I. Description, Background, & Problem Statement: This study will extend EFT (Emotional Freedom Technique) research to address post-traumatic stress disorder (PTSD) among older adults following a myocardial infarction (MI). We will conduct an EFT pilot study among MI patients over 55 meeting PTSD diagnostic criteria, using a randomized wait-list control design with a blinded interviewer administering reliable and valid measures. This study is pioneering because there have been few PTSD interventions among MI patients, and PTSD intervention research has focused on cognitive-behavioral exposure therapy (CBET). PTSD has been described as prevalent, predictable, and connected to post-MI challenges and life quality[1,2]. Approximately one million people survive MI each year. Recent research demonstrates that 10-15% of MI patients experience diagnosable PTSD[1,2,3]. Pilot studies of cognitive behavioral therapy (CBT) within the MI population show mixed results, calling for more CBT and CBET research for post-MI PTSD[4,5,6]. CBET is considered an evidence-based PTSD treatment, but whether PTSD diagnosis and CBET referral in this population takes place is unknown. Research with veterans suggests EFT holds promise for PTSD treatment[7,8,9,10]. The outcomes literature lacks rigor, however, and there is no test of EFT on those with MI and PTSD. Our study will bring attention to the neglected group of MI survivors in PTSD intervention research while expanding treatment options. Limited evidence suggests EFT may be as effective, and faster, than CBET in relieving PTSD symptoms and diagnoses[7,10]. Exploring EFT treatment for post-MI PTSD lays the groundwork for intervention research comparing EFT and CBET.

One study of eleven veterans and family members assessed for PTSD found statistically significant improvements in symptoms following EFT treatment. PTSD diagnoses were eliminated and symptoms of anxiety, interpersonal sensitivity, and somatization reduced at 30-day, 60-day and one-year follow-ups[7]. A study of seven veterans who received a standardized

EFT protocol addressing traumatic combat memories used a within subjects, time series design with the repeated SA-45 measure. This group experienced a 50% reduction in symptoms that maintained at 90-day follow-up[8]. A wait-list design conducted with 59 veterans found EFT effective. At post-test, 90% in the EFT group were no longer diagnosed with PTSD compared to 4% in the wait-list group. In addition, 86% of everyone who received EFT no longer met PTSD criteria at three-month follow-up[9].

Whereas CBET is grounded in psychology and familiar to Western scientists, researching subtle energies requires an integrative framework incorporating Eastern knowledge and neuroscience research that explain how EFT works[11,12,13]. EFT involves teaching clients to tap the body's energy meridians along with eye movements, counting, and affirmations while recalling a trauma. EFT uses brief psychological exposure to activate brain areas associated with pain and fear, and acupressure facilitates the relaxation response and counter-conditions environmental triggers, resolving PTSD[14,15].

II. Project Objectives

We anticipate that EFT will reduce post-MI PTSD symptoms and chose measures allowing us to determine specific endpoints: resolution of PTSD diagnosis, decrease in PTSD-specific symptoms, reduction of general psychiatric symptoms, and a decrease in mental health symptoms that co-occur with health concerns. We will examine four hypotheses favoring EFT over wait-list controls immediately after treatment and at 3 months: There will be a significant ($\alpha \leq .05$) decrease in: (1) PTSD symptoms (PDS); (2) clinical PTSD diagnoses (CAPS); (3) general psychiatric symptoms (SA-45); and (4) mental health symptoms (mental health subscale, SF-12). We also expect significant changes when the wait-list controls are treated after the post-testing of intervention participants.

The sample size of 24 per condition will require relatively large treatment effects to achieve statistical significance (about .7 to .8). If we do not find clinical significance, a retrospective power analysis will determine the necessary sample size to reach statistical significance. These power analyses should be invaluable as we seek funding for a larger study.

III. Project Design

Mary Sise, LCSW, DCEP has over twenty years of trauma treatment practice and over ten years of EFT intervention and training experience. She directs the Center for Integrative Psychotherapy, provides EFT supervision, and has arranged free EFT intervention for this project. She and three MSW EFT practitioners will serve as interventionists. Mary will provide 2 hours of protocol training and ongoing documented supervision.

The EFT intervention, including six 1-hour sessions using a manualized protocol, will take place in practitioners' offices. During session 1, participants will view a 15-minute film explaining brain neurobiology, including regions and brain processes affected by trauma, and EFT rationale. Interventionists will identify PTSD symptoms and begin teaching the EFT method. Session 2 involves additional teaching of EFT. The interventionist will elicit PTSD symptoms and work with the participant to recall vividly their feelings and thoughts. A subjective units of stress rating will be obtained, and EFT will be used on any part of the distressing memory. Self-care and at-home practice instructions will be provided. Sessions 3-6 will follow the same process. During the self-care portion, the interventionist will elicit a positive statement in association with the event and use EFT to integrate it into the participant's at-home practice. Sessions will be audio-taped for fidelity checks, using a form designed to ensure delivery of intervention components.

Participants will be 48 adults, 55 or older, who have experienced an MI at least six months ago (avoids spontaneous PTSD remission). An n=24 per condition was selected by power analysis for a moderate to large effect size (.72), on three of four outcome measures. Because we are screening for symptoms, and not diagnosis, we will probably have less power to detect significant differences in actual diagnoses of PTSD (see CAPS measure). We will track baseline, post-test, and follow-up PTSD diagnoses for power analyses in this pilot study and as a basis for determining screening measures and sample size for subsequent funding.

Participants will be recruited through doctors' offices, newspaper advertisements and stories, and with assistance of the American Heart Association. Screening will rule out significant adverse childhood experiences, previous PTSD, and other significant mental health disorders, while ensuring the individual exhibits symptoms. Recruitment will occur in two waves. The 24 participants screened into the study will be randomly assigned to the intervention or wait-list control condition. The 12 participants in the intervention condition will be randomly assigned to 4 interventionists. This will be repeated after a second wave of recruitment.

Design: A 2 X 3 X 4 randomized wait-list control design will be used. There will be two intervention conditions (EFT and wait-list control), 3x of measurement for the intervention group (plus an additional measurement for the wait-list group), and 4 interventionists. Because participants will be assigned randomly to interventionists, we can consider interventionist effect during data analyses. A blinded research assistant will administer all measures. Both intention to treat and treatment received methodologies will be used in analyses.

Measurement and Measures - Screening: To treat a single incidence trauma, MI, our screening goal is to eliminate participants with complicating issues. The GA will administer screening instruments through a 25-minute telephone interview. The Adverse Childhood Experiences

(ACE) questionnaire is a 10-item self-report, identifying categories of adverse childhood experiences, with good test-retest good test-retest reliability[16]. ACE Scores of 4 or more will be screened out. The PTSD Checklist-Specific (PCL-S) is a 17-item self-report. A score of 3 or above on 6 separate items indicate PTSD symptoms, making a patient eligible for participation. Developed by the National Center for PTSD, it is highly correlated to the CAPS (.93)[17] and has excellent internal consistency and test-retest reliability[18]. The EFT Study Screening Form (ESS) gathers demographic information, identifies safety issues or serious mental health disorders and gathers cardiac-specific medical information. Study eligibility requires that patients are 55 years or older, speak English, and are not suicidal, homicidal or being treated for serious mental illness.

Measurement and Measures - Outcomes: The four outcome measures will be administered during a 45-60 minute personal interview by a GA trained in each instruments' data collection methods. Data will be collected at three time points for the intervention group (baseline, post-test after the intervention, and 3-month follow-up) and four times for the wait-list group (2 "baseline" interviews at 0 months and 6 weeks, intervention post-test, and 3-month follow-up). The Posttraumatic Stress Diagnostic Scale (PDS) is a 49-item self-report instrument identifying PTSD symptoms. It has very good reliability based on high internal consistency among items (Chronbach alpha =.92), good test-retest reliability (r =.74), and good validity based on correlates with the Structural Clinical Interview for DSM (r =.82)[19].

The Symptom Assessment-45 (SA-45) is a 45-item self-report multi-dimensional psychiatric symptoms checklist with good test-retest reliability and internal consistency and good concurrent validity based on high correlations with other indices of psychiatric symptoms[20 21].

The Clinician-Administered PTSD Scale (CAPS) is a 30-item structured interview administered by the trained GA to make a PTSD diagnosis corresponding to the DSM. Developed by the National Center for PTSD, it has good psychometric properties in a number of populations and settings[22]. Reliability is high[23,24,25] and validity strong[26]. For example, in terms of concurrent validity, clinician-rated diagnosis and CAPS has overall agreement of 79%; sensitivity was .74 and specificity .84[23].

The Short Form 12-item Survey (SF-12) is a brief 12-item self-report, measuring perceived health and mental health, made up of two composite scores: physical and mental health. The SF-12 has been extensively tested in a number of populations including older adults[27] and individuals with MI[28]. It has good test-retest reliability for each of its composite scores (Physical = .89 and Mental = .76), extensive support for its validity[29,30] and adequate sensitivity to change[31].

Statistical Analyses: The primary analytic tool will be mixed effects regression using the SAS Proc Mix program, with subjects as the random effect and intervention as the fixed effect. Experiment-wise error rate will be controlled by a Bonferroni correction, with $\alpha \leq .1.25$, to correct for the four outcome measures.

IV. Detailed Budget

A. Graduate Research Assistant (GA)

Dates (administration, data entry & analysis)	UAlbany/Other	GGF
5/1/12 – 8/15/13		$4,160
8/16/12 – 5/22/13	$14,000	
5/23/12 – 8/15/13	$4,160	

B. Instruments (GGF request)

Administration	Instrument	Components	Quantity	Cost	Total
48 patients 3x (baseline, post treatment, 3 month follow-up) +24 control group post treatment data (48 x 3) + 24= 168	SF-12	NA	NA	NA	$709.40
	PDS	Manual = $38.75	1	$38.75	$668.75
		Test booklet = $18.00	1	$18.00	
		50 Score sheets & Scoring directions = $153	4	$612.00	
	SA45	SA-45 Kit (manual and 25 forms)	1	$89.00	$411.00
		25 pkg forms	7	$46.00	
	CAPS	Kit (interview booklets, guide, manual) = $110	1	$110.00	$800
		10 interview booklets = $40	16	$640.00	
		CD for reliability administration = $50	1	$50.00	
				TOTAL	$2,589.15

C. Advertisements for recruitment. (GGF request $490.85)
UAlbany $500

D. Questionnaire administration travel costs (48Ss x 3 times of measurement x .555 per mile x 15 mi). UAlbany $1,199

E. Participant gift cards (GGF)

Data collection point	# Patients	Payment	Cost
Baseline	48	$10	$480
Post-treatment	48	$15	$720

Three-month follow-up	48	$20	$960
Control group post-treatment	24	$25	$600
		Total	$2,760

F. Dissemination:

UAlbany $1,000 annual conference presentation travel costs for each full-time faculty ($2,000).

We will seek supplemental travel funds for the part-time research team member and registration costs for each team member to present: American Public Health Annual conference and Annual Gerontological Society of America Meeting ($3,000).

Develop and distribute a manual and website (estimated total $9,000). Covered by UAlbany& other.

G. UAlbany provides locking file cabinets and office space, computer equipment, data analysis software, expert statistical consultation, support staff, and other administrative support.

Total Budget (all costs) = $43,859 (+ administrative & statistical analysis support)
Requested: $10,000

V. Expected Outcomes & Timeline: Study completion is expected in 16-18 months: two months for startup (setting up account, hiring, and training), five months' recruitment (overlapping with intervention), six months for intervention and pre and post measures, three months for follow-up, ongoing data cleaning, coding and analysis (with two additional months after three month follow-up), three months to prepare presentations and articles.

Compared to the wait-list control group, we anticipate that EFT participants will experience a statistically significant decrease in PTSD symptoms (PDS) and diagnosis (CAPS), and increase in overall mental health (SF-12 subscale mental health; SA-45) immediately after intervention and at 3 months. We will present findings during at least two national conferences and publish at least one article in a leading peer reviewed journal. If changes are not statistically

significant, we will conduct a retrospective power analysis to determine the necessary sample size to reach statistical significance. This will enhance our ability to apply for funding to the NIH National Center for Complementary and Alternative Medicine (NCCAM), the National Heart, Blood and Lung Institute, the NIH National Institute on Aging, or foundation funding.

VI. Curriculum Vitae

The early career investigators, Drs. Larkin and Kaye, who have experience designing and implementing research projects, built a team that includes extensive backgrounds in EFT and randomized controlled trials. Dr. Toseland, a Distinguished Professor serving as mentor, has expertise designing and implementing randomized field trials, especially with older adults with chronic health problems. Mary Sise, LCSW, DCEP, has over twenty years of trauma treatment provision and ten years of EFT intervention and training experience. UAlbany provides a statistician, Glenn Deane, PhD. This partnership ensures timely project completion with a high level of expertise and support.

HEATHER LARKIN, Ph.D.
Assistant Professor*, School of Social Welfare, UAlbany*

Relevant Publications:

Larkin, H.; Park, G. (in press). Adverse childhood experiences (ACE), service use, and service helpfulness among people experiencing homelessness. *Families in Society.*

Larkin, H.; Felitti, V.; Anda, R. (in press). Social Work and Adverse Childhood Experiences (ACE) Research: Implications for Practice and Health Policy. *Social Work in Public Health.*

Carlson, B. Larkin, H. (2009). Meditation as a coping intervention for treatment of addiction. *Social Thought, 28(4), 379.*

LARA KAYE, Ph.D.
Research Scientist & Assistant Research Professor, *Center for Human Services Research, UAlbany*

Relevant Publications:

Kaye, L., Warner, L.A., Lewandowski, C.A., Greene, R., Acker, J.K., & Chiarella, N. (2009). The role of nurse practitioners in meeting the need for child and adolescent psychiatric services: a state-wide survey. *Journal of Psychosocial Nursing and Mental Health Services, (47)*3.

Kaye, L. & Fortune, A.E. (2004). Preparing competent practitioners: Self-rated social work skills and achievement motivation among MSW students. *The Clinical Supervisor, (23)*2, 1-13.

Peer Reviewed Conference Proceedings

Kaye, L. & Stevens, T. (2006). Hope and educational achievement in predominantly Asian American middle school students. Proceedings of the Hawaii International Conference on Social Sciences, USA, 5th annual, 757- 787.

MARY T. SISE, LCSW, D.CEP
Director, Center for Integrative Psychotherapy, Inc.

Selected Publications:

Bender, S.S.; Sise, M. (2007). *The Energy of Belief: Psychology's Power Tools to Focus Intention and Release Blocking Beliefs*. CA: Elite Books.

Clinician training video: *Using TFT with a World Trade Center Survivor,* and *Transforming Trauma with TFT.*

Recent Presentations:

Beyond Technique: Integrating Energetic & Spiritual Concepts to Heal at Root Cause. (12/6/10). 22nd Annual National Institute for the Clinical Application of Behavioral Medicine (NICABM).

Integrating Energy Psychology into Treatment of Trauma and *Energy of Change: Psychology's Power Tools to Focus Intention & Release Blocking Beliefs.* (9/10 – 10/10). NICABM.

Dr. Ronald W. Toseland, Director and Distinguished Professor, Institute of Gerontology, UAlbany School of Social Welfare, has published 6 books and over 110 articles and chapters, many on practice with chronically ill older adults and caregivers. Internationally recognized and featured in Congress for his research on groupwork practice and interventions for aging individuals, his findings guide delivery of evidence-based social and health care services to older persons. Dr. Toseland has received over $10 million in research grants and many awards including the Association for Gerontology Education in Social Work Career Achievement Award and Society for Social Work and Research Distinguished Achievement Award.

VII. Appendix: References

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