

Dynamic data-enabled stratified sampling for cancer screening trial invitations with application in NHS-Galleri

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Here we report the invitation strategy developed and used in the NHS-Galleri trial (NCT05611632)^[1,2]



Background: invitation strategy aims

1. Ensure adequate representation / equity

Target invitations so that everyone in society is represented in the study sample in adequate numbers

- High deprivation areas
- Diverse ethnic groups

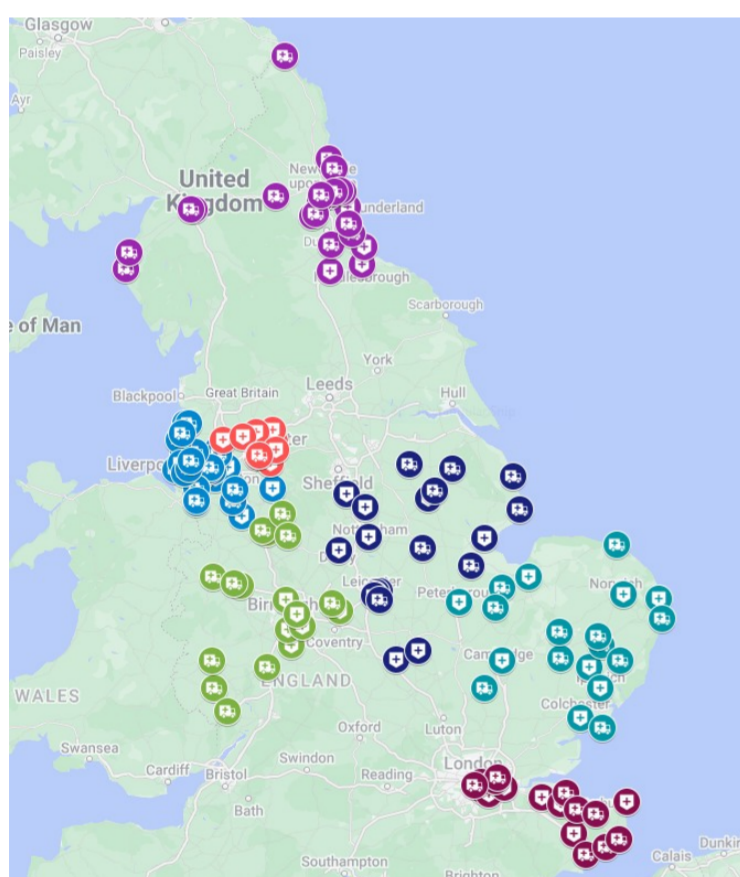
2. Account for healthy volunteer effects

Enrich the study sample to help ensure sufficient events

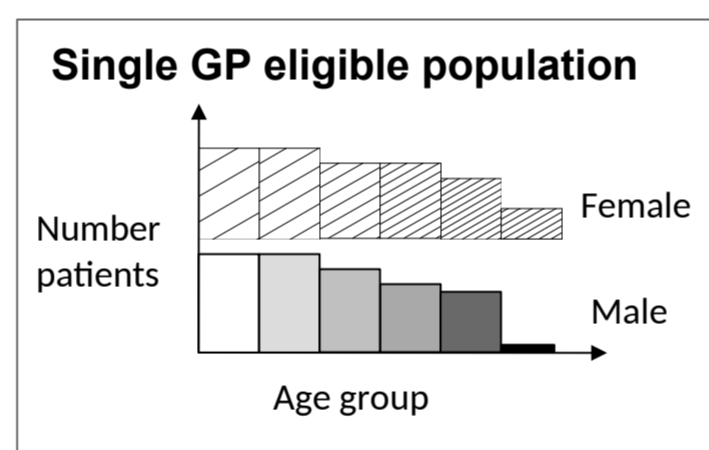
- Trial powered on Stage III/IV cancer in people aged 50-77y

Methods: stratified sampling

Choose site for mobile clinic



Select and rank prioritise local GP surgeries



Create long list of GPs

- Potential invitation population
- Rank prioritise GP surgeries by local statistics on deprivation, ethnicity and proximity

Identify and invite individuals using invitation algorithm

a) Algorithm calculates number of invitations required by GP/age/sex group, maximising a utility measure with the following constraints

- Total expected number of bookings = target
- Expected bookings by age/sex bands exceeds minimum bounds
- Expected booking in male = female
- Expected advanced cancer rate is 20% greater than population 50-77y

b) Requests for invitations sent to NHS DigiTrials in 2-3 waves ~4 weeks prior to site opening, with dynamic adjustment based on demographic factors in bookings made in earlier waves

Results: invitation algorithm

Used to send ~1.5M invitations to recruit 140,000 participants to the NHS-Galleri trial in ~10.5 months^[1]

Aimed to help achieve equity in the NHS-Galleri trial by shifting the sampling distribution towards people from lower socio-economic groups who are less likely to accept invitation

Aimed to mitigate healthy volunteer effects by requiring a minimum expected event rate of the primary outcome (stage III/IV cancer in the NHS-Galleri trial)

Conclusions

Our novel data-enabled approach to recruitment is designed to address healthy volunteer effects and inequity in health research studies

The methodology could be adapted and used to help enable future studies to better represent their target population, improve equity, diversity and inclusion of trial participants, and account for healthy volunteer effects^[2]

Watch a 10min talk about the methodology on YouTube via QR code:



References

- [1] Neal R, et al, *Cancers* 2022, 14(19), 4818 doi:10.3390/cancers14194818
[2] Brentnall AR, et al. *Clinical Trials* 2023 doi:10.1177/17407745231167369