

How much is the lack of retention evidence costing trial teams in Ireland and the UK?

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Background

- Poor retention is a major problem for clinical trials, as it can delay the implementation (or removal) of healthcare interventions, as missing primary outcome data can reduce the power of the study to detect significant findings.
- Despite the importance of retention there is a lack of evidence to support the use of retention strategies in clinical trials.
- This study aimed to estimate how much this lack of retention evidence might be costing trials in Ireland and the UK.

Methods

- We selected the top 10 most routinely used retention strategies used by Clinical Trial Units (CTUs) in the UK.
- We made assumptions as to how each of these strategies would be implemented and the costs involved.
- We applied our costing model to one hypothetical trial scenario in Ireland and the UK and to three published trial protocols.

Missing data strategies and number (N) and percentage of CTUs in the UK that routinely use the strategies		Cost range of each strategy
Newsletters	N=23, 70%	<u>Posted newsletters</u> <u>€755.17 (£649.45) - €2040 (£1754.40)</u> <u>Emailed</u> <u>€546.59 (£470.07) - €1094.17 (£940.96)</u>
A timeline of participant visits for sites	N=19, 58%	<u>Site reminder</u> <u>€79.18 (£68.09) - €112.23 (£96.52)</u> <u>Site and participant reminder</u> <u>€304.74 (£262.08) - €14803.70 (£12730.79)</u>
Inclusion of prepaid envelopes (questionnaires)	N=19, 58%	<u>€170.98 (£147.04) - €1690.00 (£1453.40)</u>
Telephone reminders	N=18, 55%	<u>Telephone reminders for trial visits</u> <u>€203.40 (£174.92) - €14691.47 (£12634.27)</u> <u>Telephone reminders for questionnaire response</u> <u>€34.58 (£29.74) - €568.62 (£489.01)</u>
Data collection scheduled with routine care	N=18, 55%	<u>€900 (£774) - €32,503.25 (£27,951.92)</u>
Site initiation training on missing data	N=18, 55%	<u>€400 (£344.00) - €7376.74 (£6344)</u>
Investigator meetings face to face	N=17, 52%	<u>€777.67 (£668.80) - €14753.48 (£12688)</u>
Routine site visits by CTU staff	N=15, 45%	<u>€777.67 (£668.80) - €14753.48 (£12688)</u>
Targeted recruitment of sites/GPs	N=15, 45%	<u>€30 (£25.80) - €1620 (£1393.20)</u>
Flexibility in appointment times	N=15, 45%	<u>€270 (£232.20) - €4050 (£3483.00)</u>

Most expensive

Moderately expensive

Least expensive

Results

- Only “newsletters”, “inclusion of prepaid envelopes” and “telephone reminders” have limited evidence showing effectiveness and much of the existing evidence is from single studies often with low GRADE (certainty of evidence) ratings (Table 1 above).
- The remaining strategies had no evidence to support their use.
- The cost of some of the strategies that are routinely used is significant, and so is the lack of evidence to support their use.

Suggestions for future research

- SWATs should be used to investigate the impact of retention strategies to provide more evidence for decision making.
- Replication of evaluations will add to the existing evidence to support/not support the use of these strategies.
- Including clear descriptions of retention strategies and their costs would be useful. The challenges of how to implement a retention strategy based on current descriptions became very clear in this work.

GRADE = Grading of Recommendations, Assessment, Development and Evaluations. SWATs = Studies Within a Trial. Full paper via QR code.

