Project Title: BurntOut: Role-Play Simulation for Building Medical Student Resiliency

Institution: CLINICAL TOOLS, INC.

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NCT 04494633

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STUDY PROTOCOL

Study Purpose and Rationale

We will assess an internet-based role-playing simulation in which medical students explore common stresses and challenges in the clinical years of medical school, identify potential coping strategies, make decisions, and perceive negative and positive outcomes associated with those choices. If successful, students will gain confidence in how to best apply attitudes and actions that ameliorate the stresses identified, investigate external wellness resources if coping mechanisms fail, and anonymously communicate the challenges to the institution in order to foster institutional change.

Physician burnout has downstream negative effects on patient care. Additionally, burnout and resiliency (the ability to recover quickly from stress and difficulties) are best addressed early in medical training so physicians can recognize poor coping strategies and build resiliency to the stresses of clinical practice. Specific health behavior topics, such as use of alcohol, are related to burnout; thus, addressing burnout decreases the risk of alcohol use in professionals.

The specific aim of NCT04494633 is to assess impact of the intervention on burnout and related indices using standardized measures adapted to be relevant to the intervention and target audience.

Methodology

During Phase II of this Small Business Innovation Research Phase II project, individuals in NCT04494633 will use the simulation and complete online assessments.

Subjects will be asked to use the simulation and fill out online surveys/instruments using personal computers with Internet connection.

Demographic information will be obtained (sex, race, age, education).

Use of the online simulation will involve engaging with scenarios presented in 3D imagery of typical challenges that medical students face, making choices on how to respond to the challenges, experiencing a storyline typical for the choice made, and reviewing feedback on the choice made. They will also be presented lessons on developing resiliency.

Summative Study Description: We will use a pre-/post-intervention parallel design with controls who also will have the opportunity to use the intervention if they choose to do so. We will recruit and enroll up to 80 medical students who are in US medical schools (DO and MD) for the two arms. The number of participants selected is based on a power analysis of our design and our experience of low dropout rate with this target audience; to reach a medium effect size we are aiming for a final sample size of 60 medical students.

Participants will 1) Complete the simulation experience: a simulation/story, educational case studies, and didactic material (taking around 2 hours over a period of around 2 weeks); and 2) Complete

pre-/post- assessments (each taking around 1 hour) plus a follow-up survey after 2-4 weeks, and will be compensated for the assessments.

The primary clinical endpoint will be burnout as measured by an adaptation of the Maslach Burnout Inventory, tailored to medical students and the content in the intervention, so that results are relevant to this specific study.

Secondary endpoints will be measured via the following assessments, all of which will be adapted/edited to be targeted to this group of users.

- Medical Student Quality of Life,
- Patient Health Questionaire 2/Patient Health Questionaire 9 aka PHQ2 and PHQ9, which are depression screening questions,
- Connor-Davidson Resilience Scale,
- Alcohol Use Disorders Identification Test aka AUDIT-C/AUDIT for alcohol use disorder and
- NIDA Quick Screen -two drug question screening for drug use,

Completion of online instruments will involve answering questions on their personal computers. For example, the assessments ask participants to self-rate their level of burnout symptoms, perception of the quality of their life, their level of resiliency, screening for alcohol and other substance use problems, screening for depression. Participation will take up to 4 hours (for use of the simulation plus assessments) over a 4-6 week period depending on the student's pace through the scenarios and participation in the optional activities.

Statistical Analysis

Study Population

Number, age, gender, ethnicity, and whether healthy volunteers. If patients, specify the disease or condition and indicate how potential subjects will be identified.

Students must be currently enrolled in a US based medical school. Women and minorities will be recruited according to their percentages in the medical student/faculty population.

Phase II Study Component	Subjects	Time
Evaluate Intervention with the Target Audience	Up to 80	≈ 4.5 hours

Planned Distribution of Subjects

We will stratify our sample to assure that we have appropriate representation of both women and minorities. Women will comprise 50% of the sample. In 2017-2018 50.7% of medical school matriculates were female1. The Association of American Medical Colleges provides the following information for matriculation in medical school in 2017 of the 21,326 matriculants.

Race/Ethnicity	**% of matriculation (2017)***
American Indian or Alaskan Native	0.7
Asian	23.3

Race/Ethnicity	% of matriculation (2017)*
Black or African-American	7.4
Hispanic, Latino, or of Spanish Origin	9.9
Native Hawaiian or Other Pacific Islander	0.1
White	50.4
Other	0.8
Multiple Race / Ethnicity	1.8
Unknown Race / Ethnicity	3.6
Non-US Citizen and Non-Permanent Resident	1.3

*Numbers total = ~ 100%

We will stratify our sample to match the US distribution of the current medical school population by gender, and by race and ethnicity.

Children

Children are defined by the NIH as those under the age of 18. The intervention is targeted for medical students and thus is only of use to adults aged 18 and over. According to the Association of American Medical Colleges (AAMC),2010-2016 https://www.aamc.org/download/321468/data/factstablea6.pdf), the minimum age of entering medical students was 20 (women) and 21 (men). Therefore, the target audience will be over the age of 21 and will not include children.

Recruitment Information

Recruitment

All participant medical students will be recruited via advertisements sent via e-mail listservs, and by posting notices on Facebook and Twitter.

Consent Process

Subjects will be e-mailed all study materials (informed consent forms if need, explanatory materials otherwise) before the scheduled test or will be invited via email to fill out secure online forms on our website. The forms will include information about the purpose of the study as well as risks in participating and possible benefits. The forms will include information about the purpose of the study as well as risks in participating and possible benefits. The forms will include the contact information for the PI and the IRB.

We will email or conduct a short phone or internet-based chat session with subjects in order to answer any questions, and confirm informed consent signatures have been witnessed prior to beginning participation in the study. Electronic signatures will be allowed where possible under 45 CFR 46 and approved by the CTI IRB. After subjects complete informed consent forms, participation can begin.

Risks and measures to minimize risks

We will make it clear to all participants that participation is voluntary and will not impact any aspect of their medical school evaluation or faculty standing. We will also stress that any information gathered on the assessment instruments or during interviews will be kept confidential and will not have any influence on current course work, grades, or evaluations.

Written or electronic consent will be obtained from all subjects prior to the interview or experience. Personal information will be collected and stored. Confidentiality will be maintained by removing any identifying information from demographic material, tests, and questionnaires. Subject ID numbers will be used rather than names in all instances. All records will be kept on a secure server with password protections and available only to the PI, Co-I, and project assistant involved in this research. All electronic records will be kept in one location in a password-protected file. Any results published from this research will not include any personal identifying information. We will assure the subjects that they can stop the interview or experience at any time.

Response to individual assessments that indicate a potential problem for a specific participant: Drs. Tanner or Rossie will review all subjects' assessment responses and directly contact any subject whose response to assessments (the PHQ9 depression assessment, substance use assessments – AUDIT and drug questions, Maslach Burnout Inventory, CD-RISK-2, Medical Student Quality of Life) are at a level that these instrument scoring indicates is of concern and in need of follow-up in total or for a significant question. Students will receive messages recommending the follow-up appropriate for their results, including education and relevant resources, recommendations for further evaluation or treatment, and encouragement. We will also provide local resource information, and offer to work with the subject to help assure that they receive appropriate care. HIPPA does not apply as this is a benign behavioral intervention and not intended to be a medical treatment delivered in a medical setting provided by a health care professional working as a health care professional.

Benefits to subjects and/or society

The personal benefits include increased awareness of the risks of physician burn out and strategies to compensate for that for both students and faculty. The information is designed to provide an educational supplement to their medical school education. It is possible that students will enjoy using the prototype simulation. These benefits will easily outweigh the risks identified above.