SWAT 65: Strategies to optimise retention to an online randomised controlled trial for relatives of people with severe mental illness

Objective of this SWAT

To determine the relative effectiveness and costs associated with a lower value (\pounds 10) compared to a higher value (\pounds 20) of reward, and conditional compared to unconditional reward, in improving retention in an online randomised trial.

Study area: Retention Sample type: Carer/Parent Estimated funding level needed: Unknown

Background

Online trials are particularly suited to evaluating self-management interventions using self-report measures [1]. Advantages of an online trial include the potential to reach a greater number and range of participants who may be underrepresented in face-to-face trials, and are more representative of the population likely to use an online intervention; to recruit more people over a shorter timeframe as many people can register and be assessed simultaneously; for secure randomisation and data entry without need for complex blinding protocols; and for a much cheaper trial due to the need for fewer staff [2]. There are also important challenges, one of which is poor retention to follow-up.

Payment incentive has the strongest evidence to support its effectiveness in increasing follow-up completion rates [3, 4]. However, the amount of payment, and whether it is offered conditionally or unconditionally remains an area of uncertainty. We will test the relative effectiveness and costs associated with a lower value (£10) compared to a higher value (£20) of reward, and whether the reward is conditional or unconditional. We will embed this SWAT in the REACT randomised trial, for the 24 week follow-up.

Interventions and comparators

Intervention 1: £10 conditional Intervention 2: £10 unconditional Intervention 3: £20 conditional Intervention 4: £20 unconditional

Index Type: Incentive

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Retention to the trial on the primary outcome measure (General Health Questionnaire, GHQ-28) at 24 weeks. Secondary: Cost (i.e. £10 versus £20)

Analysis plans

We will test the relative effectiveness and costs associated with a low value reward (£10) versus a higher value (£20) and a conditional versus unconditional reward. The REACT randomised trial requires a sample size of at least 666. Assuming that the retention rate will be 70% for a conditional reward of £10 and based on evidence that the retention rate will be increased by both a higher reward, and making it unconditional, this sample gives 84% power at the 5% significance level to determine a 10% absolute difference (from 70% to 80%) in retention between conditional or unconditional reward and lower value versus higher value reward.

Retention rates (defined as the proportion of participants who provide primary outcome data, GHQ-28, at 24 weeks) will be assessed for

1) value of the reward (£10 versus £20)

2) conditional versus unconditional nature of the reward

The number (proportion) of participants providing 24-week follow up data will be presented and compared using the chi-square test (or the Fisher's Exact test, if any expected counts are <5). The independent impact of intervention group on retention rates will be explored by including intervention group along with value of the reward (or un/conditional nature of the reward) as an explanatory variable in logistic regression.

Possible problems in implementing this SWAT

The rewards are delivered electronically, so the SWAT relies on the system working properly. If participants who receive different levels of reward discuss this among themselves, it could lead to dissatisfaction among those receiving the lower value, thereby reducing their willingness to complete the measures.

References

Mathieu E, McGeechan K, Barratt A, Herbert R. Internet-based randomized controlled trials: a systematic review. Journal of the American Medical Informatics Association 2013;20(3):568-76.
Murray E, Khadjesari Z, White IR, et al. Methodological challenges in online trials. Journal of Medical Internet Research 2009;11(2):e9.

3. Brueton VC, Tierney J, Stenning S, et al., Strategies to improve retention in randomised trials. Cochrane Database of Systematic Reviews 2013;(12):MR000032.

4. David MC, Ware RS. Meta-analysis of randomized controlled trials supports the use of incentives for inducing response to electronic health surveys. Journal of Clinical Epidemiology 2014;67(11):1210-21.

Publications or presentations of this SWAT design

Lobban F, Robinson H, Appelbe D, et al. Protocol for an online randomised controlled trial to evaluate the clinical and cost-effectiveness of a peer-supported self-management intervention for relatives of people with psychosis or bipolar disorder: Relatives Education And Coping Toolkit (REACT). BMJ Open 2017;7:e016965.

Examples of the implementation of this SWAT

People to show as the source of this idea: Professor Fiona Lobban Contact email address: f.lobban@lancaster.ac.uk Date of idea: 1/APR/2015 Revisions made by: Date of revisions: