



St. John's Medical College & Research Institute
Bangalore, India

In Collaboration with faculty from McMaster University
Canada & Duke University, USA



DIAMOND JUBILEE - 3rd Annual One-Week Course on

Randomized Controlled Trials

September 4 to 8, 2023

COURSE REPORT

60 PARTICIPANTS; 13 FACULTY MEMBERS

DESIGNED AND CONDUCTED BY

Division of Clinical Research and Training
& Department of Pharmacology
St. John's Medical College & Research Institute
Bangalore, India.

ORGANIZING TEAM

Dr. Denis Xavier, Course Director
Dr. Atiya Faruqui
Dr. Aakanksha Singh
Ms. Jayalakshmi AH

Partial financial support was provided by ICMR and CSIR, India

BACKGROUND AND INAUGURATION

St. John's Medical College and Research Institute, Bangalore, in association with the Population Health Research Institute, McMaster University, Canada, has been conducting short-term courses on health research methods since 2009.

We started with an NIH grant in 2009 for five years and continued after that. In the last 14 years, we have trained over 2000 participants from 83 institutions in 45 cities across 12 countries.

This short course exclusively focused on Randomized Controlled Trials (RCTs) provided the participants with a comprehensive understanding of the various aspects of designing, conducting and managing different types of RCTs.



Rev. Fr. Jesudoss Rajamanickam, Director, St. John's Medical College, Rev. Fr. Tony A J, Associate Director Finance, St. John's Medical College Hospital & , Dr. Tony D S Raj, Dean, St. John's Research Institute (From left to right)

We are delighted to present a brief report on our 3rd One-week course on Randomized Controlled Trials (RCTs) which was conducted from September 4th to 8th, 2023.

The Karnataka Medical Council accredited and awarded six credit points to the participants and the faculty.

The inaugural function was held on 4th September. It was attended by Rev. Fr. Jesudoss Rajamanickam, Director, St. John's National Academy of Health Sciences, Rev. Fr. Tony A J, Associate Director of Finance, St. John's National Academy of Health Sciences & Research Institute, Dr. George D'Souza, Dean of St. John's Medical College, Dr. Arvind Kasthuri, Chief of Medical Services, St. John's Medical College Hospital, Dr. Tony D S Raj, Dean of Research Institute, special guests, faculty, staff and students.



Orientation by Dr. Denis Xavier, Course Director



Session in Progress

OBJECTIVES OF THE COURSE

To provide participants with a comprehensive understanding of the various aspects of designing, conducting and managing different types of RCTs.

PARTICIPANTS

The course has been designed for faculty, postgraduate and PhD students from medical, dental, nursing and pharmacy colleges, ethics committee members, regulators, librarians and health policymakers. It may also be of interest to anyone looking to learn more about randomized controlled trials. We had 60 participants from 21 cities across India.

FACULTY

The faculty were from St. John's Medical College, St. John's Research Institute, Bangalore, McMaster University, Canada, Duke University, USA and Thrombosis Research Institute, UK.

McMaster University, Canada

Dr. Gordon Guyatt
Dr. P J Devereaux
Dr. Sanjit Jolly
Dr. Shrikant Bangdiwala

St. John's Medical College, Bangalore

Dr. Deepak Kamath
Dr. Denis Xavier
Dr. Tinku Thomas

Duke University, USA

Dr. Bradi Granger
Dr. Christopher Granger

Thrombosis Research Institute, UK

Mr. Saverio Viridone

St. John's Research Institute, Bangalore

Dr. Prem Pais
Ms. Freeda Xavier

ICMR, New Delhi

Dr. Aparna Mukherjee

COURSE METHODS

We had 20 interactive lectures, four small group protocol discussions, four journal clubs and four project presentations. There were ten lectures on various RCT designs and methods, seven on statistics, two on project management and one on Ethics.

The study designs included Complex interventions, Large Simple Trials, Factorial Trials, Cluster and Implementation Trials, Expertise-based Trials, Non-inferiority Trials, Community-based Trials, Adaptive designs, Non-inferiority Trials and Real-world evidence / Pragmatic Trials. There were sessions on human research ethics, compensation, insurance, data management, regulatory aspects and project management with a focus on RCTs.

The participants were also familiarized with statistical methods, and data preparation was explained with examples of various RCT designs. There were interactive lectures on Non-inferiority Trials and Expertise-based Trials by Dr. Gordon Guyatt and Dr. P J Devereaux, respectively, from McMaster University, Canada.

Dr. Shrikant Bangdiwala from McMaster University and Mr. Saverio Viridone from Thrombosis Institute, London, spoke on the statistical methods for each design and survival analysis, respectively.

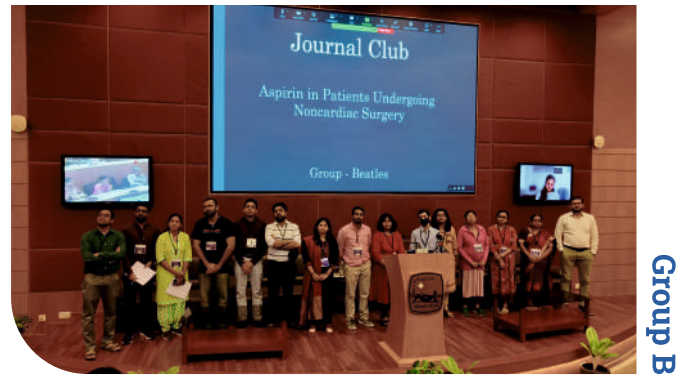
Dr. Sanjit Jolly from McMaster University took a session on Adaptive designs, and sessions on Implementation and Community-based Trials were taken by Christopher Granger and Bradi Granger, respectively, from Duke University, USA.

The **group activities** included four journal clubs (Cluster RCT, Factorial Design, Non-inferiority and Adaptive Trials) and four project presentations (Cluster RCT, Factorial Design, Non-inferiority and Large Simple Trials).

The Zen protocol sessions were conducted with discussions between the group members and the faculty on the research question, design, methods, data analysis and budget. The projects developed during the sessions were presented at the end of the course.

The speakers for journal clubs and project presentations were picked up randomly by chits. After the presentations, the entire group answered questions from the audience and faculty.

Journal Club Presentation; Group Q & A session



The following were the Journal club articles presented by the groups

Group A ISRO	Cluster RCT Effect of screening by clinical breast examination on breast cancer incidence and mortality after 20 years. BMJ 2021.	September 6, 2023
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Group B Beatles	Factorial Design Aspirin in Patients Undergoing Noncardiac Surgery (POISE-2). NEJM 2014.	September 6, 2023
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Group C Curious Cohort	Non-inferiority Dabigatran versus Warfarin in Patients with Atrial Fibrillation (RELY). NEJM 2009.	September 7, 2023
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Group D RISHI	Adaptive Design Adaptive Randomization of Veliparib- Carboplatin Treatment in Breast Cancer (I-SPY 2). NEJM 2021.	September 7, 2023
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The following projects were presented by each Group

Group A
ISRO

Factorial Design

Vitamin D & C in early sputum conversion among adults on ATT-VINDICT

No. of Centres : 5

Budget: **4.47 cr**

Group B
Beatles

Non-Inferiority Trial

Efficacy and safety of Colistin Monotherapy vs Colistin with Meropenem combination therapy in patients with Carbapenem-Resistant Enterobacterales infections: V-CARE

No. of Centres : 10

Budget: **4.13 cr**

Group C
Curious Cohort

Large-simple Trials

Efficacy of Ketamine vs ECT on Suicidal Ideation among Adults with Non-Psychotic MDD: A Multicentre Open-Label Randomized Controlled Trial: KIND Trial

No. of Centres : 10

Budget: **7.38 cr**

Group D
RISHI

Cluster RCT

Stress Alleviation with Meditation and Yoga among Medical Students in India: a cluster RCT (SwAMY trial)

No. of Centres : 14

Budget: **2.3 cr**

Project Presentation; Group question & answer session



Award to Participants

There were two categories of awards for the participants

1. Dr. Peter Sleight Award
2. Dr. Salim Yusuf Team Awards for best group performance

Dr. Peter Sleight Award:

All participants were eligible for this award. The assessment was based on tests conducted at the end of the course and their group's performance in JC and PP.



A. Dr. Avik Chaudhuri, BJMC, Ahmedabad | B. Dr. Rudresh Negi, GMC, Haldwani
C. Dr. Sasidharan Kandasamy, Mehta Hospital, Chennai

Dr. Salim Yusuf Team Awards for best group performance

The prize for the best group was awarded based on the performance in the journal club and project presentation. The journal clubs and project presentations were evaluated by 21 Judges who were invited from prestigious institutes across India. They evaluated the groups based on knowledge, clarity of presentation, quality of slides and response to the questions. A certificate and a plaque were awarded to all the participants in the winning group.



Group C - Winners of Best Group

S.No	Name	Institute	City
1	Avik Chaudhuri	B J Medical College	Ahmedabad
2	Jefry Winner G	JIPMER	Puducherry
3	K Aswathy Raveendran	Sri Manakula Vinayagar Medical College and Hospital	Puducherry
4	Kiran Kumar Prathipati	AIIMS	Nagpur
5	Krishna Chaaithanya Itta	ICMR-NIRRCH	Mumbai
6	Nitishkumar Dhirajlal Tank	ICMR-National Institute of Occupational Health	Ahmedabad
7	Prachi Priyadarshini	Novo Nordisk Service Centre India Private	Bengaluru
8	Rajeev Ranjan	AIIMS	Patna
9	Rajendra Prasad J	Siemens Health Care Pvt Ltd	Bengaluru
10	Ravi Shankar Basavaraju	Stempeutics Research Pvt Ltd	Bengaluru
11	Rudresh Negi	Government Medical College	Haldwani
12	Sasidaran Kandasamy	Mehta Multi-speciality Hospital	Chennai
13	Savitha Anne Sebastian	St Johns Medical College	Bengaluru
14	Shishirendu Ghosal	ICMR-Regional Medical Research Centre	Bhubaneswar

Certificates of CME accreditation and participation were given to candidates who had attended all the sessions.

Course Evaluation

All participants provided a structured as well as an open evaluation of all aspects of the course.

The following were the average scores of 5 in the structured evaluation as mandated by MCI:

SESSIONS	Score on 5
Lectures	4.3
Journal clubs	4.5
Project presentations	4.5
Zen Protocol	4.5
Time schedule	4.1
Overall	4.4

Open / Unstructured Feedback

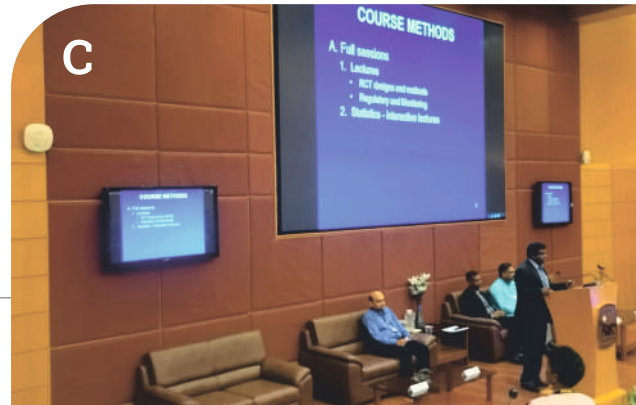
What participants liked about the course (quoted verbatim):

1. How to frame a good research questionnaire for RCT.
2. Methods to approach to conduct RCT and appropriate statistical method for which type of RCT.
3. Budget consideration during protocol design and need for DSMB
4. Much needed clarity on adaptive designs.
5. The in-depth assessment of non-inferiority designs.
6. Understanding nuances of implementing an RCT study.
7. Better understanding of statistics overall.
8. Survival analysis was really taken well, and many concepts were explained clearly. Contamination in cluster design RCT & ICC.
9. I am now encouraged to read more journals because knowledge improves only with reading.
10. Picking the right design for our research question and deciding appropriate outcome measures for RCTs.
11. Experienced faculty share their knowledge based on their own trials.
12. Overall, the structure and activities conducted were brilliant and very engaging. Lots to get inspired.
13. How to handle criticism and suggestions from others and accept different view points.
14. 'Do one job at a time' with efficiency and 'how to frame/ ask clear questions?'
15. Attitude of gratitude, collaboration and team management.

Recommendation for improvement

1. A post-workshop follow-up support mechanism may be developed since we cannot remember each and everything for a longer time.
2. Need more time to interact with the faculties and ask doubts.
3. The time schedule could have been relaxed.
4. One day evening break for Bangalore visit.
5. If we could get the slides of the lectures on the same day, it would be useful.
6. Hands-on demo sessions could be added for the statistics related to RCTs
7. Doubt-clearing sessions could be longer.

The course ended on September 8th with a valedictory function. The Course Director presented a valedictory report, and two participants from each group provided feedback on the course. The valedictory function was attended by Rev. Dr. J Charles, Associate Director, St. John's Medical College, Rev. Dr. John Thekkekara, Associate Director, St. John's Medical College Hospital and Dr. Tony D S Raj, Dean of Research Institute, special guests, faculty, staff & students.



- A.** Rev. Dr. J Charles Davis, Associate Director, St. John's Medical College, Rev. Dr. John Thekkekara, Associate Director, St. John's Medical College Hospital (Left to Right)
- B.** Dr. Tony D S Raj, Dean, St. John's Research Institute
- C.** Valedictory Report presented by Dr. Denis Xavier, Course Director

St. John's Medical College



St. John's Research Institute

Report Designed by

Division of Clinical Research & Training
St. John's Medical College & Research Institute, Bengaluru, India