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Unconditional and conditional monetary incentives to increase response to mailed questionnaires: a randomised controlled study within a trial (SWAT)

Running title: Unconditional monetary incentives for questionnaires

Ben Young[1], Laura Bedford[1], Roshan das Nair[2], Stephanie Gallant[3], Roberta Littleford[3], John F.R. Robertson[4], Stuart Schembri[5], Frank M. Sullivan[6], Kavita Vedhara[1], Denise Kendrick[1], in collaboration with the ECLS study team

[1] Division of Primary Care, University of Nottingham, Nottingham, UK.

[2] Division of Psychiatry & Applied Psychology, University of Nottingham, Nottingham, UK.

[3] Tayside Clinical Trials Unit, University of Dundee, Dundee, UK.

[4] Division of Medical Sciences and Graduate Entry Medicine, University of Nottingham, Derby, UK.

[5] Ninewells Hospital, Dundee, UK.

[6] School of Medicine, University of St Andrews, St Andrews, UK.

Correspondence:

Ben Young, Division of Primary Care, University of Nottingham, Nottingham, UK. Email: ben.young@nottingham.ac.uk

Present Address:

Ben Young, Department of Health Sciences, University of York, York YO10 5DD, UK.

Laura Bedford, Department of Family Medicine and Primary Care, The University of Hong Kong, 3/F Ap Lei Chau Clinic, 161 Main Street, Ap Lei Chau, Hong Kong

Stuart Schembri, Canberra Health Services, Garran ACT, Australia.

Abstract

Rationale, aims, and objectives: High response rates to research questionnaires can help to ensure results are more representative of the population studied and provide increased statistical power, on which the study may have been predicated. Improving speed and quality of response can reduce costs.

Method: We conducted a randomised Study Within A Trial (SWAT) to assess questionnaire response rates, reminders sent and data completeness with unconditional compared to conditional monetary incentives. Eligible individuals were mailed a series of psychological questionnaires as a follow-up to a baseline host trial questionnaire. Half received a £5 gift voucher with questionnaires (unconditional) and half were promised the voucher after returning questionnaires (conditional).

Results: Of 1079 individuals, response rates to the first follow-up questionnaire were 94.2% and 91.7% in the unconditional and conditional monetary incentive groups respectively (OR 1.78, 95% CI 0.85 to 3.72). There were significantly greater odds of returning repeat questionnaires in the unconditional group at six months (OR 2.97, 95% CI 1.01 to 8.71; p = 0.047) but not at 12 months (OR 1.12, 95% CI 0.44 to 2.85). Incentive condition had no impact at any time point on the proportion of sent questionnaires that needed reminders. Odds of incomplete questionnaires were significantly greater at three months in the unconditional compared to the conditional incentive group (OR 2.45, 95% CI 1.32 to 4.55; p = 0.004).

Conclusions: Unconditional monetary incentives can produce a transitory greater likelihood of mailed questionnaire response in a clinical trial participant group, consistent with the direction of effect in other settings. However, this could have been a chance finding. The use of multiple strategies to promote response may have created a ceiling effect. This strategy has potential to reduce administrative and postage costs, weighed against the cost of incentives used, but could risk compromising the completeness of data.

Registration: NCT01925625, SWAT96.

Keywords

questionnaires, response rates, recruitment strategies, monetary incentives, clinical trial, randomised, SWAT

Introduction

Questionnaires are commonly used research data collection tools.[1] They are often the only feasible method of measuring self-reported variables in participant groups. In large trials, the cost of collecting data using questionnaires can be relatively small. Questionnaires can reduce bias by enabling questions to be administered in a standardised way, be validated as reliably measuring certain behavioural constructs and be completed confidentially or anonymously. Online questionnaires offer some advantages over mailed questionnaires in that they are typically quicker and less costly to send in large numbers.[2] However, emails can be mistrusted and online questionnaires can achieve lower response rates than mailed ones. For example, a survey about help-seeking behaviour in out-of-hours care sent to a large Danish nationally representative sample achieved response rates of 46% to a mailed version and 36% to an emailed version.[3] Mailed questionnaires continue to be a widely used method in health research.

High response rates to mailed questionnaires can help to ensure results are more representative of the population studied. This is because responders may be systematically different in characteristics to non-responders in a way that is relevant to the study outcomes. For example, groups of greater socioeconomic deprivation and minority ethnic groups may be less likely to respond [4] and non-response may be associated with behaviours such as tobacco use and alcohol consumption.[5] Longitudinal studies that use repeated mailed questionnaires need to minimise participant attrition over time to prevent the introduction of bias and to maintain study statistical power. In publically funded research there is an ethical obligation to make best use of resources, including use of optimal strategies to incentivise participation and retention. It is therefore important to evaluate strategies to achieve high response rates to mailed questionnaires, which can be sustained.

A systematic review and meta-analysis of 94 randomised controlled trials (Edwards review) showed the offer of monetary incentives can almost double response rates to mailed questionnaires.[6] This evidence includes questionnaires mailed within a number of different contexts, which may be

expected to have a lower response rate than among those mailed as part of a SWAT. When restricted to healthcare settings the evidence is less conclusive.[7] Monetary incentives can significantly improve retention to trials compared to no monetary incentives.[6,8] Larger monetary amounts increase the odds of response by a quarter compared to smaller amounts,[6] however there is an ethical obligation to avoid undue inducement. Individuals from the most deprived socioeconomic groups can be more difficult to engage in mailed questionnaire research even when monetary incentives are offered. A UK study found a statistically significantly lower response rate in the most deprived quartile (39%) compared to the least deprived quartile (52%).[9]

Monetary incentives can be mailed along with the questionnaire (unconditional) rather than after return of the questionnaire (conditional). A number of factors influence which of these two approaches is optimal, including their effectiveness at maximising response rates. Other effects to be considered are the number of reminders that need to be sent and the quality (completeness) of data collected. Fewer reminders can reduce mailing and administration costs and can generate more useful data if questionnaires measure time-sensitive outcomes. If data are more complete this can help to maintain statistical power, lower the risk of biased estimates and reduce the need for labour-intensive further contact to collect missing data.

Dillman's Tailored Design Method, a long-established and evolving framework for best use of survey research methods, recommends modest unconditional monetary incentives based on available evidence.[10] The Edwards review performed a meta-analysis of 24 randomised studies, showing unconditional monetary incentives can increase the odds of response to final mailed questionnaires by more than half compared to conditional monetary incentives.[6] For first follow-up questionnaires the odds of response are doubled with this approach, based on 12 studies with a total of 19,724 participants.[6] A study published since the review found an unconditional incentive of ₽50 achieved a response rate to mailed questionnaires of 37% compared to 24% for a conditional ₽300 incentive.[11] However, none of these studies were conducted within clinical trials and most were not in

healthcare settings. A systematic review of SWATs to improve host trial retention did not identify any evaluations of unconditional incentives.[8]

The only published study known to the authors of unconditional monetary incentives for mailed questionnaires in a clinical trial compared them to no incentive and only examined response at one time point. It was part of a follow-up study of patients with acute whiplash injuries recruited from emergency departments. It found the unconditional incentive slightly improved both the response rate and the proportion responding without reminders.[12]

The effect of unconditional versus conditional monetary incentives on response rates of participants in a longitudinal mailed questionnaire study as part of a clinical trial has not been previously examined. By creating a social, rather than economic, exchange it is possible that unconditional monetary incentives demonstrate trust, generate goodwill and promote a sense of obligation to return questionnaires.[10,13] Alternatively, individuals may feel less obliged to return questionnaires, particularly at the final follow-up when there may be response fatigue and all available incentives have already been received. Conditional monetary incentives may provide adequate motivation to those who perceive the monetary incentive as valuable. The incentive-specific mailings may represent a further reward by providing confirmation that returned questionnaires have been received by the study.

We aimed to evaluate the effect of unconditional versus conditional monetary incentives on response rates to initial and repeat mailed questionnaires, number of reminders sent and questionnaire completeness. We aimed to do this with a longitudinal study involving questionnaires mailed to a clinical trial participant group.

Methods

Setting

We conducted a randomised controlled Study Within A Trial (SWAT), a recommended method for generating evidence of optimal approaches to the conduct of trials.[14] We used a participant cohort from a host trial of screening for lung cancer.[15] Host trial participants had been recruited through general practices in the most deprived quintile of the population of three health trusts in Scotland, UK, as measured by the Scottish Index of Multiple Deprivation (SIMD).[16] The SIMD is the Scottish Government's official tool to identify areas of relative multiple deprivation. They were also recruited through publicity campaigns and community locations, restricted to the regions covered by the health trusts. They were eligible for the host trial due to being at increased risk of lung cancer because of their age and heavy smoking history and/or family history of lung cancer.

Participant eligibility

Participants from two host trial regions of (1) NHS Greater Glasgow and Clyde (GGC) and (2) NHS Tayside were eligible for the current study. The third host trial region (NHS Lanarkshire) had not begun recruiting during the SWAT recruitment period. They had all had a blood sample taken and been asked to complete a baseline paper questionnaire in person at a research clinic for which they received no monetary incentive. It was 16 pages long and included the Hospital Anxiety and Depression Scale,[17] Positive and Negative Affect Schedule,[18] Illness Perceptions Questionnaire,[19] Cancer Worry Scale[20] and measures of health status, health anxiety, perceived risk of lung cancer and smoking behaviour. Those who did not complete the questionnaire or did not consent to further research were ineligible for the SWAT. Immediately after completing the questionnaire, they were randomised to either a lung cancer screening or control arm. If randomised to screening their blood sample was screened for autoantibodies to lung cancer. Those who subsequently received a test result (or in the control arm reached one month from baseline) within the SWAT recruitment period were eligible for the SWAT. All eligible individuals who received a positive test result were included

in the SWAT and underwent a schedule of imaging (baseline X-ray & CT scan and four 6-monthly CT scans, or until diagnosis of lung cancer) as part of the host trial.[15] Twenty-one individuals per week were randomly sampled from those becoming eligible in each of the negative test and control groups. If there were 21 or fewer eligible from either group in a week, all eligible were included in the SWAT. This weekly cap aimed to recruit from host trial groups at an approximately equal rate, due to greater numbers of participants in two of the host trial groups (negative test and control groups) than the smaller positive test group. No stopping rules were defined for the SWAT.

Randomisation

SWAT randomisation was conducted independently by a specialist at the Tayside Clinical Trials Unit using an electronic randomisation tool. Individuals were stratified by host trial group (control arm; positive test; negative test) and ordered randomly on computer-generated lists. Half of each randomly-ordered list were then allocated to the unconditional monetary incentive group and the other half to the conditional monetary incentive group. SWAT allocations were communicated to the researchers within individual participant records on the trial database. These data were transferred securely on a weekly basis from the host trial participant database to a separate database partitioned for this SWAT.

Interventions

Both groups

Eligible individuals were mailed a follow-up questionnaire similar in content and appearance to the baseline questionnaire. The A4-sized questionnaire was sent folded in half and had participants' initials and unique study ID number hand-written on the front.

Folded around the questionnaire and voucher was a letter inviting them to take part in the questionnaire study, personalised with their name and hand-signed by two researchers. It was headed with the host trial logo (Figure 1). The letter stated '*When you gave your blood sample the*

nurse said we might send you some more surveys to fill in. […] Please complete the enclosed survey and return it to us in the freepost envelope provided within the next 7 days.' The reverse side had a full-page colour graphic displaying the logos of the stores where the voucher could be spent.

The front of the white envelopes carried the study name and logo prominently in colour. Envelopes were sent with second-class postage stamps, printed address labels and a prepaid second-class return envelope enclosed. One week after the first questionnaire was mailed a telephone call was made to check receipt of the questionnaire, answer any questions and encourage its return by emphasising the importance of the research. If telephone contact was not made after two attempts, a brief scripted voicemail was left where possible.

If a questionnaire was not returned two weeks after mailing, an identical 'reminder' copy was sent with another prepaid envelope. If the questionnaire was not returned three weeks after mailing, a reminder telephone call was attempted. Two call attempts were made and, if unsuccessful, a voicemail was left where possible. If a returned questionnaire was marked by the researchers as 'incomplete' (as defined in *outcomes*) a telephone call was attempted up to five times over five separate days to collect missing data.

The first follow-up questionnaire was sent one month after baseline in those from the host trial control arm and in the other groups a week after they were sent their screening test result (approximately one month after baseline). Repeat questionnaires were sent at three, six and 12 months after baseline and an incentive was available for every questionnaire. Participants were not randomised again for repeat questionnaires. Content and length of questionnaire varied slightly at each time point for each screening group but were all 12-15 pages in length. Cover letters stated *'Thank you for returning the previous survey. It is now time for the next one to be filled in.'* Negative-test and control participants were reminded in the 12-month cover letter that it was the final questionnaire. Positive-test participants were due to be sent further questionnaires at 18 and 24 months so their 12-month letter was the same as previous letters. This SWAT considers response

rates up to 12 months only. Response rates in the initial part of the study would be reviewed to decide whether unconditional or conditional incentives would be offered with all 18 and 24 month questionnaires.

Unconditional monetary incentive

Questionnaires had a £5 multi-store paper gift voucher attached to the front with a paper clip. The letter accompanying the questionnaires was titled '*Lung Cancer Screening Scotland Study: £5 gift voucher enclosed*.' The letter stated, *'We have also enclosed a £5 gift voucher to thank you for doing this*.' Reminder cover letters were titled '*Lung Cancer Screening Scotland Study: £5 gift voucher sent to you*.'

Conditional monetary incentive

There were no gift vouchers enclosed with questionnaires and letters stated *'£5 gift voucher available'*. On return of a completed questionnaire, a £5 voucher was mailed, attached with a paper clip to a short hand-signed thank you letter. Reminder letters stated the gift voucher was 'available' rather than 'enclosed' and voicemails reminded participants that the voucher was available. Vouchers were sent regardless of whether or not a questionnaire was incomplete.

No further contact was made with any individuals who withdrew consent from the study or the host trial, or who received a diagnosis of cancer. If individuals did not return a questionnaire after both a mailed and telephone reminder, they were recorded as non-responsive and excluded from that point onwards for the purpose of this study. All mailings and telephone calls were performed by LB and BY. Individuals not included in the SWAT were not mailed questionnaires as part of the host trial.

Outcome measures

The primary outcome was the proportion of questionnaires sent that was received at the research office at each time point. Questionnaires returned partially complete were counted as received but

questionnaires returned blank (e.g. undelivered or with a request to withdraw) were not. There was no time limit applied as to when a returned questionnaire could be counted as received. Secondary outcomes were the proportion of questionnaires sent that also needed a reminder to be sent (i.e. not received at 2 weeks after mailing) and the proportion of questionnaires received that were incomplete. An incomplete questionnaire was defined as one that had more than 50% of at least one section missing. For example, if more than 10 items were missing from the 20-item Positive and Negative Affect Schedule the questionnaire was marked as incomplete. If a respondent incorrectly ticked more than one option on an item, it was treated as missing.

Data collection

Recording of questionnaires sent, received, reminders sent, incomplete questionnaires received and vouchers sent were performed using a secure web-based participant database (HIC Recruitment Tracker, Health Informatics Centre, University of Dundee).

Sample size

It was estimated that a sample size of 279 in each condition would provide 80% power to detect an absolute difference of 10% assuming questionnaire response rates of 75% (unconditional incentive) and 65% (conditional incentive) with a 0.05 significance level. The Edwards review showed an absolute difference of 16% across all studies.[6]

Blinding

Participants were not informed about the different conditions for receiving vouchers. Researchers mailing questionnaires, vouchers and making telephone reminder calls were not blinded to condition.

Statistical methods

Data were analysed in Stata 14 software. Random effects logistic regression was used for each outcome. Data had a two-level hierarchical structure with repeated measures clustered within

participants. Models were adjusted for host trial group (control/positive test/negative test), source region (NHS GGC/NHS Tayside) and host trial minimisation variables: age group; gender (female/male); smoking status at baseline (current smoker/ex-smoker). Differences in outcomes over time between groups were assessed by adding time x group interaction terms to models.

Results

The proportion of host trial participants completing the baseline questionnaire and consenting to further research was 90.5%. Participant flow is shown in a CONSORT flow diagram (Figure 2). There were 1103 individuals randomised, 1079 (97.8%) of whom were included in the analysis. Five participants in the unconditional incentive group and one participant in the conditional incentive group did not receive the allocated intervention, for reasons explained in the flow diagram. Recruitment to the SWAT took place between January 2014 and May 2015.

Characteristics of participants in each group are shown in Table 1. Individuals randomised to receive unconditional incentives were more likely to be male and individuals randomised to receive conditional incentives were more likely to be female. All other characteristics were balanced between groups. Most participants (62%) lived in either the first or the second most deprived SIMD quintiles, reflecting the focus of host trial recruitment on areas of greater multiple deprivation. Approximately 75% of participants were from the NHS GGC region, reflecting the 3:1 host trial intended recruitment ratio between our two geographical areas.

Frequencies of outcomes in each group are shown in Table 2.

Response rate

Response rates to questionnaires were high in both groups across all time points. Proportions returning the first follow-up questionnaire were 94.2% in the unconditional incentive group and 91.7% in the conditional incentive group. Odds of returning the first follow-up questionnaire are

shown in Table 3. There was no statistically significant difference between groups (OR 1.78, 95% CI 0.85 to 3.72). The number needed to incentivise (one additional completed questionnaire) was 40.

Response to repeat questionnaires

Over the three subsequent time points response rates ranged from 94.5% to 98.1% in the unconditional incentive group and 93.1% to 96.6% in the conditional incentive group (Table 2). Odds of returning mailed questionnaires at three, six and 12 months are shown in Table 3. The odds were significantly greater in the unconditional group compared to the conditional group only for the 6 month questionnaire (OR 2.97, 95% CI 1.01 to 8.71), however the absolute difference in response rates was small (2.2%). A statistically significant difference was found between groups when comparing across all study time points (OR 1.62, 95% CI 1.02 to 2.57).

Reminders sent

Incentive condition had no statistically significant effect on the proportion of sent questionnaires that needed a reminder to be sent at any of the study time points and the odds of needing to send reminders did not differ between groups over time (Table 4).

Completeness of data

The odds of the return of incomplete questionnaires were significantly greater at three months in the unconditional incentive group compared with the conditional incentive group (OR 2.45, 95% CI 1.32 to 4.55), with an absolute difference of 4.3% in incomplete questionnaire return rates. There was no difference between groups at other time points (Table 5). There was a statistically significant difference in completeness of data when adding a time x group interaction term to the model, $p = 0.04$.

Discussion

This randomised SWAT evaluated whether unconditional monetary incentives had an impact in a longitudinal clinical study on response rates to mailed questionnaires, reminders sent and completeness of data when compared to conditional monetary incentives. Those receiving unconditional incentives were more likely to return the first follow-up questionnaire than the conditional group, confirming the direction of effect in previous studies, although the difference was not statistically significant. The return of repeat questionnaires was significantly higher in the unconditional incentive group at six months but not at three or 12 months. There were no differences between groups in the need for reminders to be sent at any time point. The unconditional incentive group were significantly more likely to return an incomplete questionnaire at three months compared to the conditional incentive group.

There were high response rates to the first follow-up questionnaire in both groups, with no significant effect of unconditional incentives. The Edwards review reported greater impact on response to a first follow-up questionnaire with unconditional compared to conditional incentives (OR 2.00, 95% CI 1.54 to 2.60).[6] This could be due to a number of factors differentiating the current study from previous studies. Firstly, participants in a clinical trial may have different reasons for responding or not responding to a questionnaire. For example, higher response rates are observed when mailed questionnaires include measures that are more relevant to participants.[6,13] Ours included emotional measures, such as lung cancer worry, and behavioural smoking measures. These may have been seen as highly salient, particularly by the 31% of participants who had received a positive lung cancer screening test result. Secondly, participants were already engaged in the host trial and had completed a baseline questionnaire in person at their first host trial clinic visit. The first follow-up questionnaire in our study was very similar in content and appearance to the baseline one. We used prominent study branding (e.g. logo, colours) so questionnaires appeared integrated within the host trial and were seen as a continuation of the 'social exchange' participants were already

undertaking. Thirdly, we implemented a number of different evidence-based measures to increase response, an approach known to improve participant retention in health care research.[21] These measures included a study logo on envelopes, hand-signed covering letters, a stated deadline for return, university sponsorship, follow-up contact, and reminder questionnaires and telephone calls for all unreturned questionnaires. The use of multiple different strategies to promote response, combined with the offer of monetary incentives, could have created a ceiling effect and enhanced participation to such a level that effect of unconditional monetary incentives was marginal.

We observed significantly greater likelihood of response in the unconditional questionnaire condition at six months but not at 12 months, but the absolute difference at six months (2.2%) was small. The 6-month questionnaire was the third questionnaire participants had been asked to complete within the preceding five months. In contrast, at 12 months participants had not been sent any other questionnaires within the previous five months and no effect of unconditional incentive was observed. This could be a chance finding, or alternatively could suggest unconditional monetary incentives are more effective at increasing response where multiple repeat questionnaires have been mailed within a relatively short period.

There was no evidence that unconditional monetary incentives discourage return of mailed questionnaires in the final follow-up of a longitudinal study (when there is no further monetary incentive to do so) compared to conditional incentives. Neither did we find the greater response to the final questionnaire with an unconditional incentive reported by the Edwards review (OR 1.61, 95 CI 1.36 to 1.89).[6] However, our 12-month questionnaire was the final one for only 69% of participants.

The relationship between monetary incentive and response to mailed questionnaires may be influenced by the value of the incentive and mediated by participant characteristics.[6] For example, UK participants living in more affluent areas were significantly more likely than those in areas of greater deprivation to respond to a mailed health behaviour questionnaire with a conditional £5

incentive but not with a conditional £2.50 incentive.[9] It is therefore useful to explore whether groups from areas of greater deprivation respond differently to those in affluent areas to more proactive recruitment and data collection methods such as the offer of unconditional monetary incentives. A USA study of unconditional incentives for completing an online questionnaire found women were more likely to respond to $5 than $10 and men were more likely to respond to $10 than $5.[22] The analysis in the current study was adjusted for gender and age but the interaction between demographic characteristics and the effectiveness of unconditional monetary incentives needs to be explored further.

Cash is probably a more effective monetary incentive than gift vouchers at increasing response to mailed questionnaires. There is uncertainty because meta-analyses have treated gift vouchers as non-monetary incentives and grouped them with incentives such as keyrings and competition entries.[6,23] It has been argued that multi-store gift vouchers are perceived and valued more similarly to cash than to non-monetary incentives.[12] Our study showed that high questionnaire response rates can be achieved when gift vouchers are used in a longitudinal clinical trial.

There was no effect of unconditional incentives on the need for reminders to be sent. Unconditional incentives have been shown previously to reduce the need for reminders after two weeks [12] but the comparison group in that study received no incentive and only 46% had responded after two weeks compared to 76% in our conditional incentive group. Two-week response rates to a first follow-up questionnaire in unconditional incentive groups were 75% in our study and 58% in the previous study. This difference could be due to the one-week follow-up call we implemented or different host trial attributes. For example, those in our study with a positive screening test had ongoing participation in a host trial imaging schedule. Our study suggests there is no difference between the effectiveness of unconditional and conditional incentives at controlling the need for reminders two weeks after mailing when the 2-week response rate is high.

Unconditional incentives more than doubled the number of incomplete questionnaires returned at three months. There is little other evidence on the impact of monetary incentives on the quality or completeness of mailed questionnaire data [24,25] but researchers should be aware an unconditional approach could lead to an increase in missing data and should be prepared to undertake further contact efforts to collect it.

Pre-host trial focus groups suggested altruism was a motivator for participation in the trial but patient views were not obtained about the design of the SWAT.[26] Such involvement might highlight important factors to aid the design and interpretation of future SWATs. The financial cost of the unconditional approach should be considered, although the administration, postage and monetary incentive costs will vary depending on the context and design of each trial. For example, studies with lower response rates and those that send repeated unconditional incentives to non-responders will incur higher costs in 'lost' incentives. We found at the first follow-up questionnaire 6% of unconditional incentives were 'lost'. For studies with tighter financial constraints an alternative approach could be to target monetary incentives to those who do not respond to the first follow-up questionnaire [27] but in longitudinal studies this could incentivise delayed response over time. The cost should be balanced against that of a conditional approach, which could involve additional labour and postage, and of which response rates are the major determinant.

The novel aspect of our study is that it is the first to examine the effects of the timing of monetary incentives on longitudinal postal questionnaire data collection in a clinical trial population. The sample size and response rates exceeded our estimates. Validity of our findings is strengthened by a randomised controlled design and blinding of participants to the experiment.

Contrary to evidence associating smoking and increased socioeconomic deprivation with low response rates to mailed research questionnaires,[4,5] very high response rates were observed in our participant group. This could have been due to host trial methods that could have influenced outcomes. Participants had already demonstrated they were good questionnaire 'completers' at

baseline in order to be eligible for mailed questionnaires. It is not known what the response rate would have been in this group with no monetary incentive offered. The high response rate in both experimental conditions, and the exclusion of participants after a single non-response, may limit the generalisability of the findings outside a similar context, population and exclusion strategy. Furthermore, the participant group was <2% non-white and there is evidence non-white minority ethnic groups are less likely to respond to mailed questionnaires.[28]

Longitudinal mailed questionnaire studies within clinical trials should consider offering monetary incentives. Our findings suggest unconditional incentives resulted in a small, but significant increase in response rates, at only one follow-up time point and a small, but significant increase in incomplete questionnaire response rates, again at only one time point. Placed within existing evidence of the effectiveness of unconditional monetary incentives, the study confirms the direction of effect and extends the evidence to longitudinal clinical trial mailed questionnaires. Trials should take into account the resources required for each strategy, as well as balancing return rates against data completeness, if deciding whether to use incentives or not, or which of the two incentive strategies to use. Differences in the research question the trial is addressing, trial participants and other trial procedures and processes may impact on response rates, so trials may wish to build in a SWAT at the planning stage to evaluate which strategy is most effective during an initial period and implement the most cost-effective approach for the rest of the trial. It is important to remember that the use and timing of monetary incentives are only one component of what should be a more comprehensive strategy to maximise response rates. This includes piloting questionnaires to improve the presentation and content, sending reminders using multiple contact methods, and ensuring mailing address databases are kept up to date.

Conclusions

Unconditional monetary incentives may lead to a greater likelihood of mailed questionnaire response in a clinical trial participant group, particularly where multiple repeated questionnaires are mailed within a relatively short period. However, there was only a statistically significant difference at a single time point (6 months) but there was a difference at other time points favouring the unconditional incentive, except at 12 months where it slightly (0.5%) favoured the conditional incentive. Unconditional monetary incentives resulted in significantly greater incomplete questionnaire responses at one time point (3 months). Trials need to balance resource use, response rates and data completeness when making decisions concerning monetary incentives. The findings confirm the direction of effect in existing evidence. More research will be required to further clarify the effectiveness of unconditional versus conditional monetary incentives in a longitudinal clinical trial context and whether unconditional incentives are more effective at specific time points.

References

1. Boynton PM, Greenhalgh T. Selecting, designing, and developing your questionnaire. *BMJ.* 2004;328(7451):1312-1315.
2. van Gelder MMHJ, Bretveld RW, Roeleveld N. Web-based questionnaires: the future in epidemiology? *Am J Epidemiol.* 2010;172(11):1292-1298.
3. Ebert JF, Huibers L, Christensen B, Christensen MB. Paper- or web-based questionnaire invitations as a method for data collection: cross-sectional comparative study of differences in response rate, completeness of data, and financial cost. *J Med Internet Res.* 2018;20(1):e24.
4. Schneider KL, Clark MA, Rakowski W, Lapane KL. Evaluating the impact of non-response bias in the Behavioral Risk Factor Surveillance System (BRFSS). *J Epidemiol Community Health.* 2012;66(4):290-295.
5. Christensen AI, Ekholm O, Gray L, Glumer C, Juel K. What is wrong with non-respondents? Alcohol-, drug- and smoking-related mortality and morbidity in a 12-year follow-up study of respondents and non-respondents in the Danish Health and Morbidity Survey. *Addiction.* 2015;110(9):1505-1512.
6. Edwards PJ, Roberts I, Clarke MJ, et al. Methods to increase response to postal and electronic questionnaires. *Cochrane Database Syst Rev.* 2009(3).
7. Nakash RA, Hutton JL, Jørstad-Stein EC, Gates S, Lamb SE. Maximising response to postal questionnaires – A systematic review of randomised trials in health research. *BMC Med Res Methodol.* 2006;6(1):5.

8. Brueton VC, Tierney J, Stenning S, et al. Strategies to improve retention in randomised trials. *Cochrane Database Syst Rev.* 2013(12).
9. Robb KA, Gatting L, Wardle J. What impact do questionnaire length and monetary incentives have on mailed health psychology survey response? *Br J Health Psychol.* 2017;22(4):671-685.
10. Dillman DA, Smyth JD, Christian LM. *Internet, Phone, Mail, and Mixed-Mode Surveys: The Tailored Design Method.* Wiley; 2014.
11. Avdeyeva OA, Matland RE. An experimental test of mail surveys as a tool for social inquiry in Russia. *Int J Public Opin Res.* 2012;25(2):173-194.
12. Gates S, Williams MA, Withers E, Williamson E, Mt-Isa S, Lamb SE. Does a monetary incentive improve the response to a postal questionnaire in a randomised controlled trial? The MINT incentive study. *Trials.* 2009;10(44).
13. Nakash RA, Hutton JL, Lamb SE, Gates S, Fisher J. Response and non-response to postal questionnaire follow-up in a clinical trial--a qualitative study of the patient's perspective. *J Eval Clin Pract* 2008;14(2):226-235.
14. Treweek S, Bevan S, Bower P, et al. Trial Forge Guidance 1: what is a Study Within A Trial (SWAT)? *Trials.* 2018;19(1):139.
15. Sullivan FM, Farmer E, Mair FS, et al. Detection in blood of autoantibodies to tumour antigens as a case-finding method in lung cancer using the EarlyCDT(R)-Lung Test (ECLS): study protocol for a randomized controlled trial. *BMC Cancer.* 2017;17(1):187.
16. The Scottish Government. Scottish Index of Multiple Deprivation 2012. 2012; https://www2.gov.scot/Topics/Statistics/SIMD/DataAnalysis/Background-Data-2012. Accessed 16 May, 2019.
17. Zigmond A, Snaith R. The Hospital Anxiety and Depression Scale. *Acta Psychiatr Scand.* 1983;67(6):361-370.
18. Watson D, Clark LA, Tellegen A. Development and validation of brief measures of positive and negative affect: the PANAS scales. *J Pers Soc Psychol.* 1988;54(6):1063-1070.
19. Lancastle D, Brain K, Phelps C. Illness representations and distress in women undergoing screening for familial ovarian cancer. *Psychol Health.* 2011;26(12):1659-1677.
20. Lerman C, Trock B, Rimer BK, Jepson C, Brody D, Boyce A. Psychological side effects of breast cancer screening. *Health Psychol.* 1991;10(4):259-267.
21. Robinson KA, Dennison CR, Wayman DM, Pronovost PJ, Needham DM. Systematic review identifies number of strategies important for retaining study participants. *J Clin Epidemiol.* 2007;60(8):757-765.
22. Boulianne S. Examining the gender effects of different incentive amounts in a web survey. *Field Methods.* 2013;25(1):91-104.
23. Church AH. Estimating the effect of incentives on mail survey response rates: a meta-analysis. *Public Opin Q.* 1993;57(1):62-79.
24. Singer E, Ye C. The use and effects of incentives in surveys. *Ann Am Acad Pol Soc Sci.* 2013;645(1):112-141.
25. Yu S, Alper HE, Nguyen A-M, et al. The effectiveness of a monetary incentive offer on survey response rates and response completeness in a longitudinal study. *BMC Med Res Methodol.* 2017;17(1):77.
26. das Nair R, Orr KS, Vedhara K, Kendrick D. Exploring recruitment barriers and facilitators in early cancer detection trials: the use of pre-trial focus groups. *Trials.* 2014;15:98.
27. Hardy P, Bell JL, Brocklehurst P. Evaluation of the effects of an offer of a monetary incentive on the rate of questionnaire return during follow-up of a clinical trial: a randomised study within a trial. *BMC Med Res Methodol.* 2016;16(1):82.
28. Evans BR, Peterson BL, Demark-Wahnefried W. No difference in response rate to a mailed survey among prostate cancer survivors using conditional versus unconditional incentives. *Cancer Epidemiol Biomarkers Prev.* 2004;13(2):277-278.

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Conflict of interest

The authors have no conflicts of interest to declare.

Authors' contributions

All authors conceived the original idea for the study and elaborated the study design. FS, SG and RL sought ethical approval. LB and BY collected data, drafted the paper and undertook the analysis. DK supervised the analysis. DK, KV, RdN, and JR supervised the study. FS and SS were the principal investigators of the ECLS trial; contributed to the design of the main trial and substudies; oversaw the conduct of the study, its analysis and the manuscript preparation. All authors and the ECLS study team monitored study progress. All authors contributed to the interpretation of data, commented critically on drafts of the paper and approved the final version.

Table 1 Participant characteristics

	Both groups n (%) [missing]	Unconditional incentive n (%) [missing]	Conditional incentive n (%) [missing]
Participants	1079 (100)	538 (49.9)	541 (50.1)
Region			
NHS GGC	807 (74.8)	410 (76.2)	397 (73.4)
NHS Tayside	272 (25.2)	128 (23.8)	144 (26.6)
Screening group			
Screening - positive test	332 (30.8)	167 (31.0)	167 (31.0)
Screening - negative test	372 (34.5)	184 (34.2)	184 (34.2)
Control	375 (34.8)	187 (34.8)	188 (34.8)
Age group			
50 – 54	243 (22.5)	127 (23.6)	116 (21.4)
55 – 59	276 (25.6)	139 (25.8)	137 (25.3)
60 – 64	226 (21.0)	106 (19.7)	120 (22.2)
65 – 69	225 (20.9)	105 (19.5)	120 (22.2)
70 – 74	102 (9.5)	57 (10.6)	45 (8.3)
75	7 (0.7)	4 (0.7)	3 (0.6)
Gender			
Female	544 (50.4)	253 (47.0)	291 (53.8)
Male	535 (49.6)	285 (53.0)	250 (46.2)
Ethnic group	[14]	[7]	[7]
White British	1047 (98.3)	519 (97.7)	528 (98.9)
Other	18 (1.7)	12 (2.3)	6 (1.1)
SIMD score quintile	[9]	[6]	[3]
1 (most deprived)	446 (41.7)	233 (43.8)	213 (39.6)
2	216 (20.2)	104 (19.6)	112 (20.8)
3	163 (15.2)	73 (13.7)	90 (16.7)
4	141 (13.2)	69 (13.0)	72 (13.4)
5 (least deprived)	104 (97)	53 (10.0)	51 (9.5)
Smoking status			
Current smoker	597 (55.3)	288 (53.5)	309 (57.1)
Ex-smoker	482 (44.7)	250 (46.5)	232 (42.9)
Smoking pack year history			
Median (interquartile range)	35 (26 – 48)	49 (26 – 46)	35 (25 – 50)

Table 2 Frequency of mailed questionnaires returned, reminders sent and incomplete questionnaires returned in unconditional and conditional monetary incentive groups

Questionnaire	Unconditional monetary incentive n (% of n sent at each time point)	Conditional monetary incentive n (% of n sent at each time point)
First follow-up questionnaire (~1 month)		
Sent	538	541
Returned	507 (94.2)	496 (91.7)
Reminder sent	132 (24.5)	133 (24.6)
Returned incomplete	43 (8.0)	38 (7.0)
3 months		
Sent	505	494
Returned	477 (94.5)	460 (93.1)
Reminder sent	147 (29.1)	152 (30.8)
Returned incomplete	40 (7.9)	18 (3.6)
6 months		
Sent	475	458
Returned	466 (98.1)	439 (95.9)
Reminder sent	138 (29.1)	124 (27.1)
Returned incomplete	26 (5.5)	31 (6.8)
12 months		
Sent	462	437
Returned	444 (96.1)	422 (96.6)
Reminder sent	133 (28.8)	131 (30.0)
Returned incomplete	30 (6.5)	26 (6.0)

Table 3 Odds of returning mailed questionnaires with unconditional monetary incentives compared to a conditional monetary incentives

Questionnaire	OR* (95% CI)	P value
All time points	1.62 (1.02 - 2.57)	0.040
First follow-up questionnaire	1.78 (0.85 - 3.72)	0.125
3 months	1.55 (0.71 - 3.35)	0.271
6 months	2.97 (1.01 – 8.71)	0.047
12 months	1.12 (0.44 - 2.85)	0.810
Difference in ORs over time		0.383

*Adjusted for screening group, source region and host trial minimisation variables

Table 4 Odds of a reminder sent for a mailed questionnaire with unconditional monetary incentives compared to conditional monetary incentives

Questionnaire	OR* (95% CI)	P value
All time points	0.95 (0.74 - 1.21)	0.669
First follow-up questionnaire	0.98 (0.68 - 1.43)	0.930
3 months	0.86 (0.60 - 1.25)	0.429
6 months	1.10 (0.75 - 1.62)	0.627
12 months	0.87 (0.59 - 1.28)	0.478
Difference in ORs over time		0.702

*Adjusted for screening group, source region and host trial minimisation variables

Table 5 Odds of returning an incomplete mailed questionnaire with unconditional monetary incentives compared to a conditional monetary incentives

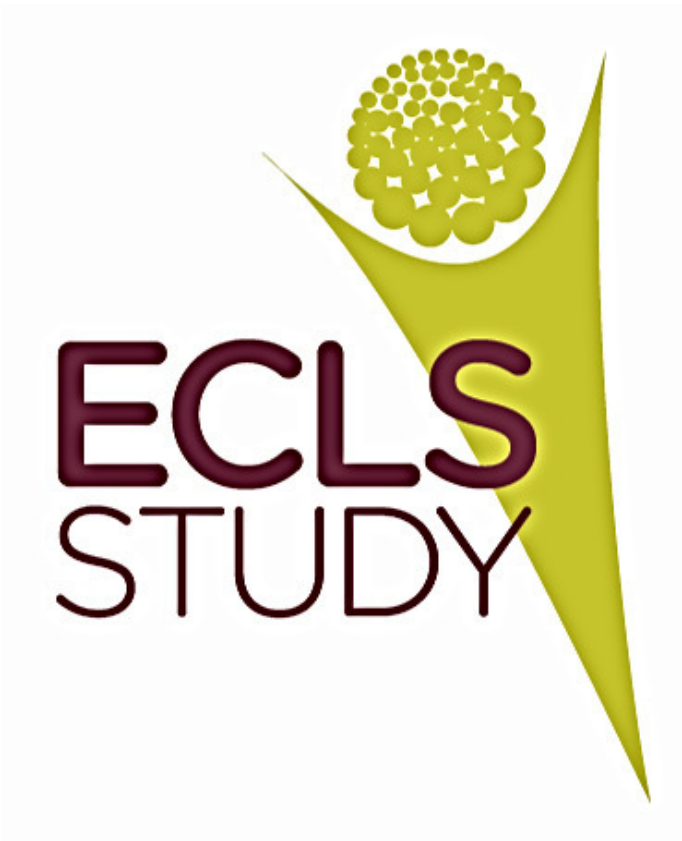
Questionnaire	OR* (95% CI)	P value
All time points	1.24 (0.91 - 1.70)	0.179
First follow-up questionnaire	1.17 (0.71 - 1.93)	0.546
3 months	2.45 (1.32 - 4.55)	0.004
6 months	0.77 (0.43 - 1.40)	0.395
12 months	1.11 (0.61 – 2.01)	0.737
Difference in ORs over time		0.041

*Adjusted for screening group, source region and host trial minimisation variables

Figures

Figure 1. Host trial logo

Figure 2. CONSORT flow diagram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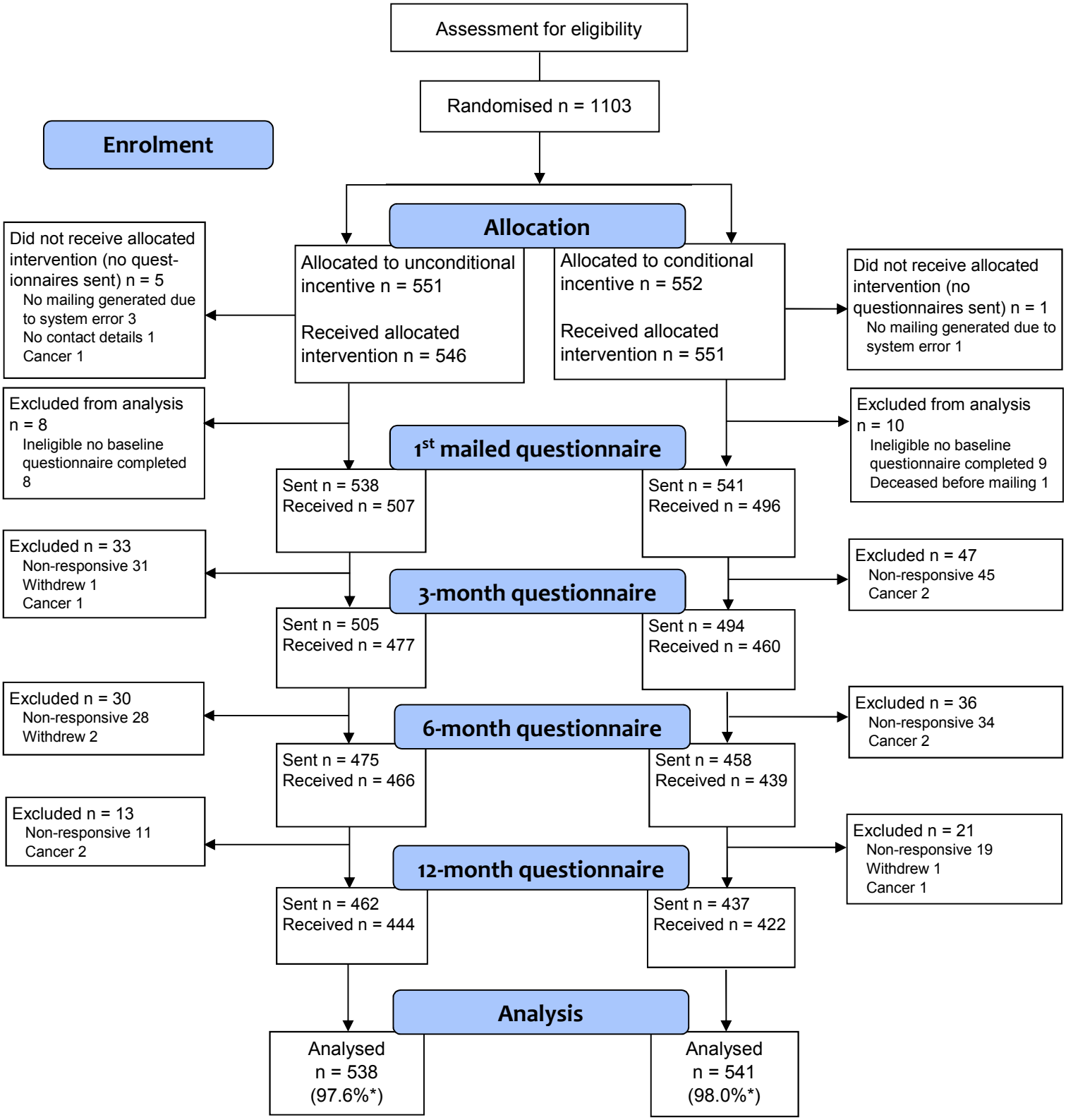

*Percentage of individuals allocated to condition.