Multicomponent Intervention Improves BMI in a Randomized Trial of Alpha-1 Antitrypsin Deficient Patients

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Background

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 (e.g., Therabands, weights) and nutritional guidance that was delivered via teleconferences and mailed materials (including handouts and DVD)

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:
  - FEV_1 < 80% predicted and FEV_1/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

Outcomes:

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

- Participants in the intervention group recorded their weight on a weekly basis during the study period using diary forms provided by AlphaNet.
- The intervention was tailored based on body mass index (BMI) at baseline, with the goal of increasing weight for individuals with low BMI (BMI ≤19), maintaining weight for individuals with normal BMI (BMI=20-25) and reducing weight for individuals with a BMI that was high (BMI >25 – 30) or very high (BMI >30).

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
- 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

Data Analysis

- The present analyses included 388 participants (intervention group - n=197; control group - n=191) who provided sufficient data for the BMI analyses.

- BMI change pre- to post- intervention was calculated as the mean change in BMI using baseline (initial weight measurement) and the last available BMI value stratified by treatment group and BMI category.

- Wilcoxon signed-rank test was used to assess significance of change in BMI within each BMI category. All statistical calculations were performed using SAS v9.4.

Results

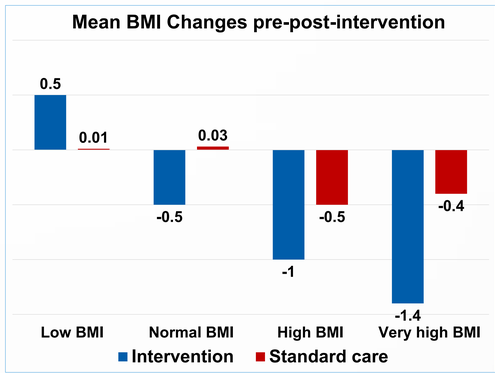
Select baseline characteristics of the participants

	Overall N=388	Intervention group N=197	Control group N=191
Age Mean (SD)	58.4 (9.1)	58.4 (9.3)	58.5 (9.3)
Gender Female , n (%)	205 (52.8)	104 (52.8)	101 (52.9)
BMI at baseline Mean (SD)	26.5 (5.9)	27.1 (6.1)	25.9 (5.8)
BMI categories at baseline, n (%)			
Low (≤ 19)	18 (4.6)	11 (5.5)	7 (3.7)
Normal (20-25)	167 (43.0)	72 (36.6)	95 (49.7)
High (>25-30)	128 (33.0)	72 (36.6)	56 (29.3)
Very High (≥ 30)	75 (19.4)	42 (21.3)	33 (17.3)

Results

Classification*	BMI
Low BMI	≤19
Normal BMI	20-25
High BMI	>25 – 30
Very High BMI	>30

* BMI classification used in data analysis



- Participants in the intervention group with low BMI demonstrated a 2.7% increase in BMI compared to an increase of only 0.06% in the control group (p = 0.52 and 0.99 respectively).
- Individuals in the normal BMI category had a 2.2% (p = 0.003) decrease in BMI in the intervention group compared to a 0.14% (p = 0.51) increase in the standard care group.
- In the high and very high BMI groups there was a greater decrease in BMI in the intervention group (3.6%, p < 0.001 and 3.9%, p < 0.001 respectively) compared to the control group (1.9%, p = 0.04 and 1.1%, p = 0.46 respectively).

Conclusion

Participation in the SFS intervention was associated with an improvement in BMI: increase in low BMI group, decrease in high and very high BMI groups.

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