

Official title: Examining the Association of Sun Salutations and Aerobic Exercise With Cognition Among Adults With Psychosocial Stress

NCT number: NCT04077645

Document date: July 24, 2019

Sun salutations- Research Protocol- Layperson

Screening & Scheduling

Participants will be contacted via phone to assess their study eligibility. Upon successfully passing the telephone screening, participants will be provided with an Informed Consent form to be signed if they wish to participate in the study. Participants can choose to come into the research lab to sign the consent form, or receive the documents via email, print, sign and send it back to us. After the participants have signed their consent forms, they will be sent an online psychosocial questionnaire to be completed. After completion of this questionnaire, they will be scheduled to come to the lab to pick up their Fitbit, to be worn for a week. After a week of tracking their physical activity using the Fitbit, they will be scheduled for 1 appointment lasting 2 hours.

Inclusion criteria:

- Anyone between the ages of 18-45 years
- Anyone with a score of 3 or higher on the Generalized Anxiety Disorder symptom checklist of the Diagnostic and Statistical Manual 5. That is, anyone meeting 3 or more symptoms, on more days of the week than not, for the past 6 months:

1. Restlessness, feeling keyed up or on edge. 2. Being easily fatigued. 3. Difficulty concentrating or mind going blank. 4. Irritability. 5. Muscle tension. 6. Sleep disturbance (difficulty falling or staying asleep, or restless, unsatisfying sleep).

Exclusionary criteria:

- Anyone who is physically active (≥ 30 minutes, 2 or more times/week, for the last 3 months) and/or a regular practitioner of Yoga or mind-body activities (≥ 30 minutes, 2 or more times/week, for the last 3 months).
- Anyone with serious chronic medical conditions that would preclude them from participating without a physician present, or anyone with a risk of seizure, or anyone having psychiatric and/or neurological disorders.
- Anyone who does not consent to wearing the Fitbit, or does not have a smartphone that allows us to download an app on their phone.
- Pregnant women.
- Anyone incapable of performing the following movements at a moderate intensity- sitting, standing, kicking, pulling, pushing, bending one's elbows, bending the body forward, bending one's knees, lying down and getting up.
- Anyone with blood pressure of 200/105 or more, and anyone who scores 1 or more on the Physical Activity Readiness Questionnaire
- Anyone refusing or unwilling to be randomized into either of the conditions.

Testing assessments

Participants will have to visit the lab, for 10 minutes, to pick up their Fitbit to be worn for 7 days, in order for us to track their physical activity. Participants will also set up one 2 hour appointment to be conducted after those 7 days. This appointment that will take place at one of our labs, depending upon availability. Our labs are located in 3 locations- Chez Centre for Wounded Veterans, Louise Freer Hall, and George Huff Hall. This appointment will be 2 hours long, and will involve baseline testing (biometrics, psychosocial questionnaires and cognitive testing), engaging in the intervention, and post intervention testing. The appointment will be conducted in the following order: Baseline testing (30 mins), intervention (30 mins), post-testing and evaluation (45 mins). The following assessments will be conducted at this appointment:

- Biometric information such as height, weight, BMI, blood pressure, and bodyfat % (~2 mins).
- Upper and lower body flexibility assessment via the sit and reach, and back scratch test (~3 mins)
- Psychosocial questionnaires to assess stress and anxiety (~5 mins).
- Cognitive assessment will include computerized and paper pencil tests, including the n-back task (20 mins), digit symbol substitution task (3 mins) and trail making test (2 mins).

Randomization

Randomization will be done on a rolling basis, and will be based on age, sex and ethnicity. Participants will be randomized once they complete wearing their Fitbit for 7 days, before showing up for their 2 hour appointment.

Group Placement & Descriptions

Following completion of the the first appointment, participants will be randomly assigned either the sun salutations group, or the aerobic exercise group, or the attention-control condition group. They will engage in either of these interventions for half an hour when they come for their 2 hour appointment.

Group placement and descriptions

Sun salutations group – Experimental treatment condition

Prior to beginning the sun salutations, a 5-minute orientation session to explain sun salutations will be held with the participants, as it is likely to be novel to them. Participants will be shown the series of yoga postures they will be engaging in, the number of repetitions of each series that they will perform, and the possible modifications to each posture. Participants will be asked to perform to the best of their ability, and refrain from over-exerting oneself. As such, participants will be told that they can begin with the modified versions in the first few series, before they are comfortable performing the actual postures. While the video-instruction will cover all these

aspects as well, the purpose of the orientation session would be to provide them with a brief overview of the activity they will be engaging in. This will help in reducing their anxiety about performing a form of physical activity that may be novel to them.

After the orientation session, participants will be guided to engage in sun salutations through a video-instruction (<https://www.youtube.com/watch?v=IKzkc3FWx7g>, beginning at 1:40). The video will have a model who will demonstrate the series of postures, while giving instructions about performing them. The video will be displayed on an iPad. They will perform 6 rounds of sun salutations, followed by breathing exercises, followed by 6 more rounds of sun salutations. Participants will have a large space, free of any obstructions, to perform the physical activity. Throughout the session, an undergraduate research assistant will be present throughout the intervention in case of emergencies.

The session will start with a warm up of 5 minutes, consisting of running on the spot and stretching exercises. Then, participants will engage in sun salutations and breathing exercises for about 25 minutes, followed by guided relaxation for 5 minutes.

Aerobic exercise group – Active comparator condition

This group will be asked to walk on the treadmill for the same amount of time (i.e. 25 minutes) at a moderate intensity (50-70% of their maximum heart rate). Participants will receive an initial 5-minute orientation and then begin at a self-selected speed for the first 5 minutes. Heart rate will be measured and monitored by an undergraduate research assistant. Speed will be increased after 5 minutes if participants have not reached the moderate zone. If participants still have not reached the target heart rate zone by the 10-min mark, the incline of the treadmill will be increased by a 5% grade until the zone is reached. Throughout the session, participants' willingness to continue and levels of perceived exertion will be assessed via standard methods (e.g., modified Borg Ratings of Perceived Exertion) and all participants will be instructed to signal to the research assistant in case they wish to stop. The emergency stop button is also available if the session exceeds the participants' expectations of what they can do and they wish an immediate end to the session.

Educational video group – Non-active, attention-control condition

The control group will be watching educational videos from YouTube for the same amount of time as the treatment group (30 minutes). The video will be an interview of a doctor providing educational health information on topics such as healthy eating (<https://www.youtube.com/watch?v=t7wSp7Y4bFM>). An orientation session of 5 minutes outlining the activity they will be doing will be held. An undergraduate research assistant will be present throughout the session, in case they need any assistance. Overall, this group will receive the same amount of attention as the treatment group.

Measurements

Psychosocial questionnaires

A battery of psychosocial questionnaires that assess focus of attention, perceived stress, and anxiety will be given to the participants before and after the physical activity session.

Biometric assessment

Participants' height, weight, BMI, blood pressure and bodyfat % (via the OMRON HBF306C Handheld Bodyfat Analyzer) will be recorded.

Flexibility

Upper body flexibility will be assessed using the back scratch test, and lower body flexibility will be assessed using the sit and reach test.

Cognitive assessment

Assessments will include computerized and paper-pencil tasks assessing working memory (n-back task), processing speed (digit symbol substitution test), and global cognition (trail making test). The assessments will be repeated at the end of the intervention session.

Intervention evaluation

This will be conducted after completion of post-testing. Participants will rate the intervention in terms of enjoyment and delivery method, by answering a questionnaire and a 10 minute interview.

Risks Associated with Participation

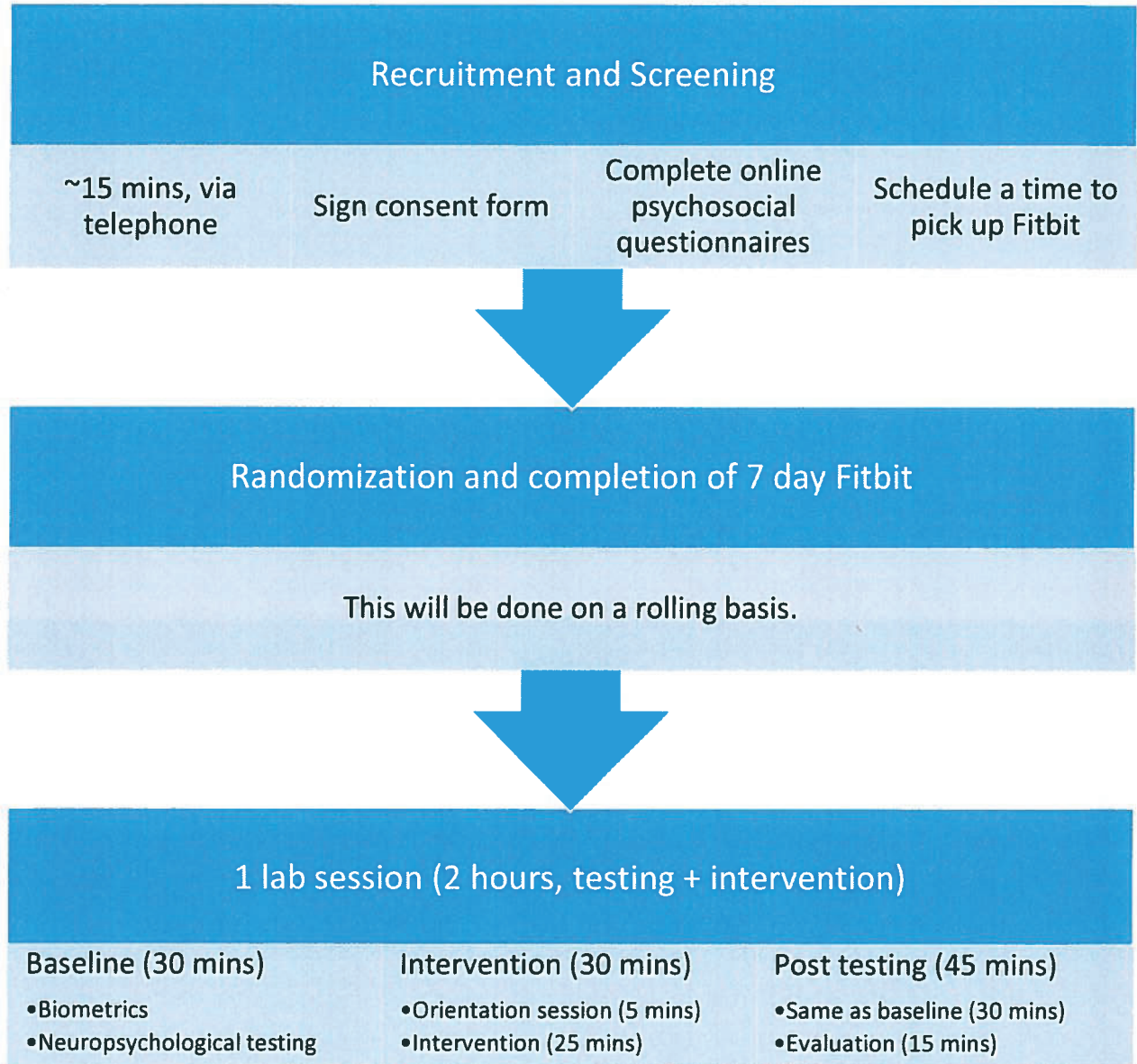
Testing and training sessions: Adults may experience some amount of frustration during our testing sessions as many of our cognitive tests are designed to be challenging. We will aim to provide sufficient time, instructions and breaks whenever possible.

Bodyfat analysis: We will be using a scale that measures bodyfat through a method known as “bioelectrical impedance.” This scale will send a small electric current through the body. Therefore, participants should not use the scale if they are pregnant, have a pacemaker or other internal electric device. We will remind them of these restrictions prior to conducting this assessment. If participants failed to disclose these conditions (or status changed since the screening was conducted), we will simply refrain from collecting these data with that participant.

General exercise risks: There is a chance of incurring minor injury and some discomfort due to the intensified use of major muscle groups that have not received a great deal of use, and from performing a form of physical activity they may not have performed before. There is also a very slim chance that sudden death or cardiac irregularities can occur while exercising. As noted, this is very rare and the benefits of exercise are known to outweigh the risks. As a preventive

measure, during the intervention, all staff members are trained in Cardiopulmonary Resuscitation (CPR), AED and First-Aid. We will also instruct participants to refrain from over-exerting themselves, and progressing gradually through the series of physical activity.

Flowchart



Measures

Construct	Instrument	Type of assessment
<i>Screening</i>		
Demographics	Screening questions	Demographics
Health History	Physical Activity Readiness Questionnaire (PAR-Q; Thomas, Reading, & Shephard, 1992)	Health
General Anxiety and Stress	Symptom checklist of Generalized Anxiety Disorder, Diagnostic and Statistical Manual V.	Psychosocial
<i>Baseline Questionnaire</i>		
Demographics	Demographics Questionnaire	Demographics
Health History	Health History Questionnaire	Health
Physical Activity	Exercise and Yoga Experience	Health
Physical Activity	Activity Choice Index	Health
Stress	Perceived Stress Scale	Psychosocial
Physical Activity	Godin Leisure-time Exercise Questionnaire	Health
Anxiety and Depression	Hospital Anxiety and Depression Scale	Psychosocial
Mindfulness	Mindfulness Attention Awareness Scale	Psychosocial
Pain	SF-36 Bodily Pain subscale McGill Pain Index Short Form 2	Health
Self-efficacy	Yoga Self-Efficacy Questionnaire	Psychosocial
Expectancy	Questions about outcome expectations	Psychosocial

<i>Pre-intervention</i>		
Physical Activity	7 day Fitbit average	Health
Heart rate	Measured via an Oxymeter	Biometric
Height and weight	Measured via Eatsmart's Digital Weight Scale	Biometric
Bodyfat % and BMI	Measured via the OMRON HBF306C Handheld Bodyfat Analyzer	Biometric
Blood-pressure	Measured via the automated OMRON 10 series	Biometric
Physical Fitness	Cardiorespiratory Fitness Questionnaire	Health
Affect	Feeling Scale (FS; Hardy & Rejeski, 1989)	Psychosocial
Stress	Visual Analog Scale for Perceived Stress	Psychosocial
State Anxiety	State Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983)	Psychosocial
Mental Fatigue	Perceived Mental Fatigue Questionnaire	Psychosocial
Working memory	n-back task (20 mins)	Cognitive
Processing speed	Digit symbol substitution task (3 mins)	Cognitive
Global cognition	Trails A and B (2 mins)	Cognitive
<i>Post-intervention</i>		
Heart rate	Measured via an Oxymeter	Biometric
Focus of attention	While you were engaged in the last activity (sun salutations/quiet rest), where was the focus of your attention? 0= external thoughts --- 10= internal thoughts	Psychosocial
Exertion	Borgs Ratings of Perceived Exertion scale (RPE; Borg, 1982)	Psychosocial

Engagement	Game Engagement Questionnaire (GEQ; Brockmyer, Fox, Curtiss, McBroom, Burkhart, & Pidruzny, 2009).	Psychosocial
Self-efficacy	Yoga Self-Efficacy Questionnaire	
Affect	Feeling Scale (FS; Hardy & Rejeski, 1989)	Psychosocial
Stress	Visual Analog Scale for Perceived Stress	Psychosocial
State Anxiety	State Trait Anxiety Inventory (STAI; Spielberger, Gorsuch, Lushene, Vagg, & Jacobs, 1983)	Psychosocial
Mental Fatigue	Perceived Mental Fatigue Questionnaire	Psychosocial
Working memory	n-back task (20 mins)	Cognitive
Processing speed	Digit Symbol substitution Task (3 mins)	Cognitive
Global cognition	Trails A and B (2 mins)	Cognitive
Intervention Evaluation	Intervention enjoyment and feasibility questions (For e.g., would you like to engage in sun salutations for a longer period of time, say, 3 times a week for 4 weeks?)	Evaluation