

New study reveals how electronic health records can benefit clinical trials

May 16 2018



A new study by Swansea University academics has indicated that the Secure Anonymised Information Linkage (SAIL) Databank can provide a simple, cost-effective way to follow-up after the completion of randomised controlled trials (RCTs). Credit: SAIL

The study entitled "Long term extension of a randomised controlled trial of probiotics using electronic health records" led by researchers in the Swansea University Medical School and the College of Human and Health Sciences, was published in *Scientific Reports*.

The findings demonstrate the potential of using anonymised routinely collected [electronic health records](#), such as those linked in SAIL, for more complete trial results. Results showed that SAIL can help track trial participants, with long term monitoring of medical interventions and health outcomes, and new insights into population health.

Typically, RCTs are relatively short term, and due to costs and resources, have limited opportunity to be re-visited or extended which means the effects of treatments cannot be scrutinised beyond the duration of the study, typically 1-2 years.

With patients' consent, data analysts can match patients to their records and access data quickly. As a result, the cost of follow-up using routine data is potentially relatively small and does not increase with the number of participants.

The study

The original RCT investigated the impact of probiotics taken during pregnancy on childhood asthma and eczema in a group of children at 6 months and then 2 years of age.

Professor Sue Jordan of Swansea University's College of Human and Health Science who led the study said: "In this study we reported on the feasibility and efficiency of electronic follow up, and compared it with traditional trial follow up. We gained new insights from outcomes electronically recorded 3 years after the end of the trial, and could then identify the differences between trial data and electronic data."

The use of electronic databases in clinical trials has been hailed as one of the major benefits of a nationwide electronic health records system. However, few studies have demonstrated this benefit, or formally assessed the relationship between traditional trial data and electronic

health records databases."

Key research findings

- Using SAIL, the retention of children from lower socio-economic groups was improved which helped reduce volunteer bias.
- Results from the electronic follow up were more reliable due to reduced risk of bias, unreliability or inaccuracy in participants' recall.
- New insights were gained from the electronic five year follow up, particularly for asthma, which typically appears after 2 years of age
- For the electronic follow up at five years, retention was still high and free of bias in socio-economic status
- Any future extension of the trial is straightforward.

Follow up of trial participants on anonymised routine electronic health care databases such as SAIL offers great potential to maximise the economic efficiency of [trials](#) and allow access to a fuller range of health information.

SAIL Associate Professor Kerina Jones is the academic lead for data governance and public engagement. She said: "SAIL is a world-class, privacy-protecting data linkage system that securely brings together routinely-collected health data.

SAIL is part-funded by the Welsh Government, and makes person-based health data available for genuine research purposes only where there is a potential for benefit. Because SAIL removes the identities of participants to protect their privacy and holds only anonymised data, researchers carry out their work without knowing the identities of the individuals."

Professor Jordan said: "The number of participants volunteering for RCTs is decreasing, particularly amongst the most economically disadvantaged. Trial data are vulnerable to misunderstandings of questionnaires or definitions of illness."

Professor Michael Gravenor, who led the data analysis for the study said: "These results lead us to conclude that using electronic [health](#) records have benefits relating to the cost-effective, long term monitoring of complex interventions which could have a positive impact for future clinical trial design."

More information: Gareth Davies et al, Long term extension of a randomised controlled trial of probiotics using electronic health records, *Scientific Reports* (2018). [DOI: 10.1038/s41598-018-25954-z](https://doi.org/10.1038/s41598-018-25954-z)

Provided by Swansea University

Citation: New study reveals how electronic health records can benefit clinical trials (2018, May 16) retrieved 13 March 2024 from <https://medicalxpress.com/news/2018-05-reveals-electronic-health-benefit-clinical.html>

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