

NIH Collaboratory Trials Publication Types

The NIH Pragmatic Trials Collaboratory makes contributions to the peer-reviewed literature on a wide range of topics relating to the design and conduct of pragmatic clinical trials embedded within healthcare systems. Every NIH Collaboratory Trial team publishes a **study design paper** and a **main outcome paper**. Many research teams also publish papers in other categories. To help researchers understand potential opportunities for publication of their work, this handout offers examples of the types of papers that commonly arise from the NIH Collaboratory Trials. For more information about publications from the NIH Collaboratory, visit rethinkingclinicaltrials.org/publications.

Background & Motivation

Includes literature reviews, commentaries, and other articles that provide clinical context, policy context, and other background for the study.

Example — **STOP CRC** — “BeneFITs” to increase colorectal cancer screening in priority populations. [JAMA Intern Med. 2014;174\(8\):1242-3.](#)

Preparatory Work

Includes stakeholder interviews, intervention development, phenotype validation, simulations, pilot studies, and other work to inform the design and conduct of the study.

Example — **Nudge** — Text message medication adherence reminders automated and delivered at scale across two institutions: testing the Nudge system: pilot study. [Circ Cardiovasc Qual Outcomes. 2021;14\(5\):e007015.](#)

Study Design

The NIH Collaboratory Trial’s milestone publication reporting the design and rationale of the study.

Example — **FM-TIPS** — The Fibromyalgia Transcutaneous Electrical Nerve Stimulation in Physical Therapy Study (FM-TIPS) protocol: a multisite embedded pragmatic trial. [Phys Ther. 2022;102\(11\):pzac116.](#)

Main Outcomes

The NIH Collaboratory Trial’s milestone publication reporting the primary results of the study.

Example — **ABATE Infection** — Chlorhexidine versus routine bathing to prevent multidrug-resistant organisms and all-cause bloodstream infections in general medical and surgical units (ABATE Infection trial): a cluster-randomised trial. [Lancet. 2019;393\(10177\):1205-15.](#)

Other Outcomes

Includes cost-effectiveness studies, qualitative evaluations, ancillary studies, and secondary analyses, such as implementation outcomes, subgroup analyses, and more.

Example — **EMBED** — Trends in emergency department visits and hospital admissions in health care systems in 5 states in the first months of the COVID-19 pandemic in the US. [JAMA Intern Med. 2020;180\(10\):1328-33.](#)

Example — **TSOS** — Post-traumatic stress disorder (PTSD) symptoms and alcohol and drug use comorbidity at 25 US level I trauma centers. [Trauma Surg Acute Care Open. 2022;7\(1\):e000913.](#)

Example — **LIRE** — Patient, provider, and clinic characteristics associated with opioid and non-opioid pain prescriptions for patients receiving low back imaging in primary care. [J Am Board Fam Med. 2021;34\(5\):950-63.](#)

Lessons Learned: Design & Analysis

Lessons learned from the study relating to the design and analysis of pragmatic clinical trials.

Example — **PPACT** — Interactive group-based orientation sessions: A method to improve adherence and retention in pragmatic clinical trials. [Contemp Clin Trials Commun. 2020;17:100527.](#)

Lessons Learned: Ethics & Regulatory

Lessons learned from the study relating to ethical and regulatory aspects of pragmatic clinical trials.

Example — **TIME** — Ethical issues in pragmatic cluster-randomized trials in dialysis facilities. [Am J Kidney Dis. 2019;74\(5\):659-66.](#)