

SWAT 93: Offer of a free yoga class to participants in the control group on completion of the trial follow-up, to enhance retention and reduce contamination

Objective of this SWAT

To evaluate the effects of offering a free yoga class versus nothing after the 12-month follow-up assessment on rates of retention and contamination in the participants in the control group of a randomised trial.

Study area: Retention, Contamination

Sample type: Participants

Estimated funding level needed: Low

Background

In many yoga trials, participants are randomised to either a yoga intervention or usual care (i.e., no yoga) control group. Given the nature of the intervention, blinding of the participants to their allocation is not possible, which can then create undesirable consequences in these trials because of disappointment among members of the control group who do not receive the yoga intervention. First, recruitment of participants for the trial may be compromised because eligible patients decline because they do not want to be randomised to the control group [1]. Second, patients who enrol may be highly motivated to undertake yoga and, therefore, those randomised to the control group may begin yoga or increase their physical activity levels independently [2]. This non-compliance by controls may lead to a decrease of power to detect a significant intervention effect. Last, patients who first agreed to participate may drop out after being randomised to the control group.

Various trial designs have been used to address these issues with control group participants: (i) instructions given before the start of the intervention, (ii) offering the intervention to control patients during the intervention period, and (iii) offering the intervention to control patients after the intervention [3]. In some trials, the control group is asked to either maintain their usual lifestyle pattern during the study period or to refrain from performing yoga or any other forms of exercise. Other trials offered the control group an alternative intervention during the study period, such as stretching exercises. Finally, in some studies an intervention is offered after completion of the study. This is the design that we have chosen to test in this SWAT.

The systematic review of Bisschop et al. provided an overview of these different types of control groups in exercise-oncology trials and explored the influence on contamination and drop-out rates [4]. The lowest contamination and drop-out rates were observed in studies with control groups that were offered an intervention after the intervention period (contamination in 7.1% of studies, excess drop-out rate $-4.7 \pm 9.2\%$), but randomised trials are needed to clarify the effects of delayed interventions.

In this SWAT, we will evaluate the effects of offering a free yoga class versus nothing after the 12-month follow-up assessment on rates of retention and contamination in the control group participants. The information leaflet for the main trial will make patients aware that some participants in the control group will be randomised to receive a one-off yoga class. After randomisation to the main trial, participants allocated to the control group will be randomised again to receive the offer of a one-off group yoga class which will take place when final follow-up is completed; or no offer. Participants randomised to receive the offer of a one-off class will be informed immediately after randomisation.

Interventions and comparators

Intervention 1: Offer of a free one-off group yoga class after the main trial's follow-up is complete

Intervention 2: No offer of a yoga class

Index Type: Incentive

Method for allocating to intervention or comparator

Randomisation

Outcome measures

Primary: Proportion of participants who return at least one questionnaire (3, 6 or 12 months).

Secondary: Proportion of participants who return all three questionnaires (3, 6 and 12 months), and proportion of control participants who report using yoga during the host trial's 12 month follow-up.

Analysis plans

Binary data will be compared using logistic regression, time to response by a Cox proportional hazards model, and completeness of response by a linear regression model. All models will adjust for age, gender, and allocation for a separate factorial SWAT that is embedded at the recruitment stage (anyone not randomised into the factorial trial will be considered in the no incentive group).

Possible problems in implementing this SWAT

Potential problems delivering the classes due to withdrawal of teachers from this aspect of the project.

References

1. Courneya KS, Forbes CC, Trinh L, Sellar CM, Friedenreich CM, Reiman T. Patient satisfaction with participation in a randomized exercise trial: effects of randomization and a usual care posttrial exercise program. *Clinical Trials* 2013;10(6):959-66.
2. Hertogh EM, Schuit AJ, Peeters PH, Monninkhof EM. Noncompliance in lifestyle intervention studies: the instrumental variable method provides insight into the bias. *Journal of Clinical Epidemiology* 2010;63(8):900-6.
3. Waters L, Reeves M, Fjeldsoe B, Eakin E. Control group improvements in physical activity intervention trials and possible explanatory factors: a systematic review. *Journal of Physical Activity and Health* 2012;9(6):884-95.
4. Bisschop CNS, Courneya KS, Velthuis MJ, Monninkhof EM, Jones LW, Friedenreich C, et al. Control group design, contamination and drop-out in exercise oncology trials: a systematic review. *PLoS One* 2015;10(3):e0120996.

Publications or presentations of this SWAT design

Examples of the implementation of this SWAT

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