

1 Study Protocol and Statistical Analysis Plan

2 **Mindful Mental Training for Surgeons to Enhance Resilience and Performance**  
3 **under Stress (“Mindful Surgeon”)**

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5 ClinicalTrials.gov Identifier: NCT03141190

6 Recruitment Status: Completed

7 **Sponsor:** University of California, San Francisco

8 **Information provided by (Responsible Party):**

9 Carter Lebares, University of California, San Francisco  
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11 **Study Description**

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13 Brief Summary:

14 Background:

15 Burnout and overwhelming stress are growing issues among surgeons and are  
16 associated with mental illness, attrition and diminished patient care. Among surgical  
17 trainees, burnout and distress are alarmingly prevalent but high inherent mindfulness  
18 has been shown to decrease the risk of depression, suicidal ideation, burnout and  
19 overwhelming stress by more than 75%. In other high-stress populations formal  
20 mindfulness training has been shown to improve mental health and buffer overwhelming  
21 stress and yet this approach has not been tried in surgery.

22 The aim of this study is to evaluate feasibility and acceptability of modified mindfulness-  
23 based stress reduction (MBSR) training among PGY-1 surgery residents and to obtain  
24 initial evidence of efficacy in regard to well-being and performance.

25 Design: A pilot randomized clinical trial of modified MBSR versus an active control.

26 Setting: Residency training program, tertiary academic medical center.

27 Participants: PGY-1 surgery residents.

28 Intervention: Weekly two-hour modified MBSR classes (compared to an active control)  
29 and 20 minutes of suggested daily home practice over an eight-week period.

30 Main Outcomes and Measures:

31 Primary outcome is feasibility, assessed along six domains (demand, implementation,  
32 practicality, acceptability, adaptation and integration), using focus groups, interviews,  
33 surveys, attendance, daily practice time and subjective self-report of experience.

34 Secondary outcomes include perceived stress, mindfulness and executive function  
35 (specifically working memory capacity), followed by psychosocial well-being (burnout,  
36 depression, resilience), performance (motor skills testing) and functional brain scans  
37 focused on areas associated with reappraisal as a surrogate for emotional control.

38 This study seeks to demonstrate the feasibility of mindfulness training in surgery PGY-  
39 1s while simultaneously providing preliminary quantitative data on the effects of  
40 mindfulness training in a randomized, controlled setting. Data will inform modifications  
41 to the MBSR curriculum that enhance feasibility and inform sample size calculations for  
42 subsequent, adequately-powered RCTs which will likely need to be multi-center trials.

43 Results could potentially impact formal medical training, the mental health of providers  
44 at every level, and the overall quality of patient care.

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Condition or disease	Intervention/treatment
Burnout Syndrome Surgery Stress	Behavioral: Mindfulness Based Stress Reduction - modified Behavioral: Active listening and reading

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47 Detailed Description:

48 Mounting evidence shows that burnout, a critical metric for dissatisfaction and distress,  
49 is a growing problem within medicine. Burnout is a syndrome associated with worse  
50 physician performance, patient outcomes, and hospital economics. The quadruple aim  
51 of healthcare underscores that physician fulfillment is a critical part of any sustainable  
52 reform and appropriately frames physician burnout and fulfillment as issues that impact  
53 everyone, not just individual providers.

54 Burnout is believed to arise from a mismatch between expectations and reality, with  
55 more than half of practicing physicians and trainees reported to suffer from this problem.  
56 Among general surgery residents, the prevalence of burnout is estimated at 69% and  
57 dramatically increases the odds of both overwhelming stress and distress symptoms.  
58 The relationship between overwhelming stress and burnout is particularly concerning  
59 because extensive evidence links overwhelming stress to detrimental effects on  
60 learning, memory, decision-making, and performance.

61 A recent meta-analysis suggests that stress management/mindfulness interventions are  
62 particularly effective at addressing burnout on the individual level. Small cohort studies  
63 and controlled trials have shown mindfulness-based interventions to be effective at  
64 reducing stress and burnout in medical students, primary care physicians, internists,  
65 and other healthcare providers.

66 In general surgery trainees, inherent mindfulness tendencies (shown to increase  
67 following mindfulness training), decrease the risk of burnout, overwhelming stress, and  
68 distress symptoms by 75% or more. This suggests that mindfulness tendencies may  
69 already be used, albeit unconsciously, to cope within the high-stress culture of surgery.  
70 Indeed, isolated studies of performance strategies that involve emotional regulation, and  
71 focused attention (qualities shared with mindfulness training) have also demonstrated  
72 improvements in surgeons' technical performance and perceived stress.

73 Mindfulness meditation training involves the cultivation of moment-to-moment  
74 awareness of thoughts, emotions and sensations (also known as interoception), the  
75 development of non-reactivity in response to stimuli (also known as emotional  
76 regulation), and the enhancement of perspective-taking regarding oneself and others.  
77 The most scientifically studied form of mindfulness training is the secular Mindfulness-  
78 Based Stress Reduction (MBSR) developed by Jon Kabat-Zinn in the 1970s. MBSR is  
79 formally trained through an eight-week codified curriculum and has been shown to  
80 decrease stress and burnout, protect executive function, and enhance performance in  
81 multiple high-stress populations.

82 In spite of such evidence, mindfulness training among surgeons has only occasionally  
83 been suggested or informally pursued, partly due to a disconnect between the  
84 indefatigable stoicism of surgery and mindfulness, which is often perceived as  
85 relaxation rather than a skill to enhance resilience. Moreover, the time pressures of  
86 surgical training make additional responsibilities and new curricula seem impossible.

87 In fact, the global effects of mindfulness training, as opposed to other interventions that  
88 target a single outcome, may prove to be its biggest asset. Individuals don't manifest the  
89 effects of overwhelming stress and burnout in identical ways, making an up-stream  
90 intervention with myriad downstream effects the most efficient method for intervening on  
91 large, diverse populations. Moreover, while other forms of skills training or mental health  
92 interventions require recurrent time away from work, mindfulness training involves an  
93 initial investment of time but then can be strengthened through practice in everyday  
94 settings - within the daily life, not separate from it.

95 To systematically examine the feasibility of formal mindfulness training during surgery  
96 internship at a tertiary academic center, we undertook the "Mindful Surgeon" pilot study.  
97 Our secondary goal is to gather preliminary evidence of efficacy, to guide future design  
98 of a scalable, adequately powered trial.

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100 **Study Design**

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Study Type: Interventional  
Actual Enrollment: 21 participants  
Allocation: Randomized  
Intervention Model: Parallel Assignment

Randomized, partially-blinded  
Masking: Double (Participant, Outcomes Assessor)

Participants do not know we are testing mindfulness only that they will be learning stress-reduction skills for surgeons

Primary Purpose: Prevention  
Official Title: Mindfulness Training to Improve Mental Health, Stress and Performance In Physicians

Actual Study Start Date: June 2016  
Actual Primary Completion Date: December 31, 2017  
Actual Study Completion Date: December 31, 2017

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103 **Arms and Interventions**

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Arm	Intervention/treatment
Experimental: Mental Training for Surgeons Mindfulness-Based Stress Reduction (MBSR, as published elsewhere extensively) slightly modified by shortening the eight weekly classes to 2 hours each and the home practice requirement to 20 minutes. Taught by a veteran MBSR teacher with greater than 10,000 hours of personal practice and nearly 10 years of formal MBSR teaching experience.	Behavioral: Mindfulness Based Stress Reduction - modified already described Other Names: <ul style="list-style-type: none"><li>MBSR</li></ul>
Active Comparator: The Mind of a Surgeon 8 weekly classes of 2 hours each with group reading and discussion of selected articles and	Behavioral: Active listening and reading group reading, listening and

stories about the ethos and experience of becoming a surgeon. Designed and administered by a surgical faculty member with extensive experience in surgical education and scholarly work in the area of the 'surgical personality'.

discussion of articles pertaining to the development and experience of the surgical personality

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## 108 **Outcome Measures**

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Primary Outcome Measure:

111 1. Change in Stress [Time Frame: baseline, 8wks (post-intervention),12-  
112 month follow-up]

113 Cohen's Perceived Stress Scale (PSS)

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Secondary Outcome Measures:

116 1. Change in Executive Function [Time Frame: baseline, 8wks (post-  
117 intervention),12-month follow-up]

118 Executive function as assessed via working memory capacity,  
119 cognitive control and executive composite components of the NIH  
120 EXAMINER battery.

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Other Pre-specified Outcome Measures:

123 1. Change in Motor skills [Time Frame: baseline, 8wks (post-  
124 intervention),12-month follow-up]

125 Performance as assessed by the Fundamentals of Laparoscopic  
126 Surgery (FLS) modules

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128 2. Change in Functional neuroanatomic changes [Time Frame: baseline,  
129 8wks (post-intervention),12-month follow-up]

130 Functional changes in areas associated with reappraisal/emotional  
131 regulation (amygdala, hippocampus, reward circuitry, appraisal

132 pathway) as evidenced by fMRI BOLD and DTI brain scans analyzed  
133 by whole brain and a prior region of interest approaches.

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135 3. Change in Psychological well-being [Time Frame: baseline, 8wks (post-  
136 intervention),12-month follow-up]

137 Burnout (Maslach burnout inventory), depression (PHQ-9), resilience  
138 (ER89), Grit (GRIT-S), mindfulness (CAMS-R)

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## 141 **Eligibility Criteria**

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Ages Eligible for Study: 18 Years and older

Sexes Eligible for Study: All

Gender Based: No

Accepts Healthy Volunteers: Yes

## 143 **Criteria**

144 Inclusion Criteria:

- 145 • UCSF surgical interns entering training. Do not meet exclusion criteria.

146 Exclusion Criteria:

- 147 • Current personal mindfulness practice, pregnancy, breast-feeding or  
148 implanted MRI-incompatible metal.

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## 150 **Contacts and Locations**

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### 152 **Locations**

#### **United States, California**

University of California San Francisco

San Francisco, California, United States, 94143

### 153 **Investigators**

Principal Investigator: Carter Lebares, University of California, San  
MD Francisco

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155 **More Information**

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Responsible Party: Carter Lebares, Assistant Professor of Surgery In  
Residence, University of California, San Francisco

ClinicalTrials.gov Identifier: NCT03141190

Other Study ID Numbers: 16-19688

Last Verified: September 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

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158 Human Subjects Protection Review Board Status: Approved

159 Studies a U.S. FDA-regulated Drug Product: No

160 Studies a U.S. FDA-regulated Device Product: No

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162 **Statistical Analysis Plan**

163 All analyses will be conducted on the intent-to-treat sample. Outcomes (from  
164 questionnaires, tests and assays) will be summarized for each group at 3 time points. I  
165 will test for inter-group differences (using independent sample t-tests and Pearson's  
166 chi- square tests). I will conduct analyses to serve as preliminary data for the design of  
167 a future RCT of efficacy. Linear mixed-effects modeling (ANCOVA) will be used for  
168 multivariate analysis, adjusting for baseline variation and calculating effect sizes.

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