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Hand-2 randomised controlled trial – recruitment successes in the current research climate

Background

Good recruitment aims to ensure research participants are representative of the target population, and sufficient enough in number to meet the sample size required for adequate statistical power. Poor recruitment may result in invalid or inconclusive results.

Randomised control trials are often designed with proactive strategies in place to promote good recruitment. However, unexpected events and factors may occur during a trial's life cycle which require reactive recruitment optimisation to maximise the chances of recruitment success.

The Hand-2 study

- The Hand-2 trial was due to commence in 2020 but was paused during the Covid-19 pandemic.
- Site opening began in 2022, though NHS capacity was still limited.
- In December 2022 industrial action began in the NHS, leading to cancelled recruitment clinics for the trial.
- It was apparent to the trial management team that recruitment optimisation was essential if recruitment targets were to be met.

Methods

Sites

21 sites were opened across England and Scotland; 9 more than planned, to account for expected delays arising from post-covid NHS capacity issues. Two sites had to close early due to these capacity issues, resulting in 19 recruiting sites.

Recruitment intervention

Hand-2 implemented a QuinteT Recruitment Intervention (QRI). This involved interviews with site staff and audio recording, with consent, recruitment discussions between clinicians and potential participants. Recordings were reviewed by the QRI team who arranged feedback presentations with clinicians to highlight good practice and offer suggestions for improvements. Key to this was ensuring clinician and patient equipoise, and that both treatments were presented fairly with pros and cons discussed openly.

Analysis of screening data

The QRI also gathered information regarding how screening and recruitment clinics were conducted at each site. This data was presented at teleconferences held with all sites together, so that sites could discuss what was working well, and where the challenges lay.

Site teleconferences

Discussions allowed for peer-to-peer support across sites, which further identified potential initiatives to drive recruitment across the trial.

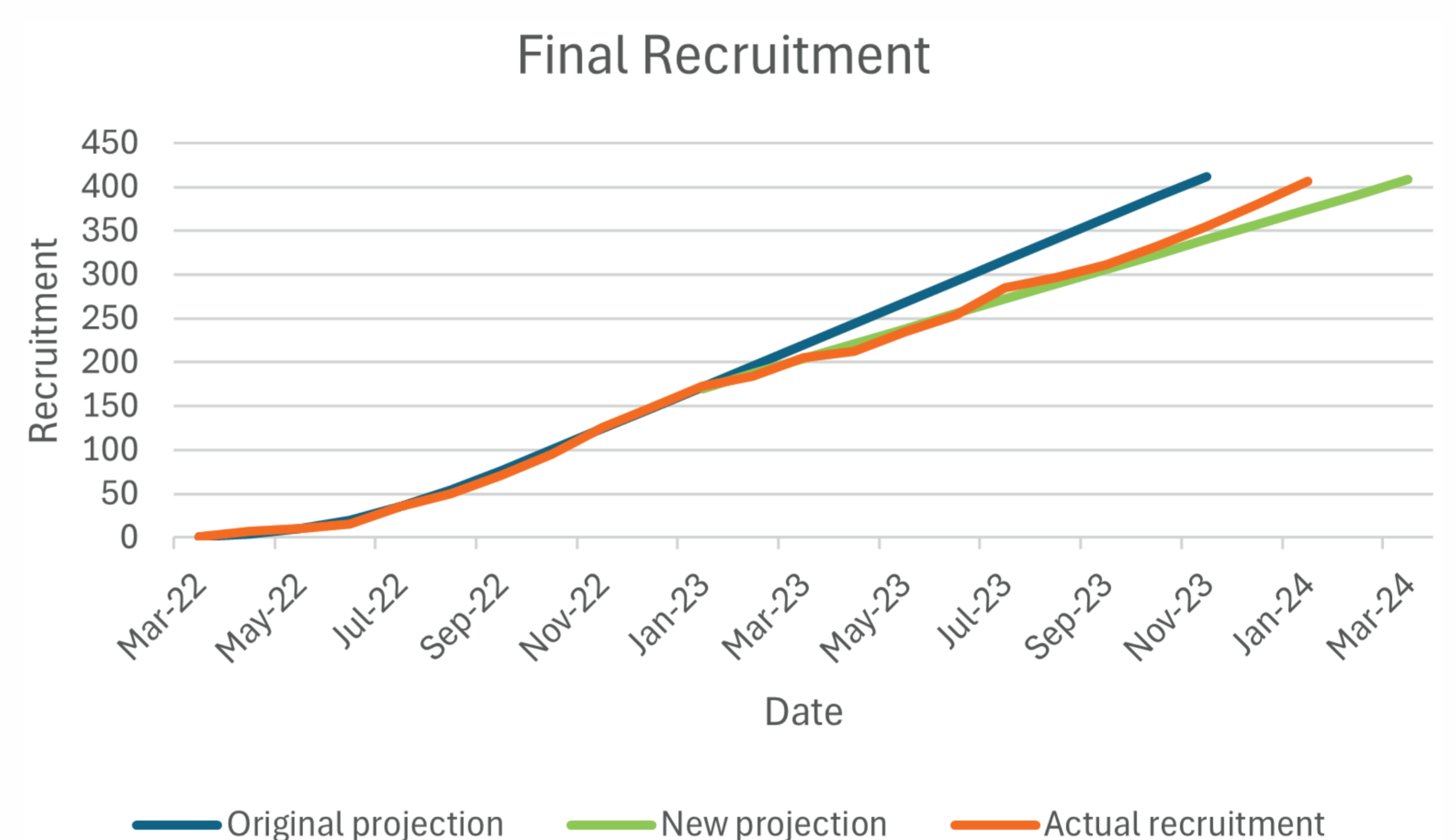
Acknowledging milestones

Such as a site completing all open data queries, or recruiting the nth participant. Small prizes were sent to sites, helping keep motivation of site staff high.

Results

Summary of issues faced

- Post-covid capacity issues
- 59 lost days due to industrial action within the NHS between December 2022 and January 2024
- Two sites having to close early due to local capacity issues



Outcomes

Hand-2 recruitment completed on 30th January 2024, just 8 weeks behind schedule. 16 of the 19 recruiting sites randomised >50% of eligible patients seen at their centres, demonstrating the success of optimising recruitment conversations via the QRI and sharing best practice via open discussion at site meetings.

Conclusion/Discussion

Trials can face expected and unexpected challenges, which can dramatically impact on recruitment activities.

Proactive implementation of strategies to improve recruitment can minimise delays to study progress.



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