PSYCHOLOGICAL AND NEUROPHYSIOLOGICAL EFFECTS OF A NON-PHARMACOLOGICAL INTERVENTION IN SUBJECTS WITH MENTAL HEALTH AND NEUROLOGICAL SYMPTOMS

RESEARCH PROPOSAL
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SWITCH ON YOUR BRAIN

A randomized clinical trial with the primary aim of investigating the psychological and neurophysiological effects of a non-pharmacological intervention in subjects with mental health and neurological symptoms.

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INTRODUCTION

We propose a **randomized clinical trial** with the primary aim of investigating the psychological and neurophysiological effects of a non-pharmacological intervention in subjects with mental health and neurological symptoms. To be specific, the non-pharmacological intervention will be the 21 Day Brain Detox with the Switch On Your Brain with the 5-Step Learning Process®, specifically using the version in the SWITCH app developed by Dr. Leaf based on her theory, research, and clinical practice. The subjects will be adults with mental health and/or neurological symptoms who are part of a clinical neurology practice (Network Neurology located in Charleston SC). The psychological effects, such as subjective psychological, physical, and social well-being, will be measured by the modified BBC Subjective Well-Being Scale (BBC-SWB). Surface Electroencephalography (EEG) with quantitative electroencephalography (QEEG) functional analysis will be used to measure functional neurophysiological effects in the subjects (see description below). In addition, bloodwork will also be taken to measure levels of telomere, DHEA/cortisol, homocysteine, and prolactin/ACTH in order to test DNA, hormone, amino acid, and hypothalamic-pituitary adrenal changes in participants respectively. The secondary aim is to determine the extent to which the knowledge, attitude, and skills of the subjects increased their ability to self-regulate and control their reactions to the events and circumstances of life causing the feelings of anxiety and depression. These are the underlying principles of 21 Day Brain Detox with the Switch On Your Brain 5-Step Learning Process® embodied in Switch On Your Brain with the 5-Step Learning Process® (SWOYB 5-Step®) used in the SWITCH app. Subject knowledge, attitude, and skills will be measured using the 21 Day Brain Detox Questionnaire (21DQ).

SIGNIFICANCE OF THE STUDY

With the increasing incidence and prevalence of intrusive thoughts, anxiety and depression as symptoms in persons of all ages throughout the world, the availability of a simple technology tool for personal use to address and ameliorate these symptoms (without addition of a pharmaceutical substance or use of a medical device) could potentially help innumerable persons of all ages to experience improved mental and physical health and well-being.

AIMS

Aim 1. The primary aim of this study is to determine if the 21-Day Brain Detox Plan with the Switch On Your Brain 5-Step Learning Process® as a non-pharmacological intervention has a substantively positive impact on psychological and neurophysiological measures in a population of subjects with mental health and neurological symptoms.

Aim 2. The secondary aim of this study is to determine if the 21-Day Brain Detox with the Switch On Your Brain 5-Step Learning Process® non-pharmacological intervention has a substantively positive impact on subject knowledge, attitudes, and skills to self-regulate and control their reactions to the events and circumstances of their life that cause intrusive thoughts, feelings of anxiety and depression as measured by the 21 Day Brain Detox Questionnaire (21DQ).

Aim 3. The tertiary aim of this study is to understand how participants who have been introduced to the 21-Day Brain Detox with the Switch On Your Brain 5-Step Learning Process® non-pharmacological intervention describe their challenges, past trauma, and sources of meaning regarding their life experiences.

METHODOLOGY

Research Design

The research design for this study will be a randomized controlled trial (RCT) using the tool, the 21 Day Brain DetoxTM with the Switch On Your Brain 5-Step Learning Process® in an app called the SWITCH app. Subjects will be randomly assigned to a “treatment” and “control” group, and will be tested on all of the study measures prior to implementing the intervention. After the pretest measures have been collected, the treatment arm will receive the 21-Day Brain Detox PlanTM with the Switch On Your Brain 5-Step Learning Process® intervention using the SWITCH app in addition to a typical standard of care (SOC) treatment, while the control arm will receive the standard of care.

Subjects will be followed over the course of the program and the study measures will be re-administered over five follow-up periods. Members of the research team will interact with the participants over the course of the study and will be the only team personnel who will know which participants have been assigned to groups. In addition, the physicians will prescribe standard of care without knowing which participants are in comparison groups. The research coordinator will also collaborate with the IT team to send the intervention to the assigned participants in the treatment arm via the SWITCH app. In addition, the outcome measures will be collected such that the evaluator will not know what groups are considered treatment and control, providing an analyst blind. Both of these researcher and the evaluator blinds will help to reduce bias in the study. As the gold standard of research, a RCT is well-suited for determining if an intervention has a meaningful effect on key outcome measures of interest and can establish high confidence in causal claims (Spieth, Kubasch, Penzlin, Illigens, Barlinn, and Siepmann 2016). In addition, this study will also contain a qualitative narrative component that will ask participants open-ended questions regarding events, circumstances, trauma, and sources of meaning. Qualitative research provides in-depth understanding of specific contexts and the meanings attributed to those contexts by participants (Patton, 1985). This component will be revisited multiple times throughout the study to build a story of the participants’ experiences related to the intervention and could also provide emergent themes that could provide additional insight.

Study Hypotheses

The following study hypotheses were formulated, namely:

- H1 There would be a positive change in the subjects' psychological, physical, and social well- being after the introduction of the 21 Day Brain DetoxTMwith the Switch On Your Brain 5-Step Learning Process®.
- H2 There would be a positive change in the subjects' anxiety symptoms after the introduction of the 21 Day Brain DetoxTM with the Switch On Your Brain 5-Step Learning Process®.
- H3 There would be a positive change in the subjects' depression symptoms after the introduction of the 21 Day Brain Detox PlanTM with the Switch On Your Brain 5-Step Learning Process®.
- H4 There would be a positive change in the subjects' intrusive thoughts symptoms after the introduction of the 21 Day Brain Detox PlanTM with the Switch On Your Brain 5-Step Learning Process®.
- H5 There would be a positive change in the subjects' neurophysiological functioning after the introduction of the 21 Day Brain Detox PlanTM with the Switch On Your Brain 5-Step Learning Process®.
- H6 There would be significant clinical differences in blood telomere, DHEA, cortisol, homocysteine, prolactin, and ACTH levels in participants after introduction of the 21 Day Brain Detox PlanTM with the Switch On Your Brain 5-Step Learning Process®.
- H7 There would be a positive change in the subjects' knowledge, attitude, and skills relating to managing anxiety, depression and intrusive thoughts and their mental health using the SWOYB 5-Step® after the introduction of the 21 Day Brain Detox PlanTM with the Switch On Your Brain 5-Step Learning Process®.
- H8 There would be a positive change in the subject's self-regulation and reactions to the events and circumstances of life leading to improvement in feelings of anxiety and depression and intrusive thoughts.

The study hypotheses are derived from the aims of this study. Hypotheses 1 through 6 nest within Aim 1 of this study, while hypothesis 7 and 8 nests within Aim 2. The null hypotheses assume that the 21-Day Brain Detox Plan with the Switch On Your Brain 5-Step Learning Process®, won't have any positive effects of on the knowledge, attitudes and skills relating to the mind-brain connection, psychological/physical/social well-being, anxiety/depression symptoms, neurophysiological parameters, and telomere, DHEA, cortisol, homocysteine, prolactin, and ACTH levels in the blood of the subjects.

Qualitative Component

To supplement the quantitative findings of the RCT, a set of open-ended questions will also be asked of the participants to help elicit a better narrative understanding of the participants' experiences related to events, trauma, and sources of meaning. This qualitative research component will seek to answer the following research question:

RQ1: How do participants who have been introduced to the 21 Day Brain DetoxTM with the Switch On Your Brain 5-Step Learning Process® describe their challenges, past trauma, and sources of meaning regarding their life experiences?

Target Population and Recruitment

The target population for this study is anyone over the age of 18 years who exhibit specific levels of mental health, depression, and/or anxiety and intrusive thoughts symptoms. 30 initial subjects - who have some level of these psychological symptoms - are necessary for this study in order to track any measurable change given the intervention. From this initial pool of 30 subjects, screening will select 14 subjects meeting all inclusion and exclusion criteria who will them receive further symptom screening, lab testing, and neurophysiologic testing as outlined in this document.

The inclusion criteria for this study consist of:

a) consent to participate in the study,

b) must be 18 years of age or older,

c) must have a score of 8 or above on the PHQ-9 scale,

d) must have a score of 5 or above on the HADS-A anxiety scale.

The exclusion criteria for this study consist of:

a) Prior experience or familiarity with Dr. Leaf's books, applications, or teachings (due to possible study bias),

b) concurrent diagnosis of epilepsy or refractory depression (due to complexity of co-morbid diagnoses)

c) currently taking prescribed psychotropic medications (due to confounding factors in brain analysis and masking of symptoms)

d) score of <8 on the PHQ-9 scale,

e) score of <5 on the HADS-A anxiety scale.

Subjects for this study will be recruited from patients and/or employees of Network Neurology, and from additional posted flyers for this clinical trial (see attachment). Flyers will be posted at Network Neurology and at area colleges and offices of doctors and therapists (with their permission) within a 15-mile radius of the Network Neurology office.

Sampling and Power Analysis

As is typical with most RCTs, a convenience sampling method will be used to sample subjects for this population. Accordingly, the results of this study cannot be generalized to the population with any degree of certainty. However, the sample will be compared in terms of demographics to the overall target population to determine if sample characteristics match the population in order to establish a modicum of representivity. An a priori power analysis will be conducted using G*Power 3.1.9.2 to determine the sample size necessary to detect a significant effect in the population.

For this study, assuming a moderate to high effect size, f = 0.30, power (1 - β) = 0.80, and alpha (α) = 0.05, for a between-within subjects analysis of variance (ANOVA) with two groups and six repeated measures, the necessary sample size needed would be a total of 14 subjects (Cohen, 1988; Erdfelder, Faul, & Buchner, 1996; Faul, Erdfelder, Lang, & Buchner, 2007).

In clinical settings, depression is prevalent at about 70-80% of a participant pool at moderate level or severe levels (> 14 on the HAM-D) (Trivedi, Rush, Wisnewski, Nierenberg, Warden, Ritz, Norquist, Howland, Lebowitz, McGrath, Shores-Wilson, Biggs, Balasubramani, Fava, and STAR*D Study Team 2006). In clinical settings, generalized anxiety disorders (GAD) are prevalent in about 50% of the participant pool at moderate level or severe levels (> 18 on the HAM-D) (Ruiz, Zamorano, Garcia-Campayo, Pardo, Freire, and Rejas 2011). Therefore the research team will recruit a total initial pool of 30 recruits in the pre-screening phase to meet these anxiety and depression prevalence rates and reach the desired sample size of 14 participants for the pilot study. Those recruits that don't meet eligibility will still be retained for a parallel study that will be used to observe the general population under the same conditions, same methods and measures, only excluding the qEEG and bloodwork measures.

Measures, Instruments, and Data Collection

This section outlines the concepts that will be measured, the instruments that will be used to capture these concepts and data collection procedures. Table 1 provides a list of each measure and the implementation schedule for each measure related to the design of the study. In order to test the effectiveness of the 21 Day Brain Detox Plan with the Switch on Your Brain 5-Step Learning Process®, most of these measures will be assessed 6 times during the intervention period of the Pilot Study. An additional follow-up measure will be conducted after three months to assess a possible attenuation of treatment effect over time:

- 2019.07.12: prior to implementation of the Plan (Day 00),
- 2019.07.19: the 7th day (Day 07),
- 2019.07.26: the 14th day (Day 14),
- 2019.08.02: the 21st day - after completing the 1st cycle (Day 21),
- 2019.08.23: the 42nd day - after completing the 2nd cycle (Day 42),
- 2019.09.13: immediately after completion of Day 63, and finally,
- 2019.12.13: three month follow-up.

Table 1. *Concept Measures and Instruments Implementation Schedule*

Measure	Pre-screen	Day 0 (pre-test) 2019.07.12	Day 7 2019.07.19	Day 14 2019.07.26	Day 21 2019.08.02	Day 42 2019.08.23	Day 63 2019.09.13	3-month Follow-up
Psychological effects (BBC-SWB)		X	X	X	X	X	X	X
Physical effects (BBC-SWB)		X	X	X	X	X	X	X
Social well-being effects (BBC-SWB)		X	X	X	X	X	X	X
Self-report Depression (PHQ-9)	X	X	X	X	X	X	X	X
Self-report Anxiety (HADS-A)	X	X	X	X	X	X	X	X
SWOYB knowledge, attitudes and skills (21DQ)		X	X	X	X	X	X	X
Neurophysiological effects (QEEG)		X			X		X	
Blood work: Telomere		X			X		X	
Blood work: DHEA		X			X		X	
Blood work: Cortisol		X			X		X	
Blood work: Homocysteine		X			X		X	
Blood work: Prolactin		X			X		X	
Blood work: ACTH		X			X		X	
Qualitative Narrative Questions (Treatment group)		X			X		X	

In order to test the effectiveness of 21 Day Brain Detox Plan with the Switch on Your Brain 5-Step Learning Process®, as presented in the SWITCH app, the EEG/QEEG and bloodwork will be performed at pre-test on day 00, on day 21, and day 63 due to the analysis complexity and costs associated with collecting complex neurophysiological data on this measure. The qualitative questions will also be administered to the treatment group via open ended questions using a survey link.

Quantitative Measures

These measures can be divided into two groups: self-assessment psychometric indicators and the neurophysiological indicators. The first of the self-assessment outcomes will observe the subject's psychological characteristics which measures three domains: psychological, physical, and social well- being, as measured by the modified BBC subjective well-being scale (BBC-SWB) instrument. The BBC-SWB is a 5 point Likert scale with 24 items and has been found both a reliable and valid instrument with Cronbach alphas that range from .74 to .95 indicating very strong reliability (Pontin, Schwannauer, Tai, and Kinderman 2013).

The participant self-report assessment of anxiety symptoms will be measured using the Hospital Anxiety and Depression Scale (HADS) instrument. The HADS-A (anxiety only) is a 4 point Likert scale with 7 items and possessing strong validity and reliability having shown Cronbach alphas that range from .68 to .93 (Bjelland, Dahl, Haug, and Neckelmann 2002). This measure will also be used to determine inclusion in the study.

The participant self-report assessment of depression symptoms will be measured using the Patient Health Questionnaire (PHQ-9) instrument. The PHQ-9 is a 4 point Likert scale with 9 items that has strong validity and reliability having shown Cronbach alphas greater than .80 (Kroenke, Spitzer, and Williams 2001). This measure will also be used to determine inclusion in the study.

The subject's knowledge, attitude, and skills of the mind-brain connection (SWOYB 5-Step®) will be assessed using the 21 Day Brain Detox Scale (21DQ) – a researcher designed instrument. This instrument captures the subject's knowledge, attitudes, and skills with regard to of the mind-brain connection. The 21DQ has shown strong structural validity and reliability in testing (publication pending). Cronbach's alphas for subfactors ranged from .615 to .905 with an overall factor that ranged from .765 to .796".

Neurophysiological effects will be measured by the electrocephalography (EEG) with quantitative electrocephalography (QEEG) source neuroimaging analysis. This quantitative measure is an essential complement to a regular EEG, and is very important to more fully understand how, where, and why our brains function the way they do, and also why we experience the troublesome symptoms which lead us to look to a health-care provider for understanding, answers, and help. An EEG/QEEG evaluation records the subject's brain waves using painless, non-invasive sensors applied to the scalp, over a 1-hour time period. It can be performed with relative ease by a skilled and experienced technologist. This FDA-approved technology uses sophisticated computerized electromagnetic source neuroimaging (ESNI) quantitative analysis, using Mitsar® and NeuroGuide® technology, which are then used to correlate with subject symptoms, their locations and networks in the brain, to determine ways to address, improve, and eliminate such symptoms.

In addition, bloodwork will be drawn from the participants at three points in the study in order to assess their levels of telomere, DHEA, cortisol, homocysteine, prolactin, and ACTH that are meant to test DNA, hormone, and amino acid changes in participants. The phlebotomist will find the proper vein by means of tying a tourniquet above the right or left arm at least 4 to 6 inches above the ante- cubital fossa while palpating for a vein that has the best reflex. 10 mL of blood will be withdrawn once the butterfly needle is inverted into the vein in the ante-cubital fossa, forearm, or hand obtaining 5 serum separate tubes. Once obtained, tourniquet will be released and needle removed with application of gauze and paper-tape in the area of the venipuncture. A total of 50 mL will be obtained in five 10 mL vials used to collect blood for analyses of ACTH, Homocysteine, Prolactin, Cortisol, DHEA and Telomere length analysis. Blood will be drawn at designated times per research protocol (Days 0, 21, and 63). Specifically, telomere is a section of genetic material at the end of each chromosome whose primary function is to prevent chromosomal fraying when a cell replicates and will be assessed to determine if the length of this cellular marker is decreased. DHEA is a natural steroid will be assessed to observe whether the adrenal glands are working correctly. Cortisol is a hormone that is important to fight or flight responses and will be assessed to determine if high levels are present or are decreasing. Homocysteine is an amino acid that will be assessed to determine if the participant has a specific vitamin deficiency. Prolactin is a hormone that is released from the pituitary gland and is associated with lactation in women. High prolactin

levels can cause dysfunction in sperm production, low testosterone, and testicular dysfunction further leading to low energy ED, problems with blood count, bone strength leading to osteoporosis and even muscle mass. If high anxiety causes elevation of prolactin it can lead to great difficulty in men (Noel, Suh, Stone and Frantz 1972). ACTH is a hormone produced from the pituitary gland that regulates cortisol levels. Inconsistent levels of telomere (Ridout, Ridout, Price, Sen, and Tyrka 2016), DHEA (Peixoto, Grande, Mallmann, Nardi, Cardoso, and Veras 2018), cortisol (Dienes, Hazel, and Hammen 2013), homocysteine (Chung, Chiou, and Chen 2017), prolactin (Gomes, Sousa, and Lima 2015), and ACTH (Amsterdam, Maislin, Droba, and Winokur 1987) in the blood have been found to have a relationship to neurological disorders like depression and anxiety and will serve an excellent measure of potential physiological bi-products of the impact of the intervention.

Last, the research team will also ask all respondents a question that captures the participant's beliefs regarding their expected benefits of treatment, in order to control for a potential expectancy effect (Boot, Simons, Stothart, and Stutts 2013). The question will be a simple Likert scale ranging from 1 to 10 with higher values indicating a strong expectation of treatment benefits.

Qualitative Questions

The qualitative narrative protocol will consist of 15 questions, 11 of which are qualitative questions that will be asked of the treatment group participants four times: days 0, 21, 63 and at the final session on December 13. The qualitative questions will consist of:

- Please describe any challenges in your life you are currently dealing with.
- If you had a crisis in your life, do you have people you could turn to and rely on? If yes, what kind of support? If no, why do you think this is the case?
- Do you find your job meaningful? Why or why not?
- Do you find your schooling meaningful? Why or why not?
- If you could consciously do something every day to make yourself happier, what would you do?
- Are you able to search reach a compromise in tough situations? If yes, what do you say and/or do? If no, what do you say and/or do?
- How good are you at dealing with uncertainty? Describe in as much detail as you can?
- In thinking about a personal dilemma, are you able to put yourself in another person's shoes or to see things from their perspective? Yes or no, please elaborate.
- Please describe any traumatic early childhood experiences you have had that you can remember.
- Please describe any traumatic experiences you have had as an adult that you can remember.
- Do you have problems sleeping? Please describe in as much detail as possible. For example, do you have difficulty falling asleep; do you wake up frequently; do you have very disturbed sleep? How often - every night? Once a week?

In terms of data collection, potential recruits will be sent a link via email to collect intake information that will capture the demographics, PHQ-9, and HADS-A (all done as self-report measures) to assess eligibility for this study. The intake forms will assess inclusion and exclusion criteria. An eligible subject must consent to taking the study, be 18 years of age or older, must score 5 or above on the PHQ-9 instrument, and must score 11 or above on the HADS-A anxiety instrument.

The eligible subject pool will be filled until the necessary 14 subject minimum has been reached. Additional recruits who are not eligible for the study based on inclusion and exclusion criteria but still consent to the study will be retained for a parallel study using the same research process (random assignment to treatment and control groups), intervention using the APP for treatment subjects, and similar measures (all self-report surveys but no qEEG measures or bloodwork) and studied separately from the participants who have symptoms of clinical depression or anxiety. This parallel study will be used to examine the effect of the intervention on a general population. Eligible subjects who commit to the study will be able to keep the SWITCH App for one year subscription as an incentive. The subjects will then be randomly assigned to treatment and control groups and will be assigned a unique identification code in order to follow and match the subjects longitudinally over all repeated measures.

The survey questionnaire will be uploaded on to Psychdata, a secure online repository for distribution to subjects. In order to administer the data collection, emails will be sent to each of the subjects on the selected days with a link that will direct subjects to a secure online survey questionnaire that contains all of the outcome measures (except the qEEG and bloodwork measures). The survey contains 80 questions and will take approximately 20-30 minutes to complete. The data will be stored securely online until all measures have been collected and will be downloaded into an SPSS file for data preparation and analysis. The survey will then be deleted from the online repository. The raw and working data will be stored in a password protected file for up to 5 years and then all data will be deleted.

Intervention

In this study, 14 individuals at Network Neurology will be used as the subjects. Due to the small number of subjects (fourteen) we are proposing a within-subject design and between subject design. Study subjects will go through the 21 Day Brain Detox Plan with the Switch on Your Brain 5-Step Learning Process® for a total of 63 consecutive days - three 21-day cycles using the SWITCH app. This technique is a mind-directed self-help mental health program, wherein the subject is directed via audio and some video through 5 scientifically researched and clinically applied steps. These steps provide a technique to help identify, face, process and manage the intrusive toxic thoughts that are causing distress including symptoms of anxiety and depression. This approach acknowledges the innate capacity of each individual to recover from their distress and difficulty over time. It recognizes that the sufferings of life cannot be medicalized, but are part of a person’s story and need to be processed and reconceptualized. It is an audio verbally guided process using a mobile application to help the subject to reconceptualize the toxic thoughts into healthy thoughts, and to automatize the newly reconceptualized thoughts. This process enables an individual to learn how to learn new insights and skills and build new memories and take control of their mind health at a pace that suits them. It therefore helps a person identify a toxic thought, break it down, and build a healthy new replacement thought and habit.

Data Storage Plan

All data will be password-encrypted and stored on a private server. Data will be kept for a period of 5-years following the completion of the study after which all digital data will be deleted and any paper information will be destroyed in a HIPAA compliant manner.

Analysis Plan

Once data has been collected at the end of the study period, the data will be screened for invalid cases, variables coded and scales computed, and the variables will be subjected to assumptions testing to ensure the validity of statistical inference. Attrition and missing data will be assessed to determine the proportion of the missing data and the structure using Little's missing completely at random (MCAR) test (Little 1988). This test determines whether the structure of the missing values is randomly distributed (MCAR) or systematically distributed in the data. If the test determines that the missingness is random, listwise deletion will be considered for analysis. If the test determines that it is systematic, missing replacement procedures using multiple imputation (MI) will be considered (Little and Rubin 2002).

The analysis of the data for this study will proceed with a mixed (between-within subjects) analysis of variance (ANOVA) with two groups (treatment and control groups) over six repeated measures (pretest and five follow up measures). The overall main effects of group, time, and the interaction of group and time will be assessed to determine if the effects of the intervention had an effect on the study outcomes. However, study hypotheses will be tested by observing the interaction effects and a hypothesis will be accepted when the test shows significant mean differences of the treatment group in the desired direction for an outcome over time. Pairwise group comparisons over time will be calculated using the Bonferroni method to adjust for multiple comparisons. As is typical for an ANOVA, the effect size for this statistical test is the partial strength of the main and interaction effects. The alpha (α) level for this study will be set at .05. The data will be analyzed using IBM SPSS v25.

The analysis for the qualitative portion of the project will include thematic analysis of responses to the 8 open-ended questions. Data will be uploaded and coded in NVivo 12. First cycle coding, involving initial coding, and second cycle coding, involving categorization (Saldaña, 2015), will be applied to the data. Once coding is finalized, categories will be organized into emergent themes that are focused on answering the study's qualitative research question. Data collected from the three time points (baseline, day 21, and day 63) will be categorized and compared with one another for similarities and differences.

Ethical Considerations

Consistent with the Belmont Report (National Commission for the Protection of Human Subjects 1978) all subjects will be treated with respect for persons, beneficence, and justice. Prior to consent, recruits for this study will be provided disclosures that inform them of the purpose of the project, their ability to choose not to participate, their protection of subject confidentiality, and the risks and benefits of participating. Recruits will be given the opportunity to not consent to participating if they choose not to. They will be allowed to stop participating at any point during the study. The identity of the subjects will be kept confidential, however, they will not be kept anonymous primarily because their identity will be necessary for researchers to ensure that subjects are matched properly across longitudinal measures or to remove duplicate cases in data screening.

The study will not include any vulnerable populations as defined by the Department of Health and Human Services (DHHS) guidelines (Office of Human Research Protections 2018). There will be minimal risk to the subjects as the intervention does not involve procedures that will cause physical harm to them. However, the outcome measures in the survey do ask questions involving a

subject's level of depression and anxiety and intrusive thoughts. Incentives will be provided to ensure that subjects remain in the program for the duration of the study - this will be a one-year subscription to the SWITCH APP. The incentives are not gratuitous and would not be considered coercive. At the end of the pilot study, the data will be de-identified to ensure subject confidentiality and will be stored in a password protected file for five years before the data will be destroyed (deleted).

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