Impact of the API scheme from a CTU perspective

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API scheme

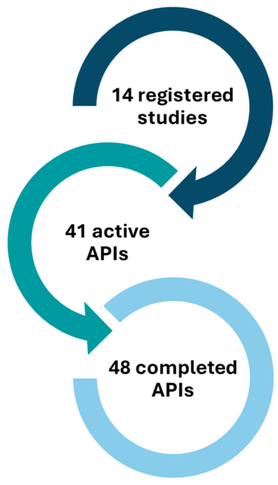
APIs (associate principle investigators) carry out 6 months training on an NIHR portfolio study under the mentorship of the local PI. Reported benefits for the CTU include:

Increased Data Quality
Speedier Delivery
Enhanced Recruitment

Within the NCTU, benefits of the scheme have been reported anecdotally. We aim to provide evidence of these benefits in relation to recruitment.

Within the NCTU we have:

- 14 studies are registered to the scheme
- 41 active APIs
- 48 APIs have completed their training



Methods

Characteristic	Trials (n=8) (%)
Type of trial	
CTIMP	5 (62.5)
intervention	3 (37.5)
Clinical Area	
children	1 (12.5)
musculoskeletal disorders	2 (25)
anaesthesia, perioperative medicine and pain management	1 (12.5)
reproductive health and childbirth	1 (12.5)
mental health	1 (12.5)
respiratory disorders	1 (12.5)
trauma and emergency care	1 (12.5)
Population	
adults	6 (75)
paediatric	2 (25)
Target sample size	
mean (SD)	853 (696)
median (IQR)	403 (359, 1686)
min, max	314, 2400

Table 1 Characteristics of included trials

API registration data from the NIHR champions dashboard has been collated with recruitment data from NCTU trials. Only definitive, multicentre UK trials with individual randomisation have been included (table 1). We have determined whether site recruitment improved after API registration where recruitment data was available for 3 months pre and post-API registration, using all sites where this data was available across 6 NCTU studies as described in table 1. We have also looked at the effect of API registration on the total number of randomisations in the 3 months pre and post-API registration.

Results

At 18 of the 32 sites included in chart 1, there were more randomisations in the 3 months pre-API registration than in the 3 months post-API registration. When looking at the individual trials the difference between randomisation pre and post-API registration is marginal.
Total recruitment figures across all included trials show a small increase in the recruitment post-API registration (chart 2). This difference is again marginal when looking at the individual trial data. Using regression analysis, a 0.5 (95%CI: -0.5 - 1.5) increase in 3 months recruitment post-API registration was observed.

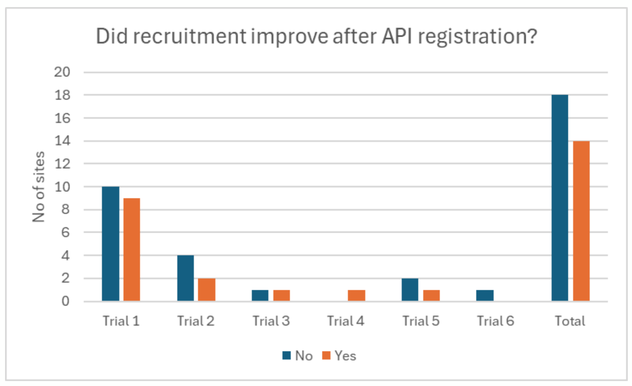


Chart 1. Site improvement in recruitment 3 months post API registration

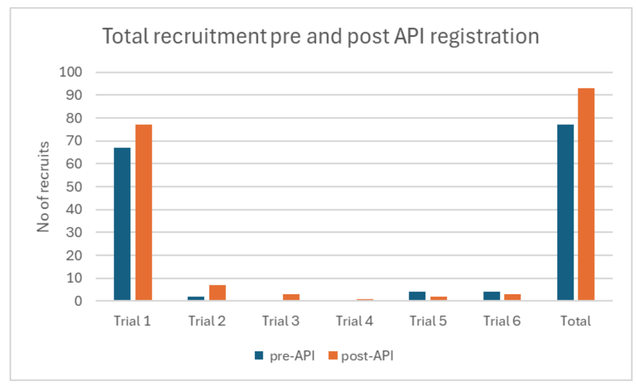


Chart 2. Total recruitment 3 months pre and post-API registration

We made comparisons of total recruitment figures, for trials where recruitment was complete, across sites with no API, or at least one API registered over the course of the study. There were only 3 trials (89 sites) eligible for inclusion, with 69% being non-API registered and 31% being API registered. No difference in recruitment rates between groups was observed when comparing using a linear regression model.

Discussion

Limitations of the dataset

The recruitment data for the 3 months pre-API registration was very limited for most of the included trials. As the API scheme has become more widely embedded and uptake to the scheme has been adopted across new trials at the NCTU, many sites have an API registered right from the start of the study as soon as a site opens to recruitment. As a result the baseline data available for this study was very limited.
The NCTU is a single trial unit with only 14 studies registered to the API scheme, and a wide variety of study size. Some trials have only a very small number of recruiting sites, or limited recruiting opportunities where rare conditions or diseases are being studied, further reducing the available data for this study.
Where total recruitment across study sites was investigated, due to the small sample size and the relatively large imbalance between groups, definitive conclusions could not be drawn. API sites only comprised a small proportion of the total number of sites.

Benefits

The early API registration prevented us from gathering a large body of evidence regarding recruitment pre and post-API registration, but having an API registered during or soon after set-up can be a great advantage for sites in assisting with preparations for site opening, getting the study up and running, and helping to enrol the first recruit without delay.

Further work

Benefits of the API scheme on recruitment have been demonstrated on an individual study level, by Newman et al (1). We aimed to show the benefit on a unit wide level, but the limited dataset has prevented us from drawing any firm conclusions. A collaborative project across multiple trial units would greatly increase the available dataset and scope for demonstrating any effect on recruitment associated with API registration. Other advantages of the API scheme could be investigated. Possible avenues include looking at set-up times at sites with APIs registered prior to recruitment commencing, this could be followed up with a comparison of time to initiation of recruitment at such sites. It would also be interesting to look at the levels of data queries and time to solve those queries at sites where APIs are involved in this aspect of the study. The API scheme is widely recognised by anecdotal evidence as having very positive impact at a site level, with benefits to many other outcomes that could be investigated in future studies..

1. Associate Principal Investigators and the HEAL-COVID trial: good for trainees, good for trials. January 2024 Trials 25(1)

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