ICTMC 2022 – CHICO efficient design abstract submission

Title: A more efficient approach to randomised controlled trials in primary care using routinely collected practice-level data

Presentation Theme: Design – Innovative design

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Introduction

Conducting randomised controlled trials (RCTs) in primary care is challenging; recruiting patients during time-limited or remote consultations can increase selection bias and physical access to patients' notes is costly and time-consuming. A more light-touch approach, with practice-level intervention adoption, which avoids recruiting individuals, is possible. The CHICO (CHIldren's COugh) cluster RCT aimed to reduce antibiotic prescribing in children presenting with respiratory tract infection and cough, using a clinician-focused intervention that was integrated into primary care practice computer systems. By using routinely collected data, aggregated at the practice level for the primary outcomes, we removed the need to recruit individual participants.

The change from a traditional patient-level research design in our previous feasibility CHICO RCT to a light touch practice-level design used in the full RCT, provided an opportunity to look at the barriers and facilitators to a more efficient trial design and the impact on practice recruitment, engagement, understanding of research and data collection.

Methods/Approach

We collected data on practice level characteristics, at baseline and follow up, as well as intervention usage and acceptability during follow up. Primary outcomes were collected using routinely collected data from Clinical Commissioning Groups (CCG) (hospitalisations) and the NHSBSA ePACT2 dashboard (dispensing). Feedback on the roles of Clinical Research Networks (CRNs) and CCGs in

recruiting practices were obtained from a short questionnaire sent to all CRNs and semi-structured interviews with a convenience sample of 5 key individuals in CRNs and CCGs.

Results

We recruited 294 of the intended 310 practices (95%) representing 336,496 registered 0-9 year-olds (5% of all 0-9 year-old children). Practices included in the trial were slightly larger, had slightly lower baseline prescribing rates and were located in more deprived areas than the English average and reflecting the national distribution. Engagement with CCGs and their understanding of their role in this research was variable. Engagement with CRNs and installation of the intervention was straight-forward although the impact of updates to practice IT systems and lack of familiarity required extended support in some practices. Data on the co-primary outcomes was almost 100%.

Discussion

The infrastructure for efficiently designed trials within primary care in England is viable and should be promoted where appropriate, particularly where routinely collected electronic health records are available for primary outcomes.