Incentives to enhance retention and reduce contamination

The main trial PIS will make patients aware that some participants in the usual care group will be randomised to receive a one-off yoga class. After randomisation to the main trial, participants allocated to the usual care 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.

Objective of this methodological study: 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 usual care group participants.

Intervention: Offer of a free group yoga class

Comparator: No offer of a yoga class

Method for allocating to intervention or comparator: Simple 1:1 randomisation will be used to allocate usual care participants to receive, or not to receive, the offer of a free yoga session at the end of their participation in the trial.

Outcomes
Primary outcome: The proportion of participants in each group who return at least one questionnaire (three, six or 12 months).
Secondary outcomes: The proportion of participants who return all three questionnaires (three, six and 12 months), and the proportion of usual care participants who report use of non-GYY Yoga throughout the trial follow-up.

Sample size calculations
All usual care participants in the host trial will be randomised into this embedded trial, assuming that the embedded trial begins at the same time as the host trial. The host trial recruited 454 participants (240 intervention; 214 usual care). A sample size of 214 would give us 80% power to detect an increase in the percentage of participants returning at least one questionnaire (three, six or 12 months) from 85% in the no offer arm to 96% in the offer arm.

Analysis plan
Binary data will be compared using logistic regression.