Ancillary study to BUMPES: Protocol for the evaluation of the effects of an offer of an incentive on the rate of questionnaire return

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1. Background

Maximising follow-up rates for postal questionnaires for randomised controlled trials is an important aspect of a well designed and well conducted study. Loss to follow-up can lead to bias and compromise the internal and external validity of the results.

Use of incentives to promote questionnaire return in clinical trials has been researched. Existing systematic reviews suggest they are effective,[65, 66] but not all studies have sufficient funds to use them. Promising an incentive once data are returned can reduce the cost burden of this approach. Brueton *et al.*[66] showed evidence that an offer of a monetary incentive was comparable to the addition of a monetary incentive with the questionnaire (pooled risk ratio 1.04, 95% confidence interval 0.91 to 1.19). However, it may be possible to provide further cost-savings if the offer was restricted to the reminder letters only.

We propose to evaluate the effect of promising a monetary incentive at first mail out versus a promise on reminder letters only, with the incentive being posted out on receipt of a completed follow-up questionnaire. This randomised controlled trial (RCT) will be nested within the BUMPES RCT (a study of position during the late stages of labour in women with an epidural) and will be carried out on a population of women in the UK one year after the birth of their first child.

2. Objective

To assess the effectiveness on the return rate of the 1 year follow-up postal questionnaires for BUMPES of a promise of a monetary incentive made at the point of sending the questionnaire for the first time compared to a promise made on reminder letters only.

3. Trial Design

Parallel group, randomised controlled trial nested within BUMPES.

4. Study setting

All women randomised into the BUMPES study, who consented to be contacted at 12 months and who have not yet been sent their 1 year follow-up questionnaire, will be included. The BUMPES study is a multicentre randomised controlled trial in women who are admitted to a participating labour ward ≥37 weeks' gestation with no previous pregnancy and with a low dose epidural in situ. A follow-up questionnaire is sent to the woman asking for information on their health and wellbeing, as well as health service use 1 year following the birth of their baby.

5. Eligibility criteria:

Inclusion criteria

- Recruited to BUMPES
- Consented at recruitment to receive follow up questionnaire
- 1 year questionnaire not sent

Exclusion criteria:

- Women who had stillbirths
- Women whose infants have died
- Address details unknown
- Woman and infant not living at same address

6. Interventions

Women will be randomly allocated to the following two groups:

1. Incentive cover letter. This will contain details of a promise of a monetary incentive when the questionnaire is first sent. A £10 gift voucher redeemable at high street shops will be sent to the woman on return of a completed questionnaire. The covering letter will include a sentence explaining that the voucher is to thank participants for their time and effort. All reminder letters will include a sentence about the incentive.
2. Incentive reminder letters. The standard cover letter (as currently used) will not mention any incentive. All subsequent reminder letters sent if the questionnaire is not returned, will detail the promise of an incentive. A £10 gift voucher redeemable at high street shops will be sent to the woman on return of a completed questionnaire.

For both groups women will also be contacted electronically or via text messaging if the contact details have been collected. The content of the emails and texts sent will reflect the group to which the woman was randomised. All women will also be provided with an option of completing the questionnaire online.

7. Outcomes

The primary outcome will be questionnaire return, defined as receipt of a completed or partially completed questionnaire at the BUMPES office. As a secondary outcome we will analyse the number of questionnaires returned without chasing by the study team. There is a standard procedure for chasing missing questionnaires; if the incentive increases the proportion returned without chasing this will save time for the study team. We will also report the total cost of the vouchers sent out by nested study arm.

8. Sample size and feasibility

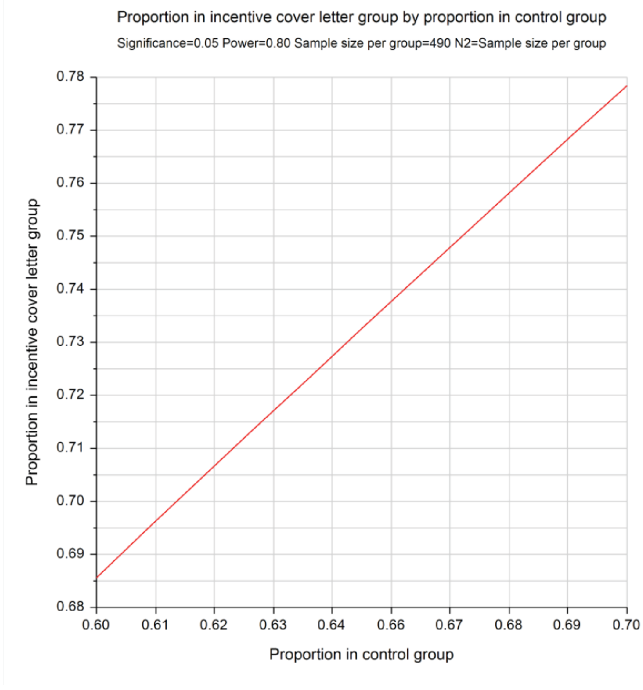
The sample size will be predetermined by the numbers of questionnaires remaining to be sent at the point of start of the nested study.

BUMPES started recruiting in October 2010 and finished in January 2014. A total of 3236 women were randomised. It is estimated that approximately 1,150 women will remain to be followed up at the start date of this study (currently estimated to be beginning August 2014). Assuming that approximately 15% of these women will be excluded from receiving the questionnaire due to stillbirth, infant death, address details unknown or different to the infant, 980 women will be eligible to be randomised in the nested study (approximately 490 per group).

In order to assess the detectable effect size possible with the given sample size, we need to estimate a control group risk based on current literature. Khadjesari *et al*[67] investigated the use of an offer of an incentive (a £10 Amazon gift voucher) versus no offer of an incentive on follow-up rates in an online trial. They found an increase of 9% (95% CI 5% to 12%) when using the offer of an incentive. Kenyon *et al*[68] investigated the use of a monetary incentive included in reminder letters versus no incentive and found an improvement in the response rate between the two groups of 11.7% (95% confidence interval 4.7% to 18.6%).

The follow-up questionnaire return rate for BUMPES up to June 2014 was 59%. Assuming that this could increase by at least 5% with the use of an offer of an incentive either with an incentive cover letter or an incentive reminder letter only, a sample size of 980 is sufficient to demonstrate an increase in questionnaire return of 8% from 64% in the incentive reminder letter group to 72% in the incentive cover letter group at a 2-sided 5% significance level with 80% power. Figure 1 illustrates the proportion detectable in the incentive cover letter group for control group risk varying between 60% and 70%. The detectable difference lies between 8% and 8.5% for varying control group estimates.

Figure 1: Proportion in incentive cover letter group by proportion in control group



Randomisation to the incentive nested study will start as soon as practical, and continue until all questionnaires and reminders have been sent.

9. Randomisation

Allocation will be by computer random number generation stratified by BUMPES allocation and by centre.

Randomisation to incentive cover letter or incentive reminder letter will occur at each woman's next follow-up point during the conduct of the BUMPES study. Each BUMPES participant will be randomised to incentive cover letter or incentive reminder letter once only.

10. Blinding

Trial staff will be aware of allocation due to the nature of the interventions, and the practicalities involved in sending the letters and the vouchers.

11. Data collection

Recording of questionnaire receipt, date received and voucher sent will be made using the current trial administration systems. Postal versus online receipt will also be recorded.

12. Statistical analysis

Baseline demographic information will be summarised by randomised group using frequency counts and percentages for categorical data and means and standard deviations, or medians with interquartile ranges for continuous data.
Differences in risk and risk ratios along with their 95% confidence intervals to compare the proportions of questionnaires returned between randomised group will be presented.

13. Consent

No consent from participants will be sought for this trial.

14. Dissemination

The results of this study will be submitted for publication in a peer reviewed journal, and disseminated to the relevant Cochrane review group. The Medical Research Council Methodology Hubs will also be notified as they are collecting information on such studies for a database of RCT methodological work.

15. Funding

No additional funding will be required to carry out this study. All costs will be covered by the BUMPES study Health Technology Assessment award.