

Kenneth M. Lee

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RESEARCH INTERESTS

Clinical trials; Cluster randomized trials; Stepped-wedge designs; Cross-over designs; DiD; Multilevel data; Time-varying treatment effects; Informative sizes; Self-controlled case series; Causal inference; Estimands; Palliative care

EDUCATION

Duke-NUS Medical School, Singapore Aug 2020 – Aug 2024
Doctor of Philosophy (PhD), Biostatistics
Committee: Dr. Yin Bun Cheung (Advisor), Dr. Roger Vaughan (Chair), Dr. Bibhas Chakraborty, Dr. Jialiang Li

Vassar College, Poughkeepsie, New York Aug 2014 – May 2018
Bachelor of Arts (BA), Neuroscience

PROFESSIONAL EXPERIENCE

Research Assistant Professor [Epidemiology] July 2026 – Present
University of Pennsylvania, Department of Biostatistics, Epidemiology, & Informatics, Philadelphia, Pennsylvania

Post-Doctoral Researcher [Biostatistics] Sep 2024 – June 2026
University of Pennsylvania, Department of Biostatistics, Epidemiology, & Informatics, Philadelphia, Pennsylvania
Mentors: Dr. Michael Harhay, Dr. Katherine Courtright, Dr. Scott Halpern, Dr. Fan Li (Yale University)

- Studied the consistency of common model-based estimators for individual and cluster-level estimands in the analysis of cluster randomized trial designs with informative sizes and unmeasured confounding.
- Provided statistical support in the design and analysis of pragmatic cluster randomized trials for improving patient-centered outcomes in palliative care.

Graduate Researcher [Biostatistics] Aug 2020 – Aug 2024
Duke-NUS Medical School, Centre for Quantitative Medicine, Singapore
Mentor: Dr. Yin Bun Cheung

- Evaluated time-varying treatment effects and fixed effects models in different cluster randomized trial designs.
- Developed a novel bias-reduction method in self-controlled case series studies with event-dependent outcomes.

Visiting Researcher [Biostatistics] Mar 2024 – Apr 2024
Duke University, Duke Global Health Institute, Durham, North Carolina
Mentors: Dr. Elizabeth Turner, Dr. Avi Kenny

- Researched exposure and calendar time-varying treatment effects in stepped-wedge cluster randomized trials.

Biostatistician (part-time) Jan 2022 – Jul 2022
Singapore Clinical Research Institute, Singapore
Mentor: Dr. Mihir Gandhi

- Reviewed statistical analysis plans and used SAS to generate and analyze ADaM datasets for clinical trials

Bioinformatician (part-time) Dec 2021 – Feb 2023
Treat Therapeutics, Singapore

- Programmed a pipeline to output reports for canine gut microbiomes using Bioconductor in R and Picrust2.

Research Associate [Neuroscience] Jul 2018 – Jul 2020
NYU Langone Health, Neuroscience Institute, New York, New York
Mentor: Dr. James Salzer

- Studied the role of MYPT1 in the assembly of the axon initial segment in mouse layer V pyramidal neurons.

PUBLICATIONS

1. Janke, A. T., Haimovich, A. D., Cussen, M., Fung, C. M., Samuels-Kalow, M. E., Baymon, D. E., ..., **Lee, K. M.**, ... & Friedman, A. B. (2026). Time to Inpatient Management for Boarding Emergency Department Patients. *JAMA*. [<https://doi.org/10.1001/jama.2026.13302>]
2. **Lee, K. M.**, Forbes, A. B., Kasza, J., Copas, A., Kahan, B. C., Young, P. J., ... & Li, F. (2026). What is estimated in cluster randomized crossover trials with informative sizes? A survey of estimands and common estimators. *Statistical Methods in Medical Research*, 35(9), 1980-2000. [<https://doi.org/10.1177/09622802261470087>]
3. **Lee, K. M.**, Turner, E. L., & Kenny, A. (2025). Analysis of Stepped-Wedge Cluster Randomized Trials When Treatment Effects Vary by Exposure Time or Calendar Time. *Statistics in Medicine*, 44(20-22), e70256. [<https://doi.org/10.1002/sim.70256>]
4. **Lee, K. M.**, & Li, F. (2025). How Should Parallel Cluster Randomized Trials With a Baseline Period be Analyzed? — A Survey of Estimands and Common Estimators. *Biometrical Journal*, 67(3), e70052. [<https://doi.org/10.1002/bimj.70052>]
5. Courtright, K. R., ..., **Lee, K. M.**, ..., Halpern, S. D. (2025) Nudging clinicians to promote serious illness communication for critically ill patients: a pragmatic cluster randomized trial. *JAMA Internal Medicine*, 185(5), 510-520. [<https://doi.org/10.1001/jamainternmed.2025.0090>]
6. **Lee, K. M.** (2025). Advantage Federer: The expected value of tennis. *Significance*, 22(2), 8-11 [<https://doi.org/10.1093/jrssig/qmaf005>]
7. **Lee, K. M.**, Yang, G. M., & Cheung, Y. B. (2024). Inclusion of unexposed clusters improves the precision of fixed effects analysis of stepped-wedge cluster randomized trials with binary and count outcomes. *BMC Medical Research Methodology*, 24(1), 254. [<https://doi.org/10.1186/s12874-024-02379-z>]
8. **Lee, K. M.** & Cheung, Y. B. (2024). The fixed effects model for robust analysis of stepped-wedge cluster trials with a small number of clusters and continuous outcomes: a simulation study. *Trials*, 25(1), 1-18. [<https://doi.org/10.1186/s13063-024-08572-1>]
9. **Lee, K. M.** & Cheung, Y. B. (2024). Estimation and reduction of bias in self-controlled case series with non-rare event dependent outcomes and heterogeneous populations. *Statistics in Medicine*, 43(10), 1955-1972. [<https://doi.org/10.1002/sim.10033>]
10. **Lee, K. M.** (2024). Boxing with George EP Box. *Significance*. [<https://significancemagazine.com/boxing-with-george-box/>]
11. **Lee, K. M.** & Cheung, Y. B. (2024). Cluster randomized trial designs for modeling time-varying intervention effects. *Statistics in Medicine*, 43(1), 49-60. [<https://doi.org/10.1002/sim.9941>]
12. **Lee, K. M.**, Ma, X., Yang, G. M., & Cheung, Y. B. (2022). Inclusion of unexposed clusters improves the precision of fixed effects analysis of stepped-wedge cluster randomized trials. *Statistics in Medicine*, 41(15), 2923-2938. [<https://doi.org/10.1002/sim.9394>]
13. Arndtsen, C., Ballon, J., Blackshear, K., Corbett, C. B., **Lee, K.**, Peyer, J., ... & Duncan, K. A. (2020). Atypical gene expression of neuroinflammatory and steroid related genes following injury in the photoperiodic Japanese quail. *General and comparative endocrinology*, 288, 113361. [<https://doi.org/10.1016/j.ygcen.2019.113361>]

MANUSCRIPTS

1. **Lee, K. M.**, Harhay, M. O., & Li, F. Saturation in G: simple & robust causal inference in cluster randomized trials with informative cluster sizes. (under review) [<https://doi.org/10.48550/arXiv.2608.28943>]

2. **Lee, K. M.**, Li, F. Fixed-Effects Models for Causal Inference in Longitudinal Cluster Randomized and Quasi-Experimental Trials (under review) [<https://doi.org/10.48550/arXiv.2604.07756>]
3. **Lee, K. M.**, Fang, X., Li, F., Harhay, M.O. Who's Winning? Clarifying Estimands Based on Win Statistics in Cluster Randomized Trials (under review) [<https://doi.org/10.48550/arXiv.2602.11403>]
4. Carthon, J., ... , **Lee, K. M.**, ..., Gollineli, D. Transitional Care Program Supporting Medicaid-Insured: A Stepped-Wedge Cluster-Randomized Trial (under review)
5. Mobley, A., ... , **Lee, K. M.**, ..., Altice, F. L. Syndemic profiles of incarcerated men living with HIV in Malaysia transitioning back to the community: A Latent Class Analysis. (under review)

PRESENTATIONS

1. **Lee, K. M.** (2026, September). *Discussing: "How to achieve model-robust inference in stepped wedge trials with model-based methods?"* Invited oral presentation at the International Biometric Society Journal Club.
2. **Lee, K. M.** (2026, May). *Who's Winning? Clarifying Estimands Based on Win Statistics in Cluster Randomized Trials.* Invited oral presentation at the 39th New England Statistics Symposium, Storrs, CT.
3. **Lee, K. M.** (2026, May). *Fixing Cluster Trials: Robust asymptotic inference for fixed-effects regression in longitudinal cluster designs.* Submitted oral presentation at the Fifth International Conference on Stepped Wedge Trial Design, York, England.
4. **Lee, K. M.** (2026, January). *The dual time zone problem: Solution to a Common Complication in the Analyses of Cluster Randomized Trials.* Invited oral presentation at the Stanford University Quantitative Sciences Unit, Palo Alto, CA.
5. **Lee, K. M.** (2025, December). *Fixing cluster trials & the dual time zone problem: Solutions to Common Complications in the Analyses of Cluster Randomized Trials.* Invited oral presentation at the University of Pennsylvania CCEB DBEI Epidemiology Seminar, Philadelphia, PA.
6. **Lee, K. M.** (2025, November). *The dual time zone problem: Analysis of Stepped-Wedge Cluster Randomized Trials When Treatment Effects Vary by Exposure Time or Calendar Time.* Submitted oral presentation at the 11th Annual Meeting on Current Developments in Cluster Randomised Trials & Stepped Wedge Designs, Birmingham, England.
7. **Lee, K. M.** (2025, March). *Mixed up Mixed Effects: Estimands, Estimators, and Informative Sizes in Cluster Randomized Trials.* Invited oral presentation at the University of Pennsylvania CCEB DBEI Epidemiology Seminar, Philadelphia, PA.
8. **Lee, K. M.** (2025, January). *Mixed up Mixed Effects: Estimands, Estimators, and Informative Sizes in Cluster Randomized Trials.* Invited oral presentation at the Duke University Department of Biostatistics and Bioinformatics, Durham, NC.
9. **Lee, K. M.** (2024, November). *Parallel cluster randomized trials with a baseline period: Estimands, Estimators, and Informative Cluster Sizes.* Submitted oral presentation at the 10th Annual Meeting on Current Developments in Cluster Randomised Trials & Stepped Wedge Designs, Birmingham, England.

10. **Lee, K. M.** (2024, June). *Estimation and reduction of bias in self-controlled case series with non-rare event dependent outcomes and heterogeneous populations*. Invited oral presentation at the Health Sciences Authority, Singapore.
11. **Lee, K. M.** (2024, June). *Modelling exposure time-varying treatment effects in cluster randomized trials*. Invited oral presentation at the University of Birmingham, Birmingham, England.
12. **Lee, K. M.** (2024, March). *Cluster randomized trials for modelling time-varying treatment effects*. Invited oral presentation at the Duke Global Health Institute, Durham, NC.
13. **Lee, K. M.** (2023, September). *Boxing with George Box*. Invited oral presentation at the Royal Statistical Society (RSS) International Conference 2023, Harrogate, England
14. **Lee, K. M., Cheung Y. B.** (2023, September). *Cutting the Gordian Knot: Partitioned Analysis of Self Controlled Case Series of non-rare recurrent events*. Submitted oral presentation at the Royal Statistical Society (RSS) International Conference 2023, Harrogate, England.
15. **Lee, K. M., Poh, Z. W., Yeung K. F.** (2022, February). *Monitoring of treatment response in metastatic colorectal cancer patients with cfDNA*. Submitted oral presentation at the Duke-NUS PhD Student Research Symposium 2022, Duke-NUS, Singapore.

POSTERS

1. **Lee, K. M., Cheung Y. B.** (2023, October). *Cluster Randomized Trial designs for modelling time-varying intervention effects*. Poster presentation at the 15th Duke-NUS Early Career Scientists Association (DUNES) Scientific Symposium, Singapore.
2. **Lee, K. M., Cheung Y. B.** (2023, October). *Cluster Randomized Trial designs for modelling time-varying intervention effects*. Poster presentation at the Duke-NUS PhD Student Research Symposium 2023, Singapore.
3. **Lee, K. M., Cheung Y. B.** (2023, September). *Robust Monitoring of Vaccine and Drug Safety using the Self-Controlled Case Series*. Poster presentation at the SingHealth Duke-NUS Scientific Conference 2023, Singapore.

HONORS & AWARDS

FDA-OCE-ASA Oncology Educational Fellowship	Oct 2024
Duke University School of Medicine 2024 Pre-Doctoral Research Exchange Award	Mar 2024
(Finalist) Royal Statistical Society 2023 Statistical Excellence Award for Early-Career Writing	Jun 2023
(1 st Place) Duke-NUS 2022 PhD Student Research Symposium	Feb 2022
Khoo Pre-Doctoral Fellowship	Aug 2020

TEACHING EXPERIENCE

Core Instructor	Nov 2024 – Present
University of Pennsylvania, Pragmatic Clinical Research Institute, Philadelphia, Pennsylvania	
Instructing clinicians about common statistical considerations for the analysis of cluster randomized trials	
Guest Lecturer (EPID 7020)	March 2025 – Present
University of Pennsylvania, Perelman School of Medicine, Philadelphia, Pennsylvania	
Guest lecturer for “EPID 7020: Advanced Topics in Epidemiologic Research”, discussing statistical analysis considerations for clustered study designs	

ADDITIONAL EXPERIENCE

FDA-OCE-ASA Oncology Educational Fellow	Oct 2024 – May 2025
Food and Drug Administration, Oncology Center of Excellence, American Statistical Association	
Participating in workshops on statistics in oncology drug development, research, and regulatory policy.	

Student (part-time)

Oct 2019 – May 2020

NYU School of Professional Studies, New York, New York

- Completed Advanced Python, Data Visualization for Business, The Art of Data Visualization.

Volunteer Statistician

Aug 2019 – Feb 2020

Statistics Without Borders

Mentor: Dr. Janet Raboud

- Used R to characterize, clean, and visualize data collected from the organization membership survey.

Biostatistics Trainee

Jun 2018 – Jul 2018

Emory University, Summer Institute for Training in Biostatistics (SIBS), Atlanta, Georgia

Mentors: Dr. Reneé Moore, Dr. Lance Waller, Dr. Xavier Higgins, Dr. Raphiel Murden, Dr. Andrea Lane

- Analyzed the efficacy of sleep apnea treatments and identified biomarkers of chronic kidney disease.

Undergraduate Thesis Researcher

Sep 2016 – May 2018

Vassar College, Department of Neuroscience, Poughkeepsie, New York

Mentors: Dr. Kevin Holloway, Dr. Kelli Duncan

- Identified the role of steroid hormones in response to traumatic brain injury in the Japanese quail brain.

Undergraduate Summer Researcher

May 2016 – Aug 2016

Rutgers-RWJMS, Department of Neuroscience and Cell Biology, New Brunswick, New Jersey

Mentors: Dr. Long-Jun Wu, Dr. Ukpong Eyo

- Identified the role of the microglia P2Y₁₂ receptor in neuroprotection, seizures and microglia development.

REFEREEING

Statistics in Medicine, The BMJ, BMJ Open, Statistical Methods in Medical Research, Journal of Causal Inference, International Journal of Epidemiology, Clinical Trials, BMC Medical Research Methodology, Frontiers in Medicine

TECHNICAL SKILLS

R, SAS, Python, LaTeX