Title of Protocol: Inner Engineering Online (IEO) Intervention for a Specific Company Employee Program

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PART B
STUDY DESCRIPTION

TITLE OF PROTOCOL	**Inner Engineering Online (IEO) Intervention for a Specific Company Employee Program**
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B1. PURPOSE OF PROTOCOL

The purpose of this study is to determine the effects of a web based intervention called "Inner Engineering Online (IEO)" on the burnout states, stress and overall well-being of employees in a company.

The specific aims include:

1. To test feasibility and acceptance of IEO through assessment of participation, compliance, protocol adherence & study satisfaction.
2. To quantitatively assess the effects of IEO on measures of Burnout, Stress & well-being among the participating employees.
3. To determine the effect of IEO on measures of well-being among control employees after they cross over to the intervention group at the end of first phase.

B2. SIGNIFICANCE AND BACKGROUND FOR THE STUDY

Burnout is described as a syndrome resulting from chronic workplace stress that has not been successfully managed. It is characterized by exhaustion, depersonalization, and reduced professional efficacy.[1] Several studies have evaluated interventions that are aimed at identifying and ameliorating burnout, or components of burnout such as high stress and sleep disturbances. [2-4] Meditation, specifically, has shown to be an accessible and efficient method for combating stress, burnout, and promoting a sense of well-being.[5]

Inner Engineering Online (IEO) is a web based intervention administered by the Isha Foundation, a not-for-profit, global, volunteer-based organization. IEO is widely practiced around the globe, but lacks a systematic evidence base. The Inner Engineering Online program is a holistic tool for promoting well-being that teaches individuals how to mindfully and effectively respond to daily stressors using yogic sciences. The program offers guided meditation and yoga practices to promote harmonizing mind-body-emotion and energy of the individual while simultaneously promoting mindfulness, joy, and vitality.[6]

Studies reveal that Inner Engineering meditation and yoga practices improve mental clarity, emotional well-being, productivity, and inner peace while reducing perceived stress and compulsive behaviors. These studies suggest that practice of Inner Engineering meditation may be a pragmatic treatment for stress reduction.[6]

S2Tech is a reputed company providing Information Technology (IT) support to businesses in 35 states of United States of America for over 22 years. The company is looking to promote mindfulness and combat burn out and stress in its employees while voluntarily supporting research studies assessing these markers. The Company is offering the standalone Inner Engineering Online (IEO) course from Isha foundation for all its interested employees primarily to combat stress. While the participants are encouraged to participate in this study, research participation is entirely optional for the participants and will not impact their relationship with their employees in any form. The primary purpose is for the company to offer programs to combat stress and research is optional.

In this randomized controlled trial, differences in overall stress, burnout and wellbeing will be assessed for employees participating in IEO, an online mind-body course that incorporates both meditation and yoga.

The following specific aims are to be accomplished via this study:

- **Specific Aim 1:** To test the feasibility and acceptance of Inner Engineering Online through assessment of participation, compliance, protocol adherence and study satisfaction.
- **Specific Aim 2:** To quantitatively assess the effect of IEO on measures of burnout, stress, and well-being among study participants.
- **Specific Aim 3:** To determine the effect of IEO on measures of well-being among the control-group after they cross-over to the intervention group at the end of first phase.

The study will be conducted in 2 phases. The first phase will accomplish specific aims 1 and 2, while specific aim 3 will be accomplished in the second phase.

References:

1. WHO. Burn-out an "occupational phenomenon": International Classification of Diseases [Internet]. 2019 May 28. Available from: https://www.who.int/mental_health/evidence/burn-out/en/
2. Shioata MN, Keltner D, John OP. Positive Emotion Dispositions DifferentiallyAssociated with Big Five Personality and Attachment Style. The Journal of Positive Psychology. 2006. 1(2): p. 61-71.
3. Ryan RM, Frederick C. On Energy, Personality, and Health: Subjective Vitality as a Dynamic Reflection of Well-Being. Journal of Personality, 1997. 65(3): p. 529-565.
4. Ryan RM, Deci E. To Be Happy or To Be Self-Fulfilled: A Review of Research on Hedonic and Eudaimonic Well-Being. Annual Review of Psychology. Fiske S. Editor. 2001. Annual Reviews: Palo Alto. CA. p. 141-166.
5. Zeidan F, Johnson S, Diamond B et al. Mindfulness meditation improves cognition: Evidence of brief mental training. Consciousness and Cognition. 2010. 19(2) p: 597-605.
6. Peterson CT, Bauer S, Chopra D et al. Effects of Shambhavi Mahamudra Kriya, a Multicomponent Breath-Based Yogic Practice (Pranayama), on Perceived Stress and General Well-Being. Journal of Evidence-Based Complementary & Alternative Medicine. 2017: p. 1-10.

B3. DESCRIPTION OF RESEARCH PROTOCOL

A. Study Design – Overview, Methods, Procedures

Study Overview:

This study involves evaluation of the effects of Inner Engineering Online (IEO) intervention by employing validated questionnaires aiming to measure stress and well-being in the form of a survey to company employees participating in the study.

In order to evaluate this, we randomize the participants into either of the two groups: one who participate in the IEO activities daily for the first 30 days and the other who do not participate in the IEO activities during the first 30 days. We then evaluate stress and burnout along with measures of well-being in these participants using validated electronic instruments at baseline and at the end of the 30 days. This is phase 1 of the study.

For the phase 2, we cross-over the group 2 participants and provide them with the IEO intervention. We follow them through another 30 days and then evaluate measures of stress, burnout and well-being using validated instruments at the end of these 30 days.

Enrollment:

The recruitment is done by the S2Tech company using flyers for advertisements at the company. The recruitment process also involves awareness campaigns, word of mouth announcements as well as advertising flyers on the social media and official websites of the company.

The research team sends a public survey link, where participants can confirm their interest in the study and get detailed information of the study procedures after the company recruits potential participants during awareness campaigns organized by the company.

If they are interested in participating after receiving the email, they will be directed to REDCap where they will be asked a few screening questions to ensure study eligibility. Participants who are eligible will then be directed to an electronic consent form.

Randomization:

Participants will be randomized into one of the two groups using [Simple Randomization Technique] by REDCap. Participants will be randomized into:

1. Intervention Group: Participants will receive the Inner Engineering Online Intervention for a total of 30 days (4 weeks)
2. Control Group: Participants will read a book/journal of their choice for 25 minutes each day for a total of 30 days (4 weeks)

Study Procedure:

We will be administering a brief survey to willing participants after they provide electronic consent. If a participant decides to participate, they will receive a paper survey to complete, or they can complete the survey online via an anonymous REDCap survey link.

The Isha Foundation (which is responsible for the Inner Engineering Online Course) has agreed to send participants an email which contains detailed instructions on how to perform the IEO intervention after the electronic consent has been signed. The Isha Foundation receives the participating employee emails from the company, as they are the primary instructors for the intervention.

Subjects will be randomized following the consent into two groups.

Group 1 will be asked to complete the Inner Engineering Online course which includes completing 7 meditation and yoga course modules in a duration of 30 days. They will be given an IEO activity diary and will be asked to keep a track of their progress. The activity diary will be collected from them on a

weekly basis for 30 days.

After 4 weeks (i.e., 30 days) they will be administered the same set of survey questionnaires which was asked before the intervention was administered. All communications will be conducted electronically or via phone.

Group 2 will be asked to read a book or journal of their choice for 30 minutes at a time for 30 days. They will also be asked to complete a reading log every day to keep a track of their progress every day for 30 days.

Once 30 days is over they will be asked to complete the IEO intervention, which includes practice of meditation and yoga daily for another 30 days while maintaining an IEO activity diary. Group 2 will be asked to complete set of questionnaire at baseline, 30 days and after 60 days.

Surveys will be administered at two time points for group 1 at baseline and at 30 days, whereas three time points for group 2 that is baseline, 30 days and 60 days.

Apart from the surveys, the participants are advised to maintain a reading log or an activity diary for each week. These documents will be collected electronically, either via direct online submission or a scanned copy to be uploaded and sent to a redcap survey link at the end of each week. In order to account for national holidays and personal circumstances, participants may submit their activity diaries and/or reading logs within 2 weeks of the 30 day and 60 day time point.

30 day Follow Up:

We aim to follow up with the participants after 30 days of initial study completion. For Group 1 participants this period coincides with Group 2 study completion surveys at 60 days, whilst group 2 will receive these follow up surveys at 30 days after their study period completion (i.e. at 90 day time point).

These follow up surveys include the baseline surveys, i.e. the same set of questionnaires administered as a part of the study. In addition, a set of compliance questions aimed at collecting information on whether or not IEO was practiced post the study period and its perceived effectiveness in participant's life with possible reasons for non-compliance are included in this follow up questionnaire.

Final Survey:

These surveys are being sent out after the study analysis has been completed and aim's to look at long term compliance to (IEO) intervention and its impact on the participants lives. The survey captures both qualitative and quantitative data on how the study has impacted their lives and provides information on the study acceptance.

Questionnaires:

The following questionnaires are incorporated into the study survey and will be administered to the study participants at the aforementioned time points.

Mindfulness Attention Awareness Scale (MAAS):
MAAS is a 15 question validated instrument that assesses mindfulness and attention while performing routine activities of daily living. Participants are asked to rate on a scale of 1 (Almost Always) to 6 (Almost Never) to assess the frequency of occurrence of each experience. Mean is then computed using items from each of the 15 questions to create a MAAS score.

Perceived Stress Scale (PSS):
PSS is a 10 question validated instrument that assesses stress. Participants are asked to rate on a scale of 0 (never) to 4 (very often) how often they agree with various statements. Items from each of the 10 questions are then summed to create a total perceived stress score.

Maslach Burnout Inventory - General Services Survey (MBI)
This survey consists of 16 questions across three dimensions: exhaustion, cynicism, and professional efficacy. Each question is scored on a scale from 0 (never) to 6 (everyday). The points from each dimension are added to provide a total score for that dimension. Average scores for each dimension are also computed.

Dispositional Positive Emotion Scale- Joy Subscale (DPES-Joy)
The joy subscale of DPES is a 6 item questionnaire that measures a dispositional tendency to feel joy in life. Participants report their level of agreement to each item on a scale of 1 (Strongly agree) to 7 (Strongly disagree). Mean is computed for the combination of all 6 items.

Centre for Epidemiological Studies: Depression Scale (CES-D)
This scale aims to measure depressive symptomatology and consists of 20 questions on how the participant felt or behaved in the past week. The questions are rated on a scale of 1 (Rarely or none of the time, less than 1 day) to 4 (Most or all of the time, 5-7 days). Possible range of scores is 0-60 with higher scores indicating the presence of more symptomatology.

Emotional Distress and Anxiety Short Form- 7 Item Questionnaire measuring Anxiety
This is a short survey used to assess for anxiety in participants. The questionnaire includes 7 questions which are rated on a scale of 1 (Never) to 5 (Always). Sum is computed for the responses and scores range between 7-35, with higher scores indicating greater severity of anxiety.

IEO Activity Diary:
The IEO activity diary is a tool which helps the participants to keep a track of their activities each week. This enables the study team to measure compliance and protocol adherence by the participants.

Reading Log:
The reading log is a tool which helps the participants to keep a track of their reading each week. This enables the study team to measure compliance and protocol adherence by the participants.

B. Statistical Considerations

a. ***Sample Size Justification:***

In this survey based, randomized cross-over study, we are looking at the feasibility of implementing an Inner Engineering Online Intervention on a group of willing company employees. Since it is a feasibility study, we plan to enroll a minimum of 60 participants. Data from these participants will be used to power a larger trial based on the outcomes such as stress, burnout & overall well-being measured during the course of the study.

b. ***Data Analysis:***

Baseline characteristics of participants will be recorded. Continuous data will be presented as means ± standard deviation or median (interquartile range) depending on the distribution of the data and assessed with a parametric or non-parametric t-test, as appropriate. Normality will be assessed with the Shapiro-Wilk test. Categorical data will be presented as frequencies and proportions and assessed with a chi-square or Fisher's exact test. SAS 9.4 (SAS Institute Inc., Cary, NC) will be used for all analyses with two-sided p-values < 0.05 considered statistically significant.

Analysis of Aim 1:

Trial feasibility and adherence will be assessed using data from how often participants in the intervention group complete their IEO activities. This would be reported as the proportion of completed activities out of the total required per protocol. Similar analysis would be done for the control group and adherence to protocol too would be ascertained as a proportion of instance of protocol deviation out of total required activity per protocol. Participant satisfaction will be measured using an internally developed survey. Continuous and dichotomous data will be reported and assessed in a similar fashion as above.

Analysis of Aim 2:

Given the continuous nature of the scales used to assess stress, burnout and measures of well-being, differences between groups will be assessed with a parametric or non-parametric t-test. Although we expect that randomization should account for any differences between baseline characteristics, unadjusted and adjusted linear regression may be utilized in order to account for differences that persist. Our primary analyses will be assessed using intention-to-treat principles. In order to assess whether there are differences between baseline and at six weeks, we will employ the use of paired t-tests as appropriate.

Analysis of Aim 3:

To assess the effect of IEO intervention on the control group following its cross-over to the intervention will be assessed using a parametric or non-parametric t-test. Although we expect that randomization should account for any differences between baseline characteristics, unadjusted and adjusted linear regression may be utilized in order to account for differences that persist. Our primary analyses will be assessed using intention-to-treat principles. In order to assess whether there are differences between baseline and at six weeks, we will employ the use of paired t-tests as appropriate.

C. Subject Selection

Inclusion Criteria:

- Age ≥18 years
- Interest in Inner Engineering Online (IEO) Program

Exclusion Criteria:

- Low English proficiency
- Not currently residing in United States

Subjects will be enrolled without regards to race, gender, or vulnerable category status.

B4. POSSIBLE BENEFITS

We cannot guarantee any direct benefit to study participants. Insights gained from this trial may allow us to better understand the association between meditation and stress/burnout and propose an approach to combat it. If successful, results of this trial could be used to inform other studies.

B5. POSSIBLE RISKS AND ANALYSIS OF RISK/BENEFIT RATIO

Potential physical risks of the study interventions: The IEO intervention is simple and only involves meditation & yoga practices. As such, there are no physical risks expected with the IEO intervention. Similarly, by assessing stress, burnout or well-being measures; we do not anticipate any risk of physical harm to any of the research subjects.

Potential psychological risks: It is possible that there could be psychological or emotional risk to subjects in this study if they were to become aware of their performance in assessments and more so than they would be if they were not participating in the study. Subjects will not be given the scores of their assessments, but if they were to become aware of a decline in their performance this could be stressful or disconcerting to the subject. Additional counseling regarding any psychological or emotional distress stemming from this will be provided by the Principal Investigator at the request of the subject.

Risk of breach of confidentiality: As with any research study, there is a small risk associated with a breach of confidentiality. All research staff for this trial has been extensively trained in how to handle confidential data and how to minimize the possibility of this risk. To mitigate this risk, electronic data and that on paper will be kept in confidential, locked file cabinets and secure offices and/or on password-protected computers. Subjects will also be assigned a unique study ID to minimize this risk.

Risk/Benefit Ratio*:* IEO intervention has no expected risks and the knowledge gained could potentially lead to studies that focus on improvement of stress, burnout and overall long-term well-being of general population. Research team members will attempt to mitigate any of the possible risks described above; therefore, we believe the risk/benefit ratio is in keeping with allowing conduct of the trial.

B6. RECRUITMENT AND CONSENT PROCEDURES

Recruitment

The recruitment is done by the S2Tech company using flyers for advertisements at the company. Recruitment process also involves word of mouth announcements as well as advertising flyers on the social media and official websites of the company.

The research team sends a public survey link, where participants can confirm their interest in the study and get the detailed information of the study procedures after the company recruits potential participants during awareness campaigns organized by the company.

If they confirm interest in study after receiving the email, they will be directed by REDCap to a page where they will be asked a few screening questions to ensure study eligibility. Participants who are eligible and willing to participate in the study will be directed to an electronic consent form.

Please see the attached flyer, approval to post, and electronic enrollment script

Consent

Electronic Consent will be obtained following a few screening eligibility questions to ensure study eligibility in willing participants. The study procedures will be described in detail, including the perceived risks and benefits. The electronic consent will emphasize that participation is completely voluntary.

In addition, we will provide contact information for the study team to ensure that all of the participant's questions are answered prior to providing consent. Electronic consent will then we obtained from willing participants prior to initiation of any study procedures.

Please see the attached electronic enrollment script.

Subject Protection

It is unlikely that participants will be vulnerable to coercion or undue influence in this study. Participants will be informed that their decision to participate or not to participate is entirely voluntary. Participants will have the ability to discontinue their participation at any time. Their decision to withdraw or discontinue the study will in no form affect their relationship with the company.

B7. STUDY LOCATION

Privacy

All efforts will be taken to ensure participant privacy. All study interactions will be completed electronically or via the phone, in a private location that is comfortable for the participant.

Throughout the study, only the minimum required information will be collected, assuring participant privacy during the study protocol.

Data collection will occur only on password-protected computers secured by the BIDMC firewall or in REDCap directly. Data collected will be limited to only the minimum necessary to accomplish the stated research purposes.

Physical Setting
Electronic consent will be obtained from eligible participants. Study procedures can be completed by patients privately in their home. Follow up assessments will occur via online surveys or phone.

Data will be stored on password-protected computers behind the BIDMC firewall or in REDCap directly, which is accessible to only the study team. Study investigators have been trained to maintain PHI in a secure and compliant manner

B8. DATA SECURITY

All electronic data will be stored in REDCap and/or on password-protected servers behind the BIDMC firewall. Any data collected on paper will be stored in locked file cabinets or in secure offices. All data would directly be entered into REDCap database.

No individual identifier will be obtained from the company other than the email for sending surveys. Each subject will be assigned a study-specific ID number. A crosswalk between the participants and their study IDs will be maintained on password-protected computers by members of the research team. At no time will this crosswalk be shared outside the study team.

All data would be directly entered into REDCap database and at the completion of the study all identifiable will be deleted and data analysis will occur using only the participant's study ID, to further ensure confidentiality of their responses

B9 Multi-Site Studies

Single Center Study- N/A

Is the BIDMC the coordinating site? ☐ Yes ☒ No

Is the BIDMC PI the lead investigator of the multi-site study? ☐ Yes ☐ No

B10 Dissemination of Research Results

Please explain whether you will be able to thank subjects and provide research results and, if so, how this will be accomplished. If you do not think this is feasible, appropriate or applicable to this research, please specify why.

Patients will be thanked for their time throughout the study. Because study results are likely to be published a few years after a given subject's participation, study investigators are concerned that mailing the published manuscript and an additional thank-you note years after participation risks violating subject privacy, as mailing addresses are increasingly likely to change with passing time. It is out of the scope of this study to continue tracking mailing addresses after study completion.

However, an aggregate result at the end of the study will be shared with the participating company (S2Tech) and Isha Foundation. Individual participant data or results will never be disclosed to anyone.