Robert Eric Dinenberg, M.D., M.P.H.
Fellow, UCSF Occupational and Environmental Medicine

PROTOCOL

- **Title and Investigators**

Can a mindfulness meditation intervention decrease burnout among health care providers?

Robert Eric Dinenberg, M.D., M.P.H.

- **Abstract**

A healthcare consulting company provides interventions to hospitals in order to optimize patient satisfaction scores for a given hospital sector. Two hospital sectors from two different hospitals (both clients of the healthcare consulting company) are matched and randomized into a control group that consists of the healthcare consulting intervention as usual and an experimental group that consists of healthcare the healthcare consulting intervention plus a home study mindfulness intervention for the healthcare providers of the hospital sector. The 8-week mindfulness intervention consists of distributing iPods (supplied by the healthcare consulting company) loaded with 1 minute, 5 minute, 10 minute, and 20 minute guided audio meditations. Orientation to the mindfulness program as well as weekly education is put on Utube so participants can access the education remotely.

A two sample unpaired t test will compare measurements of healthcare provider burnout before and after the intervention in the experimental group and in the control group. Burnout will be assessed by the Maslach Burnout Inventory, a validated 22-item instrument that measures burnout. Levels of mindfulness will be assessed by a validated 2-Factor Mindfulness Scale. The association of change in mindfulness with change in burnout will be examined using Pearson correlations. This randomized trial will reject or accept the null hypothesis that change in burnout measurements is the same in control and experimental groups. The association of change in mindfulness with change in burnout will be demonstrated.

- **Specific aims**

1. Does a mindfulness based intervention decrease burnout among health care providers?
2. Is there an association of change in health care provider mindfulness with change in health care provider burnout?

- **Significance**

Hospitals and other health care organizations seek to optimize patient experience. One way to optimize patient experience is to focus on the well being of the health care provider. Research shows that stress reduces health care providers' abilities to establish strong relationships with patients (Pasture 1995). Stress also reduces concentration (Askenasy 1996) and negatively impacts decision-making skills (Lener 1997). An intervention that helps health care providers with stress management can be seen as a way to better serve patients.

A particular intervention that helps with stress management and other mental health outcomes is based on teaching participants how to practice mindfulness meditation. A systematic review of randomized controlled trials on mindfulness-based stress reduction and mindfulness-based cognitive therapy included 21 articles and concludes that evidence supports that mindfulness bases stress reduction improves mental health.

Studies that focus on mindfulness based interventions for health care professionals are few in number. One randomized controlled pilot study on a mindfulness-based intervention for health care providers reports that the mindfulness-based intervention decreased stress, increased quality of life and increased self-compassion for participants (Shapiro 2005). A before-and-after study published in JAMA (Krasner 2009) notes improvements in burnout scores for healthcare providers after a mindful communication intervention and notes that findings warrant randomized trials involving a variety of practicing physicians.

- **Methods**

Two hospital sectors scheduled to receive a healthcare consultation company intervention designed to optimize patient experience are randomly designated as either experimental group or control group. Both groups are asked to complete both the Maslach Burnout Inventory and the 2-Factor Mindfulness Scale at the beginning of the study and again at the completion of the study. All health care providers of the experimental group are invited to participate in the 8-week mindfulness intervention. The experimental group receives the health care consultant intervention plus the mindfulness intervention and the control group receives only the health care consultant intervention.

- **Overview of design**
    - **time frame and nature of control**

The intervention is 8 weeks long. Each week participants will access (via uTube) a short educational video on the practice of mindfulness meditation. Participants will be encouraged to access the guided meditations that are loaded on the iPods they receive at the beginning of the study. Participants are asked to access both the guided meditations and the uTube educational segments on their own time so this is a home study course on mindfulness meditation. The control group receives health care consultant intervention as usual with no additional mindfulness intervention.

- **Study subject**
    - **selection criteria, target and accessible populations**
    - **plans for sampling, recruiting and retaining subjects**

Target populaton:
Health care providers

Accessible population:
Health care providers in a hospital sector

Selection criteria:
Well suited to the research question, representative of target populations and available, representative of accessible populations and easy to study. Health care providers will be engaging (with hospital leadership support) in the consultant intervention so cooperation with the study is anticipated.

Sample type:
Convenience sample

Recruitment method:
Hospital administrator and hospital consultant support the project. All health care providers of the hospital sector are invited to participate.

- **Measurements**
    - **predictor variables (intervention, if an experiment) and potential confounders**
    - **outcome variables**

Predictor variable:

Intervention (participation in a program that teaches participants how to practice mindfulness meditation)

Outcome variable:

Burnout scores for the hospital health sector in the study

- **Statistical issues**
    - **hypotheses and sample size estimates**

1. Null Hypothesis:
Change in mean health care provider burnout scores after 8 weeks of treatment is the same in health care providers treated with an 8 week mindfulness meditation intervention as it is in health care providers who do not receive a mindfulness meditation intervention.
Alternative Hypothesis:
Change in mean health care provider stress scores after 8 weeks of treatment is different in health care providers treated with an 8 week mindfulness meditation intervention from what it is in health care providers who do not receive a mindfulness meditation intervention.
2. Effect size = 4.1
3. Standardized effect size = effect size / standard deviation (stated in study) = 0.62
4. alpha (two-sided) = .05; beta = 1 – 0.80 = 0.20
PREDICTOR=dichotomous, OUTCOME=continuous > test= unpaired t test
Using Table 6A, this design would require about 45 participants per group.

Krasner, M, Association of an Educational Program in Mindful Communication with Brunout, Empathy, and Attitudes Among Primary Care Physicians. JAMA 302(12): 1284-1293, September 2009.