Community Intervention Trials

- Intervention (experimental) study in epidemiology
  - Clinical trials / Randomized Controlled Trials
  - Community Intervention Trials / Field Trials / Cluster Randomized Trials

Clinical Trials

- Intervention targets individual
- Each participants are randomly assigned to either of treatment or control
- Treatment is usually newly developed or newly implemented drug, therapy, or preventive measure such as vaccine
- Control is placebo or current standard treatment
- The researcher follows up to compare the outcomes between two groups
- Usually matching and blinding (participants and/or enumerator don’t know the assignment of each) are done.
- Intervention is limited to applicable to individual

Community Intervention Trials

- https://learning.eupati.eu/mod/book/view.php?id=665&chapterid=547
- https://methods.sagepub.com/ency/edvol/encyc-of-epidemiology/chpt/community-trial
- To emphasize the actual intervention in the community (not in laboratory), “field trial”
  - Vaccines must be checked about unexpected adverse side effect in field trials as phase 4 after public implementation
- When random assignment is done, “cluster randomized trial”
  - https://unimelb.libguides.com/whichstudytype/ClusterRandomisation
  - https://unimelb.libguides.com/whichstudytype/CommunityFieldTrial
  - https://wkc.who.int/resources/publications/i/item/9789240057968
  - https://vimeo.com/452608697?fl=pl&fe=vl(Part of https://rethinkingclinicaltrials.org/)
- In social epidemiology and environmental epidemiology, intervention measure is given to the community. Improvement of air pollution, sanitation, and social capital are not applicable to individual
- Random assignment of program implemented community and control community is done
- Sometimes blinding is impossible.
- When setting adequate control community is impossible, changes between intervention program are evaluated using difference-in-difference (DID) method (sometimes to adjust the effect of secular trend)

Secular trend is sometimes difficult to decompose

- Ali, M.A., Uetake, T. and Ohtsuki, F. (2000), Secular changes in relative leg length in post-war Japan. Am. J. Hum. Biol., 12: 405-416. https://doi.org/10.1002/(SICI)1520-6300(200005/06)12:3<405::AID-AJHB11>3.0.CO;2-M
  - Relative leg length in postwar Japan continuously increased
  - Many changes occurred
    - Nutritional improvement
    - From tatami-mat and seiza (sitting on floor with folding legs) to sitting on chair
    - Avoiding carrying heavy loads
  - No definite control group
- Public health policy implementation can be evaluatedby DID
  - Coady Wing, Kosali Simon, Ricardo A. Bello-Gomez. 2018. Designing Difference in Difference Studies: Best Practices for Public Health Policy Research. Annual Review of Public Health 39:453-469. https://doi.org/10.1146/annurev-publhealth-040617-013507

Drinking water fluoridation to prevent dental caries

- AST DB, SCHLESINGER ER. The conclusion of a ten-year study of water fluoridation. Am J Public Health Nations Health. 1956 Mar;46(3):265-71. https://doi.org/10.2105/ajph.46.3.265
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Five-City project to lower the risk of cardiovascular diseases

- Farquhar JW et al. (1985) The Stanford Five-City Project: design and methods. American Journal of Epidemiology, 122(2): 323–334. https://doi.org/10.1093/oxfordjournals.aje.a114104
- Fortmann SP et al. (1995) Community Intervention Trials: Reflections on the Stanford Five-City Project Experience, American Journal of Epidemiology, 142(6): 576–586. https://doi.org/10.1093/oxfordjournals.aje.a117678

Salt-reduced bread to prevent hypertension

- Gressier M, Sassi F, Frost G. Contribution of reformulation, product renewal, and changes in consumer behavior to the reduction of salt intakes in the UK population between 2008/2009 and 2016/2017. Am J Clin Nutr. 2021 Sep 1;114(3):1092-1099. https://doi.org/10.1093/ajcn/nqab130
- Riis NL, Lassen AD, Bjoernsbo K, Toft U, Trolle E. Dietary Effects of Introducing Salt-Reduced Bread with and without Dietary Counselling—A Cluster Randomized Controlled Trial. Nutrients. 2022; 14(18):3852. https://doi.org/10.3390/nu14183852