tDCS for Increasing Exercise Adherence in Individuals with Elevated Depressive Symptoms

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Background

Depressive symptoms predict poor exercise adherence. (1, 2) (3), (4) (5-7) (8) (9) (10) (11) (12) and depression-specific characteristics (e.g., affect) are related to physical activity (PA) levels. A cardinal symptom of depression is dysregulated affect – i.e., lower levels of positive affect and higher levels of negative affect (13, 14). Positive affect has been consistently identified as a significant correlate of PA levels across a myriad of populations including: Parkinson's (15), arthritis (16), ovarian cancer survivors (17), dementia (18), cardiovascular disease (1, 19), osteoporosis (20), knee patients (21), and college students (22, 23). On the other hand, negative affect is inversely related to PA (1, 17, 21, 22, 24). The dysregulation in affect seen in depression is particularly concerning when it comes to PA level. Those with elevated depressive symptoms are placed at a disadvantage for maintaining regular physical activity in the long-term.

Affective responses to exercise can influence exercise adherence. While individuals almost universally "feel good" after engaging in PA(25), there is a fair amount of affective variability *DURING* exercise – some individuals increase in positive affect and others in negative affect (26-28). In particular, increases in positive affect predict both intentions to engage in exercise(29) and actual exercise behavior (28, 30-33). While research on the affective experiences of exercise in those with depression has been limited, recent work suggests that those with a history of depression experience less of an increase in positive affect following PA(34). Higher levels of depressive symptoms has also been associated with greater perceived physical exertion with exercise (35) and, in our own work, reduced PA enjoyment. Therefore, if those with depression experience exercise as more challenging and less rewarding than nondepressed individuals, it can impact their likelihood of maintaining PA in the long-term.

While physiological cues overwhelm the affective experience at higher exercise intensities, cognitive factors (e.g., self-regulation, attentional bias) influence affect at lower intensities (dual mode theory; (36)). For example, negative mood also appears to be interfere with obese, sedentary individuals' ability to self-regulate physical activity resulting in lower levels of exercise participation (37). Further the inability to direct attention away from unpleasant stimuli (i.e., attentional bias; (38, 39)) is a hallmark of depression (40) resulting in negative affect. Individuals with affective disturbances experience difficulty with attentional bias toward unpleasant emotions during exercise(41). Additionally, a growing body of electroencephalogram (EEG) studies support the notion that exercise is an emotion-eliciting event (42). A recent review of 11 EEG studies examining the relation between affect and PA (43) concluded that a single session of exercise results in an asymmetric pattern of activity in the prefrontal cortex: greater left frontal activity before exercise is associated with greater positive affect during exercise, whereas, greater right frontal activity results in increases in negative affect during exercise. This is particularly relevant for individuals with depression who, in both EEG and fMRI studies, have been found to show greater relative activity in right vs. left DLPFC (44), (45). Given the inherent difficulties in regulating affect experienced by depressed individuals, they may be "handicapped" in their ability to positively experience exercise, which may contribute toward their lower levels of physical activity. Yet, regular physical activity is critical for decreasing health risks (e.g., obesity, diabetes, heart disease) in this population and interventions to improve the affective experience of PA could have a high public health impact.

Transcranial direct current stimulation (tDCS) as a novel approach toward regulating affective processes. tDCS is a form of noninvasive brain stimulation which has been investigated in a broad range of populations (46, 47), and has shown promise in impacting a wide variety of cognitive and affective processes, such as working memory (e.g., (48, 49)), motor learning (e.g. (50, 51)) and emotion regulation (e.g., (52-54)). tDCS uses low current electricity (typically 1-2mA) to modulate neuronal excitability in targeted brain areas via two electrodes placed on the head. tDCS acts via slight alterations to membrane potentials in areas underlying electrodes, with typical settings (e.g., two electrodes, 1mA current) resulting in increased likelihood of neuronal firing under the anode and decreased likelihood of neuronal firing under the cathode. As tDCS modulates the likelihood of neuronal firing, but does not directly induce an action potential (like transcranial magnetic stimulation; TMS), it may be particularly promising in combination with behavioral interventions to enhance activity in neural circuits already in use. tDCS has been used in a large number of individuals and has been found to be relatively safe, with the vast majority of reported side effects being mild and transient (e.g., headache, fatigue; (55)). Moreover, tDCS has practical benefits over other forms of neuromodulation (e.g., TMS, deep brain stimulation) as it is significantly less costly and more

portable, making it more practical for widespread implementation (see Image).
While tDCS of DLPFC has been investigated as an intervention for depression with some (though not universal) support for efficacy (46, 56-58), studies have suggested tDCS of DLPFC may improve cognitive control over emotional information (52-54, 59, 60) and corresponding reductions in the emotional valence of negative stimuli. Interestingly, these changes do not appear to be explained by a change in mood, further supporting the notion that differences observed are likely due to improved cognitive control over emotional material (53, 60). Consistent with these findings, in depressed patients reduced attentional bias to emotional stimuli has been found following anodal tDCS to DLPFC(54). Given the central role of the affective experience of exercise to long-term PA and given experimental findings relating tDCS of DLPFC to improved emotion regulation, the combination of tDCS (of DLPFC) with an exercise program may be a promising approach to improve exercise adherence.

Experimental Method

Brief Description of Subjects

Eligible participants will: (a) be between 18 and 65 years of age, (b) be low active (i.e., less than 90 min of moderate-intensity exercise/wk for the past 6 mos.), (c) have elevated levels of depressive symptoms (i.e., Center for Epidemiological Studies Depression Scale score $\geq$10), (d) be interested in starting an exercise program in the next month, and (e) able to walk one mile on a treadmill. Exclusion criteria include: (a) history of mania or hypomania, (b), history of psychotic disorder, (c) current DSM-5 diagnosis of anorexia nervosa, bulimia nervosa, or other eating disorder for which an exercise intervention would be contraindicated, (d) DSM-5 moderate and severe substance use disorder (e) current suicidality or homicidality, (f) current DSM-5 diagnosis of major depressive disorder (MDD) that is not currently being treated with pharmacotherapy or psychotherapy (g) physical disabilities or medical problems that would prevent participation in moderate intensity exercise (i.e., physician denied medical clearance), may be contraindicated for tDCS (e.g., seizure disorder), or other study procedures (e.g., contagious skin disease), (h) current pregnancy or intent to become pregnant during the next 8 weeks, (i) pacemaker or metal implanted in the cranial cavity, (j) psychiatric medication changes within 6 weeks prior to study entry.

Study Design

The goal of the proposed study is to test the preliminary efficacy of tDCS combined with an 8-week aerobic exercise intervention for increasing adherence to exercise in individuals with elevated depressive symptoms. Participants will be randomized to receive the 8-week exercise intervention plus anodal tDCS of DLPFC (AE+tDCS) or sham tDCS of DLPFC (AE+sham). Outcomes will be assessed at end-of-treatment (EOT) as well as at 3-and 6-month follow-up.

Specific Procedures or Treatments

Initial Screening and Medical Clearance Procedures. Interested individuals will contact our research staff and we will conduct a screening of participants' current level of physical activity and depressive symptoms. Participants appearing to meet study criteria will be scheduled for a more comprehensive baseline assessment. Research staff will obtain informed consent and then participants will be evaluated using the diagnostic and screening measures detailed below to confirm eligibility. Participants will also complete a brief computer task at the initial appointment and at the end of the 12-week program that is designed to test working memory. The task involves matching letters to those on screen and lasts approximately 10 minutes. At this interview, we will obtain a release of information to contact their primary care physician (PCP) to request medical clearance for engaging in moderate-intensity exercise AND for engaging in tDCS. In addition to the PCP's own clinical judgment, the PCP will be provided with a list of medical issues that would exclude the participant from exercise and/tDCS. We have successfully used this approach in previous exercise intervention studies. Upon receiving medical clearance, participants will undergo a standardized 1-mile Rockport treadmill walk test, administered by an exercise physiologist, in order to obtain a baseline measure of cardiorespiratory fitness.

Study Assessments. All participants will complete a baseline assessment, as described above, as well as follow-up interviews at EOT and 3- and 6-months after baseline. Assessments will include

evaluator-administered interviews and self-report questionnaires, as well as measures of physical health and activity level (e.g., body composition, blood pressure, accelerometry). Additionally, the SAFTEE-SI will be administered weekly to assess for side effects of the intervention (see Human Subjects section for additional detail). Specific assessments to be used and the timepoints at which they will be administered are presented in Table 1 (below). Participants will be completing questionnaires on a laptop computer or tablet device, using REDCap (see Data Analysis Overview), for ease of data collection. From our prior experience conducting exercise interventions in psychiatric populations, we expect to be able to contact 80-90% of participants at follow-ups.

Randomization and Intervention Conditions. After the medical clearance, participants will be randomized to AE+tDCS or AE+sham. These conditions will differ only in whether active or sham tDCS is being delivered. Participants, evaluators, and those delivering the tDCS will all be blinded to condition. Each intervention session will begin with 20 minutes of either active or sham tDCS, followed by supervised aerobic exercise.

tDCS. tDCS is a form of noninvasive brain stimulation which uses low amplitude current (typically 1-2 mA) to modulate excitability of underlying cortex (61). The stimulation is delivered via two electrodes placed on the scalp. Current passes between them resulting in altered cortical excitability. If tDCS is delivered for a sufficient duration (e.g., >10 min,) these excitability changes have been found to persist for up to 1 hour (62, 63). The device is battery-powered and is adjustable in intensity and duration of stimulation delivered. A review of clinical research with tDCS noted that "tDCS has been tested in thousands of subjects worldwide with no evidence of toxic effects to date" (46). The most common side effects include mild local sensations at the electrode sites, including tingling or itching, (55, 64) moderate fatigue, and headache (64).

In the present study, each participant will undergo a 20-minute session of either active or sham tDCS of DLPFC during each intervention session in a between-subjects design. Each session of tDCS will be immediately followed by the supervised AE (see "Aerobic Exercise Component" section below). Active tDCS intensity will be 1 mA. The anode and cathode are each contained in a 5x5cm rectangular sponge (25 cm^2). The anode will be placed over left DLPFC (F3 on the EEG 10-20 system) and the cathode over the contralateral supraorbital region (just above the right eyebrow). Stimulation will be delivered via two saline-soaked surface sponge electrodes and a battery-driven, constant current stimulator (NeuroConn DC Stimulator Plus). This device includes a study mode, in which subject-specific codes are entered to deliver active or sham stimulation, keeping the administrator blinded. Sham stimulation will use a "ramp up/ramp down" method in which stimulation will be ramped up and back down over a 30-second period. This approach has been found to be an effective sham condition in previous studies using tDCS at 1-2mA (49, 56, 65). Immediately following the 20-minute tDCS period participants will engage in a supervised moderate-intensity aerobic exercise session. These procedures will occur 3x/week for 8 weeks.

Aerobic Exercise Component. After having received either tDCS or sham, participants will engage in an AE session at Butler Hospital's Fitness Facility. Exercise sessions will be 20-30 minutes of moderate-intensity aerobic exercise on a treadmill. These sessions will be supervised by an exercise physiologist who will monitor their heart rate and blood pressure to ensure safety and that activity is occurring at a moderate-intensity (i.e., 64-76% of age predicted maximal heart rate). Participants will be asked to rate their affect and RPE (see C.9.b) during exercise sessions. Sessions will include a 5-min warm-up and a 5-min cool-down to ensure safe exercise procedures. Participants will be asked to answer questions about affect before, during, and after exercise. An additional working memory task that involves remembering numbers will be completed three times during the AE intervention (detailed above). In the later weeks of the study, participants will be instructed to gradually increase physical activity outside these supervised sessions toward a goal of 150 minutes of moderate-intensity aerobic exercise per week. Participants will be provided with resources for increasing their physical activity at home.

Fitbit Alta activity tracker. Participants will be asked to wear the Fitbit Alta activity tracker daily. A g-mail account will be created for each participant in order to register the trackers on Fitbit.com. In doing so, the investigators will have access to the participant's activity data throughout the course of the study. No identifying information will be entered into this account. The participant will not be given

access to this account, in order to allow tracking of activity while reducing effect of the Fitbit on behavior. Participants will be able to see the display on the Fitbit Alta tracker, which provides data for the day it is being worn. We will sync the participant's Fitbit at each session using a study computer.

Data Analysis

Sample Size Considerations. We aim to have a total of 60 participants complete the study (approximately 30 per group). Based on our previous work, we expect approximately 10-20% attrition. Therefore, we will aim to enroll a total of 72 participants to obtain our desired sample size of 60.
Primary Hypotheses: We will first examine patterns of missing data to determine possible mechanisms of missingness and will explore different techniques to impute missing data values[145,146]. To test our first primary hypothesis, we plan to use a mixed modeling approach to test for differences in MVPA between conditions across time-points (EOT, 3- and 6-month follow-up). To test our second aim 1 hypothesis, we will conduct a between-groups t-test to examine whether session attendance differs between groups during the 8-week intervention.

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CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT – BUTLER HOSPITAL

tDCS for Increasing Exercise Adherence in Individuals with Elevated Depressive Symptoms

Sponsorship

This study is being paid for by a grant from the National Cancer Institute.

Research Project Summary

You are invited to participate in a research study designed to test the effects of transcranial direct current stimulation or tDCS – a type of noninvasive brain stimulation – on people's exercise habits. You have been invited to participate because you have said you are interested in starting an exercise program and are experiencing some depressive symptoms. Your participation in the study will last for approximately six months, including initial assessments, an eight week exercise program, and three follow-up assessments. The eight-week exercise program will require three visits to our research lab each week over the eight weeks. Assessments will last about two hours each. You will complete two days of assessments before starting the exercise program, and three separate assessments after completing the exercise program - one at the end of the program, as well as three and six months after your baseline assessment.

In order to decide whether or not you wish to be a part of this research study, you should know enough about its risks and benefits to make an informed judgment. This consent form gives you detailed information about the research study which a member of the research team will discuss with you. This discussion should go over all aspects of this research: its purpose, the procedures that will be performed, risks associated with the procedures, possible benefits of participation and possible alternatives. Once you understand the study, you will be asked if you wish to participate; if so, you will be asked to sign this form.

Description of Procedures

If you decide to participate, you will be asked to come in for several assessments, as well as complete an eight-week program combining exercise and tDCS.

Baseline Assessment and Medical Clearance. If you decide to participate, you will first complete an interview with one of our research staff members to confirm that you are eligible for the study. Our study staff will ask you questions to learn about you and your exercise habits, and determine if this study is a good fit for you. You will be interviewed by research staff and will also complete some forms and questionnaires on a computer. These will include questions about your exercise habits, eating, physical health, and psychiatric symptoms. You will also be asked to complete a brief computer task at the initial appointment and at the end of the 8-week program that is designed to test working memory. The task involves matching letters to those on screen and lasts approximately 10 minutes. You will be asked to wear an accelerometer (e.g., small device that counts your movements so that we know how active you are) for a week before each assessment time point including baseline. This, and other study assessments, will be audiorecorded.

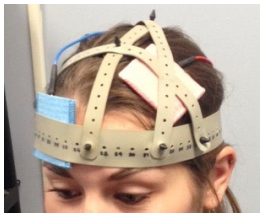
Before becoming a participant in this study, we will need to receive medical clearance from your primary care physician (PCP). We will ask you to give us your signed permission to be in contact with your PCP. Your PCP will be receiving a letter that explains what is involved in this study. Your PCP will then indicate whether or not the study is safe for you. However, it is your

responsibility to inform study staff of current medical conditions and of changes in your health that take place over the course of the study to ensure your continued safety in the exercise program.

After receiving medical clearance, we will determine your current level of fitness by having you participate in a treadmill exercise test. An exercise physiologist on our study team will do the test with you and all procedures will be discussed with you prior to the test. During the exercise test, you will be walking on a treadmill at a speed that you can comfortably maintain for one mile (i.e. you choose the speed). During testing, your heart rate and blood pressure will be monitored. If you feel dizzy, weak, or very short of breath, or if you have chest pains or any other adverse signs and symptoms, the test will be stopped. During this exercise testing session, we will also measure your weight, height, and percent body fat.

It is possible that, based on the interview, medical screen, and/or exercise test, you will not be found eligible to participate in this study. In addition, if you are unable to walk one-mile on the treadmill, you will not be eligible to participate in this study.

Exercise Program with tDCS. After the baseline assessment, you will complete an eight week exercise program which will combine tDCS and exercise. This program will require you to attend program sessions three times each week for the eight weeks. Each session will last about an hour. As part of this program you will have either active tDCS or simulated tDCS - which one you get will be assigned randomly, like the flip of a coin, and neither you nor the study staff you meet with will know which one you are getting. You will have either the active or simulated (sham) tDCS for approximately 20 minutes at the beginning of each exercise program visit. In order to provide the active or sham stimulation, two wet sponges containing electrodes will be placed on your head. These sponges will be held in place by large rubber bands. During the stimulation period, these sponges and rubber bands will remain on your head (see image).



All study participants will participate in a moderate-intensity aerobic exercise program, regardless of the type of tDCS they get. During each visit, participants will complete 30 minutes of exercise in our study gym at Butler Hospital, using exercise equipment at this facility (e.g., treadmills, stationary bikes, elliptical machines). Each workout session will also include a 5-10-minute warm up and 5-10 minute cool down. Throughout the 8 week program, you will be asked to keep a log of any type of exercise you do each day. You may also be asked to answer questions about how you feel before, during, and after exercise, and complete a brief working memory number task.

In order to track your physical activity, you will be asked to wear a Fitbit device each day during the course of the 8-week program. We will set-up a Fitbit account for your tracker on Fitbit.com, which you will not have access to. However, you will be able to see your daily activity data on the tracker's display. At your first exercise session, we will provide you with instructions on how to wear and use the Fitbit. At the beginning of each exercise session thereafter, we will sync the Fitbit data using a study computer. After you have completed the study, the Fitbit is yours to keep and you can choose to create an account on Fitbit.com if you'd like.

Follow-up Assessments. At the end of the eight-week program, you will come in for another assessment, similar to the baseline assessment. Again, you will be interviewed by our study staff

and will be asked to complete some forms and questionnaires on a computer. As in the baseline assessment, we will have you walk on the treadmill and we will gather information on your physical health. You will also be asked to wear an accelerometer (e.g., small device that counts your movements so that we know how active you are) for a week before each assessment. You will come back and complete similar assessments three months and six months after completing your baseline assessment.

Risks and Inconveniences

There are minimal risks associated with participating in a submaximal exercise test (used to predict maximum aerobic ability) and a regular exercise program such as the one we offer in this study. You may experience general fatigue (tiredness) during your participation in these activities. You may also experience sprains, muscle pulls, shin splints, or bone injuries. Precautions should be taken to prevent such injuries, such as careful adherence to your exercise prescription. In addition, during exercise, your heart rate and blood pressure will increase, and under extreme conditions, this can lead to a serious cardiac event (such as heart attack). The possibility of experiencing a serious cardiac event has been estimated to be less than 2 per 20,000 in exercising adults.

You may experience mild and temporary stress associated with completing the self-report measures. You can choose to not answer any given question or discontinue the study at any time. You may also find the computerized working memory task to be tedious and/or boring. You may choose to discontinue the task at any point.

You may also experience worsening depressive symptoms. As part of the study, we will closely monitor your depressive symptoms with questionnaires and brief interviews. This may also include receiving a phone call from study staff when you miss a session. If your depressive symptoms were to significantly worsen, we may want to contact your mental health treatment provider.

There is some risk with tDCS. There is a risk of skin irritation and temporary redness on your scalp where the stimulation occurs. Local skin burns are also possible; however, these would be considered extremely rare given the type of tDCS used in this study. Hypomania, (feelings of elevated mood or too much energy), has also been reported in a small percent of people who received daily tDCS for depression. In one study where daily tDCS was used for depression with or without antidepressant medication, as many as 5-6% of people developed hypomania. In most cases, the hypomania went away after stopping tDCS or by making adjustments to medications. However, the overall risk of hypomania occurring with tDCS is still unclear. Thus, this may be a risk. Other side effects such as temporary headache, nausea, and fatigue are sometimes reported with tDCS, as well. It is possible that tDCS may have other unforeseen side effects. We will monitor you closely for skin burns and discomfort. However, if you experience discomfort, please tell us immediately. A physician will be on-call during all tDCS procedures. We will also check in with you regularly during your weekly visits about any side effects you may be experiencing.
We will make all efforts to protect your confidential information. However, in any study there is always a risk that your confidential information could be disclosed, despite our best efforts to protect your information. In order to keep the audio recordings of assessments confidential and private, research staff will transfer the digital audio file to a secure drive after the assessment or treatment session and delete it from the audio recorder. These files will not be labeled or stored with your name or any other identifying information and will be deleted at the end of the study.

Women Please Note: The effects of tDCS as used in this study during pregnancy are unknown. Therefore, if you are a woman able to bear children who is pregnant, who may be pregnant, who is planning to become pregnant, or who is currently breastfeeding, we cannot include you in this study at this time. For women of child-bearing age, we will do a pregnancy test at the beginning of the study to make sure you are not pregnant. We will specifically ask you to let us know if you change your mind and decide to become pregnant during the study.

Benefits

You may have health benefits from starting a new exercise program as part of this study. However, we cannot guarantee that you will benefit. The main benefits of this study are to help researchers and clinicians develop future interventions to help people start and continue to exercise.

Economic Considerations

You will receive up to $200 for completing all study visits/procedures. You will receive $50 for completing the baseline assessment, $50 for completing the assessment at the end of the exercise program, and $50 for each of the 3- and 6-month follow-up assessments. These amounts will be distributed by a check from Butler Hospital or gift cards to a local store, whichever you choose.

Depending on the amount of payment you might receive for your participation in this study, you might have to provide your name, address, and taxpayer ID or Social Security number to the Butler/CNE Research Accounting Department. In order to receive $300 or more for participation in research, you will have to complete and sign a W-9 form. If you are paid $600 or more in any calendar year for research participation, the IRS will be notified of the total amount you were paid, in accordance with federal regulations. You should ask the researcher for more information if you have questions about this process.

In Case of Injury

We will offer you the care needed to treat any injury that results directly from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer.

Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for any injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed on the last page of this consent form.

Alternative Treatments/Alternative to Participation

No treatments are being offered as part of this study for any physical or mental health problem. As an alternative to participating in this study, you may also seek to begin an exercise program on your own, with your physician's advice to do so, and utilize community resources such as gyms, bike paths, etc.

Financial Disclosure

Not applicable.

Voluntary Participation

You are free to decide whether or not to participate in this study, and you are free to withdraw from the study at any time by informing the researchers verbally or in writing. If you decide you do not wish to provide additional protected health information to the researchers, you may withdraw from the study. Research information collected up to the time that you decide to withdraw will remain as part of the study data. A decision not to participate or to withdraw from the study will not adversely affect future interactions with Butler Hospital or Brown University. Your participation in the study may be terminated by the researchers without regard to your consent; in that case, you are entitled to an explanation of the circumstances leading to that decision.

Confidentiality and Protection of Your Health Information

You will not be personally identified in any reports or publications that may result from this study. The confidentiality of the information you provide to us will be maintained in accordance with state and federal laws. To keep your information safe, we will store all information in locked file cabinets and on password protected secure computer servers. To the extent possible, we store identifying information (such as your name or address) separately from study data (such as questionnaires that you complete). In addition to keeping research data, we will place a note with a brief description of study involvement and procedures (including tDCS procedures) in a Butler Hospital medical record. All identifying information except what is part of your medical record at Butler will be destroyed 6 years after the completion of the study.

If you tell us something that makes us believe that you or others have been or may be physically harmed, we will report that information to the appropriate agencies if required by law**.** In Rhode Island, we are required to report child abuse and neglect and elder abuse to state authorities.

General information about this study has been or will be submitted to the federal clinical trial registry databank, which can be accessed on the Internet at www.ClinicalTrials.gov.

If you sign this document, you give permission to Drs. Abrantes and Garnaat (study directors) and their research staff at Butler Hospital to use and share your health information that identifies you, for the purpose of conducting the research study described above.

Your health information related to this study may also be shared with and used by individuals outside of Butler Hospital, including:

- Your primary care provider. We will ask you to sign a release of information for that provider. Your primary care provider will let us know if it is safe for you to begin an exercise program. We may also contact him/her during the study to discuss any changes in your health status that may impact your ability to engage in exercise.
- Specialty mental health care providers for whom you provide a release of information. If there is a change to your mental health status (e.g., you become more depressed or experience new symptoms and may need more treatment), we will communicate with your mental health provider about this.
- Other healthcare and public safety professionals, if we are concerned that you are at risk of hurting yourself or others.

The health information that we may use or share with others for research purposes includes any information that you give us as part of your study participation, and results of any assessments that we do as part of the study.

Your health information may also be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Butler Hospital is required by law to protect your health information. Individuals outside of Butler that receive your health information may not be required by Federal privacy laws (such as the HIPAA Privacy Rule) to protect it, so we can not guarantee that they will not share it without your permission.

Please note that:

- You do not have to sign this consent form, but if you do not, you may not participate in or receive research-related treatment in this study.
- Butler Hospital may not withhold treatment or refuse to treat you, based on whether you sign this consent form.
- You may change your mind and revoke (take back) this consent and authorization at any time. If you no longer want to give us permission to use your health information for this research study, you must contact one of the Principal Investigators, Ana Abrantes or Sarah Garnaat and you will be instructed to provide a written statement.
- Even if you revoke (take back) this consent and authorization, Butler researchers may still use or share health information about you that they already have obtained, when doing so is necessary to maintain the integrity or reliability of the current research.
- You generally will not have access to your personal health information related to this research until the study is completed. At the conclusion of the research and at your request, you will have access to your health information that Butler Hospital maintains in a designated record set, according to the Notice of Privacy Practices provided to you by Butler Hospital. The designated record set includes medical information or billing records used by doctors or other health care providers at Butler Hospital to make decisions about individuals.
- Your health information will be provided to you or to your physician if it is necessary for your care.

This Authorization will expire when all the activities associated with this research study have concluded.

Questions

In preparation of this consent form, it was necessary to use several technical words. Please ask for an explanation of any that you do not understand.

Authorization: I have read this form and decided that _____

_____

(name of subject)

will participate in the project described above. Its general purposes, the nature of my involvement, and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent form.

_____

_____

_____

Signature

_____

_____

_____

Relationship (self, parent, guardian)

_____

_____

_____

Date

_____

_____ _____

_____

Signature of Principal Investigator
Telephone

or

_____

_____ _____

_____

Signature of Person Obtaining Consent
Telephone

If you have further questions about this project or about research-related injuries, please contact Ana Abrantes, Ph.D. at 401-455-6440 or Sarah Garnaat, Ph.D. at 401-455-6659. If you have questions about your rights as a research subject, please contact Linda L. Carpenter, M.D., Chair, Butler Hospital Institutional Review Board, at 401-455-6349.

THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX HAS BEEN COMPLETED BY THE IRB OFFICE

THIS FORM IS VALID UNTIL

DATE:

IRBNET ID#

BUTLER IRB REFERENCE#

BY (ADMINISTRATOR):