Appendix 1 (as submitted by the authors)

EXPO Trial: Feasibility objectives, indicators and results

Objectives

To assess the feasibility of performing a multicenter study on the effectiveness of exercise training to treat the post-thrombotic syndrome.

Outcomes: Feasibility indicators

The following criteria were established *a priori* as indicators of the feasibility of our study design: proportion of screened patients who meet eligibility criteria, more than 30%; proportion of eligible patients who provide consent, more than 30%; losses to follow- up among randomized patients, less than 20%; and level of adherence among patients in the Exercise Training group, more than > 60%. Level of adherence in the Exercise Training group was calculated as the proportion of prescribed exercise sessions that the patient attended [1-3]. We also quantified the proportion of Exercise Training patients who completed their exercise logs each week and the number and type of exercise sessions recorded. In addition, as a means of evaluating adherence to prescribed exercise in the Exercise Training group and potential contamination in the Control group, we measured habitual physical activity levels at each assessment visit using the interviewer-administered version of the validated "short-form last 7 day recall" International Physical Activity Questionnaire (IPAQ) [4].

Statistical analysis

We calculated the proportion of screened patients who fully met trial eligibility criteria, the proportion of eligible patients who consented to participate, the proportion of randomized patients who dropped out of the trial (in total, and by allocated intervention), and the proportion

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of Exercise Training patients who attended at least 60% of their scheduled exercise training sessions (judged to be "adherent"). We documented reasons for non-eligibility, lack of consent, drop-out and lack of compliance.

Results

From 2007-2008, 95 patients were screened, of whom 69 (73%) met study eligibility criteria. Of these, 43 (62%) consented to participate. Among consenting patients, 43 completed the baseline assessment; 35 completed the 3-month visit; 39 completed the 6-month visit; and 35 completed the end of study exercise stress test (Figure 1, manuscript). Three Exercise Training patients withdrew between the baseline and 3-month visit (2 for time constraint issues, 1 for unknown reasons). One Exercise Training patient was lost to follow up after the 3-month visit.

Adherence to allocated intervention

The mean number of trainer sessions attended (in person or by phone) by Exercise Training patients was 9.5 of a maximum possible 15, and 62% of patients attended 60% or more of the trainer sessions (pre-specified adherence threshold) (Appendix Table). In the Exercise Training group, there was a rise in the proportion of patients who reported higher levels of habitual physical activity levels at 3 months and at 6 months compared to the Control group (Appendix Table). Self-reported habitual physical activity level was low in 14.3%, moderate in 52.4% and high in 33.3% of participants. Overall, the proportion of patients each week who completed their exercise log was 60% or higher for each of the first 5 months, and about 40% for the remaining month. Among log completers, the average number of sessions reported was 3.1 per week for strengthening exercise, 5.1 per week for stretching exercise, and 3.8 per week, with an average of 150.5 minutes spent per week for aerobic exercise. All patients in the Control group attended the initial educational presentation on post-thrombotic

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syndrome, and more than 80% of patients were successfully contacted for each of the 1, 2, 4 and 5 month phone call follow-ups.

Interpretation

Our trial design was shown to be feasible based on the attainment of all pre-specified feasibility indicators. To encourage and assess adherence to the training program, patients were asked to complete exercise log booklets after each exercise episode. We noted that completion of logs tended to fall off in the final month of follow-up, but were unable to determine if there was a parallel diminution in actual performance of the prescribed exercise. However, our results suggest that the amount of exercise actually done was enough to effect improvement in the primary outcomes and many of the secondary outcomes.

Although the rate of drop-out was low (9% overall) (see Figure 1 of manuscript), all drop-outs occurred in the Exercise Training group. In planning a larger trial, we will consider designing an exercise program that requires less face-to-face time with an exercise trainer and can be done independently at home or at work.

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Appendix Table. Indicators of adherence to study intervention in Exercise Training and Control groups

Indicator	Exercise Training (n=21)			Control (n=22)		
Number training sessions attended*: mean (SD) Total In person By phone	9.5 (5.1) 7.7 (5.2) 1.8 (2.1)			Not applicable		
Number of patients who attended ≥ 60% training sessions; n (%)	13 (61.9%)					
Self reported habitual physical activity category ^	**Baseline (n=20)**	**3 months (n=17)**	**6 months (n=17)**	**Baseline (n=22)**	**3 months (n=19)**	**6 months (n=22)**
Low; n (%)	1 (5.0)	0 (0.0)	3 (17.6)	5 (22.7)	7 (36.8)	4 (18.2)
Moderate; n (%)	10 (50.0)	11 (64.7)	6 (35.3)	12 (54.5)	4 (21.1)	12 (54.5)
High; n (%)	9 (45.0)	6 (35.3)	8 (47.1)	5 (22.7)	8 (42.1)	6 (27.3)

Table 2, notes

* Patients were asked to attend a total of 15 sessions

^ As measured by "short-form last 7 day recall" International Physical Activity Questionnaire (IPAQ) [4]. IPAQ category could not be calculated at baseline in one patient in Exercise Training group due to missing data.

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Reference List

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