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EXPLORING THE HAWTHORNE EFFECT USING A BALANCED INCOMPLETE BLOCK DESIGN IN THE ASPIRE CLUSTER RANDOMISED CONTROLLED TRIALS

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Background:

The Hawthorne effect is a non-specific treatment effect: an alteration in behaviour as a response to the interest or attention received through observation and assessment leading to an overestimate of the effectiveness of an intervention [1, 2]. If the Hawthorne effect is unbalanced across trial arms, resulting treatment estimates may be biased [2].

Action to Support Practices Implementing Research Evidence (ASPIRE) is a UK NIHR-funded programme aiming to develop and evaluate interventions to promote adherence to evidence-based quality indicators in general practice. Multifaceted implementation packages were adapted to target four indicators and evaluated using anonymised, routinely collected electronic health records in two parallel cluster randomised controlled trials (cRCTs) in West Yorkshire general practices.

Methods:

Balanced incomplete block designs, with each trial having two arms, were intentionally chosen to equalise Hawthorne effects whilst maximising power and efficiency [3, 4]. Each trial evaluated the effect of adapted implementation packages on adherence to two of four indicators: diabetes control and risky prescribing in trial 1; blood pressure control and anticoagulation in atrial fibrillation in trial 2. Within trials, implementation packages were assumed to be independent with respect to their effect on the indicators, thus practices randomised to the implementation package for one indicator acted as control practices for the other implementation package and vice versa.

A fifth, non-intervention control group was included to enable a secondary analysis testing for evidence of Hawthorne effects. General practices allocated to this control group received none of the ASPIRE adapted implementation packages. According to the theory, if a Hawthorne effect is present the non-random aspect of the differences in the intervention effects in the primary analysis can be attributed to the fact that practices were aware of being observed (resulting in improvements to adherence to indicators) and is not attributable to the intervention. Further, we expect the intervention effect in the primary analysis will be smaller than in the secondary analysis utilising the non-intervention control practices.

Results:

ASPIRE recruited 178 general practices using an opt-out approach; 80 randomised to trial 1; 64 randomised to trial 2; with 34 randomised to the non-intervention control group. The implementation package reduced risky prescribing (OR=0.82, 97.5% CI (0.67 – 0.99)) but had no statistically significant effect on the other primary endpoints. We will present an analysis exploring the Hawthorne effect in both trials, using the non-intervention controls and discuss the implications for future implementation trials.

Conclusions:

Using a balanced incomplete block design and including randomised non-intervention controls could inform the design and analysis of future RCTs, particularly those utilising routinely collected data in implementation research.

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