Patient participation in clinical trials: the **barriers** facing patients and their effect on future ophthalmology trials

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Introduction and Aims

Patient participation in clinical trials is key in ensuring safety and efficacy of clinical treatments and advancement of research. (1,2)

Participation in ophthalmology trials can be poor, with barriers including uncertain efficacy and concerns regarding side effects. (3)

Aims:

1. Identify participant-related barriers to trial participation.
2. Identify participant perception of workplace policies.
3. Explore employer policies allowing employees to participate in clinical trials.
4. Understand the implication of patient participation barriers in future ophthalmology research.

Methodology

Data was collected from surveys sent to members of the public and healthcare professionals. The survey assessed:

- Whether participants are more willing to participate in trials as a healthy volunteer or a patient,
- Whether participants are willing to take annual leave or unpaid leave,
- Understanding of employer policies.

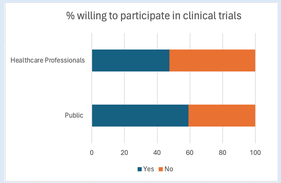
Statistical analysis using SPSS was used to compare participant groups.

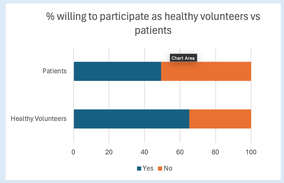
Freedom of Information requests were sent to councils to obtain information regarding employer policies on leave for clinical trials.

Results

Survey results:

- 501 public responses and 132 healthcare professional (HP) responses.





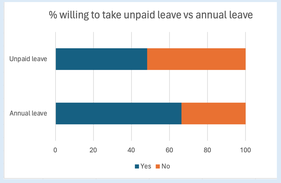


Figure 1a. Percentage of participants willing to participate in trials. 1b. Percentage of participants willing to participate as healthy volunteers vs patients. 1c. Percentage of participants willing to take annual leave vs unpaid leave.

A) Members of the public were more willing to participate in trials compared to HPs (59.1% vs 47.4%, p<0.001).

B) Respondents were more willing to participate as healthy volunteers rather than patients (65.2% vs 49.3%, p<0.001)

C) Respondents preferred to take annual leave rather than unpaid leave (66.3% vs 48.3%, p<0.001).

Participant awareness and perception of of employer policies:





Figure 2a) Participants are unsure if employer has a policy to allow paid time away for trials or b) if employer would allow paid leave.

48% of respondents believed their employer did not have policies relevant to trial participation in place and 33.6% of respondents were uncertain. 64.4% of HPs were unsure if employer would give them 5-7 days of paid leave.

Current employer policies:

88.9% of government organisations did not have specific policies in place, with 30/336 suggesting alternative options such as annual leave or sick leave.

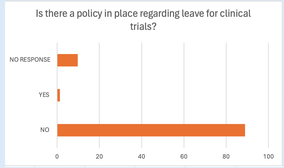


Figure 3. Most organisations did not have specific policies in place.

Discussion

- Public respondents – unclear why more likely to participate in trials than healthcare professionals.
- Healthy volunteers – concerns of receiving substandard treatment or developing complications when unwell.
- Annual leave– though AL is for holidays/time with family, participants want to be paid for their time.

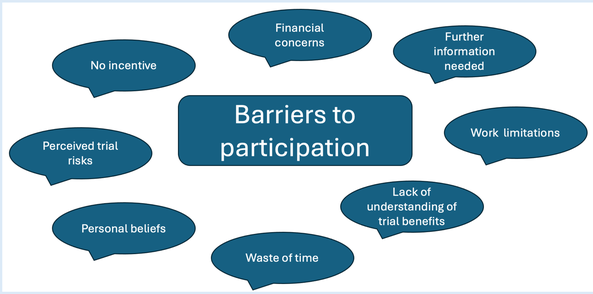


Figure 4. Freetext answers are categorized into patient-reported barriers, with financial concerns being the main barrier.

Conclusion and next steps

1. A key barrier to participation is perceived financial impact of trials.
2. Incentives and being paid for time spent is a potential way to increase participation.
3. Most participants are either unsure of workplace policies or believe there are no policies in place to allow participation in trials.
4. Most organisations do not have specific leave for trials.

Future implications:

Institutional change: policies allowing volunteers and patients to take part in trials e.g. specific forms of leave.

National change: policies to promote trial benefits e.g. financial incentives.

References:

1. Mills *et al.* (2006) *Barriers to participation in clinical trials of cancer: A Meta-analysis and systematic review of patient-reported factors*, *The Lancet Oncology 2006; 7: 141-48*.
2. Kaanoi, M. *et al.* (2002) *Oncologists' knowledge, attitudes and practices related to cancer treatment clinical trials*, *Hawaii medical journal*.
3. Liang, J. *et al.* (2024) 'Factors influencing willingness to participate in ophthalmic clinical trials and strategies for effective recruitment. ', *International Journal of Ophthalmology*, 7(1), pp. 157–163. doi:doi: 10.18240/ijo.2024.01.21.