# Research Designs and Applications for Health Professionals

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Center for Spirituality, Theology and Health

DukeMedicine

# Overview

1:30-2:45

- Purpose of this session – continue to think about formal or informal research that chaplains, nurses, psychologists, physicians, and other caregivers can do
- Examples of latest research at Duke
- Duke-Glendale religious psychotherapy study
- Duke-Glendale religion & telomere length in caregiver study
- Duke-VA-U.S. Military study of moral injury in PTSD
- Research by non-researcher clinicians
- Further resources

# Duke-Glendale Religious Psychotherapy Study (integrating religious beliefs into psychotherapy)

Participants:
Persons with major depression and chronic medical illness

132 participants randomized to either religious-integrated cognitive behavioral psychotherapy (RCBT) or conventional secular CBT (CCBT), half on the East Coast (Durham) and half on the West Coast (Glendale)

Ten 50-min sessions each over 12 weeks

Primary outcome was depressive symptoms 4, 8, 12, 24 wks
Secondary outcomes were meaning and purpose, optimism, generosity, gratitude, therapeutic alliance, spiritual struggles (negative religious coping), suicidal thoughts

# Research Questions

1. Is Religious-Integrated Psychotherapy (RCBT) more effective than Conventional Psychotherapy (CCBT) in relieving depressive symptoms in persons with major depressive disorder and chronic medical illness?

2. What are effects do RCBT vs. CCBT have on purpose and meaning in life, optimism, generosity toward others, gratitude (thankfulness), spiritual struggles, and suicidal thoughts?

3. Are there also effects on immune and endocrine functions that are otherwise altered in major depression?

4. Do genetic polymorphisms of the serotonin transporter gene influence treatment response?

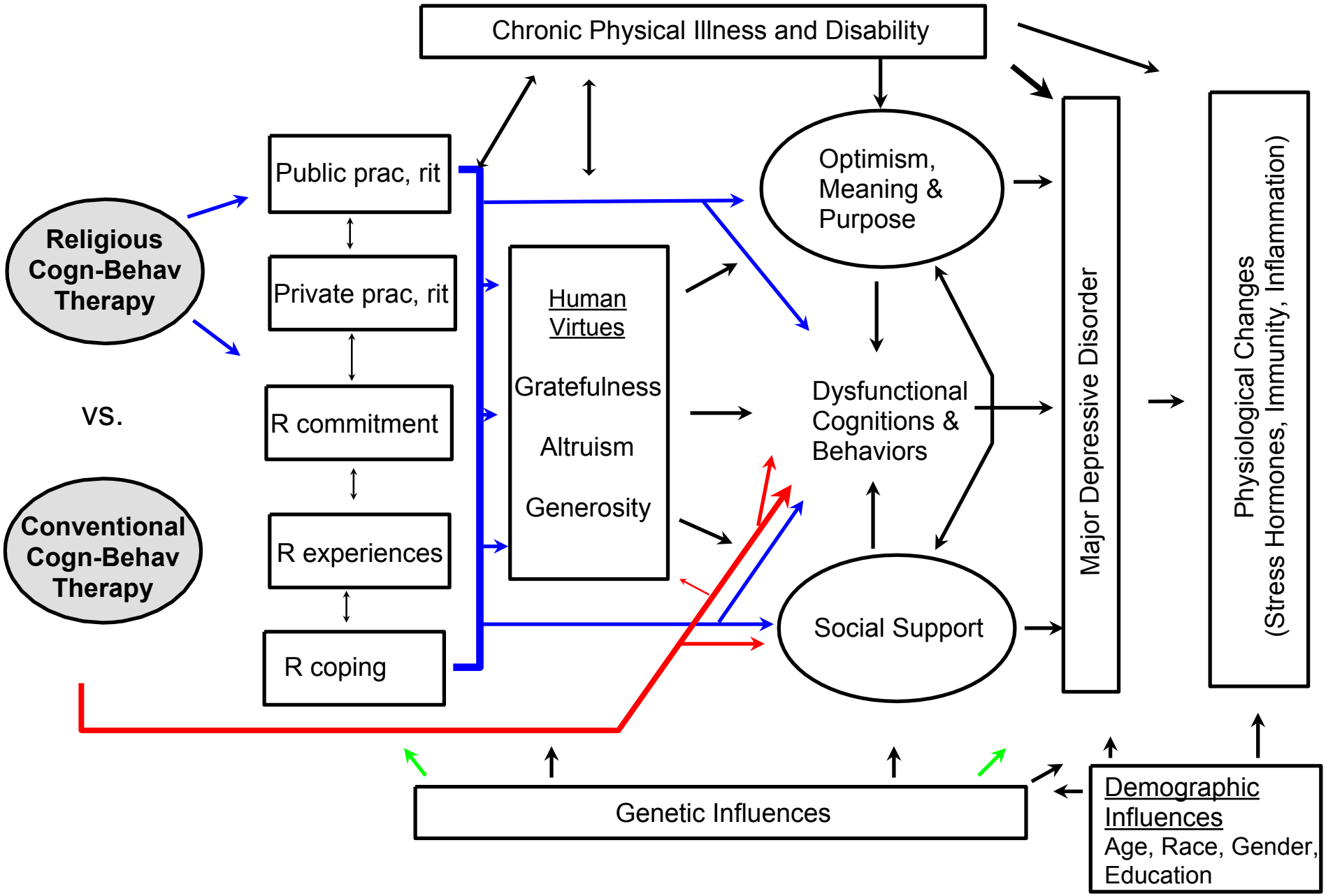
# 5 religious-integrated psychotherapies:

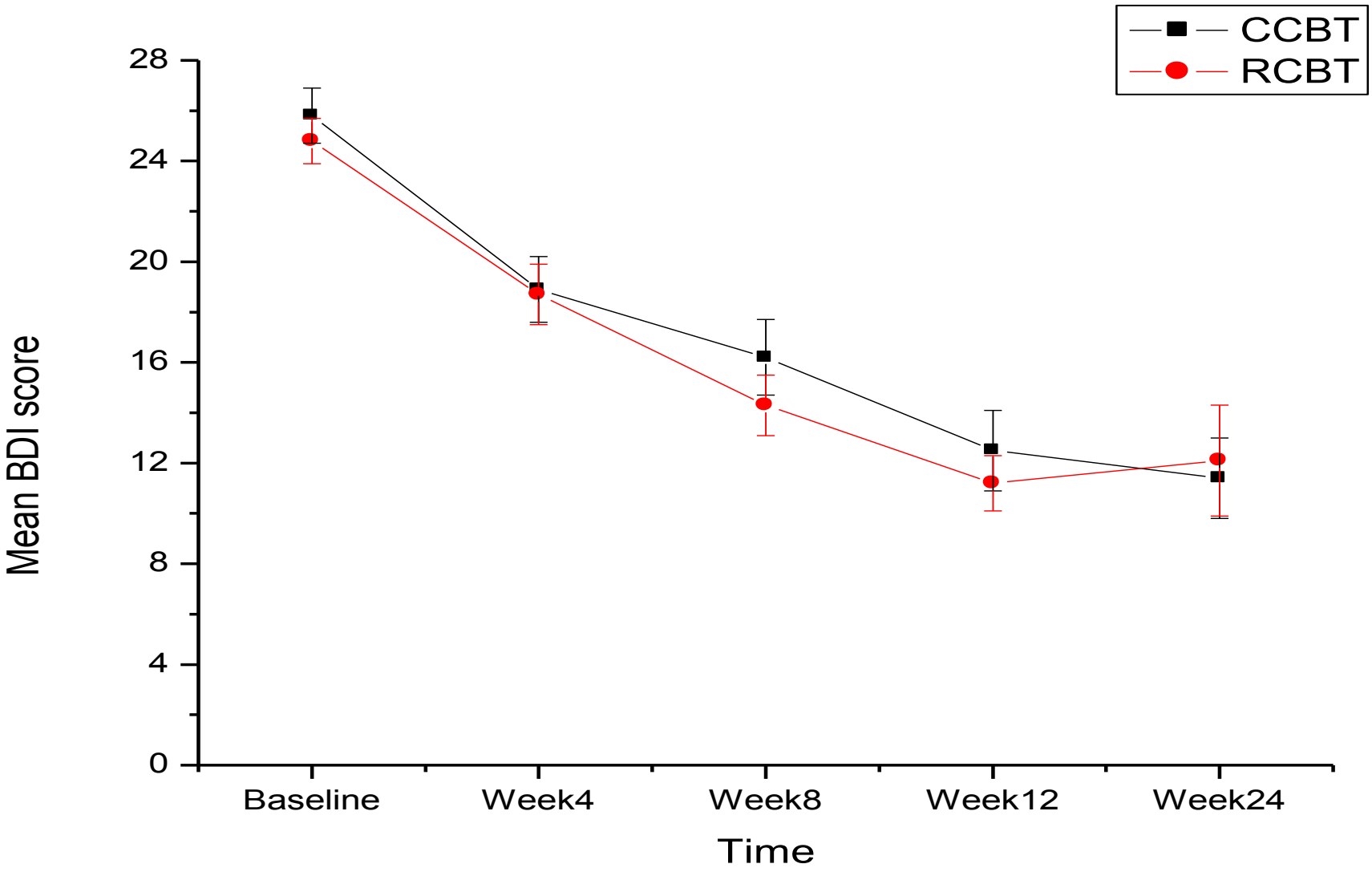
Christian
Jewish
Buddhist
Muslim
Hindu

Manuals and workbooks now up on our Duke website:
http://www.spiritualityandhealth.duke.edu/index.php/religious-cbt-study/therapy-manuals

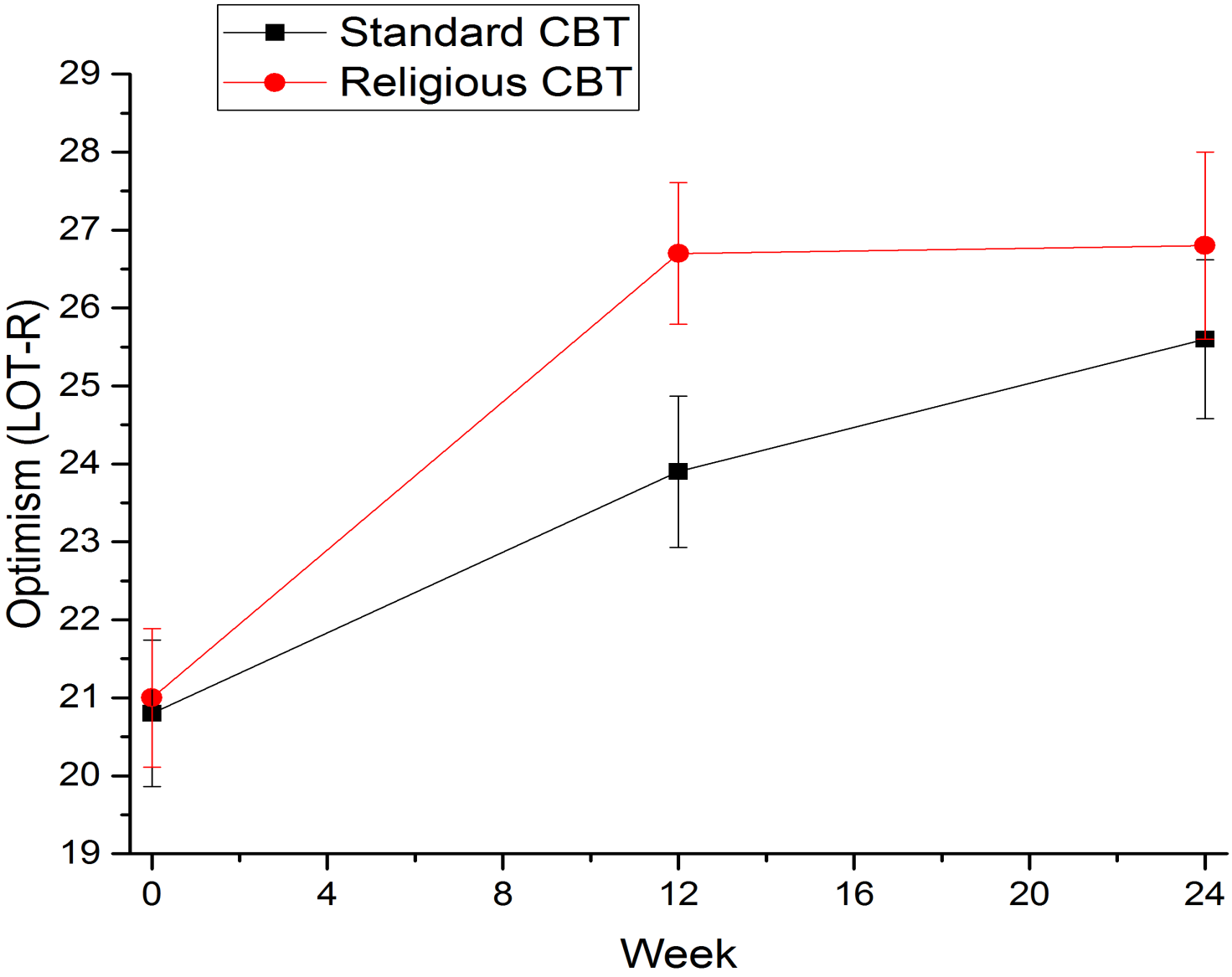
And soon to have a training video on website as well

# Research Study for Treatment of Depression in Chronically Ill, Disabled



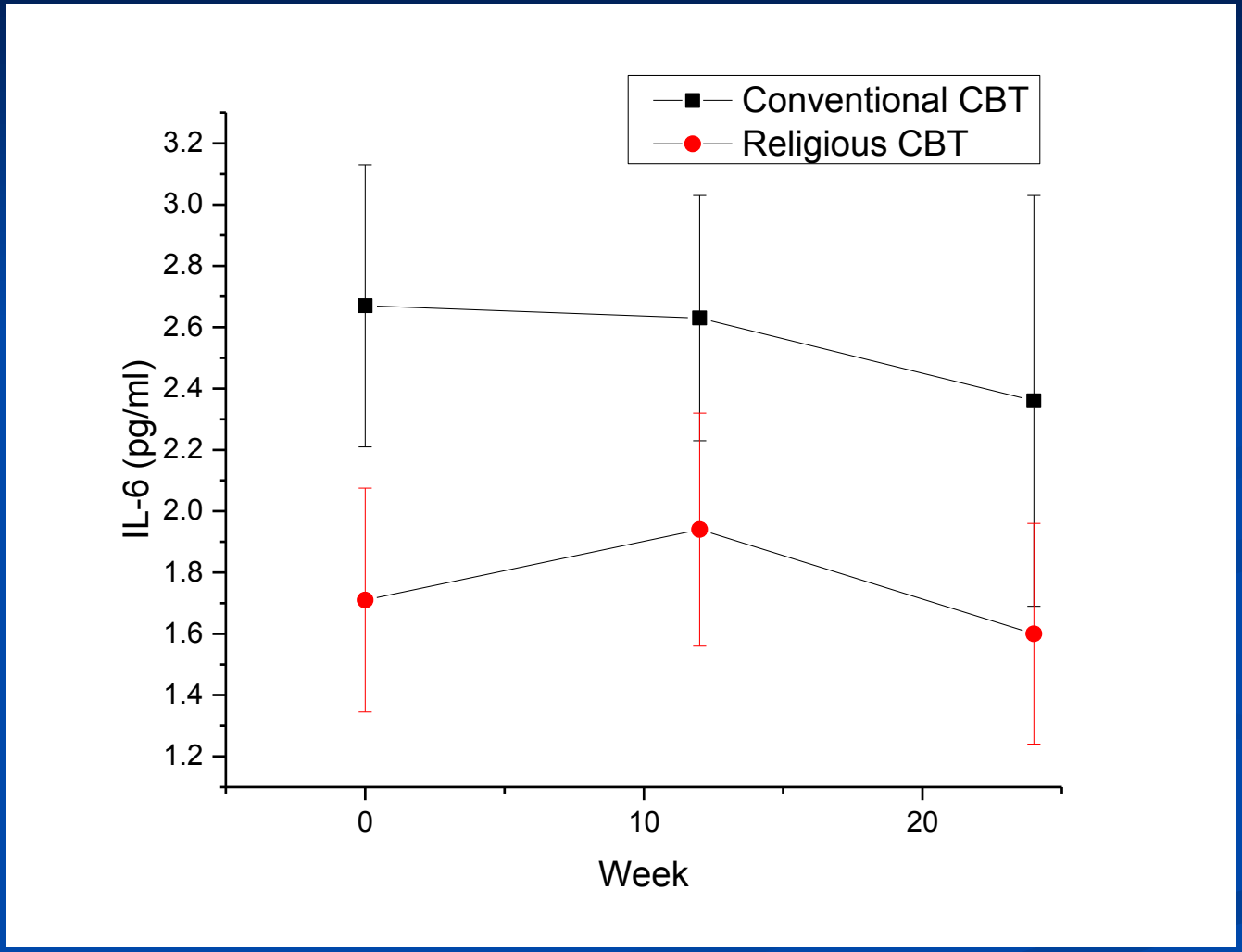



Koenig et al. Journal of Nervous and Mental Disease 2015; 203(4):243-251



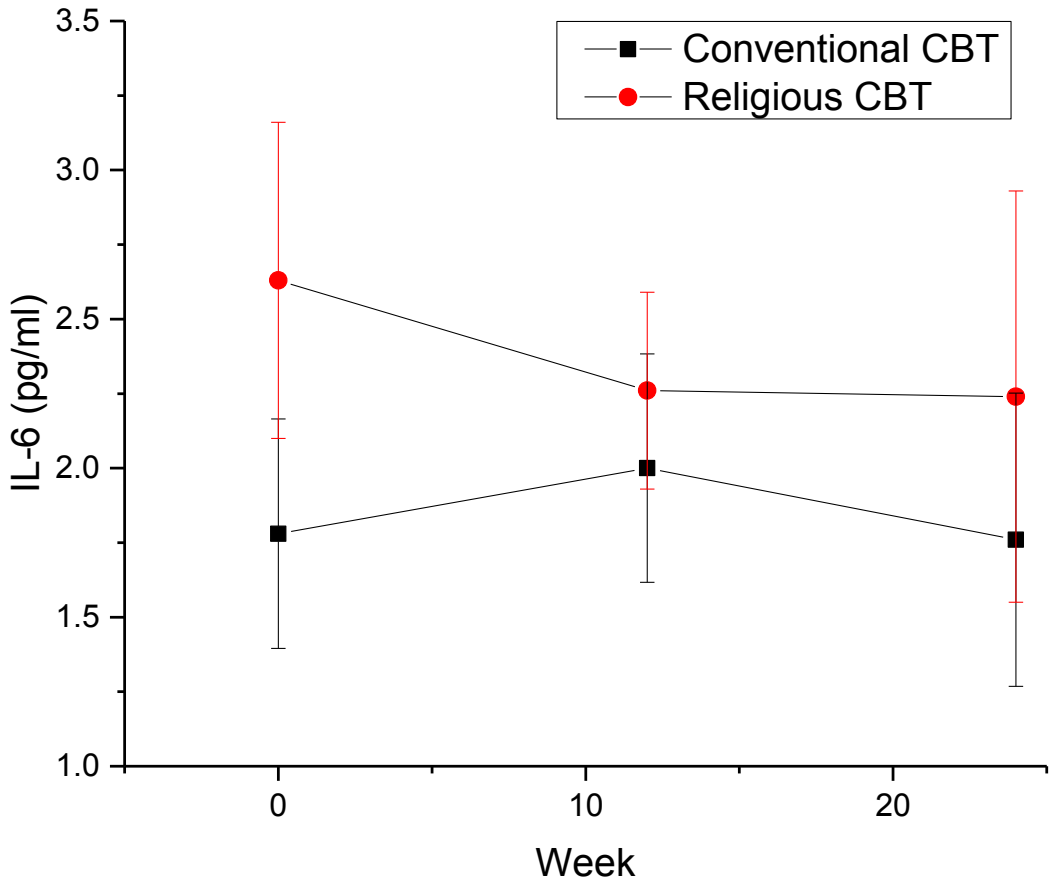

Difference significant between RCBT and SCBT at 12 week f/u (t=-2.10, p=0.038) in per-protocol analysis
Koenig et al. Depression & Anxiety 2015, in press

# Religious CBT Study - Low Religiosity



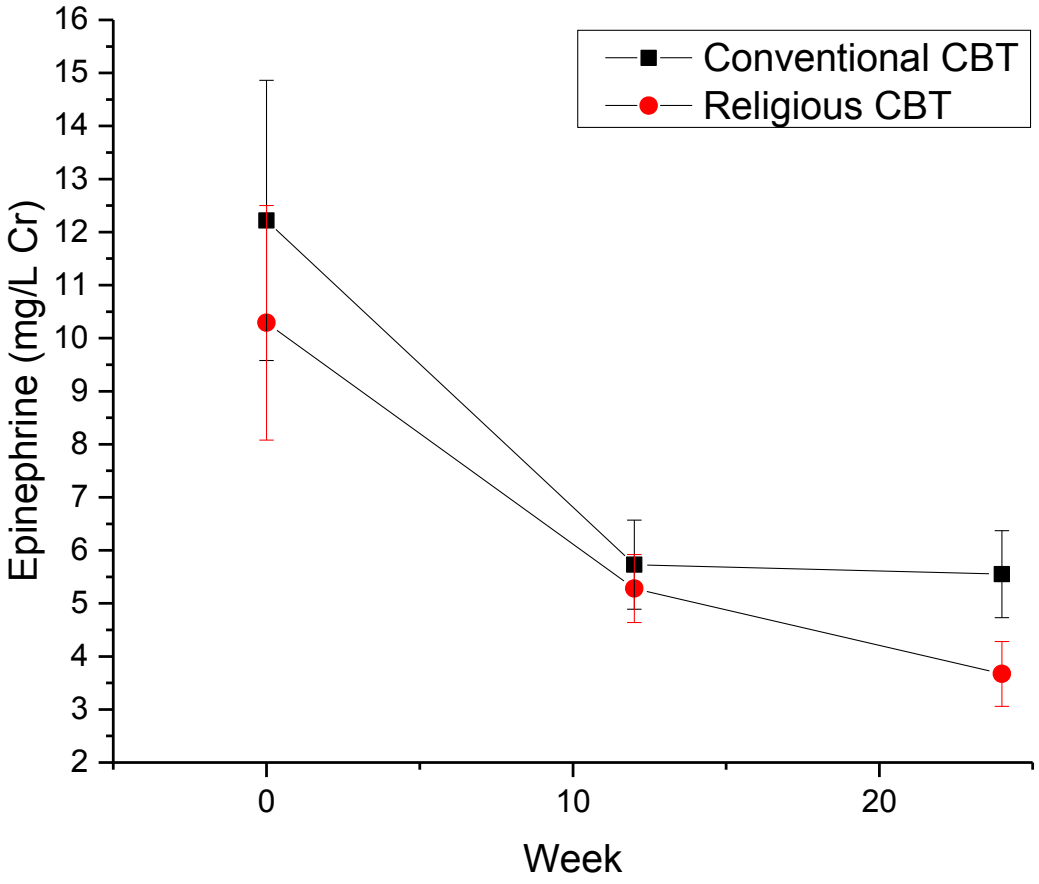

Main effect of group B =0.48, p=0.01 (n=44)
Berk et al. Open Journal of Psychiatry 5(3): 238-259

# Religious CBT Study - High Religiosity




Main effect of group B=-0.47, p=0.05 (n=45)
Berk et al. Open Journal of Psychiatry 5(3): 238-259

# Religious CBT Study – Epinephrine Levels

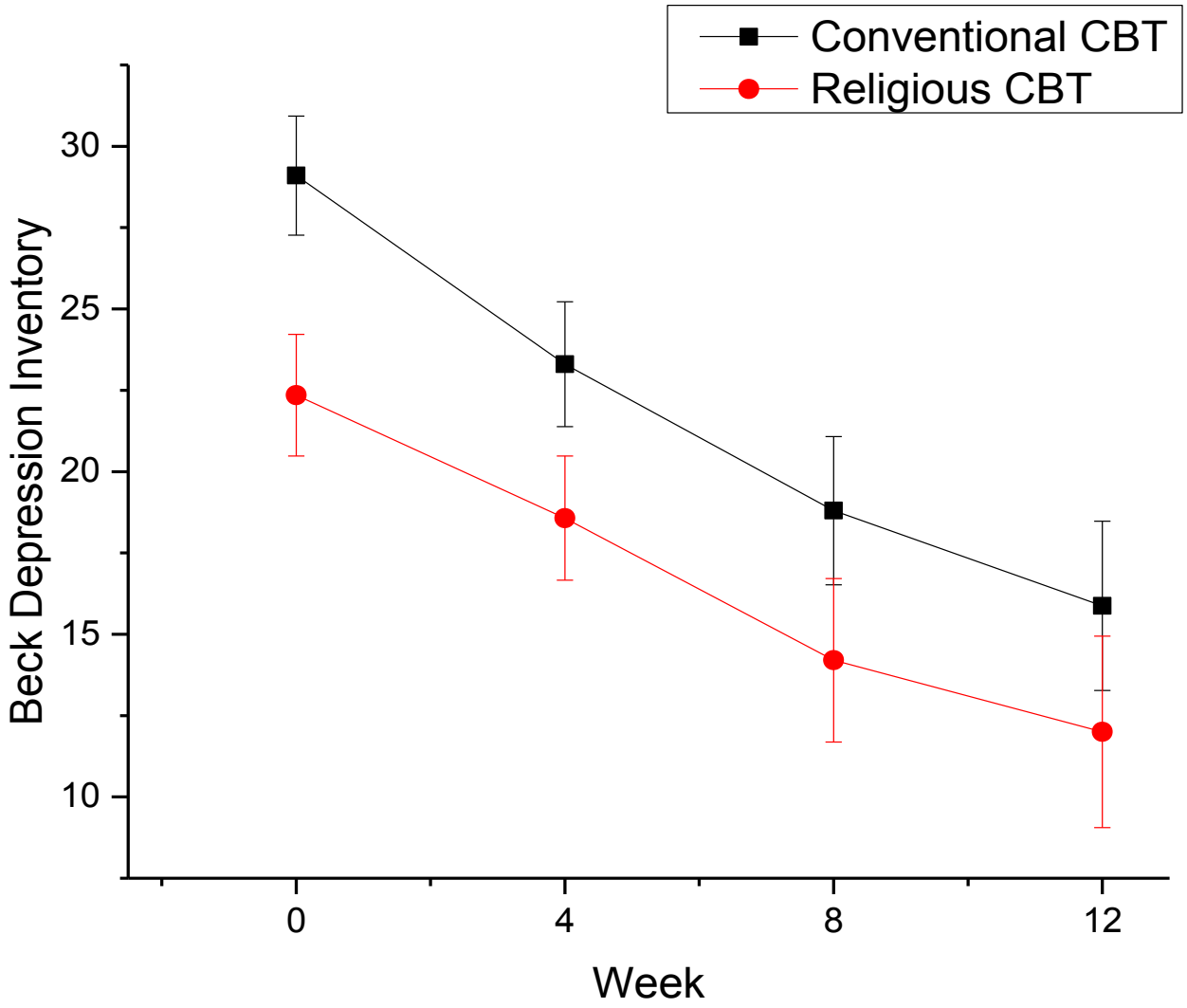



Main effect of group B=-0.19, p=0.156 (n=125)
Berk et al. Open Journal of Psychiatry 5(3): 238-259

# Genetic Analyses Results

Few associations were found between these polymorphisms and religious involvement, although they were consistent.

- Religious attendance was less frequent in those with one or more high-risk genotype in the overall sample
- Blacks with $L_G$ genotypes of the rs25531 polymorphism were less likely to attend religious services or have daily spiritual experiences
- Blacks with high risk alleles of any gene were also less likely to attend religious services
- Among men, daily spiritual experiences and overall religiosity were also lower in the presence of any high risk alleles
- Participants with low religiosity and C/G genotype of HTR1A were more likely to respond to CCBT than RCBT.




Treatment response in those with low religiosity and HTR1A genotype C/G (B=6.99, SE=3.24, df=88, t=2.16, p=0.03, n=38)

Koenig et al. Austin Journal of Psychiatry & Behavioral Sciences 2015; 2(1): 1036

# Duke-Glendale Caregiver Study

(251 women ages 40-75 caring for a family member with significant disability)

(1) Is religiosity related to caregiver adaptation?

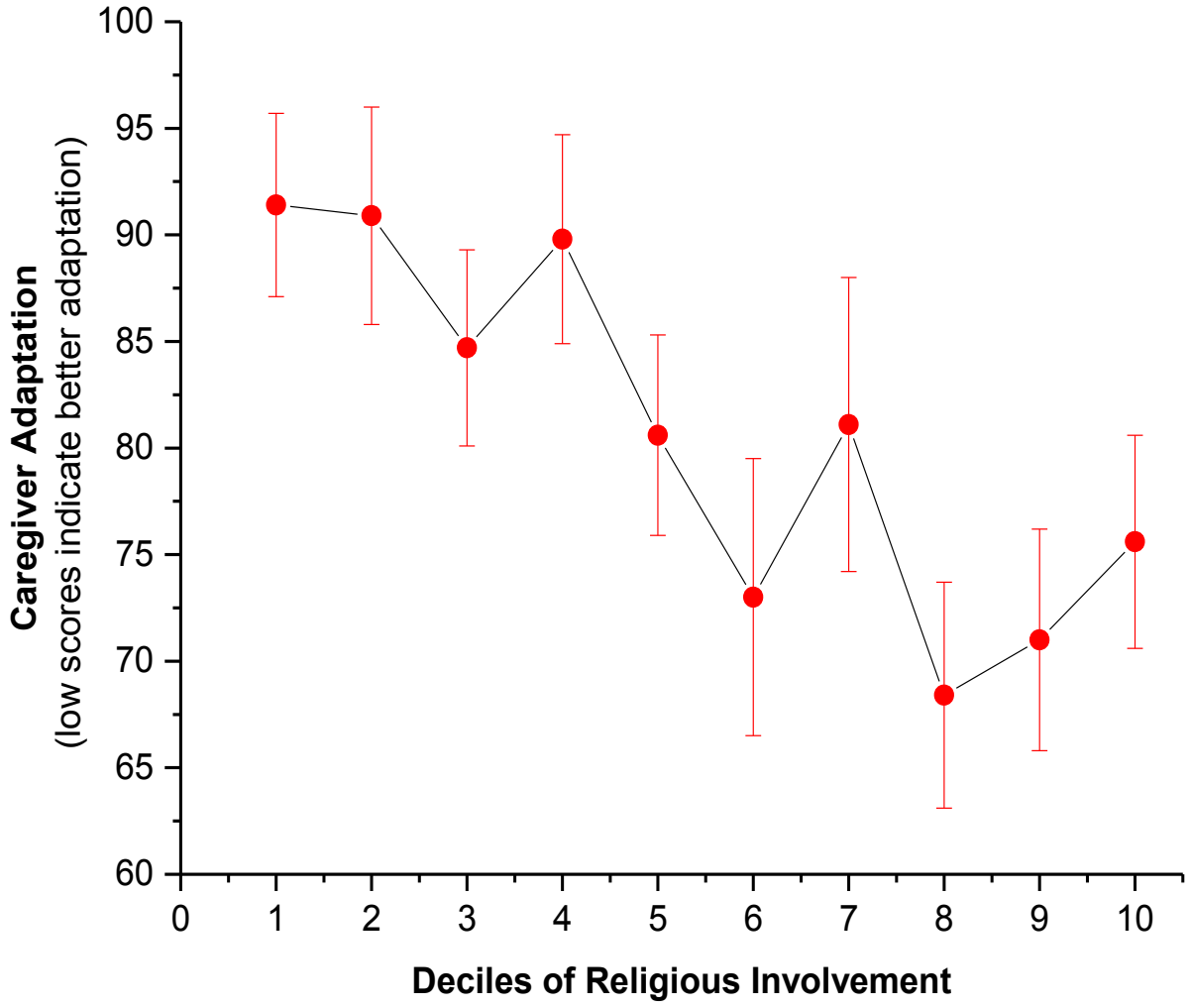
(perceived stress, depressive symptoms, caregiver burden, etc.)

(1) Is religiosity related to telomere length?

Cross-sectional study involving a questionnaire and a blood sample

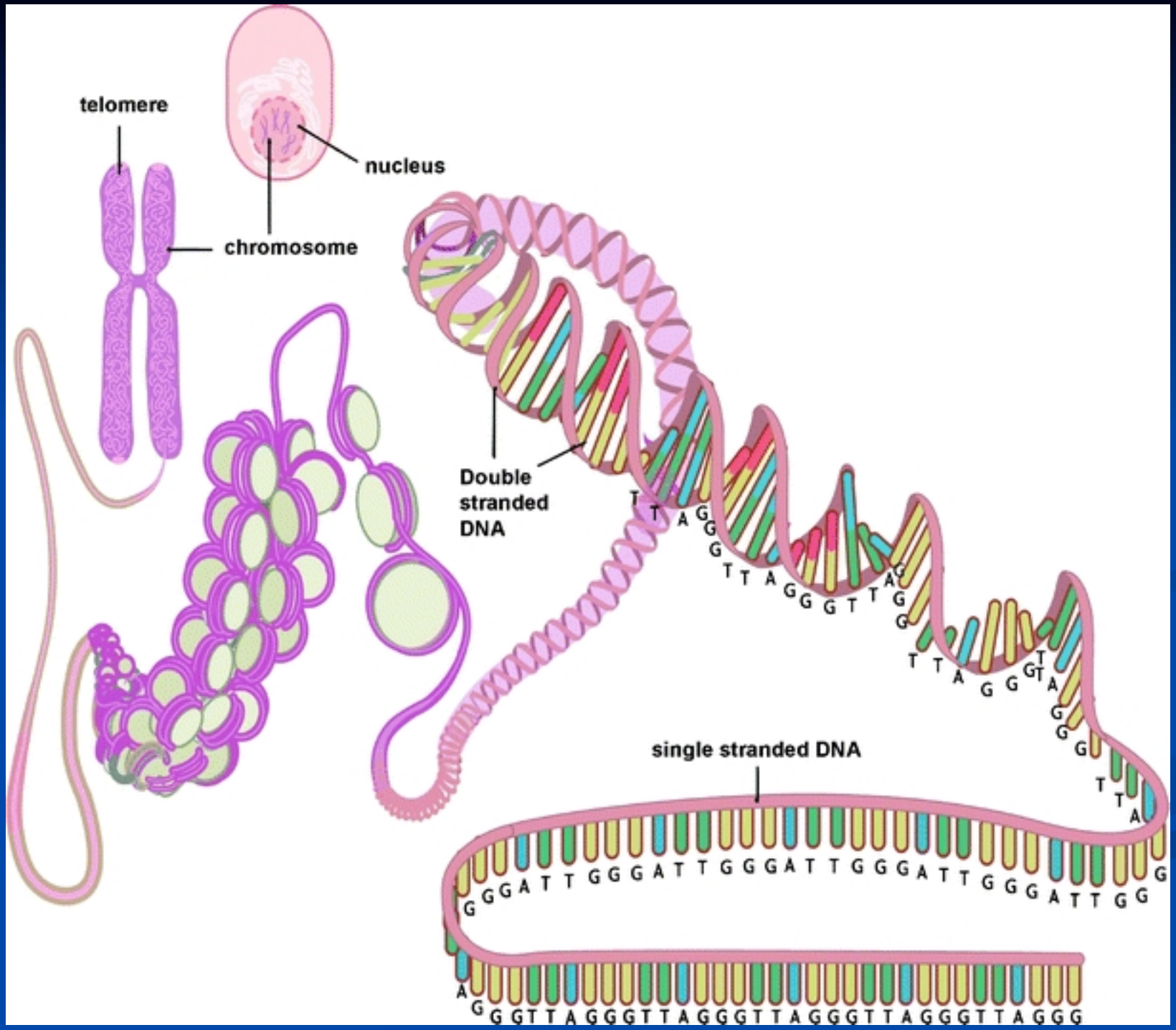
Cost: $60,000

# Caregiver Adaptation



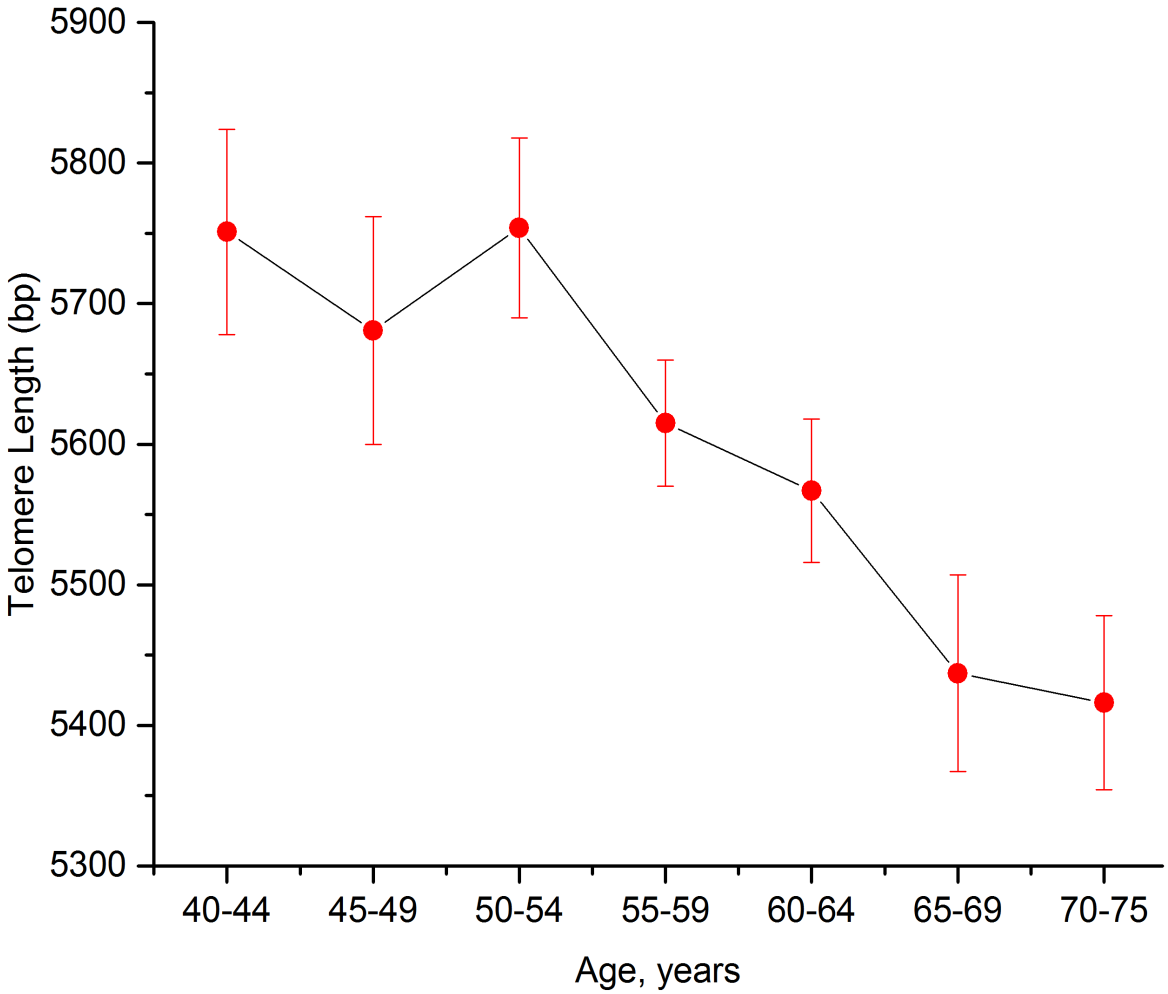
# What are Telomeres?

Telomere regions are found at the ends of chromosomes and contain non-coding DNA material that helps to prevent the loss of important DNA from chromosome ends during cell division. These telomere regions shorten after each cell replication cycle. When the telomere region shortens to a critical point, the result is genomic instability, end-to-end chromosome fusion, and loss of ability for cell replenishment. The cell goes into senescence and organ degeneration may occur because cells can no longer replicate to maintain homeostasis.


telomere
nucleus
chromosome
Double stranded DNA
single stranded DNA

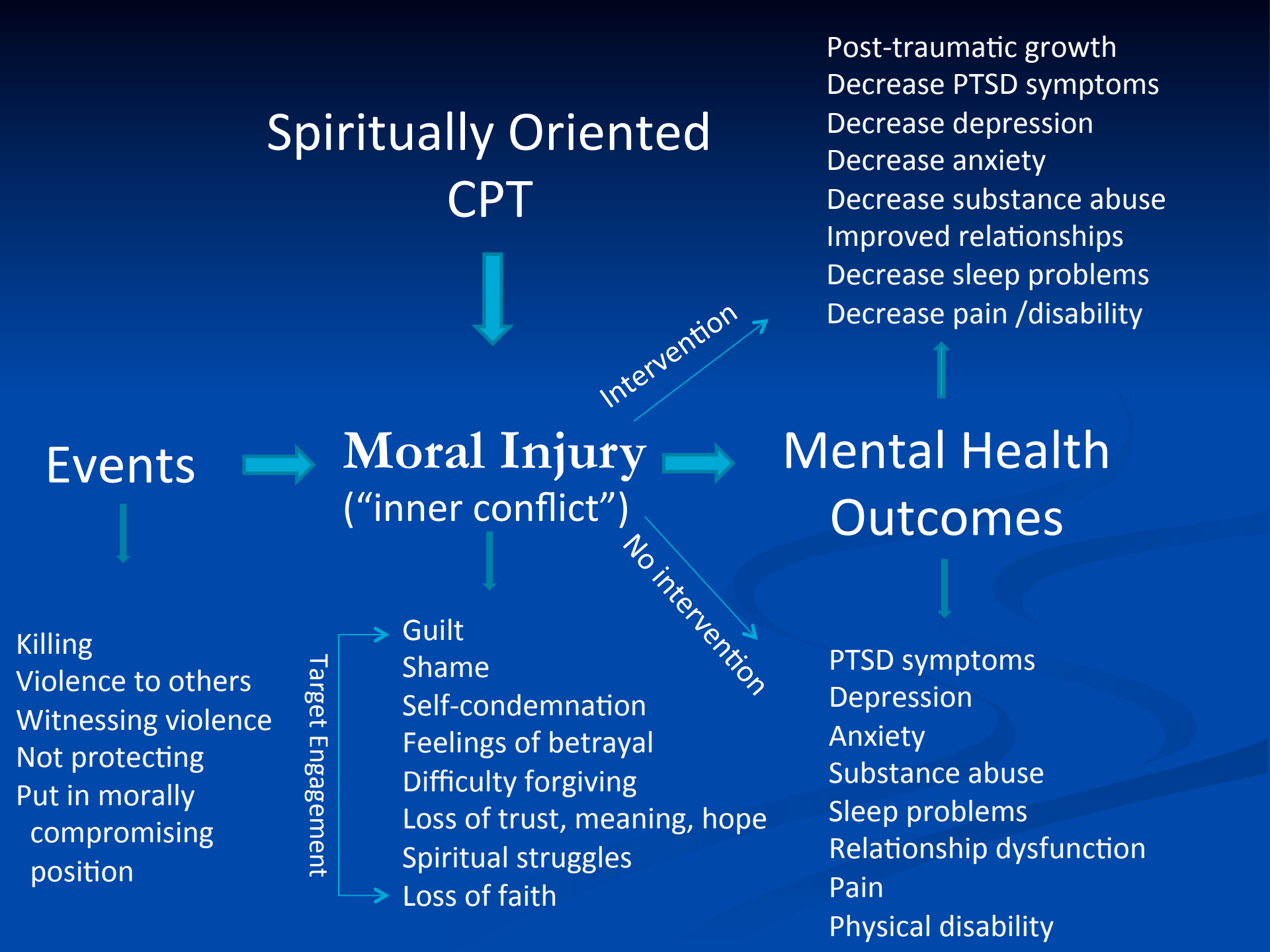
# Does Religious Involvement Reduce the Effects of Caregiver Stress on Telomere Shortening?

# **Results** (pending)




Journal of Nervous & Mental Disease, in submission

# Spiritually Oriented Cognitive Processing Therapy for Inner Conflict (Moral Injury) in Active Duty Soldiers / Veterans with PTSD and Physical Illness: A pilot study


Spiritually Oriented CPT
Post-traumatic growth
Decrease PTSD symptoms
Decrease depression
Decrease anxiety
Decrease substance abuse
Improved relationships
Decrease sleep problems
Decrease pain /disability
Intervention
Events
Moral Injury
("inner conflict")
Mental Health Outcomes
No intervention
Killing
Violence to others
Witnessing violence
Not protecting
Put in morally compromising position
Target Engagement
Guilt
Shame
Self-condemnation
Feelings of betrayal
Difficulty forgiving
Loss of trust, meaning, hope
Spiritual struggles
Loss of faith
PTSD symptoms
Depression
Anxiety
Substance abuse
Sleep problems
Relationship dysfunction
Pain
Physical disability

# Specific Aims:

#1. Develop a *manual-based* SOCPT for engaging the Moral Injury target

#2. Determine receptivity of soldiers/veterans to SOCPT for Moral Injury (in terms of subject recruitment and retention)

#3. Determine if SOCPT is superior to conventional CPT in relieving Moral Injury

#4. Determine if SOCPT is superior to CPT in relieving PTSD symptoms via reduction in Moral Injury

#5. Determine if SOCPT is superior to CPT in relieving co-morbid depression, anxiety, substance abuse, and improving overall functioning via reduction in Moral Injury

# Research Methods: Original Design

- randomized clinical trial
- 300 soldiers and veterans randomized to RCPT (n=150) vs. CPT (n=150) (d=0.38)
- 12 sessions of RCPT or CPT delivered over 6 weeks
- 6 master's level licensed therapists, 2 at each site (subjects randomly assigned to)
- follow-up at 3 weeks, 6 weeks, 12 weeks, 24 weeks
- 24-month recruitment period; 36-month study

Direct Cost: $2.4 million

# Research Methods: Current Design

Collection of pilot data without funding support:

- Conduct surveys at four sites (two active duty Army [Fort Gordon, Fort Bragg] and two VA [Charlie Norwood and Durham], n=100 each site), assessing soldiers/veterans returning from combat with PTSD symptoms, to:
- (1) determine the prevalence of MI symptoms (i.e., guilt, shame, self-condemnation, difficulty forgiving, feeling betrayed, loss of trust, loss of meaning and purpose in life, spiritual struggles, and loss of faith);
- (2) develop and test the psychometric properties of a multi-dimensional measure of MI symptoms
- (3) identify spiritual resources that can be utilized to address MI
- (4) determine receptivity of soldiers/ veterans to a spiritually-oriented intervention for MI
- (5) determine the interest level of soldiers/veterans in participating in a study that examines SOCPT for MI; and
- (6) examine the relationships between MI, spiritual resources, and PTSD symptoms (along with comorbidities such as depression, anxiety, relationship dysfunction, substance abuse).

# Research Methods: Current Design

Collection a pilot randomized clinical trial with funding support:

- 50 soldiers and veterans randomized to SOCPT (n=25) vs. CPT (n=25) (d=0.70)
- 12 sessions of SOCPT or CPT delivered over 6 weeks
- 2 psychologists and 2 chaplains trained in both SOCPT and CPT (subjects randomly assigned to)
- follow-up at 3 weeks, 6 weeks, and 12 weeks
- 6-month recruitment period; 12-month study

Direct costs: $287,000

# Research Methods: Inclusion/Exclusion Criteria

Inclusion criteria:

- soldier/veteran returning from a combat theater
- diagnosis of PTSD or subthreshold PTSD on SCID-5/ CAPS
- score of 27 or higher on the PCL-5 (i.e., ≥40 on PCL-S)
- comorbid physical illness resulting from combat injury or other medical illness lasting 1 month or more
- religion at least somewhat important

Exclusion criteria:

- significant cognitive dysfunction (< 14 on abbreviated MMSE)
- receipt of CPT within the past 4 weeks
- active suicidal ideation

No other exclusions (age, gender, depressive disorder, bipolar disorder, anxiety disorder, substance abuse to be documented at baseline, along with medications)

# Research Methods: Recruitment Sites

**Eisenhower Army Medical Center**, Fort Gordon, Augusta, GA
- 10 new and 40-50 ongoing cases of PTSD per month
- many non-diagnosed soldiers identifiable by advertisements/ screening

**Charlie Norwood – VA Medical Center**, Augusta, GA
- 90 new veterans with PTSD per month and follow 150-200 veterans with PTSD (447-bed facility)
- many non-diagnosed veterans identifiable by advertisements

**Womack Army Medical Center**, Fort Bragg, Fayetteville, NC
- 10 new and 40-50 ongoing cases of PTSD per month
- many non-diagnosed soldiers identifiable by advertisements

**Durham VA Medical Center**, Durham, NC
- 45 new veterans with PTSD per month and follow 75-100 veterans with PTSD (271-bed facility)
- many non-diagnosed veterans identifiable by advertisements

# Types of Research Design

**(1) Research involving summarizing others' research**

- Review of literature (non-systematic)
- Review of literature (systematic)
- Meta-analysis of existing studies

**(2) Original research**

- Observational research
  - qualitative studies (including case reports)
  - cross-sectional studies (caregiver study)
  - prospective studies

- Experimental studies
  - clinical trials, single group
  - randomized clinical trials (RCBT vs. CCBT study)

# Research by Practitioners

(1) Many types of projects could be done without funding

(2) Qualitative research – systematic clinical observations
- interesting cases of benefit or harm

(3) Simple cross-sectional studies
- attitudes of HP toward spiritual assessment or intervention
- attitudes of patients (receptiveness) toward spiritual assessment or intervention
- spiritual needs of patients in local healthcare setting
- use of religion or spirituality to cope in local settings

(4) Collaborate with experienced researchers

# **Chaplain Interventions** – positive findings

Iler AL, Obenshain D, Camac M (2001). The impact of daily visits from chaplains on patients with chronic obstructive pulmonary disease (COPD): A pilot study. Chaplaincy Today 17:5-11.

Hospitalized patients with COPD were alternately assigned to either a chaplain-visited intervention group or a non-chaplain visited control group. The chaplain intervention consisted of 4.2 visits (on average), which lasted approximately 20 min in duration each. Intervention included prayer (100%), and two-thirds involved venting over painful emotions. All visits were made by a single chaplain (Iler). After controlling for baseline anxiety, chaplain visited patients had significantly less anxiety on discharge ($p=0.05$) compared to controls. Length of stay was also shorter for visited patients (5.7 days vs. 9.0 days, $p=0.002$), such that visited patients stayed 3.3 fewer days on average (37% reduction in average length of stay). Patients who did not agree to participate in the study had even longer lengths of stay than control patients (12.6 days). Finally, satisfaction with quality of care was significantly higher in the chaplain-visited group ($p=0.01$), and they also tended to recommend the hospital to others ($p=0.056$), compared to control patients.

# **Chaplain Interventions** – negative findings

Bay, P. S., Beckman, D., Trippi, J., Gunderman, R., & Terry, C. (2008). The effect of pastoral care services on anxiety, depression, hope, religious coping, and religious problem solving styles: A randomized controlled study. Journal of Religion & Health, *47*(1), 57-69.

Hospitalized patients undergoing CABG were randomly assigned to either a chaplain-visited intervention group (n=85) or a non-chaplain visited control group (n=85). The chaplain intervention consisted of 4 visits w pt and 1 visit w family (44 min total time); 1 visit before surgery and 3 visits afterward w pt. Intervention included listening, supportive pastoral care, focus on single question (general coping), identify and discuss hopes, focus on positive future, focused on grief related to limitations of disease; psychological issues appeared to be focus, not religion. All visits were made by a single chaplain (PS Bay). Patients assessed at 1 month and 6 months. No differences between groups found on anxiety, depression, hope, number of hospital readmissions, unscheduled physician office visits, post-surgery length of stay, or cost of hospitalization. Positive religious coping increased and negative religious coping decreased (at 6 mo).

# **Chaplain Interventions** – positive findings

Marin DB, Sharma V, Sosunov E, Egorova N, Goldstein R, Handzo GF (2015). Relationship between chaplain visits and patient satisfaction. Journal of Health Care Chaplaincy 21(1):14-24

Examined data on chaplain visits and patient satisfaction from HCAHPS and Press Ganey surveys involving 8,978 patients discharged from Mount Sinai Hospital over an 18 months. Chaplain encounters were recorded in the electronic medical record. Questions on the HCAHPS survey that assessed patient satisfaction were: (1) "What number would you use to rate this hospital during your stay?" (0-10); (2) "Would you recommend the hospital to your friends and family?" (1-4). Questions on the Press Ganey survey were: (3) "Overall rating of care given at hospital"; (4) "Likelihood of your recommending this hospital to others"; (5) "Degree to which hospital staff addressed your spiritual needs"; and (6) "Degree to which hospital staff addressed your emotional needs" (1-5). Also assessed were age, gender, race, and ethnicity, as well as education, religious affiliation, language spoken at home, and self-rated health (poor to excellent). **Results**: Patients visited by a chaplain (n=498) compared to those not visited (n=8,480) were more likely to have poor health status. In bivariate analyses, overall care given at the hospital ($p<0.01$), rating of hospital during stay ($p<0.05$), likelihood of recommending hospital to friends and family ($p<0.05$), and degree to which spiritual needs were met ($p<0.01$) were all significantly greater among chaplain-visited patients. When patient characteristics were adjusted for in regression models, all six indicators of patient satisfaction were significantly higher among chaplain-visited patients.

## Summary

1. There is much exciting new research on religion/spirituality and health that is now being conducted, and new results are being reported regularly

2. Practitioners can do research even if they are not researchers

3. Practitioners are ideally positioned to identify potentially effective spiritual interventions that could be examined in observational studies or clinical trials

4. Practitioners must obtain a basic understanding of research methods and procedures, and must then network with established researchers at academic medical centers

5. Practitioners have creative ideas and patients to study them in, but need researchers with the ability to design and manage research projects and acquire the necessary funding for the research

# Further Reading

1. *Spirituality and Health Research: Methodology, Measurement, Analyses, and Resources* (Templeton Press, 2011)

2. *Handbook of Religion and Health* (Oxford University Press, 2001; and Second Edition, 2012)

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Exploring Research on Religion, Spirituality & Health

- Summarizes latest research
- Latest news
- Resources
- Events (lectures and conferences)
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# www.spiritualityandhealth.duke.edu

CENTER FOR SPIRITUALITY, THEOLOGY AND HEALTH
DUKE UNIVERSITY



The Center was founded in 1998, and is focused on conducting research, training others to conduct research, and field-building activities related to religion, spirituality, and health. In addition, we serve as a clearinghous for information on religion, spirituality and health, and seek to support and encourage dialogue between researchers, clinicians, clergy, and others interested in the intersection.

## Goals & Focus

The three main goals of the Center are:

- Conducting interdisciplinary research on spirituality, theology and health
- Training and supporting those wishing to do research on the topic
- Building a community of researchers, clinicians, clergy, and others interested in dialogue and discussions related to spirituality, theology and health
- Informing the public about relationships between religion, spirituality and health

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## Upcoming Events

Summer Workshops

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2008
2009
2010

**STH Seminars, View Videos**

**9th Annual David B. Larson Memorial Lecture**

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DukeMedicine

# Summer Research Workshop

August 10-14, 2015

Durham, North Carolina

5-day intensive research workshop focus on what we know about the relationship between spirituality and health, applications, how to conduct research and develop an academic career in this area. Leading spirituality-health researchers at Duke, the Veterans Administration, and elsewhere will give presentations:

-Strengths and weaknesses of previous research
-Theological considerations and concerns
-Highest priority studies for future research
-Strengths and weaknesses of measures of religion/spirituality
-Designing different types of research projects
- Primer on statistical analysis of religious/spiritual variables
-Carrying out and managing a research project
-Writing a grant to NIH or private foundations
-Where to obtain funding for research in this area
-Writing a research paper for publication; getting it published
-Presenting research to professional and public audiences; working with the media

**Partial scholarships are available for the financially destitute**

**If interested, contact Harold G. Koenig: Harold.Koenig@duke.edu**

# Open Discussion

(till 2:45)