaluation

The results of the questionnaire were evaluated and compared. The questionnaire covered all topics discussed during the workshop. A total of 35 points could be obtained for responding correctly to 13 questions. The mean score (standard deviation) before the workshop was 16.5 (6.93) compared to 25.5 (5.05) after the workshop. This difference (+9) was statistically significant ($t(30) = -4.2$; $p<0.001$), showing a marked improvement in knowledge on clinical trials. Participants were also asked to rank the workshop in the following domains: quality of the lectures, quality of the practical exercises, quality of the reading material, pace of the course and the amount of subject material covered. Overall, the workshop was well received (**Figure 1**).

Participants appreciated the interactive nature of the workshop; the practical exercises and the quality and timeliness of the presentations. They also noted some points for improvement such as: the need to develop a concrete trial proposal as part of the workshop, to reduce the amount of material covered and to allocate more time for practical sessions. In addition, they recommended a follow-up workshop with more French material.

Conclusion

The workshop was well received and resulted in significant knowledge gains amongst participants. The next steps will involve continuous support to all participants who wish to conduct RCTs and accrued efforts to deliver locally relevant material in terms of context and language.

Acknowledgements

This workshop was supported by the Effective Health Care Research Consortium which is funded by UKaid from the Department for International Development. It was organised by the Centre for Development for Best Practices in Health/Yaounde Central Hospital. We also wish to thank Professor Thabane from McMaster University for his availability during the workshop.

Tables and figures

Table 1: Topics proposed by participants of clinical trials workshop

Table 2: Workshop outline

Figure 1: Overall assessment of clinical trials workshop by participants (n=12)

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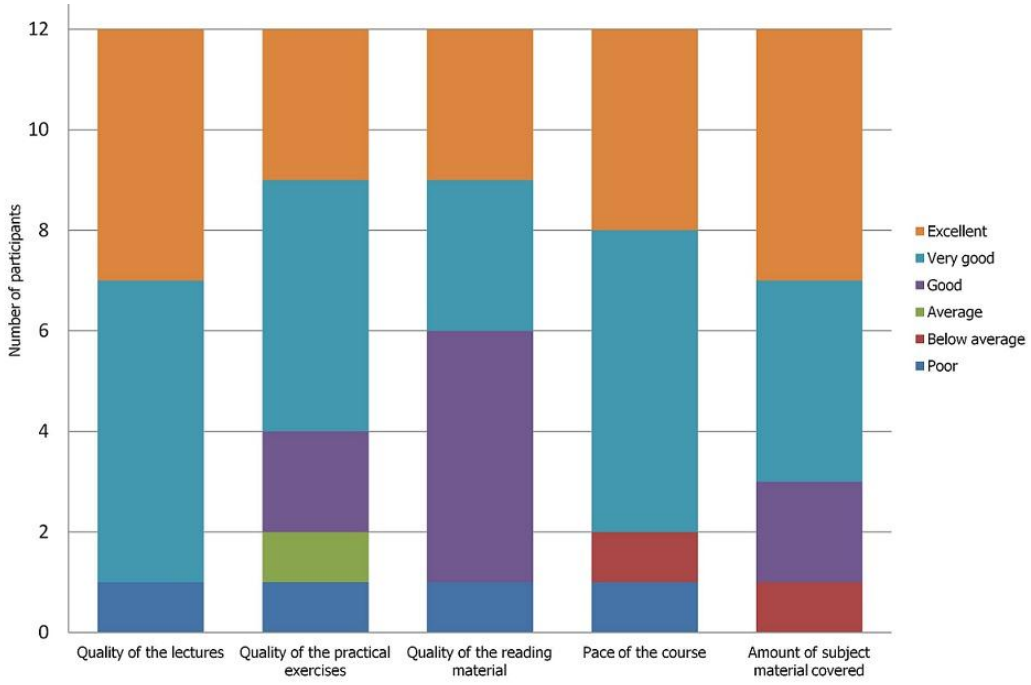

Figure 1: Overall assessment of clinical trials workshop by participants (n=12)

Table 1: Topics proposed by participants of clinical trials workshop
Topics
The effect of artemisinin of precancerous cervical lesions
Routine Calcium supplementation for hypertensive disorders
Breast feeding and fitness training for pregnancy weight gain
Comparative efficacy of postoperative antalgics
Iron supplementation for voluntary blood donors
Efficacy of various nutrient supplementations
Efficacy of azithromycin for toxoplasmosis in pregnancy
Efficacy of different knowledge translation strategies for changing practice
Efficacy of Papaya leaves in typhoid fever

Table 2: Workshop outline

Objective	Topics covered	Readings and Internet resources
1) Distinguish clinical trials from other forms of clinical research	Clinical research and study design	Study designs: http://www.cebm.net/?o=1039; http://www.healthknowledge.org.uk/e-learning/epidemiology/practitioners/introduction-study-design-is-rct
2) Describe the different phases of clinical trials	Phases of clinical trials	[9]
3) List the steps involved in conducting a clinical trial	Equipoise	[10]
	Research question formulation	[8] Asking focused questions: http://www.cebm.net/index.aspx?o=1036
	Overview of the steps involved in clinical trials	[7]
4) Understand key concepts in design, analysis and reporting of clinical trials	Feasibility of clinical trials and pilot studies	[11]
	Obtaining permission to conduct clinical trials in Cameroon	List of documents required for ethics approval from the National Ethics Committee List of documents required for administrative approval from the Ministry of Health
	Estimating the required sample size for a clinical trial	[12] Online sample size calculators: http://www.stat.ubc.ca/~rollin/stats/ssize/ http://statpages.org/proppowr.html Free software for sample size estimation: http://www.brixtonhealth.com/pepi4windows.html
	Randomization, Sequence generation, Allocation concealment & Blinding	[13-17]
	Follow-up and attrition	[18, 19]
	Reporting a clinical trial	[20]
5) Understand the limitations of clinical trials	Challenges and limitations with clinical trials	[21, 22]
6) Describe variants in clinical trial design	Pragmatic versus explanatory trials	[23, 24]
	Additional resources for clinical trials	Ethics: www.elearning.trree.org; www.tcps2core.ca General resources: www.globalhealthtrials.tghn.org Trial registration: www.pactr.org; www.clinicaltrials.gov Management of clinical trials: [25]