Introduction

Clinical trials provide the body of scientific evidence on which healthcare in the UK is based, the NIHR believe they are key to advancing medical knowledge and improving patient care. Despite the unquestionable benefits of clinical trials, recruiting participants is often difficult, and recruitment issues are a major reason for clinical trials failing

Patient choice is a key driver of recruitment success, therefore understanding the reasons for non-participation may help better inform clinical trial design and grow recruitment.

Here we report the findings of a questionnaire designed to evaluate the reasons why primary care patients decided not to participate in a commercial clinical trial and, based on these findings, outline recommendations to grow recruitment.

Methods

The questionnaire comprised of 20 statements (reasons for non-participation that were rated by the participants) and an open question (other reasons).

Local GPs identified 250 eligible patients (invited to participate in a commercial clinical trial but had declined) and issued them with an invite letter, patient information leaflet (PIL) and questionnaire.

A basic statistical analysis was carried out on how the 20 statements were rated and thematic content analysis (identifying common themes) was carried out on the other reasons for non-participation.

Results

Forty (n=40) responses were received and the results from the statistical analysis are summarised in Figure 1.

The main reasons for non-participation of patients in clinical trials related to commitment and time, whether that be due to the clinical trial requiring too many visits to the GP practice (n=21, 53%), the patient not having enough time to participate (n=16, 40%), the study lasting too long (n=12, 30%), patients having too many family commitments (n=12, 30%) or not being able to visit the GP practice during the day (n=8, 20%).

Other major reasons were perceived ineligibility, either by the patient or GP and risk of a negative experience relating to the patients health i.e. worried about being taken of current treatment (n=11, 28%) or concerned about side-effects of the study medication (n=10, 25%).

These results were supported by the thematic content analysis as similar themes for non-participation were identified. Reasons stated included -

“. . . I would not have been allowed to take the time off work ”.

“I would be taken off some of my existing medication, which works and I can’t afford to let a check infection affect my asthma”.

Discussion

The results may suggest that too much is expected of patients in a clinical trial or could be an indication that patients have misunderstood what is expected of them.

Concerns about being taken off current medication or possible side-effects of the study medication could infer that patients have not fully understood the PIL.

The results also reflect the current restrictions of GP practice services i.e. usually Monday to Friday, 9 to 5. (This is changing with the Governments “NHS 7 day services” plans).

Findings from this study informed the following key recommendations:

1. Involve experts such as GP Investigators in the early stages of protocol development to comment on feasibility i.e. do they think patients would be likely to participate
2. Involve a PPI (Patient & Public Involvement) panel in designing the PIL to ensure it is easy to understand and is written in plain English.
3. Offer face-to-face appointments to potential participants to discuss the study prior to issuing the PIL.
4. Offer flexible appointment times
5. Use a GP investigator who is known to patients.
6. Combine study visits with routine visits.

Conclusion

This study highlights the main barriers patients face when invited to participate in a commercial clinical trial hosted by primary care. The recommendations made could be used to inform future recruitment procedures and grow participation.