

Virginia Tech Active For Life Study

for more information
contact llutes@vt.edu +1 540.2

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Benefits

You may expect the following compensation/benefits for your participation:

- It is likely that you will increase your aerobic fitness and/or muscle mass over the course of program. In addition, you may experience some weight loss as a result of the nutrition program and increased physical activity. Research shows that physical changes are associated with decreased risk of disease and decreased premature mortality if you maintain your new habits after completion of the program. In order to help you maintain your healthy lifestyle, we will provide you with a plan that you can use on your own after you complete our program.
- You will receive three sub-maximal exercise tests and cardiovascular assessments (blood pressure, heart rate, cholesterol, fasting glucose, and triglycerides), along with reports that you may provide to your family physician. These tests typically cost from \$250 to \$300 at a healthcare facility.
- You will receive three nutritional analyses. These types of analyses typically cost \$50 per session.
- You will be working one-on-one with a qualified trainer in a personal training facility. This type of training would normally cost \$50-\$100 per session.
- You will be working one-on-one with a qualified nutritionist in a personal training facility. This type of training would normally cost \$25-\$50 per session.

Overall, not only will you likely decrease your risk for disease, you will also receive approximately \$3500 worth of assessment procedures at no cost!



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Criteria

Does this study sound like something you would be interested in? If so, you might be exactly who we are looking for!

Below is a list of the type of individuals we are seeking to participate in this study.

- Males between the ages of 27-45 and females between the ages of 27-45
- Individuals who are currently sedentary and have been for the past 6 months. That is, participants who do not currently participate in an exercise or activity program more than one day a week would be considered sedentary.
- Individuals who consider themselves to be overweight.



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About the Investigators and Study Personnel

We recognize that in order to better understand, and learn how to enhance the health and well-being of individuals, gathering several different perspectives is crucial to long-term success. Therefore, we are excited that this study is crosscutting with professionals contributing from various departments and specialties. Each member of the study and his or her affiliation is outlined below.



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Appendix C

On-Line Screening Form

Virginia Tech Active For Life Study

for more information
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Now that you have read the description of the study, assessment procedures, participation criteria, and may be interested in participating in the Active4life study, please fill out the screening form below:

It is important to know that you are in NO WAY OBLIGATED to participate in the study by completing this form. Rather, completing this form allows you to see if you qualify for the study.

Contact Information

First Name:

Last Name:

Street Address:

City:

State:

Zip:

Home Phone:

Work Phone:

Email Address:

Best way/time to reach you:

Medical Information

1. Do you currently have health insurance?

2. Do you currently have a family physician?

3. Height : ft in

4. Current Weight (in pounds): lbs

5. Sex

6. Please Select a Valid Statement Below.

7. Age (in years) years

8. Are you *currently* exercising?

9. Please indicate how many days a week you exercise. Please indicate 0 if you do not currently exercise. (0-7) days

10. Please enter how long are you active each session? Again, if you are not exercising then please indicate so with a value of 0 (minutes) (0-180)

11. Do you smoke?

12. Please choose a valid statement from below.

- 13. Has your doctor ever said that you have a heart condition AND that you should only do physical activity recommended by a doctor?
- 14. Do you feel pain in your chest when you do physical activity?
- 15. In the past month, have you had chest pain when you were not doing physical activity?
- 16. Do you lose your balance because of dizziness or do you ever lose consciousness?
- 17. During exercise, have you ever felt suddenly faint, dizzy, or lost consciousness?
- 18. Do you have a bone or joint problem that could be made worse by a change in your physical activity?
- 19. Do you know of, or can think of, any other reason why you should not do physical activity?
- 20. Do you have diabetes or high blood sugar?
- 21. Do you have high blood pressure?
- 22. Are you currently taking medication to control blood pressure?
- 23. Do you have high cholesterol?
- 24. Are you currently taking medication to control cholesterol?
- 25. Are you currently taking any medication for a heart-related condition?
- 26. Are you currently taking any prescription or over-the-counter medications for weight-loss?
- 27. Please describe any any over-the-counter medication for weight loss that you are currently taking. Please enter NONE in the field if you are not taking any.
- 28. Do you have heart disease (had had a heart attack, bypass, or angioplasty)?
- 29. Has anyone in your family had a cardiac event (described in the question above) which was fatal before the age of 55?
- 30. Have you been told that you snore?
- 31. Have you been told that you stop breathing when you sleep?
- 32. Do you wake frequently during the night?
- 33. Do you sweat excessively during the night?
- 34. Do you wake during the night gasping for breath?
- 35. Have you recently gained weight?
- 36. Are you excessively sleepy during the day?
- 37. Do you frequently get morning headaches?
- 38. Which race do you consider yourself to be?

I would like to know if I am eligible for the study.

Appendix D

Informed Consent

Center for Research in Health Behavior
Department of Psychology
Virginia Tech
Blacksburg, VA 24061- 0274

Informed Consent for Participation in Research Project

Title: Efficient and Effective Exercise Training and Innovative Weight Loss Approach

Purpose and Background:

Considerable public health research shows the importance of aerobic fitness and strength for reducing the risk of numerous diseases, disabilities, and premature death. Until recently, it was believed that attaining good levels of fitness and strength required hours of training per week. A better understanding of the mechanisms involved in inducing fitness and strength adaptations suggests that with specific prescriptive, progressive protocols, appreciable levels of fitness and strength *may* be obtained in minimal training time per week. This study will utilize exercise protocols following specific prescriptions and test their efficacy with standard measures of fitness and strength. Further, some new promising research has shown that modest reductions in food intake combined with exercise have led to continued weight loss and/or maintenance over a two-year period. Many people cite lack of time for exercise and feelings of deprivation during weight loss attempts as reasons they do not stick to programs. In this respect, our program may help break barriers to exercise training and weight management.

Testing Procedures:

In order to participate, you must not be performing a structured exercise program or be regularly physical active at the present time (and for the past six months) and be a male 27 to 45 years or female 27 to 55 years with no more than two other risk factors for coronary disease as ascertained through completion of the standard medical clearance form and assessment procedures. Females must not be pregnant or breastfeeding. You must have health insurance that will remain in effect during the course of the study. If you meet the criteria, we will make an appointment with you so that you can be assessed at a human performance lab on campus.

Specifically, you will be asked to complete the following procedures at three different time points: 1) before the starting the study, 2) 16 -weeks after the beginning of the study, and 3) 32 -weeks after the beginning of the study:

- Complete questionnaires that request your opinion about your current level of activity and related activities, health related quality of life, mood, and confidence in completing and maintaining different activities.
- Complete nutrition evaluations at the beginning, over the course, and at the end of the study.
- Complete activity evaluations at the beginning, over the course, and at the end of

the study. Evaluating current levels of activity will be aided by the use of a pedometer that counts every step you take over the course of a day. The pedometer looks like a small pager and clips onto your belt or waistband.

- Complete a strength test of approximately 15 minutes in order to determine your current level of strength. This test will be performed on resistance training machines and will assess the 6-repetition maximum strength of your chest, legs, back of legs (hamstrings), shoulders, upper back, lower back, and abdominals. The 6-repetition maximum strength is the amount of weight you can lift with only 6 repetitions. You will sit down in the exercise equipment and be asked to lift the weight stack 6 times, exhaling each time you push the weights. A 1-minute rest will be given between each trial. The weight will be increased if you can perform more than 6 repetitions, and the test will terminate when you can *only* perform 6 repetitions at a given weight through the full range of motion.
- Allow us to complete body composition measurements including height, weight, and body circumferences.
- Complete a bicycle exercise test of approximately 8-12 minutes and allow us to measure your fitness level based on 80% of your estimated peak heart rate, as well as your oxygen consumption, heart rate, and blood pressure. This test will be performed in a laboratory in the War Memorial Gym on Virginia Tech's campus. In order to measure how much oxygen you use during this exercise, we will ask you to breathe into a lightweight rubber mouthpiece. During exercise, a mouthpiece will be placed in your mouth to collect expired oxygen and carbon dioxide in order to calculate oxygen uptake, or VO_2 . Since your heart rate will be monitored by electrocardiogram, 12 electrodes will be placed on your torso. These electrodes detect heart muscle activity. They do not emit any electricity, and you will not feel any pain from these electrodes. Small patches (quarter-size) of chest hair may need to be shaved in order to properly place the electrodes on your skin.
- Allow us to obtain small venous blood samples during your three assessment visits in order to measure how your cardiovascular system is adjusting. In addition, in order to determine your current level of cholesterol and glucose levels, we ask that you fast for a period of 12 hours in order to obtain fasting blood sample in order to obtain current levels.
- Complete a Bone density test in order to determine your current level of adipose tissue around the midsection of your body. This test will be performed in a laboratory in Wallace Hall on Virginia Tech's campus. You will need to bring clothes that have no zippers or wires (such as shorts and a T-shirt), or you may need to put on a hospital-type gown if your clothing has metal in it. You will lie face up on a table where the bone density scanner will hover over your body. You will not feel anything other than slight table movement for optimal scanning. A certified x-ray technician will perform the test.

These assessments will be done over three different sessions, lasting approximately 2.5 hours in total, at the three different designated time points.

Training Programs:

Following the initial testing, you will be randomly assigned to one or three possible.

Group #1

This group will participate in an aerobic and strength training program, two days a week, at our private exercise lab located on North Main Street with a certified personal-trainer. In addition, this group will receive a nutrition and exercise education program, based on the USDA Dietary Guidelines.

Group #2

This group also will receive the aerobic and strength program outlined above along with a new promising weight management and activity plan focused on maintaining long-term nutrition and activity behaviors. The nutrition program will involve meeting with a nutritionist once or twice per week for 15 minutes immediately following the exercise session. Participants in this group will need to keep records of their daily activity (which involves writing the total number of steps accrued on a step counter at the end of the each day). In addition, participants in this group will be asked to keep a record of their food intake on a daily basis. In addition, participants in this group will exercise in different location in the area. Further, participants will be asked to bring family and/or friends to the center one time in order to discuss ways to support new activity and nutrition behaviors.

For both exercise groups, an aerobic and strength-training program will be developed based on individual levels of fitness and strength. Each training session will include both an aerobic and strength training component conducted by a certified personal trainer. Together, each session will last approximately 30 minutes.

Group #3

For the first 32 weeks, participants placed in this group will serve as a critical wait-list-control comparison. During this time, individuals in this group must agree not to change any of their current activity or dietary habits. However, following this period, all individuals in this group will receive an exercise and nutrition program.

Possible Risks of Participation:

Because of the way the protocols are constructed and because you successfully completed the baseline exercise test in the presence of an Emergency Medical Technician (EMT), which is done at a higher level than the training program, you do not present any risk factors, and there is little or any danger in participating in the study. Possible risks during *maximal* exercise testing include fast or irregular heartbeats, dizziness, fainting, and remote possibility of heart attack, stroke, or sudden death (1 in 10,000 individuals run the risk of complications requiring hospitalization or risk of sudden death). However, the risks associated with this cycle test are much less since it is of lesser (submaximal) intensity. In order to minimize risk further, an Emergency Medical Technician will be on hand at all baseline tests. You may feel slight embarrassment during the body fat testing. In order to minimize this, trained personnel will conduct the tests in a private

area. There may be some initial soreness from the testing or starting this new training program, but we plan on using a few easier training sessions at the beginning to minimize soreness and to teach you how to correctly perform exercise movements. A technician certified in CPR and for exercise training and testing will direct all tests and training sessions. There is little risk associated with any of these tests. A very small radiation risk is possible from the bone density testing. There is no risk with the nutrition counseling or wearing of the pedometer.

During the course of exercise training or testing, we may find that some people might need additional medical referral. We will work with your primary care physician to make appropriate referrals, but you are responsible for any medical costs incurred by such referral.

Benefits of Participation:

You can expect the following compensation for your participation in this 6-12 month study:

- You will be receive three sub-maximal exercise tests and resting and exercise cardiovascular assessment (blood pressure, heart rate, cholesterol, fasting glucose, triglycerides), along with reports that you may provide to your personal family physician. These tests typically cost from \$250 to \$300 per test in a healthcare facility. This equates to approximately \$750-\$900.
- You will receive at least three nutritional analyses over the 6-month study. These types of analysis normally cost \$50 per session. This equates to approximately \$150. Depending on which group you are assigned to, you may receive weekly nutrition analyses. This would then equate to approximately \$800.
- You will be working one-on-one with a qualified trainer during every workout in a private facility. This type of training would normally cost anywhere from \$50-\$100 per session, and you will be getting this service included as part of your participation. This type of program equates to approximately \$2400 over the 16-week intervention.
- You will also receive one-on-one counseling with a qualified nutritionist and behavioral interventionist in a private facility. This type of training would normally cost \$25 per session. Over the course of the intervention, this equates to approximately \$550.

Overall, you will receive approximately \$4150-\$4950 in assessments and contact all for free with your participation.

In addition, it is likely that you will be able to increase your aerobic fitness and/or muscle strength in the 16-week program. You may experience some weight loss as a result of the nutrition program and increased physical activity. Such changes are associated with decreased risk of disease and disability and premature mortality if you maintain your new habits after completing the program. We will help you design a plan that you can use on your own after you complete our program.

Freedom to Withdraw:

You may withdraw your consent to participate at any time without any penalty to you.

Confidentiality:

All the information you provide to us on any forms or tests will be kept in a locked area. This information will be available to key project employees only. You will be assigned a number that will be used on research forms and you will not be identified in any research reports.

Participant' s Responsibilities:

1. You must accurately report your medical history;
2. Inform your exercise trainer and tester of any unusual symptoms such as chest pain, dizziness, nausea, or joint pain.
3. Inform the staff personnel of any change in health status (diagnosis of a major illness or even minor illnesses such as a cold) that affects your ability to participate in exercise training or testing.

Approval of Research Procedures

The Institutional Review Board at Virginia Tech, a committee that reviews all research on campus involving human subjects, has approved this project.

Consent

I (print name) _____ have read and understand the informed consent and conditions of this procedure. I have had all my questions answered. I hereby give my voluntary consent for participation in this study.

Signature of Participant: _____ Date: _____

Should I have any questions about this procedure or its conduct, I can contact:

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Appendix E

Perceived Skills Questionnaire

Program Content Evaluation Form

Participant #: _____

Date: _____

The following are questions that are related to the individual nutrition and exercise counseling that you received by your leader throughout the program. Please rate how much you either agree or disagree with the following statements.

The issues discussed in the Active4LIFE program have prepared me for:

1) Maintaining my good exercise habits after the Active4LIFE program has ended.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

2) Transitioning my exercise program to my home and/or community center.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

3) Designing an independent exercise plan I can live with.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

4) Anticipating problems that might interfere with my exercise schedule.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

The issues discussed in the Active4LIFE program have prepared me for:

5) Developing solutions to cope with potential barriers that might interfere with my exercise schedule.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

6) Resuming regular exercise after I have missed for a few days.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

7) Identifying key factors that trigger lapses in my exercise program.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

8) Learning to accept lapses in my exercise program as challenges to overcome rather than failures.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

9) Maintaining my healthy eating habits after the Active 4LIFE program has ended.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

The issues discussed in the Active4LIFE program have prepared me for:

10) Recognizing healthier carbohydrate choices.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

11) Understanding the difference between healthy and unhealthy fats.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

12) Using strategies for healthy social eating.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

13) Anticipating problems that might interfere with healthy food choices.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

14) Developing solutions to cope with potential barriers that might interfere with healthy food choices.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

The issues discussed in the Active4LIFE program have prepared me for:

15) Resuming healthy eating after I have lapsed for a few days.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

16) Identifying key factors that trigger lapses in my healthy food choices.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

17) Learning to accept lapses in my healthy eating choices as challenges to overcome rather than failures.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

18) Understanding how emotions can affect eating choices.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

19) Recruiting social support to help me maintain my healthy eating and exercise behaviors.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

The issues discussed in the Active4LIFE program have prepared me for:

20) Seeing recent improvements in exercise and eating behavior as a lifestyle change.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

21) Setting and obtaining personal eating and exercise goals.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Appendix F

Leader Evaluation Questionnaire

Counselor Evaluation Form

Participant #: _____

Date: _____

The following are questions related to the quality of the counseling I received from my Active4LIFE counselor. Please rate how much you either agree or disagree with the following statements.

My Active4LIFE counselor:

1) Was prompt and professional.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

2) Was easy to work with.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

3) Was understanding regarding scheduling conflicts and setbacks.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

4) Was sometimes inappropriately critical of me.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

My Active4LIFE counselor:

5) Genuinely cared about my progress in the program.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

6) Was helpful in answering any questions that I had.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

7) Was genuine in her interactions with me.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

8) Made me feel like an individual

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

9) Made me feel insignificant.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

10) Is someone who I would like to work with again.

1	2	3	4	5
Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree

Appendices G & H

BCT Manual (16-week and 12-week)

(Please contact the author in order to obtain a copy of the manual(s))

**The vita has been removed from
the scanned document**