SWAT 255: Effectiveness and cost-effectiveness of offering a choice of gift voucher incentive for increasing participant recruitment and retention rates in the Halo trial

Objective of this SWAT

To assess the effectiveness and cost-effectiveness of offering a choice of gift voucher incentive for increasing participant recruitment and retention rates in the Halo trial.

Additional SWAT Details

Primary Study Area: Recruitment & Retention Secondary Study Area: Incentives and engagement Who does the SWAT intervention target: Participants Estimated resources needed to conduct the SWAT: Low

Estimated cost of the SWAT (£): There are no additional costs associated with this SWAT.

Findings from Implementation of this SWAT

Reference(s) to publications of these findings: Primary Outcome Findings: Cost:

Background

This Study Within a Trial (SWAT) [1] is embedded in a randomised trial of Halo, a multi-component digital intervention to increase correct and consistent condom use amongst 16-24 year olds (ISRCTN51957984).

Monetary incentives are commonly used to encourage trial participation and improve retention by motivating participants to complete follow-up questionnaires or attend assessment appointments. Cochrane methodology reviews have found that monetary incentives may improve recruitment and retention compared to no incentives, but the certainty of the evidence is low [2,3].

Systematic reviews of recruitment and retention strategies [2-4], the James Lind Alliance recruitment and retention priority-setting exercises [5,6], and research from the NIHR-funded Implement SWATs and Trial Forge SWAT Network all identify monetary incentives as a key area for evaluation [7]; and there are important uncertainties about the effectiveness of different incentive types, including whether to offer cash or vouchers, and if using vouchers, which types are most effective. Discussions with approximately 40 trial teams in the UK and Ireland, as part of the Implement SWATs programme, revealed that while most institutions provide monetary incentives, implementation varies widely, often without an evidence-based rationale.

One potentially effective, but untested, incentive strategy is offering participants a choice of gift vouchers from different retailers. Previous SWATs evaluating voucher incentives have only provided a single type of voucher, such as from AmazonTM or Love2Shop. Flexibility in voucher choice may be particularly appealing to younger participants (aged 16–24 years at baseline) in the Halo Trial and might positively impact recruitment and retention rates. It is theorised that vouchers for use in supermarkets may be particularly appealing to young people with a lower socio-economic status or students. Furthermore, observations on ethical consumption among young people have found that their purchasing choices are often guided by social, environmental, and ethical considerations [8,9]. As part of these ethical considerations, some participants may view certain retailers, such as AmazonTM, as problematic due to reported concerns over their social, environmental, and ethical practices [10].

Host Trial Population: -

Host Trial Condition Area: Public Health and Prevention

Interventions and Comparators

Intervention 1: Potential participants will be offered a choice of gift vouchers from one of the following three retailers: Amazon™, Life:style or Love2Shop. They will be informed that they will

have a choice of voucher in the participant information sheet (PIS). The PIS will include information on the key features of each of the three vouchers, and a link to the retailers' websites for full information on where these can be spent and how they are redeemed. The vouchers will be sent electronically by email. Participants will be asked to choose their preferred voucher at baseline, immediately upon completion of eligibility questions at the end of the PIS, and this same voucher type will be given at all subsequent timepoints. The vouchers will be offered on a conditional basis, given in varying amounts for completing trial activities.

Intervention 2: Participants will not be offered a choice of voucher and will be sent the standard voucher, which is an Amazon™ voucher. The voucher, consisting of a code to enter at checkout, will be sent electronically by email. The vouchers will be offered on a conditional basis, given in varying amounts for completing trial activities.

Method for Allocating to Intervention or Comparator: Randomisation

Outcome Measures

Primary Outcome: Recruitment rate, defined as the proportion of SWAT participants who are randomised into the Halo trial.

Secondary Outcomes: 1) Retention rates, defined as the proportion of SWAT participants retained in the Halo trial for 3, 6 and 12-month follow-up.

- 2) Time to collection of outcome data (days from scheduled date) for 3, 6 and 12-month follow-up.
- 3) Number of reminders sent to participants before completion of follow-up assessment for 3, 6 and 12-month follow-up.
- 4) Questionnaire completeness (e.g., primary outcome measure obtained) for 3, 6 and 12-month follow-up.
- 5) Unit costs, defined as the costs incurred for each participant in the SWAT. If the effect of the intervention is positive, the cost-effectiveness outcome will be reported as the incremental cost per additional participant recruited.
- 6) Harms or unintended effects, to be collected as feedback from participants about the vouchers they received (i.e., number of participants who provided feedback and a short description of the feedback as negative or positive).

The effects of the strategies in different participant populations will be explored, including sex, age, ethnic and socio-economic subgroups.

Analysis Plans

An 'intention-to-treat' analysis will be performed. The primary outcome will be the absolute (risk difference) and relative difference (odds ratio) in recruitment rate (i.e., proportions randomised to the host trial between those offered a choice of voucher (intervention group) and those not offered a choice of voucher (control group).

For the primary outcome analysis, comparison of the response rate between the two SWAT groups will use logistic regression. The between-groups difference will be presented as number (%) and as both adjusted absolute (i.e., risk difference) and relative (i.e., odds ratio or relative risk) effect estimates, with 95% confidence intervals from the logistic regression model. Demographic characteristics, including age and ethnic group will be presented descriptively as mean (standard deviation) or number (%), as appropriate.

The following methods will be used for the secondary outcome analyses:

- 1. Retention rates: Numbers (proportions) retained in the two SWAT groups at each time-point will be analysed following the same method as the primary outcome, using suitable statistical techniques.
- 2. Time to collection of outcome data: The between-groups difference in time taken to collection of outcome data will be analysed using techniques suitable for time to response (event) data such as Kaplan-Meier curves, log-rank test or Cox regression. Time zero will be set as 'day before expected completion date' (equivalent to adding 1 to the time variable to avoid exclusion from the analysis set).

- 3. Number of reminders sent to participants before completion of follow-up assessment: The number of follow-up reminders will be compared using a Poisson regression model, or a zero-inflated Poisson regression model if there is a large quantity of zeros.
- 4. Questionnaire completeness: The analysis of questionnaire completeness will be as for the primary outcome.
- 5. Costs: All relevant costs associated with each intervention will be aggregated to estimate the average cost per participant in each SWAT group. Unit costs, both direct and indirect including the costs of the vouchers will be calculated and reported in GB£ and adjusted to current price levels, with any necessary inflation adjustments made using the Consumer Price Index. The cost-effectiveness outcome will be reported as the incremental cost per additional participant recruited or retained (if the effect of the intervention is positive). This should be calculated by dividing the difference in unit costs between the intervention and control groups by the percentage point difference in recruitment or retention rates between these groups.
- 6. Harms or unintended effects: will be reported descriptively using any feedback from potential participants in relation to the incentive they received, such as number of participants who provided feedback and a short description of the feedback, as negative or positive.

Subgroup analysis may also be performed for key demographic subgroups (sex, age, ethnicity and socio-economic status) by adding interaction terms to the logistic regression model, where the sample size is deemed sufficiently large.

Possible Problems in Implementing This SWAT

References Cited in This Outline

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- 2. Treweek S, Pitkethly M, Cook J, et al. Strategies to improve recruitment to randomised trials. Cochrane Database of Systematic Reviews 2018;(2):MR000013. doi: 10.1002/14651858.MR000013.pub6
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- 4. Gkekas A, Evans A, Parker A, et al. A systematic review of economic evaluations alongside studies within a trial (SWATs) for improving recruitment and retention in randomised controlled trials. Research Methods in Medicine & Health Sciences 2023;4(3):94-112. doi: 10.1177/26320843221147838
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- 6. Brunsdon D, et al. What are the most important unanswered research questions in trial retention? A James Lind Alliance Priority Setting Partnership: the PRioRiTy II (Prioritising Retention in Randomised Trials) study. Trials 2019; 20:593.
- 7. Parker A, Way R, Okanlawon AA, et al. WP1: Identifying and prioritising trial recruitment and retention strategies. OSF 2024, February 8. doi: 10.17605/OSF.IO/CZ829 8. Banaji S, Buckingham D. THE CIVIC SELL: Young people, the internet, and ethical consumption. Information, Communication & Society, 2009;12(8):1197–223. doi: 10.1080/13691180802687621
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References to This SWAT

Source of This SWAT

People to show as the source of this idea: Halo trial team- University of Hertfordshire Dr Stefanie Williams- Trial Manager Professor Katie Newby- Joint-Chief Investigator Professor Katherine Brown- Joint-Chief Investigator

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