Enclosing a pen reduced time to response to questionnaire mailings: an embedded RCT and meta-analysis

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Abstract

Objective

To assess the effectiveness of including a pen in postal questionnaires on response rate, necessity of reminders, time to response and completeness of response to the primary outcome question (POQ).

Study design and Setting

A two-arm RCT embedded within the SCOOP (Screening of older women for prevention of fracture) trial. Women, aged 70-75 years, were randomised to receive a pen with their questionnaire (n=3826) or to receive the questionnaire alone (n=3829). The results were combined with another embedded RCT in a meta-analysis.

Results

A response rate of 92.4% was observed in the pen group compared to 91.3% in the control group (OR=1.16, 95% CI:0.98-1.37, p=0.08). There was a difference in reminders required (OR=0.88, 95% CI:0.79-0.98, p=0.02), time to response (HR=1.06, 95% CI:1.01-1.11, p=0.01) and some difference in the completeness of response to the POQ (OR=1.18, 95% CI:1.00-1.39, p=0.05). The pooled OR from the meta-analysis for response rate was 1.21 (95% CI:1.05-1.39, p=0.01).

Conclusion

Inclusion of a pen with postal questionnaires potentially has a positive impact on response rates and the number of reminders required. There may be some reduction in time to response. Studies of different participant groups are needed to test the effectiveness over more diverse populations.

Keywords: Randomised controlled trial, Postal questionnaire, Response rate, Pen, Incentive, Embedded trial

Running title: Enclosing a pen in postal questionnaires

What is new?

- Including a pen with follow-up questionnaires reduces the number of reminders required and the time to response.
- Meta-analysis with the only other existing trial-within-trial in this field reiterates the potential effectiveness of improving questionnaire response by also sending a pen.
- Enclosing a pen in postal questionnaires is an effective low-cost way to improve reponse in randomised controlled trials.

1. Introduction

Postal questionnaires are a useful tool in health research and are frequently employed as a means of collecting outcome data in randomised trials. They are particularly useful in contexts where interview techniques would result in considerable expense, resource use, or participant burden. Postal questionnaires can also be beneficial in reducing observer bias and social desirability bias where patient responses are anonymised [1, 2].

There is an increasing demand from funders for efficient trials. Preparing and distributing a large number of postal questionnaires can be both time consuming and costly. Consequently, a major consideration of improving the efficiency of trials is ensuring response rates are high for the first mailing sent out to participants; thus reducing the time, resources and costs associated with reminders and follow-up telephone calls. Poor response to postal questionnaires will reduce a study's statistical power and potentially introduce selection bias both in survey research and randomised controlled trials leading to poorer quality results from which reliable conclusions cannot be drawn [3, 4]. Although guidelines exist to aid the design of questionnaires, including tailoring surveys based on a priori knowledge of the topic and the intended population of respondants [5, 6], this does not always ensure high response rates. It is therefore important to identify other viable methods of increasing response rate and maximising retention.

Some of the established methods of increasing response rates, such as monetary recompense for participation and sending postal questionnaires via recorded delivery [7-9], are costly. Additionally, there is debate over whether monetary incentives are truly ethical. A cheaper and less contraversial method of increasing response rate is to include a non-monetary incentive with the questionnaire such as a pen; however, there is disagreement in the literature as to whether or not this is sufficiently effective.

There have been a number of systematic reviews appraising the literature surrounding non-monetary incentives to increase response rates [3, 7, 10]. Together, these have identified five trials evaluating the effect of adding a pen or pencil to

postal mail outs on response rate [11-14]. Two of these aimed to increase response rates to stand-alone surveys, one to clinicians [12] and one to smokers [11], one aimed to increase response to a study recruitment invitation [14], and two aimed to increase response to a study follow-up survey [13, 14]. Only one of these trials took the same methodological approach as the present work, embedding a trial of including a pen to increase response rate within an ongoing host trial [10]. The study was a 2x2x2 factorial trial embedded within the TOMBOLA study (Trial Of Management of Borderline and Other Low grade Abnormal smears) of cervical cytology surveillance, evaluating the effect on response rates of: i) enclosing a TOMBOLA-branded pen with the questionnaire; ii) sending the questionnaires by first class post (as opposed to second class); and iii) enclosing a preaddressed return envelope on which there was a second class postage stamp (rather than a freepost business-reply envelope) [13]. The study population was women due to receive a TOMBOLA psychosocial questionnaire between June and August 2003 for the 12, 18, 24, 30, 34 or 36 months' follow-up. A statistically significant increase in response rate was found when a pen was included with the questionnaire (from 61.5 to 68.5%, p=0.002; odds ratio 1.36, 95% CI 1.04 to 1.79). Although the study reported an increase in staff time, due to the necessity to manually frank envelopes containing a pen for postage, given the small price of the pen (14 pence), the method was considered relatively low cost for the level of effectiveness.

Of the four trials that were not embedded within a broarder randomised controlled trial, two reported a significant increase in response [13, 14], whilst the remaining two actually reported a decrease in response rate, though not significantly [11, 12]. There was considerable heterogeneity between the studies in terms of sample size, target population (study participants, clinicians, general public), and the reason for mailout, i.e. invitation to a trial, cross-sectional survey or follow-up survey.

Given the different efficacy outcomes between trials, the impact of enclosing a pen with postal queastionnaires may be different for different populations and in different contexts.

In this paper we describe an RCT we conducted that was embedded in the SCOOP study (Screening of older women for prevention of fracture) trial which is a large

pragmatic screening trial among older women for the prevention of fractures [15]. Both the wider SCOOP study and the pen sub-study gained ethical approval from North West Research Ethics Committee.

2. Methods

The primary aim of this trial was to compare the effect of receiving a trial-branded pen with the 60-month follow-up questionnaire of SCOOP participants with receiving the 60-month follow-up questionnaire alone on response rates. The trial was embedded within the Medical Research Council funded SCOOP trial (ISRCTN 55814835), a randomised controlled trial assessing the effectiveness and cost-effectiveness of screening for osteoporosis in older women for prevention of fractures. The primary outcome for SCOOP was self-reported fracture of any bone over the previous 12 months.

The secondary aims of this trial were to assess whether receiving the pen had an effect on: the number of reminders sent, the completeness of the response to the primary outcome question, the level of completeness of the questionnaire as a whole, and the time to return the questionnaire to the study centre.

2.1. Population, design and intervention

SCOOP participants were aged 70-85 at the onset of the trial and were recruited from GP practices in 2008. Women were randomly allocated to either the screening or control arm. Those in the screening arm received a 10-year fracture risk assessment calculated using a WHO risk algorithm computed from baseline questionnaire data and bone mineral density values measured via a DXA scan in selected participants [16, 17]. Where risk assessment values lay above an age-dependent threshold, the prescribing of standard treatment (oral bisphosphonates) was considered by the participant's GP. For women in the control arm, fracture risk was not calculated and participants continued to receive usual care.

All trial participants were followed up using postal questionnaires at 6 and 12 months post-randomisation and then annually up to five years. The pen trial was initiated in

the fifth year of follow-up when participants were considered most at risk of becoming lost to follow-up. Prior to the introduction of the pen trial, the questionnaire content and administration process at each time-point had been consistent, although a study newsletter was added to 50% of the follow-up questionnaire packs at the 36 months follow-up [18] and to all 48 month follow-up questionnaire packs. Reminder notices were sent approximately 18 days after the initial questionnaire if no response had been received by that time. Following continued non-response, a follow-up telephone call was administered approximately 12 days after the follow-up reminder notice. After three attempts to contact participants by telephone the participant was considered a non-responder at that particular time-point.

2.2. Sample size and randomisation

As is usual with an embedded trial within a trial, a formal power calculation was not undertaken and the sample size was constrained by the number of participants remaining consented to receive the 60 month follow-up paper questionnaire. Five of the seven centres recruiting to SCOOP took part in the pen study, giving a good geographical spread of women. We anticipated that sending out around 4,000 pens would provide approximately 60% power to detect an absolute difference of 5% (2p = 0.05) in response rates between the two groups, assuming a control rate of 90%.

A computer randomisation package was used to allocate all eligible participants to either receive a pen bearing the SCOOP study logo with their 60-month questionnaire or receive their 60-month questionnaire alone. No additional pens were included with any subsequent reminder mailings.

2.3. Outcomes

The primary outcome measure was the overall questionnaire response rate, which was calculated as the number of participants who returned the 60-month follow-up questionnaire divided by the number of participants who were sent a questionnaire. The secondary outcome measures were: whether a reminder was required (number of participants requiring a reminder mailing divided by the number of participants who were sent a questionnaire); completeness of the response to the primary

outcome question (number of participants with a response for the main trial primary outcome question divided by the number of participants returning a questionnaire); and time to response (length of time taken to return the questionnaire). In a post-hoc secondary analysis recommended by the reviewer, we compared the level of missingness across 26 key variables in the questionnaire between the two groups. These included the primary analysis question, two key questions on current medication use, the 12 items of the SF-12, the 5 items of the EQ-5D Index, and the 6 items of the State-Trait questionnaire. For most of the other items in the questionnaire, a response was conditional on the answer to either the primary analysis question or the two key medication questions, and so these items were not counted in this analysis.

2.4. Statistical analysis

All analyses were conducted in Stata version 13 [19] using 2-sided tests at the 5% significance level on an intention-to-treat basis. Categorical data were compared using logistic regression, time to response by a Cox proportional hazards model, and count of missing items by negative binomial regression. All models were adjusted for both the pen sub-study allocation (pen or no pen) and the SCOOP main trial group allocation (screening or control). The odds ratio (OR), hazard ratio (HR) or incidence rate ratio (IRR) associated with the pen allocation variable from each model is presented with its 95% confidence interval (CI) and p-value.

2.5 Meta-analysis

We searched the recent Cochrane systematic review of interventions to reduce trial attrition for embedded trials of enclosing a pen with a questionnaire mailing and found a single study by Sharp and colleagues (described previously [10]). We combined the results of this study with ours in a fixed effects meta-analysis.

2.6 Costing

The pen incurs a cost both in the purchase (18 pence) and additional postage costs (additional 22 pence). Bases on the observed difference in response of 1.1%, an

estimate of the potential cost per retained participant due to the inclusion of a pen is calculated accounting for the observed reduction in the number of reminders. The cost of preparing and sending a reminder notice was estimated at £1.97 per reminder (considering paper and printing (£0.50), postage including outgoing and return envelopes (£0.95) and two mintues of secretarial time (£0.52)).

3. Results

12495 women were recruited into SCOOP from seven centres; and five centres (who had recruited 9008 women to SCOOP) agreed to take part in the pen sub-study. We randomised 7655 participants (1353 participants had died or had withdrawn from questionnaire follow-up in the preceding 60 months) with 3826 (50.0%) women allocated to receive a pen with their 60-month questionnaire (intervention group), and 3829 (50.0%) to receive their 60-month questionnaire alone (control group). Some individuals were excluded from the analysis: death before mailing (n=64; n=32, intervention; n=32, control); participant opted to receive follow-up by telephone only (n=2; n=1, intervention; n=1, control); participant lost to follow-up (n=3; n=1, intervention; n=2, control); participant declined further self-report before mailing due (n=3; n=2, intervention; n=1, control); and mailing not sent in error (n=1, intervention participant) (Figure 1).

The randomisation was known not to have been adhered to in 26 participants in the intervention group. These participants did not receive a pen with their mailing as allocated but were included in the pen arm for analysis under the principles of intention-to-treat.

Questionnaire response rate

The total number of participants returning a 60-month follow-up questionnaire was 6962 out of 7582 (91.8%). Analysis showed that there was weak evidence of a difference in response rates between the two groups (pen: 3500/3789 (92.4%); no pen: 3462/3793 (91.3%); OR 1.16, 95% CI 0.98 to 1.37, p=0.08).

Reminders sent

The total number of participants requiring a reminder mailing to be sent out was 1794 out of 7582 (23.7%); 853 out of 3789 (22.5%) in the intervention group and 941 out of 3793 (24.8%) in the control group. Analysis showed that there was evidence of a difference in the proportion of participants requiring a reminder between those that received a pen with their original mailing and those that did not (OR 0.88, 95% CI 0.79 to 0.98, p=0.02).

Completeness of the response to the primary outcome question

Of those individuals returning a 60-month questionnaire, the total number with a complete primary outcome measure was 6958 out of 6962 (99.9%). Analysis showed that there was some evidence of a difference in the proportion of participants providing complete primary outcome data in the 60-month questionnaire (pen: 3499/3500 (100.0%); no pen: 3459/3462 (99.9%); OR 1.18, 95% CI 1.00 to 1.39, p=0.05).

Level of completeness of the questionnaire

The distribution of the number of missing responses is virtually identical between the pen and no pen groups (Figure 2). Three-quarters of participants had a valid response for all 26 items (pen: 2658/3500 (75.9%); no pen: 2635/ 3462 (76.1%)). There was no evidence of a difference in the level of completeness of the questionnaire between the two groups (IRR 1.00, 95% CI 0.87 to 1.16, p=0.95).

Time to response

The median time taken to return the 60-month questionnaire was 13 days (interquartile range [IQR] 8 to 20 days) in the pen arm, and 13 days (IQR 8 to 21 days) in the no pen arm. There was evidence of a difference in the time to response between the two arms (HR 1.06, 95% CI 1.01 to 1.11, p=0.01; Figure 3).

Meta-analysis

A meta-analysis of this study with the other 'trial within a trial' identified from the Cochrane systematic review that evaluated the use of enclosing a pen with a mailing to improve response rates [13] yielded a pooled OR of 1.21 (95% CI 1.05 to 1.39, p=0.01) (Figure 4). This is similar to our observed OR of 1.16 (95% CI 0.98 to 1.37, p=0.08). There is negligible heterogeneity in the meta-analysis (chi-squared 1.02, df=1, p=0.31; I^2=2.1%).

Costing

Assuming the 1.1% difference in response rates was a 'true' effect, the number of participants required to be sent a pen to achieve one additional returned questionnaire relative to not being sent a pen is 91 (1/0.011=90.9); therefore, the cost per additional participant retained is approximately £36 (91 x 40 pence).

However, including a pen did save on resource use, most notably the cost of preparing and sending reminder mailings, which is estimated at £1.97 per reminder. The absolute difference in the percentage of participants in the two groups who were sent a reminider mailing was 2.3%. Therefore, approximately (1/0.023) 43 people are required to be sent a pen to prevent one reminder mailing and to save £1.97. Consequently, approximately two fewer reminder mailings are required per retained participant reducing the cost per retained participant to an estimated £32.

4. Discussion

We have undertaken a large embedded 'trial within a trial' of including a non-monetary gift in the form of a trial-branded pen with postal questionnaires to older women recruited into the SCOOP trial of screening for osteoporosis. The absolute difference in proportion of returned questionnaires was 1.1% (from 91.3% to 92.4%), and the odds ratio of 1.16 (95% CI 0.98 to 1.37) was of borderline statistical

significance (p=0.08). Given the low cost of adding a pen to the mail out, even a small improvement in response rate could be considered beneficial.

The results did show evidence of a significant reduction in the number of reminder notices required and the time to response. The difference in time to response was small (Cox proportional hazards regression HR 1.06, 95% CI 1.01 to 1.11); however, with such a large sample size, this small effect is statistically significant (p=0.02). There was further evidence of an improvement in the completeness of the response to the primary outcome question, but not to the level of completeness of the questionnaire as a whole.

These findings add to a small number of studies exploring the value of adding a pen to postal surveys. Whilst some trials have indicated populations or contexts where the addition of a pen may not be beneficial, such as within a clinician-based population [12], the present work suggests that the addition of a pen may be valuable for an older female patient population already participating in a randomised controlled trial. The findings are consistent with an earlier trial that showed an increase in response to a follow-up survey [14], and a trial that showed an increase in response to a recruitment mailout [14]. The findings are also broadly consistent with those of an earlier sub-study conducted within the SCOOP trial which explored pre-contact with a SCOOP newsletter six weeks before the 24-month questionnaire [18]. An increased response rate of 1.5% was observed, which, whilst statistically significant, was small. The small differences we observed in this and the SCOOP embedded pen trial will be partially a function of the very high underlying response rates, which exceed 90%, making it difficult for any intervention to have a large effect. Nevertheless, retaining an additional participant per 91 is likely to be worthwhile when we consider the costs of doing so and the costs of the initial recruitment, treatment and follow-up of the participant which would be wasted in the event of non-response.

Taken together, the findings from the present trial and those from previous work suggest there are likely to be populations for whom the addition of a pen to postal questionnaire holds more value as an incentive. Further research across a range of participant groups should be considered to evaluate this.

Although conducted on a large sample (thus increasing the power to the study), there are some limitations to this study. First, the response rate in the population as a whole was high (91.8%), likely due to an already robust follow-up method incorporating both postal reminders, newsletters and telephone calls. Additionally, the SCOOP study also had a comprehensive system for monitoring lost to follow up participants and deaths which means that questionnaires were not sent to anyone who it was known to the team would not respond which may have had an impact on overall response rate. It may be that in trials that do not have these processes the effect on the response may be more marked. Therefore, the study had a limited capacity in which to increase response rates and consequently, the true value of adding pens to postal questionnaires may not mave been realised. Second, although large, the sample was constrained entirely to older females which somewhat limits the generalisability to other samples. Nevertheless, the study has clearly highlighted the potential value of including a pen in postal questionnaires, both to improve response rate and save on resources.

5. Conclusions

We conclude that the addition of a pen in postal questionnaires does have a positive impact on response rates to questionnaire follow-ups of RCT participants. The response rate increased, the time to response was slightly reduced and fewer reminders were sent. Cost savings are achieved as a consequence of the reduction in the number of reminders required, saving resources and staff time. Further studies in different participant groups would be helpful to test the effectiveness over more diverse populations. Indeed, both existing studies (TOMBOLA and SCOOP) are comprised entirely of women so whether men respond to the enclosure of pens is unknown.

Figure 1. Flow diagram for SCOOP pen sub-study

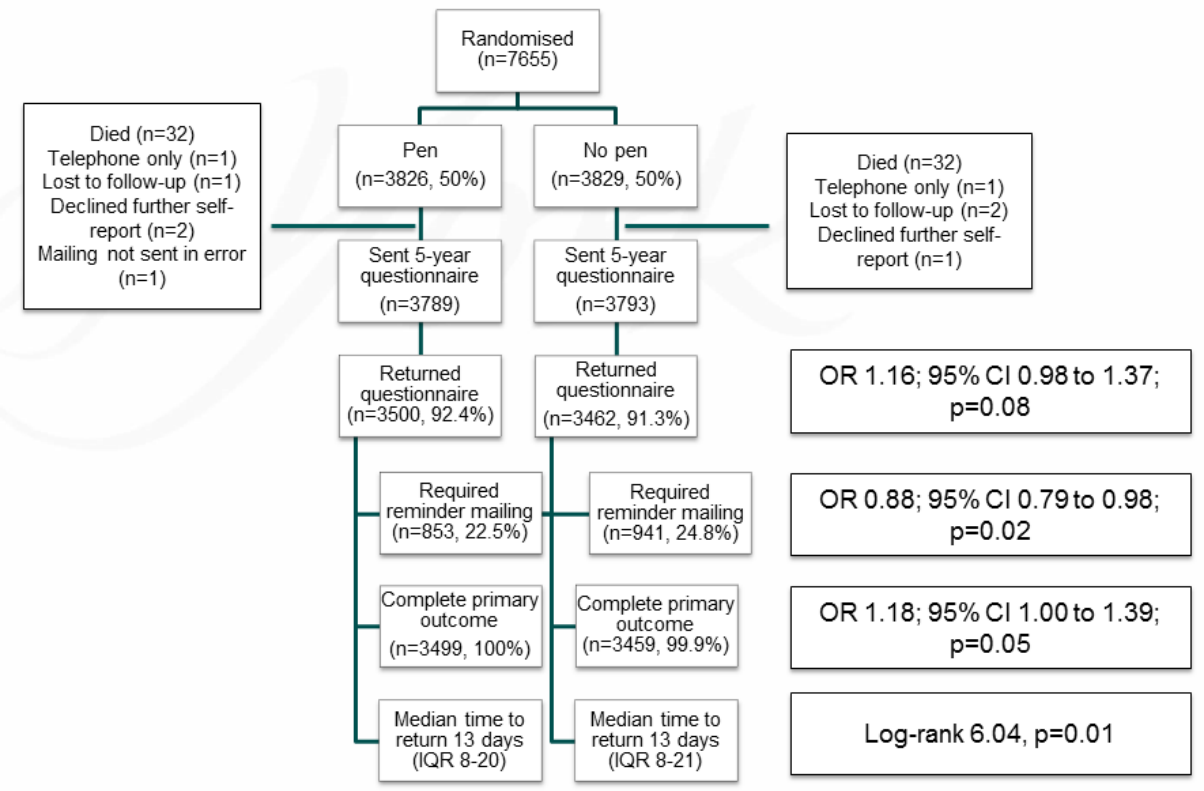


Figure 2. Distribution of number of missing items in questionnaire between pen and no pen groups

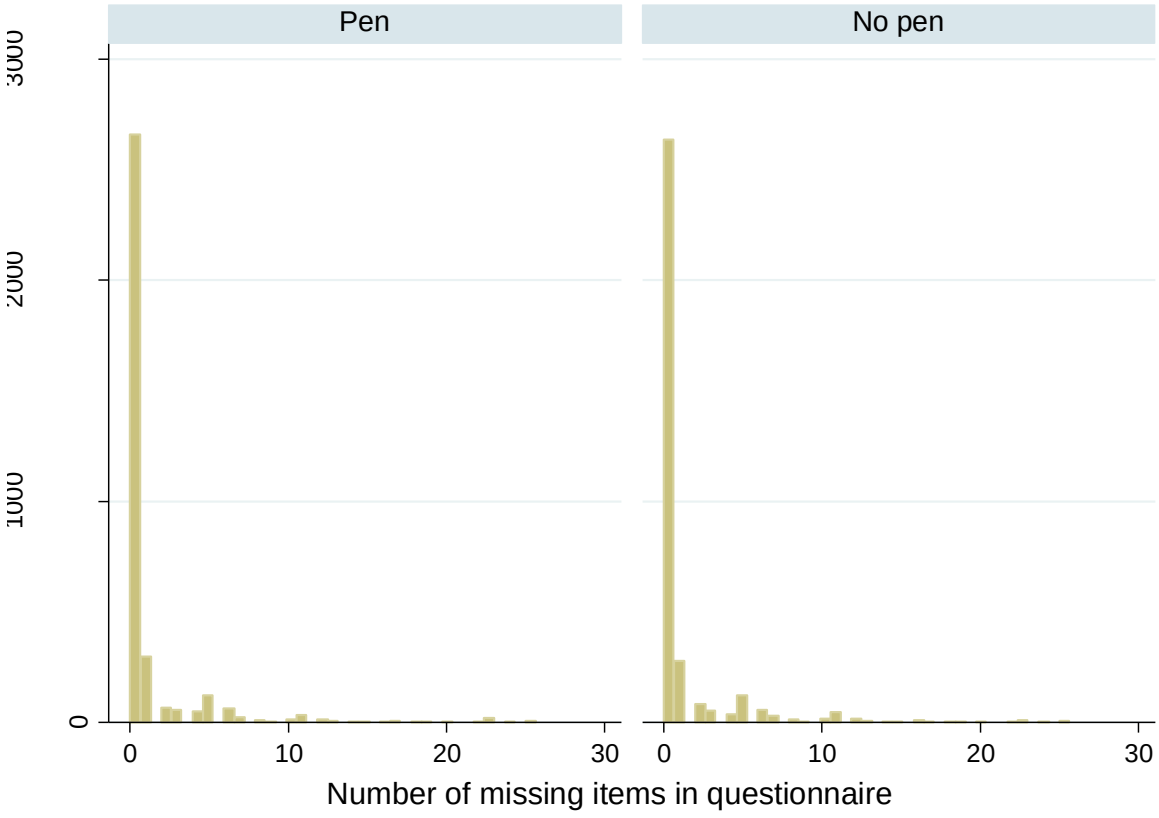


Figure 3. Kaplan-Meier curve for time to response

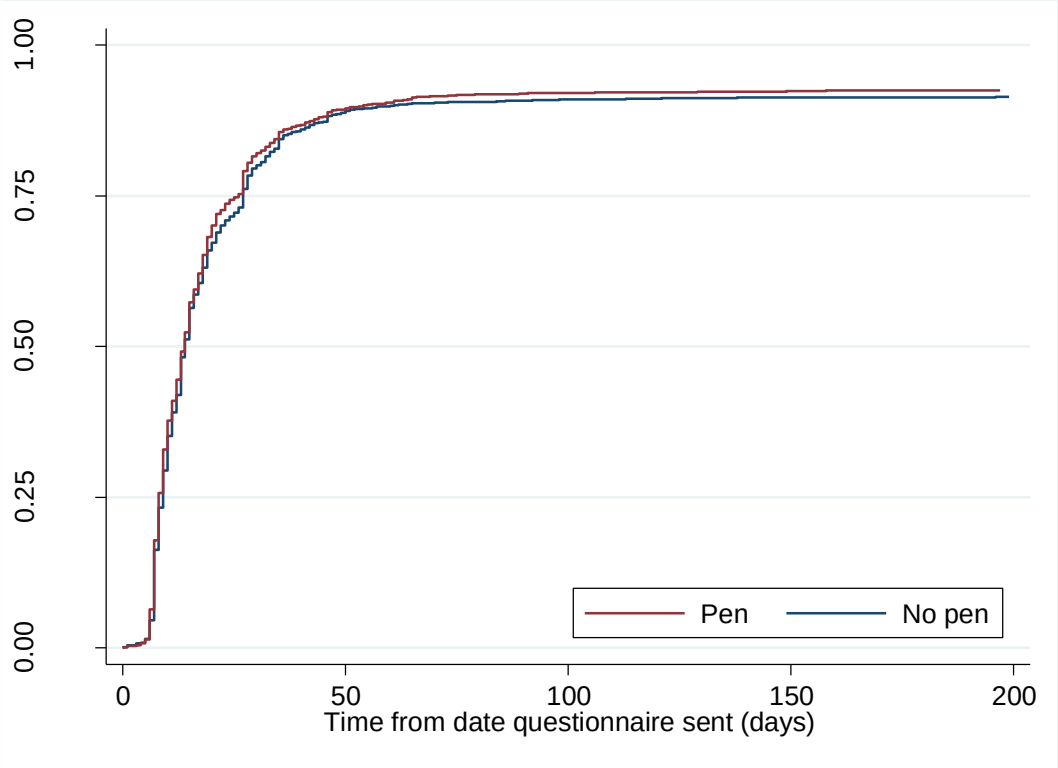
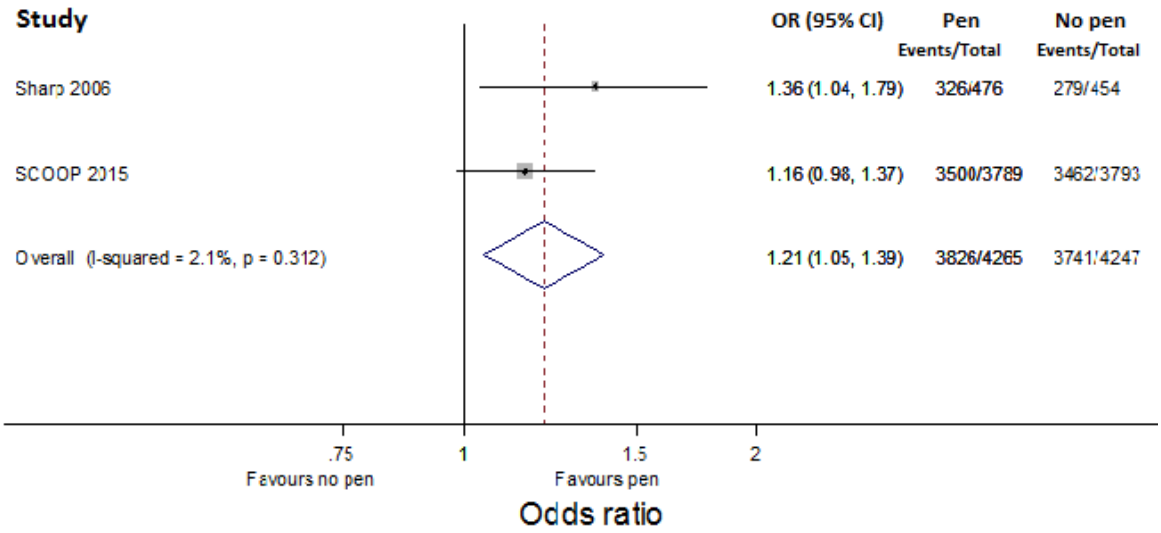


Figure 4. Meta-analysis of embedded studies of pens



Competing interests

We declare that all authors have no non-financial interests that may be relevant to the submitted work.

Ethical approval

This sub-study was approved by the North West Research Ethics Committee.

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Transparency declaration

We can confirm that the manuscript presents an honest, accurate and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

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