



Increase in Exercise Activities in Alpha-1 Antitrypsin Deficient Patients: Results of a Randomized Trial



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Introduction

The **Step Forward Study (SFS)** is a randomized double-blinded controlled trial evaluating a 5-year-long multi-component intervention versus standard of care in improving health outcomes among individuals with alpha-1 antitrypsin deficiency (AATD).

AlphaNet's Disease Management and Prevention Program (ADMAPP) has numerous positive effects on participants' quality of life, however many still remain far from their ideal weight being over- or underweight.

SFS study was designed to determine whether intensive distance intervention will increase exercise activity and assist participants in weight changes.

Materials and Methods

Study Design:

- The study enrolled 500 participants who were randomized 1:1 into standard of care as outlined in the ADMAPP or standard of care plus a multi-component intervention that included exercise aids and nutritional guidance that was delivered via teleconferences and mailed materials (including handouts and DVD)

Randomization:

- Individuals in both arms continued participating in ADMAPP.
- In addition to that, respondents randomized to the intensive intervention group received educational materials promoting physical activity, nutritional guidance via teleconferences and mailed materials as well as exercise aids (e.g., Therabands, weights, peddlers, exercise balls, etc.).

Outcomes:

- Primary outcome was self-reported number of exercise minutes
- Secondary outcomes included weight and BMI

Inclusion Criteria:

- Males or females age ≥ 18 years at the time of entry
- Diagnosis of alpha-1 antitrypsin deficiency
- Evidence of pulmonary disease with one or more of the following:
 - FEV₁ < 80% predicted and FEV₁/FVC < 0.70
 - Emphysema on a previous CT scan of the chest
 - Receiving augmentation therapy for lung disease
- Accessible by telephone
- Ability and willingness to complete monthly and semi-annual questionnaires by telephone interview
- Ability and willingness to provide informed consent

Data Analysis:

- Out of 500 subjects enrolled in the SFS study, the present analyses included 417 participants who provided sufficient data for the analyses of exercise activities.
- Average minutes of exercise by type, and mean total number of active minutes were analyzed stratified by the intervention group.
- The results for categorical variables were reported by frequencies and proportions, and for continuous variables as mean + SD (min, max).
- Values between the groups were compared using t-test and ANOVA, and Chi-squared test respectively.
- All statistical calculations were performed using SAS v9.4.

SFS Study Events

Interventions

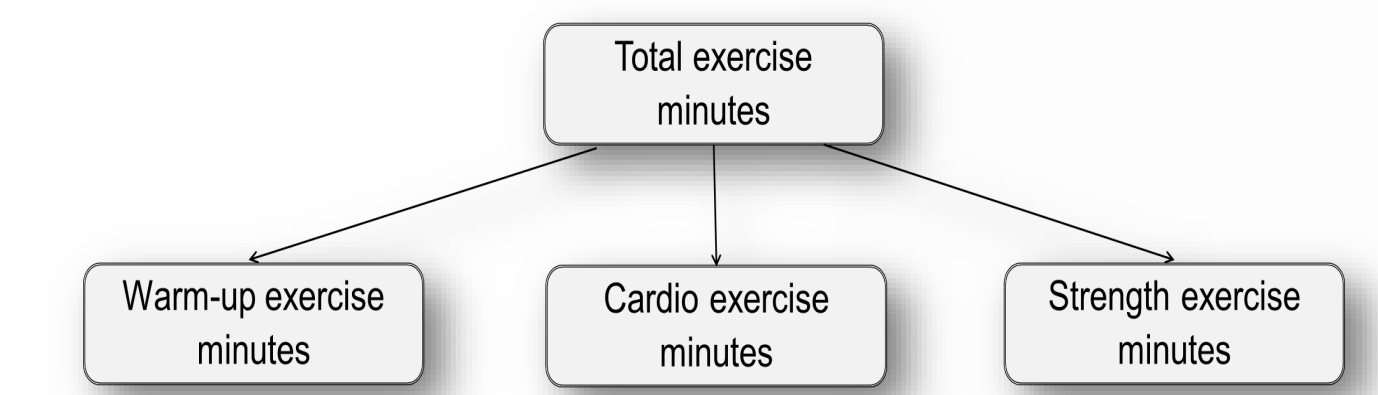
Intervention 1- Oct 2009	Exercise bands and exercise poster with instructions
Intervention 2- Jul 2010	SFS Diet and Nutrition small group teleconference live and audio recordings organized by BMI groups
Intervention 3- Feb 2011	SFS "Breathing Techniques in Alpha-1" instructional DVD
Intervention 4- Jul 2011	"Ask the Dr. Intervention"-a series of small group teleconferences presented by Dr. Sandhaus in which registered participants could ask questions regarding diet and exercise
Intervention 5- Feb 2012	Exercise Ball (tailored to each participant's height) with accompanying instructional poster
Intervention 6- Jul 2012	Exercise Peddler
Intervention 7-Apr-Nov 2013	AlphaNet's Virtual Pulmonary Rehabilitation (VPR) Program VPR teleconferences conducted in May, August and November 2013 VPR participants were asked to mail to AlphaNet a Pre and Post-Assessment /Fitness Card at the beginning and end of the VPR program

Mailings to Both Control and Intervention Groups

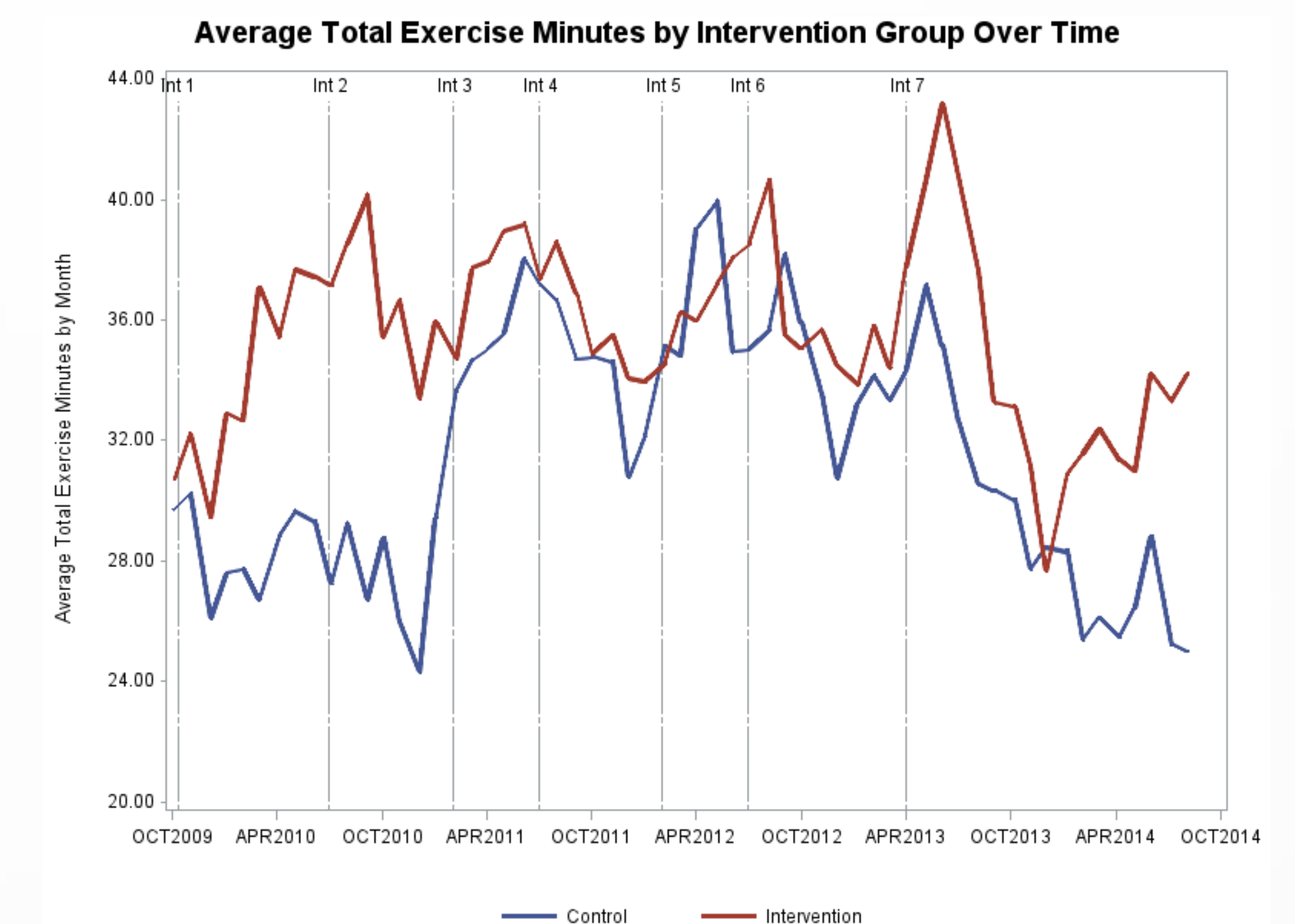
○ Spirometers	<ul style="list-style-type: none"> • NDD EasyOne mass-flow spirometers, pre-programmed with respondent's individual measurements of height, gender, race, DOB • Letter on proper procedure for spirometer data download • Eleven subsequent spirometer downloads and flash drive exchanges
○ University of San-Diego Self-Assessment tool	
○ Pedometers accompanied by a letter on its proper use	
○ Harmonica with instructional pamphlet	
○ "Physiology of exercise" audio recording by Dr. Sandhaus	
○ AlphaNet Family Cookbook	
○ Pulse Oximeter with a log for daily recordings	
○ iPads with AlphaNet app for personal data recording and instructional manual	

Results

Participants recorded minutes of exercise (warm-up, cardio, and strength) in their daily diary forms provided by AlphaNet.



- Participants in the control group (n=205, mean age 57.9±9.6, 45.9 % males) reported 31.5 (SD=4.2) average number of total exercise minutes in their daily diaries.
- Participants in the intervention group (n=212, mean age 58.0±9.3, 49.1 % males) reported 35.5 (SD=3.3) average number of total exercise minutes in their daily diaries. This was significantly greater than in the control group (p<.0001).



- Participants in the intervention group reported an average of cardio-minutes: 20.0 (SD=15.1), warm up-minutes: 6.0 (SD=5.8), and strength-minutes: 10.4 (SD=10.1) in their daily diaries.
- Participants in the control group reported an average of cardio-minutes: 19.5 (SD=15.7), p=0.73, warm up-minutes: 5.8 (SD=7.6), p=0.76, and strength-minutes: 12.2 (SD=13.6) in their daily diaries.

There was no significant difference between the intervention groups in mean exercise minutes stratified by workout types (p=0.13).

Conclusion

Adding intensive fitness intervention to ADMAPP resulted in increased exercise activities among AATD patients.

References

- Alpha-1 Disease Management and Prevention Program: The Big Fat Reference Guide to Alpha-1; Senior Editor and primary author: Robert A. Sandhaus. Multiple contributing authors. AlphaNet Press 2004; also available at www.AlphaNetBFRG.org
- Sandhaus, R. A. (2013). Calendars. <http://www.alphanet.org/media/newsletters/AlphaNetter-Fall-2014.pdf>