



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

in Collaboration with faculty from

McMaster University, Canada and Duke University, USA

IV Annual One-week Course

on

Randomized Controlled Trials

21-25 October 2024

Course Report

Course Director: Dr. Denis Xavier

Organizing Team

Dr. Atiya Faruqui

Dr. Aakanksha Singh

Ms. Jayalakshmi AH

Designed and Conducted by

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

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 a 5-year NIH grant in 2009 and continued after that. In the last 15 years, we have trained over 2258 participants from 83 institutions in 45 cities across 11 countries.

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

We are delighted to present a brief report on our IV One-week course on RCTs conducted from 21 to 25 October 2024.

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

Objectives of the Course

- a** Equip participants with a comprehensive understanding of the various aspects of designing, conducting and managing different types of RCTs.
- b** Facilitate interaction with like-minded professionals from varied health fields and explore collaborations.

Participants

The course has been designed for faculty, postgraduates, and PhD students from medical, dental, nursing, and pharmacy colleges, as well as ethics committee members, regulators, librarians, and health policymakers. It may also interest anyone looking to learn more about randomized controlled trials. We had 34 candidates from 15 cities in India and Sri Lanka.



Faculty

The faculty were from St. John's Medical College, St. John's Research Institute, Bangalore, McMaster University, Canada, Duke University, USA, The George Institute for Global Health and ICMR, New Delhi.

McMaster University, Canada

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

St. John's Research Institute, Bangalore

Dr. Prem Pais
Ms. Freeda Xavier

The George Institute, New Delhi

Dr. Niveditha Devasenapathy

ICMR, New Delhi

Dr. Aparna Mukherjee

St John's Medical College, Bangalore

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

Duke University, USA

Dr. Bradi Granger
Dr. Christopher Granger

Course Methods

We had 22 interactive lectures, four small group protocol discussions, four journal clubs and four project presentations. There were 12 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, stepped wedge 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 spoke on the statistical methods for each design and survival analysis. Dr. Niveditha Devasenapathy from The George Institute took sessions on adaptive and stepped wedge designs, and sessions on implementation and community-based trials were taken by Dr. Christopher Granger and Dr. 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 & budget. The projects developed during the sessions were presented at the end of the course.

The speakers for journal clubs and project presentations were chosen randomly through lots. After the presentations, the group provided clarifications on queries from faculty and participants.

Journal Club Presentations



Group A



Group B



Group C



Group D

Following were the topics presented by each group :

Group	Study Design	Study Title
A Mega Trialist	Factorial	Aspirin in Patients Undergoing Non-cardiac Surgery (POISE-2). NEJM 2014 .
B Confounders	Adaptive	Adaptive Randomization of Veliparib- Carboplatin Treatment in Breast Cancer (I-SPY 2). NEJM 2021 .
C Curious Cohort	Non-Inferiorty	Dabigatran versus Warfarin in Patients with Atrial Fibrillation (RELY). NEJM 2009 .
D Dyanmic	Cluster RCT	Effect of screening by clinical breast examination on breast cancer incidence and mortality after 20 years. BMJ 2021 .

Project Proposal Presentations



Group A



Group B



Group C



Group D

Following were the topics chosen by each group for the group project:

Group	Study Design	Study Title	No. of Centres	Budget
A Mega Trialist	Large Simple	The iTIMES Trial Intravenous Thiamine in the Management of Infantile Shock	24	7.15 Cr
B Confounders	Factorial	The MaSS Study Effect Of Mannitol, Hypertonic Saline & their combination in reducing mortality in Acute Stroke Pts	2	41.5 Lacs
C Curious Cohort	cRCT	Ease-up Trial Effectiveness of multi-component intervention on neck pain among desk-based workers	16	95.8 Lacs
D Dyanmic	Non-Inferiorty	CAROLES Efficacy and safety of Cariprazine versus Olanzapine monotherapy for schizophrenia	5	97.3 Lacs

Award Ceremony

There were 2 categories of awards for the participants:

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

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.



Dr. Benedicta Sthuti Kumar
Indian Institute of Public Health, Shillong



Dr. Onkar Awadhiya
AIIMS, Nagpur



Dr. Shreya Bhat
Bangalore Medical College, Bangalore

Dr Salim Yusuf Team Award

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.



Winners - Group A, Mega Trialist

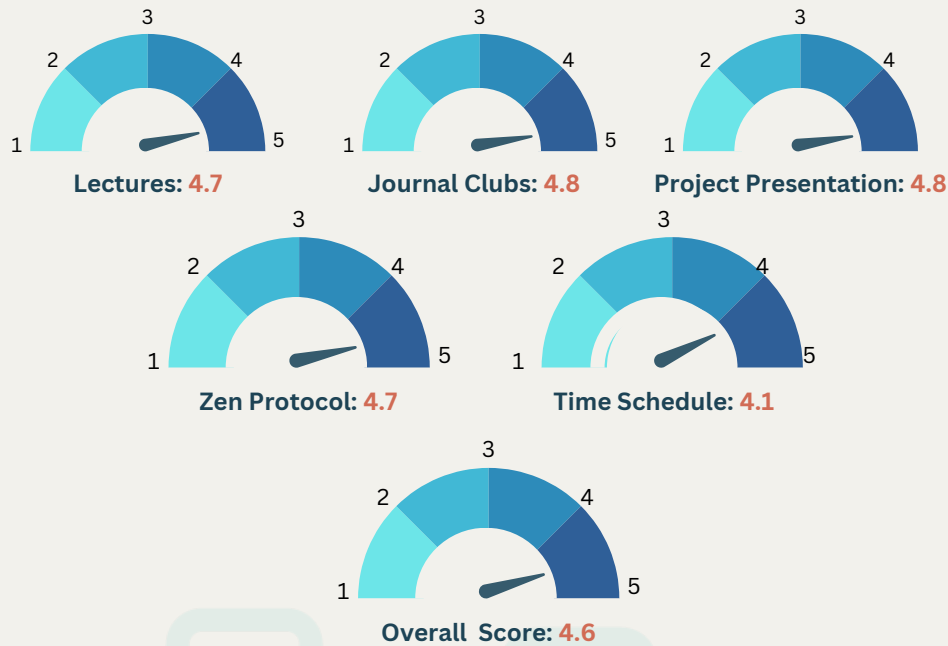
Sl. No	Name	Institute	City
1	Aashna Khatri	B J Medical College and Civil Hospital	Ahmedabad
2	Benedicta Sthuti Kumar	Indian Institute of Public Health	Shillong
3	Divya SK	St John's Medical College and Hospital	Bengaluru
4	Komal K B	KLE College of Physiotherapy	Hubballi
5	Mackwin Kenwood Dmello	K S Hegde Medical Academy	Mangalore
6	Nirav S Amin	B J Medical College and Civil Hospital	Ahmedabad
7	H R Palangasinghe	University of Colombo	Colombo
8	Senthil Amudhan Rajamoorthy	NIMHANS	Bengaluru
9	Sushma P	Bangalore Medical College and Research Institute	Bengaluru

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

Course Evaluation and Feedback

All participants provided a structured and open evaluation of all aspects of the course.

The following were the average scores out of 5 in the structured evaluation:



Feedback



- How to present an article in a journal club.
- Statistics class on parametric and non-parametric tests, various statistical methods involved in RCT studies and Non-inferiority margin calculation.
- Learnt about types of RCT in detail. I got to know about how to design a trial, regulatory requirements for conducting a trial and where to apply for funds.
- There was so much focus on methodology that I think we will not make any major error while designing a trial.
- Information on different types of software for data collection & entry.
- Learnt about budgeting, DSMB & its role.
- Thank you Dr Xavier for teaching an overwhelming subject such as statistics with so much enthusiasm. I appreciate your humor. Your zeal & enthusiasm is contagious.
- Thank you to the whole team with faculty and management for giving us such a wonderful hands on workshop. It means a lot. It was my first workshop that too of such high quality. Please don't skip this training any year and keep organizing as long as you can.
- I had a great time while I was here. Especially hearing all the non-technical as well as technical comments from Dr Denis was the best part. Learning will be carried for life.



- Overall very good experience. Management was excellent. Every faculty is good.
- I got really impressed by the friendliness from both academic & non-academic staff & I did not feel like “Non-Indian” (from my 1st visit to the 3rd visit at St. John’s 2022, 2023 & 2024).
- Well organized. Meticulously planned. Good time management. Good food & excellent hospitality. Excellent team. A big thank you to Denis Sir for keeping everything in place for the entire 5 days.
- Appreciate Dr. Tinku & Dr. Srikanth for Statistics classes. Dr. Niveditha’s two sessions were excellent.
- To dream big and think out of the box.
- How to make friends from various disciplines and work in a team.
- How to make power point presentation.
- To know what we don’t know & work on it
- Doing research for the benefit of the patients is the most important thing about doing it.
- How to communicate effectively and critique constructively and punctuality.
- This was an excellent networking opportunity for someone new to public health/ Research.



Suggestions

- The course could have been stretched out to 2 weeks.
- Quality & variety of food.
- Completing the sessions before 5.30pm.
- F&Q at the end of every day.
- I was actually expecting some hands-on, perhaps randomization tool and analysis of RCT data would have been better.
- Course can be spaced & extended at least by a day.
- If you can add a few questions at the end of each lectures (like PJ did) would be great.
- If possible please ensure that lunch is served hot.
- Keep pure statistics sessions early in the morning.
- An official statement of the intensity of the course that could be shared with our employer.
- A post workshop follow-up session to re-enforce the learnings.

Valedictory

The course ended on 25 October with a valedictory function. The Course Director presented a valedictory report, and one participant from each group provided feedback on the course. The valedictory function was attended by Rev. Fr. Jesudoss Rajamanickam, Director of St. John's National Academy of Health Sciences, Dr. Arvind Kasthuri, Chief of Medical Services at St. John's Medical College Hospital, and Dr. Tony D S Raj, Dean of the Research Institute, faculty, staff, and students.



Director
St. John's Medical College Hospital



Dean
St. John's Research Institute



Chief of Medical Services
St. John's Medical College Hospital



Valedictory Report Presentation

The course director, Dr. Denis Xavier, announced the awards. The Director of St. John's Medical College Hospital handed over Plaques and Certificates to the top 3 participants, and the Chief of Medical Services and Dean of St. John's Research Institute presented plaques and certificates to the group winners.



St. John's Medical College



St. John's Research Institute

**Division of Clinical Research and Training
St. John's Medical College and Research Institute, Bangalore**