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Pros and cons of using anonymised linked routine data to improve efficiency of randomised controlled trials in healthcare: experience in primary and emergency care

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Background

The use of anonymised routine linked data in designing and conducting randomised controlled trials (RCTs) has great potential. Sample sizes can be large, inclusion rates high and follow up periods prolonged, while the disruption to participants' usual routines may be minimised. However, challenges and limitations in using routine linked data in RCTs remain.

Aims

To describe, in primary and emergency settings, challenges and opportunities associated with designing and conducting RCTs using anonymised linked routine data to identify study participants and gather outcomes.

Methods

Synthesis of trial designs used, regulatory processes followed and findings from three trials: PRISMATIC; SAFER 2; TIME

Results

In each of these trials we have used routine linked data as a key part of the research study design:

PRISMATIC (a stepped wedge trial of predictive risk stratification in primary care) utilised linked data outcomes related to emergency admissions to hospital, GP activity and outpatient appointments. Outcomes were included for 230,000 people registered to participating GP practices in the Swansea area

SAFER 2: a cluster randomised trial of referral to falls services by ambulance paramedics included linked data outcomes related to subsequent emergency episodes for 4,655 patients across three UK regions

TIME: feasibility trial of Take Home Naloxone randomised by city; routine linked data used to identify population for inclusion in follow up and outcomes

Regulatory processes - ethics, research and information governance permissions - have caused delay in each trial; inclusion rates have been much higher than is usual in RCTs (outcomes for >80% of eligible patients); large trials have been achievable at reasonable cost (each trial <£2,000,000). Questions remain about differences between self reported and routinely available outcomes; and between routine data outcomes collected prospectively and through the anonymised linked route.

Conclusions

There are clear benefits in using anonymised linked data outcomes in trials but further research is required to understand costs and limitations

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