Results
This review identified 151 individually randomised controlled trials from 778 NIHR HTA reports. The final recruitment target sample size was achieved in 56% (85/151) of the RCTs and more than 80% of the final target sample size was achieved for 79% of the RCTs (119/151). For 34% (52/151) of trials the original sample size target was revised (downward in 79% (41/52)). The median recruitment rate (participants per centre per month) was found to be 0.92 (IQR 0.43 to 2.79) and the median retention rate (proportion of participants with valid primary outcome data at follow-up) was estimated at 89% (IQR 79% to 97%).
Conclusions
Based on this review for most publicly funded trials the recruitment rate is likely to be between 1 and 2 participants per centre per week (4 to 10 a month). There is considerable variation in the consent, recruitment and retention rates in publicly funded RCTs. In practice, recruitment rates will vary, depending on whether the target population is acute, where opportunistic recruitment will target incident cases, or chronic, where database recruitment can effectively target prevalent cases. It will also vary according to whether the intervention is therapeutic or preventive and the base incidence and prevalence rate of the condition. Investigators should bear this in mind at the planning stage of their study and not be overly optimistic about their recruitment projections.

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Do higher monetary incentives improve response rates part-way through a randomised control trial?

Jessica Wood[1], Jonathan A. Cook[2], Jemma Hudson[1], Alison McDonald[1], Hanne Bruhn[3], Angus J. M. Watson[4]
[1]Centre for Healthcare Randomised Trials (chart), Health Services Research Unit, University of Aberdeen; [2]Nuffield Department of Orthopaedics, Rheumatology & Musculoskeletal Sciences, University of Oxford; [3]Health Economics Research Unit, University of Aberdeen; [4]Department of Surgery, NHS Highland
Correspondence: Jessica Wood
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Background
During routine monitoring in the ethos study (a surgical trial comparing Stapled Haemorrhoidopexy with Traditional Haemorrhoidectomy for the treatment of grade II-IV haemorrhoids), it was found that the response rates to the 12 and 24 month follow-up postal questionnaires were lower than expected. Literature reviews looking at methods to increase response rates identified monetary incentives as one potential way to boost response rates1-2. Two Studies With-in a Trial (swats) were conducted within ethos to assess the effectiveness of a small unconditional voucher and a higher value conditional voucher on response rates to the postal questionnaires. Following no effect of a lower value voucher incentive (£5.00) being found in increasing response rates in the study (SWAT1), the team designed an additional study to evaluate if a higher value monetary incentive would be more effective in increasing questionnaire response rates.
Methods
Participants enrolled in ethos who had not yet received their 12 and/or 24 months follow-up questionnaires were included in SWAT2. All participants were sent a covering letter with their postal questionnaires which informed them that they would receive a £30 high street voucher as a token of appreciation upon receipt of a completed questionnaire. The primary analysis was a before and after analysis of the effect of the voucher in increasing response rates at each time-point. A sensitivity analysis was also carried out due to the overlapping influence of SWAT 1.
Results
In total 586 and 562 participants were included in the 12 and 24 month analyses respectively in SWAT2. Results showed no statistical evidence of an effect on the response rates at both 12 and 24 month time-points. Similarly, the sensitivity analyses results showed no evidence of a difference in the 12 month response rates after the incentive was given. At 24 months there was a slight increase in response rates (before 71.4%, after 75.9%) but it was not statistically significant, 95% CI [0.87,1.80].
Discussion
Both studies highlight that, despite current literature to the contrary, the use of monetary incentives may not increase questionnaire response rates in all study populations and could even have a negative impact. There are a number of contextual aspects which may explain this unexpected finding. Care is needed when introducing a new intervention into an ongoing trial. Future evaluations of incentives are needed to explore the impact of contextual issues which may moderate their impact and influence in different study settings.

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Recruitment aids for a phase II randomised trial in low risk bladder cancer

Steven Penegar[1], Rebecca Lewis[1], James Catto[2], Joanne Cresswell[3], Leyshon Griffiths[4], Micki Hill[1], John Kelly[5], Allen Knight[6], John McGrath[7], Laura Wiley[1]
[1]The Institute of Cancer Research; [2]University of Sheffield; [3]South Tees Hospitals NHS Foundation Trust; [4]University Hospitals of Leicester NHS Trust; [5]University College London; [6]Patient representative; [7]Royal Devon & Exeter NHS Foundation Trust
Correspondence: Steven Penegar
Trials 2017, **18(Suppl 1):**P66

Background
Non-muscle invasive bladder cancer (NMIBC) is a locally recurring disease for which patients undergo long term surveillance following initial diagnosis. CALIBER is a multicentre phase II feasibility study comparing intravesical chemotherapy (chemoresection) with surgery (standard of care) in patients with recurrent low risk NMIBC (2:1 chemoresection:surgery randomisation). The primary aim is to assess complete response to chemoresection and the trial is randomised to test feasibility of recruitment to a larger randomised phase III trial.
It was anticipated that patient recruitment would be challenging due to the need to identify potential participants at the time of recurrence prior to treatment, complex risk stratification criteria and varied treatment pathways across participating sites. As such we developed recruitment aids with the aim of raising awareness amongst potential participants, ensuring site staff remain aware of the trial and promoting effective liaison between site staff when suitable patients are identified.
Methods
From the outset of the trial, ethics approved short patient information leaflets and posters have been available to highlight the trial to patients attending surveillance visits. A staff poster was also provided to raise awareness amongst staff conducting surveillance. A CALIBER specific risk calculation tool was introduced in March 2016 as an aid to assess eligibility. We surveyed 34 participating centres about their use of these aids and their use of the tools was compared to their average recruitment.
Results
Responses were received from 26/34 centres. 25/26 (96%) are using at least one of the short patient information leaflet, patient poster, clinician poster or eligibility. Average monthly recruitment does not appear to increase with increased use of the tools, with a median recruitment of 0.21 for the 8/26 (31%) sites using two tools and 0.03 for the 6/26 (23%) sites using all four.
Since distributing the CALIBER risk calculator, the number of eligibility queries received by the coordinating clinical trials unit has substantially decreased. Initial feedback from centres suggests it is a useful tool for local pre-screening. Centres are advised to print the