

Substudy 4: Does offering a free yoga session to control participants after the 12-month follow-up assessment enhance retention and reduce contamination?

Introduction

In many yoga trials, participants are randomised to either a yoga intervention or a 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. 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.⁹³ Further, 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.⁹⁴ This non-compliance by controls may lead to a decrease of power to detect a clinically important intervention effect. Last, participants randomised to the control group may experience resentful demoralisation and withdraw from the trial.

Various trial designs have been used to address these issues with control group participants: (1) instructions given before the start of the intervention (e.g. 'Please don't change your level of exercise/physical activity during the course of the study'⁹⁵), (2) offering an alternative intervention to control patients, such as education about exercise, stretches, etc. and (3) offering the intervention to control patients after the intervention (e.g. in wait-list or cross-over study design).⁹⁶ The latter strategy was evaluated in this SWAT.

The systematic review of Bisschop *et al.*⁹⁵ provided an overview of these different types of control groups in exercise-oncology trials and explored the influence on contamination and dropout rates.⁹⁵ The lowest contamination and dropout rates were observed in studies with control groups that were offered an intervention after the intervention period (contamination in 7.1% of studies, excess dropout rate $-4.7 \pm 9.2\%$), but randomised trials are needed to clarify the effects of delayed interventions.

The objective of this methodological SWAT was to evaluate the effects of offering a free yoga class after the 12-month follow-up assessment versus no offer on rates of retention and contamination in the usual care group participants.

Methods

Study design

This SWAT was a two-armed RCT embedded in the GYY trial.¹ The SWAT was registered with the Northern Ireland Network for Trials Methodology Research SWAT repository on 1 April 2019 (SWAT93; www.qub.ac.uk/sites/TheNorthernIrelandNetworkforTrialsMethodologyResearch/SWATSWARInformation/Repositories/SWATStore/).

Participants

This study included participants allocated to the usual care arm of the GYY trial. Participants in the intervention arm were included in a different retention SWAT, namely the inclusion or not of a pen with the 3-month follow-up questionnaire (described in the previous section).

After randomisation to the main trial, participants allocated to the usual care group were immediately randomised again to receive: the offer of a one-off group yoga class which would take place after their 12-month follow-up is completed, or no offer. Participants randomised to receive the offer of a one-off class were informed immediately after randomisation.

Participants were informed in advance, via the main trial PIS, that some participants in the usual care group would be randomised to receive a one-off yoga class. Specific consent for the SWAT was not obtained; this was approved by the REC as it was considered low risk. Written informed consent for the GYY main trial was obtained from all participants who took part.

Intervention

Intervention

Offer of a one-off GYY class which took place after the final (12-month) follow-up was completed.

Comparator

No offer of a yoga class.

Outcome measures

The primary outcome was the proportion of participants in each group who returned at least one of the follow-up questionnaires (3, 6 or 12 months). Secondary outcomes included the proportion of participants who returned all three follow-up questionnaires and the proportion of usual care participants who reported use of non-GYY yoga throughout the trial follow-up.

Sample size

All usual care participants in the host trial were randomised into this embedded trial. The host trial recruited 454 participants (240 intervention; 214 usual care). A sample size of 214 gave us 80% power to detect an increase in the percentage of participants returning at least one follow-up questionnaire from 85% in the no-offer arm to 96% in the offer arm.

Randomisation

Simple 1 : 1 randomisation was used to allocate usual care participants to receive or not to receive, the offer of the free yoga class.

Statistical analysis

Analyses were conducted under the principles of ITT using two-tailed tests at the 5% significance level. Analyses were conducted in Stata version 17.³⁴ Binary data were compared using logistic regression. The treatment effect is presented as an OR with an associated 95% CI and *p*-value.

Results

In total, 214 participants were randomised into the usual care group of the GYY trial, of which 111 (51.9%) were allocated to receive the offer of the free yoga class and 103 (48.1%) to receive no offer.

Usual care participants offered a free yoga class were slightly more likely to return at least one of the post-randomisation follow-up questionnaires (*n* = 104, 93.7%) than usual care participants not offered a free yoga class (*n* = 91, 88.4%), though this difference was not statistically significant (OR 1.96, 95% CI 0.74 to 5.19; *p* = 0.18).

There was no evidence of a difference in the likelihood of participants returning all three post-randomisation follow-up questionnaires (offer of a free yoga class *n* = 87, 78.4% vs. no offer *n* = 82, 79.6%; OR 0.90, 95% CI 0.46 to 1.77; *p* = 0.76).

There was no evidence of a difference in the likelihood of participants reporting use of non-GYY yoga throughout the trial follow-up (offer of a free yoga class *n* = 15, 13.5% vs. no offer *n* = 15, 14.6%; OR 0.92, 95% CI 0.42 to 1.98; *p* = 0.83).

Discussion

The results of this trial do not indicate any demonstrable benefit of offering a free yoga class versus no offer after the 12-month follow-up assessment on rates of retention and contamination in the usual care group participants in the GYY trial. Although usual care participants offered a yoga class were slightly more likely to return at least one of the post-randomisation follow-up questionnaires compared to 'no offer' participants, the difference was not statistically significant. However, this trial was underpowered to detect a 5 percentage point difference, as was observed.

To our knowledge, this is the first SWAT investigating the offer of a single free intervention session after study completion on retention and contamination within a control group of a trial. Our study does not support the findings of Bisschop *et al.*,⁹⁵ where the lowest contamination and dropout rates were found in control groups offered an intervention after the intervention period; however, this is not entirely comparable to our study as it combines different intervention offers and not just a single free intervention session. Our study supports the finding of Courneya *et al.*⁹⁷ in terms of contamination, who suggest that offering the intervention to control participants at the end of the study was not sufficient to eliminate the contamination. In the study by Courneya *et al.*,⁹⁷ however, participants were asked not to initiate any structured exercise over the course of the intervention, so again not entirely comparable to our study.

The strength of this study was that it was a randomised trial; however, since it was conducted in a population of older adults with multimorbidity, particularly during the COVID-19 pandemic, findings may not be generalisable to other populations or contexts.

The GYY trial provided information on the importance of the control group in the PIS at the start of the study that may have lessened the potential benefit of the offer of a free yoga class at the end of the study on contamination. It was pointed out by Courneya *et al.* that a suggested solution to contamination is to ensure that participants understand the implications of random assignment and what is expected of them in each group before joining the study.⁹⁷ Alternatively, participants in the control arm may have under-reported yoga participation because they know it is important for the control group to abstain from yoga practice. It did not, however, state in the GYY trial PIS that control participants should not practise yoga or take part in other exercises.

Being assigned to a control group may be disappointing to participants and, consequently, some may continue or begin an exercise programme despite their group assignment.⁹⁸ Additional physical activity may introduce unintended confounders. Participants not offered the free yoga class may have therefore been more likely to take up another non-yoga physical activity, knowing they were not going to be offered a yoga session at the end of the trial; however, we were unable to monitor this as participants did not record other physical activity they were taking part in, only yoga. Researchers rarely monitor contamination rates, presumably because it is assumed that participants in the control group will not exercise.⁹⁷ Measures of contamination with not only the exercise intervention but other physical activities in control groups should therefore be considered in future studies.

The GYY trial implemented additional retention strategies including sending a text message to participants a few days before their postal questionnaire arrived, an unconditional £5 'thank you' payment and reminder questionnaires and phone calls. All of these may have lessened the potential benefit of the offer of a free yoga class at the end of the study on retention. Future studies should therefore consider other retention strategies they are implementing if they want to test the true effects of offering the intervention to control participants once the study has been completed.

The knowledge about the free yoga class was given at the beginning of the trial only. Perhaps a reminder at each follow-up would have increased the effects of the offer. Participants also had to wait 12 months to be offered the free yoga class, which could potentially be too long a time. Future studies should look at adding reminders of the incentive at various time points in the study, such as at each follow-up, which may improve follow-up return rates.

The offer in this study was for one free yoga class only. A longer free yoga course might have increased the effects of the offer. Future studies should therefore look at the length of a free delayed intervention offered.

It would be valuable for future studies to evaluate control group experiences of the design of the delayed intervention incentive.

Offering a free yoga class versus no offer of a free yoga class after the 12-month follow-up assessment did not have any significant effects on rates of retention and contamination in the usual care group participants in the GYY trial. Future studies should consider using reminders about the offer, other retention and contamination strategies used to ensure they are not diluting the effects of the offer and the length of free sessions they are offering, for example, more than one free session. It would also be beneficial for future studies to evaluate control group experiences of the design of the delayed intervention incentive.