Religion, Spirituality and Health

"Mini" Research Workshop

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DukeMedicine

9:00-12:00

Overview

1. Measurement of religion/spirituality
2. Highest and lowest priority studies
3. Developing a research question
4. Observational studies
5. Randomized clinical trials
6. Funding research at Loma Linda University

Measurement of Religion and Spirituality

1. Categories of measurement 9:00-9:35
2. Method of administration
3. Dimensions of religion and religiousness
5. Religion specific scales
6. Critiques of common scales
7. Examples of scales

Categories of Measurement

1. Qualitative – focus is on the subject's story, details of personal experience, attempts to derive patterns, meaning and understanding of phenomena

2. Quantitative – focus is on numbers, amounts of or degrees of something; seeks to objectify; looks for numerical correlations & predictions; seeks to assess impact or change in terms of numbers

3. Mixed qualitative-quantitative (mixed methods)

4. Focus in this session on measurement is **QUANTITATIVE**

Method of Administration

(with regard to questionnaires used in quantitative research)

1. Self-administration: self-report (most, easy, less $$)

2. Interviewer-administered (more $$)
   a. self-report (what subject reports)*; elderly, sick, less cooperative
      Examples: CES-D, SCL-90, DUREL
   b. observation (observer-rated)
      Example: Hamilton Depression Scale, CGI Scale
   c. combined self-report & observation
      Example: structured clinical interviews (SCID, DIS, CIDI, MINI)

*Interviewer must be very careful how they ask the questions, so as not to bias subjects' responses (training needed)

Dimensions of Religion and Religiousness

1. Religious denomination or affiliation
2. Religious belief or orthodoxy
3. Religious practices (public)
4. Religious practices (private)
5. Subjective religiousness (or importance of religion)
6. Religious motivation, commitment
7. Religious well-being
8. Religious coping (general vs. specific)
9. Religious history
10. Religious support (church/synagogue-related)
11. Religious experience (mysticism, love of God)
12. Religious giving ($$, volunteer)
13. Religious knowledge (scripture)
14. Religious growth
15. Religious maturity

Dimensions of Religion and Religiousness

Shorter categorization

1. Organizational religiosity (behavioral – social)
2. Non-organizational religiosity (behavioral - private)
3. Subjective religiosity, motivation, commitment (cognitive)

Religion-Specific Scales

Most scales developed in Protestant and Catholic Christians; no scales for non-traditional groups (Jehovah Witnesses, Unitarian, etc.)

1. **Jews**: *JCOPE* (Rosmarin. J Clin Psychology 2009; 65:670-683); 6-item *Trust-Mistrust in God Scale* (Rosmarin et al. Int'l J Psychiatry Med 2011; 41(3):253–261.

2. **Hindus** – 19-item *Santosh-Francis Scale of Attitude Towards Hinduism* (SFSAH) (Francis, 2008), 15-item *Hindu RCOPE* (Tarakeshwar, 2003)

3. **Buddhists** – 24-item *Attitudes toward Buddhism / Sikhism Scales* (Thanissaro. Mental Health, Religion & Culture 2011; 14:797-803);
   44-item *BCOPE* (Phillips et al. 2012. Journal for the Scientific Study of Religion, *51*(1), 156-172)

4. **Muslim** - 13-item *Muslim Religiosity Scale* (Al Zaben … Koenig. J Religion & Health 2015; 54(2):713-730)

5. **New Age Spirituality** – 22-item *New Age Orientation Scale* (Grangvist. JSSR 2001; 40:527-545)

Commonly Used Scales

1. Fetzer Institute multi-dimensional R/S scale (GSS norms for 38-item) (Fetzer Institute, info@fetzer.org)
   (**minus** forgiveness, values, and meaning; or model as mediators or outcomes)

2. Intrinsic and Extrinsic Religiosity Scales (Hoge, Allport)

3. Duke University Religion Index (DUREL) (5-items)

4. Belief into Action (BIAC) Scale (10-item)

5. Religious Commitment Inventory (RCI-10) (10 items)

6. Paloutzian & Ellison's Spiritual Well-being Scale (religious & existential subscales)

7. FACIT-Sp (cancer) (meaning and faith subscales)

8. Spiritual Transcendence Scale (Piedmont and others)

Commonly Used Scales

9. RCOPE scales (14-item, 7-item, long version) (Pargament)

10. Religious Coping Index (3-item, observer-rated, Koenig)

11. Daily Spiritual Experiences scale (Underwood) (Fetzer booklet)

12. Krause religious support scale (support received & given)

13. Religious history scale (no really good scales out there; Fetzer booklet)

14. Religious preference (see Fetzer booklet, pp 81-84)

15. Many other scales (see *Measures of Religiosity* by Hill & Hood, 1999, Religious Education Press, Birmingham, AL) ($100)

16. Koenig HG, Al-Zaben F, Khalifa DA, Al Shohaib S (**2014**). Measures of religiosity, Chapter 19. In Boyle GJ, Saklofske DH, Mathews G (eds), Measures of Personality and Social Psychological Constructs. San Diego, CA: Academic Press (Elsevier), pp 533-564 ($63.65 used for entire book)

Recommended Measures

(depends on your purpose)

1. Comprehensive: BMMRS - Fetzer scale (abbreviated; minus forgiveness, values, meaning subscales; 31 items)

2. Overall best religious commitment scale:
   a) Belief into Action Scale (BIAC) (10 items)
   b) Hoge Intrinsic Religiosity Scale (10 items)
   c) Religious Commitment Inventory (10 items)

3. Shortest: DUREL (5 items)

4. Correlates with everything: Negative RCOPE (7 items)

5. Religious support (Krause)* (8 items)

* Part of Fetzer BMMRS scale

Examples of Commonly Used Scales

10-item Religious Commitment Inventory

(Journal of Counseling Psychology 50: 84-96)

1. I often read books and magazines about my faith.
2. I make financial contributions to my religious organization.
3. I spend time trying to grow in understanding of my faith.
4. Religion is especially important to me because it answers many questions about the meaning of life.
5. My religious beliefs lie behind my whole approach to life.
6. I enjoy spending time with others of my religious affiliation.
7. Religious beliefs influence all my dealings in life.
8. It is important to me to spend periods of time in private religious thought and reflection.
9. I enjoy working in the activities of my religious affiliation.
10. I keep well informed about my local religious group and have some influence in its decisions.

(1= not at all true of me, 5=totally true of me)

10-item Hoge Intrinsic Religiosity Scale

Journal for the Scientific Study of Religion 1972; 11:369-376

1. My faith involves all of my life
2. In my life, I experience the presence of the Divine (i.e. God)
3. Although I am a religious person, I refuse to let religious considerations influence my everyday affairs (**R**)
4. Nothing is an important to me as serving God as best as I know how**)**
5. My faith sometimes restricts my actions
6. My religious beliefs are what really lie behind my whole approach to life
7. I try hard to carry my religion over into all my other dealings in life
8. One should seek God's guidance when making every important decision
9. Although I believe in religion, I feel there are many more important things in life **(R)**
10. It doesn't matter so much what I believe as long as I lead a moral life **(R)**

R=reverse score
Score each 1-5, definitely not true to definitely true, range 10-50
Higher scores indicate greater intrinsic religiosity

11-item Allport-Ross Extrinsic Religiosity Scale

Journal of Personality & Social Psychology 1967; 5, 432-443

1. What religion offers me most is comfort when sorrows and misfortune strike.
2. One reason for my being a church member is that such membership helps to establish a person in the community.
3. The purpose of prayer is to secure a happy and peaceful life.
4. It doesn't matter so much what I believe so long as I lead a moral life.
5. Although I am a religious person I refuse to let religious considerations influence my everyday affairs.
6. The church is most important as a place to formulate good social relationships.
7. Although I believe in my religion, I feel there are many more important things in my life.
8. I pray chiefly because I have been taught to pray.
9. A primary reason for my interest in religion is that my church is a congenial social activity.
10. Occasionally I find it necessary to compromise my religious beliefs in order to protect my social and economic well-being.
11. The primary purpose of prayer is to gain relief and protection.

Duke University Religion Index (DUREL)

American Journal of Psychiatry 1997; 154:885-886

Spanish, Portuguese, Chinese, Romanian, Japanese, Thai, Persian, Arabic, Hebrew, Russian, Ukrainian, German, French, Italian, Norwegian, Dutch , Danish, Malaysian, Filipino, Serbian, Korean, Hindi, Indonesian, Lithuanian, Polish, Tamil, and Tagalog versions available

(1) How often do you attend church or other religious meetings?
[never (1) to more than once/wk (6)]

(2) How often do you spend time in private religious activities, such as prayer, meditation or Bible study? [rarely or never (1) to more than once a day(6)]

(3) In my life, I experience the presence of the Divine (i.e., God).
[definitely not true (1) to definitely true (5)]

(4) My religious beliefs are what really lie behind my whole approach to life.
[definitely not true (1) to definitely true (5)]

Belief into Action Scale (BIAC)

(Arabic, Persian, Chinese, and Spanish versions available)

Koenig HG, Nelson B, Shaw SF, Al Zaben F, Wang Z, Saxena S (2015). Belief into Action scale: A brief but comprehensive measure of religious commitment. Open Journal of Psychiatry 5 (1): 66-77

1. Please circle the highest priority in your life now? (most valued, prized)

1. My health and independence
2. My family
3. My friendships
4. Job, career or business
5. My education
6. Financial security
7. Relationship with God
8. Ability to travel & see the world
9. Listening to music and partying
10. Freedom to live as I choose

2. How often do you attend religious services? (circle a number below)

Never	Rarely	Couple times/yr	Every few mos	About once/mo	Several times/mo	About every wk	Every week	More than once/wk	Daily
1	2	3	4	5	6	7	8	9	10

3. Other than religious services, how often do you get together with others for religious reasons (prayer, religious discussions, volunteer work, etc.)?

Never	Rarely	Couple times/yr	Every few mos	About once/mo	Several times/mo	About every wk	Every week	More than once/wk	Daily
1	2	3	4	5	6	7	8	9	10

4. To what extent (on a 1 to 10 scale) have you decided to place your life under God's direction?

Not at all (really haven't thought about it)				To a moderate degree					Completely, totally
1	2	3	4	5	6	7	8	9	10

5. What percentage of your gross annual income do you give to your religious institution or to other religious causes each year?

0%	Less than 1%	1%-2%	3%-4%	5%-6%	7%-8%	9%-10%	11%-12%	13%-14%	15% or more
1	2	3	4	5	6	7	8	9	10

6. On average, how much time each <u>day</u> (in 24 hrs) do you spend listening to religious music or radio, or watching religious TV?

0 (never)	1-5 min	6-10 min	11-20 min	21-30 min	31-60 min	More than 1 hr, less than 2 hr	More than 2 hr, less than 3 hr	3-4 hrs	5 hrs or more
1	2	3	4	5	6	7	8	9	10

7. On average, how much time each <u>day</u> do you spend reading religious scriptures, books, or other religious literature?

0 (never)	1-5 min	6-10 min	11-20 min	21-30 min	31-60 min	More than 1 hr, less than 2 hr	More than 2 hr, less than 3 hr	3-4 hrs	5 hrs or more
1	2	3	4	5	6	7	8	9	10

8. On average, how much time each <u>day</u> do you spend in private prayer or meditation?

0 (never)	1-5 min	6-10 min	11-20 min	21-30 min	31-60 min	More than 1 hr, less than 2 hr	More than 2 hr, less than 3 hr	3-4 hrs	5 hrs or more
1	2	3	4	5	6	7	8	9	10

9. On average, how much time each <u>day</u> do you spend as a volunteer in your religious community or to help others for religious reasons?

0 (never)	1-5 min	6-10 min	11-20 min	21-30 min	31-60 min	More than 1 hr, less than 2 hr	More than 2 hr, less than 3 hr	3-4 hrs	5 hrs or more
1	2	3	4	5	6	7	8	9	10

10. To what extent (on a 1 to 10 scale) have you decided to conform your life to the teachings of your religious faith?

Not at all (really haven't thought about it)				To a moderate degree					Completely, totally
1	2	3	4	5	6	7	8	9	10

Scoring instructions:

(1) Recode Q1 as follows: 7=10, all other answers=1

(2) Sum recoded Q1 + Q2 through Q10 to arrive at total score (range 10-100)

Religious Support

Krause, N. (1999). Religious support. In Fetzer scale (short form).

I. Received

1. How often do the people in your congregation make you feel loved and cared for?
2. How often do the people in your congregation listen to you talk about your private problems and concerns?

II. Provided

3. How often do you make the people in your congregation feel loved & cared for?
4. How often do you listen to the people in your congregation talk about their private problems and concerns?

III. Negative interaction

5. How often do the people in your congregation make too many demands on you?
6. How often are the people in your congregation critical of you & the things you do?

IV. Anticipated support

7. If you were ill, how much what the people in your congregation be willing to help out?
8. If you have a problem or were faced with a difficult situation, how much comfort would the people in your congregation be willing to give you?

Negative RCOPE

Pargament et al. (1998). J for Scientific Study of Religion, 37: 710-724

1. I wonder whether God had abandoned me.
2. I felt punished by God for my lack of devotion.
3. 3. I wondered what I did for God to punish me.
4. I questioned God's love for me.
5. I wondered whether my church had abandoned me.
6. I decided the Devil made this happen.
7. I questioned the power of God.

[0 = A great deal, 1 = Quite a bit, 2 = Somewhat, 3 = Not at all]

Religious & Spiritual Struggles

Exline et al (2014). Psychology of Religion and Spirituality 6(1):208-222

1. Felt as though God had let me down	**Divine**
2. Felt angry at God	Divine
3. Felt as though God had abandoned me	Divine
4. Felt as though God was punishing me	Divine
5. Questioned God's love for me	Divine
6. Felt tormented by the devil or evil spirits	**Demonic**
7. Worried that the problems I was facing were the work of the devil or evil spirits	Demonic
8. Felt attacked by the devil or by evil spirits	Demonic
9. Felt as though the devil (or an evil spirit) was trying to turn me away from what was good	Demonic
10. Felt hurt, mistreated, or offended by religious/spiritual people	**Interpersonal**
11. Felt rejected or misunderstood by religious/spiritual people	Interpersonal
12. Felt as though others were looking down on me because of my religious/spiritual beliefs	Interpersonal
13. Had conflicts with other people about religious/spiritual matters	Interpersonal
14. Felt angry at organized religion	Interpersonal
15. Wrestled with attempts to follow my moral principles	**Moral**
16. Worried that my actions were morally or spiritually wrong	Moral
17. Felt torn between what I wanted and what I knew was morally right	Moral
18. Felt guilty for not living up to my moral standards	Moral
19. Questioned whether life really matters	**Meaning**
20. Felt as though my life had no deeper meaning	Meaning
21. Questioned whether my life will really make any difference in the world	Meaning
22. Had concerns about whether there is any ultimate purpose to life or existence	Meaning
23. Struggled to figure out what I really believe about religion/spirituality	**Doubt**
24. Felt confused about my religious/spiritual beliefs	Doubt
25. Felt troubled by doubts or questions about religion or spirituality	Doubt
26. Worried about whether my beliefs about religion/spirituality were correct	Doubt

[0 = not at all, 1 = a little bit, 2 = somewhat, 3 = quite a bit, 4=a great deal]

Muslim Religiosity Scale

Al Zaben … Koenig (2015). Journal of Religion and Health 54(2-3):713-730; 1144-1147)

1. 1. How often do you attend group religious services for worship and prayer at Mosque or in small group at work or in your home (obligatory prayers) (Fard)?

2. How often do you pray alone in private (Nawafl)?

3. Are you regular in prayer or do you sometimes sum 2 or more of your obligatory prayers (Fard) with each other or skip?

4. How often do you read or recite the Qur'an or other religious literature (magazines, papers, books) in your home?

5. How often do you listen to or watch religious programs on radio or TV?

6. Do you give Zakat to poor each year?

7. Do you give money to poor as a free gift (not obligatory like Zakat)?

8. How often do you fast from food/water (Sawm)?

9. How often do you make Hajj?

10. How often do you make Umrah?

11. In my life, I experience the presence of Allah/God

12. My religious beliefs are what really lie behind my whole approach to life

13. I try hard to carry my religion over into all my other dealings in life

(response categories range from 1-5, responses vary)

Jewish Religiosity Scale (JCOPE)

1. I ask G-d to forgive me for things I did wrong
2. I get mad at G-d
3. I try to e an inspiration to others
4. I try to see how G-d may be trying to teach me something
5. I think about what Judaism has to say about how to handle the prob
6. I do the best I can and know the rest is G-d's will
7. I look forward to shabbat
8. I talk to my rabbi
9. I look for a stronger connection to G-d
10. I question whether G-d can really do anything
11. I pray for the well-being of others
12. I pray for g-d's love and care
13. I wonder if G-d cares about me
14. I try to do Mitzvot (good deeds)
15. I try to remember that my life is part of a larger spiritual force
16. I question my religious beliefs, faith and practices

Buddhist Cope (BCOPE) Scale (examples of items on 14 dimensions)

Phillips et al. (2012). Journal for the Scientific Study of Religion, *51*(1), 156-172.

1. Morality: coping with stress by acting in ways that help others/do no harm.
2. Meditation: focusing in a relaxed, nonjudgmental way on a particular object.
3. Sangha Support: talking to other Buddhists to receive affirmation, comfort, and assistance in times of stress.
4. Dharma: obtaining information about Buddhism to cope with stress
5. Active Karma: focusing on the fact that you can control your actions, and these actions have consequences for you & others.
6. Punishing Karmic View: defining a stressor as a punishment for past actions.
7. Fatalistic Karma: believing that your actions have consequences for you and others, and these consequences will occur no matter what you do.
8. Impermanence: realizing that most things change
9. Inter-Being: understanding that everything is connected and nothing
10. Not-Self: reflecting on the idea that there is no sustaining individual self (as the idea of self often leads to stress).
11. Right Understanding: trying to view the world—including stressful
12. Lovingkindness: coping with stress by being nonjudgmental, empathic, kind, and compassionate to oneself and others.
13. Equanimity: looking to Buddhism for a major transformation, to maintain balance in life circumstances (not getting too high/low
with good/bad news).
14. Bad Buddhist: believing one has failed to live up to Buddhist principles.
15. Right Thought: acting with good intentions while dealing with stress.
16. Mindfulness: nonjudgmental awareness and acceptance of everything in the present moment—your body, thoughts, behavior,
emotions, and surroundings.
17. It's Not Easy Being Buddhist: expressing unpleasant feelings about the difficulties of practicing Buddhism while dealing with stress.

Summary

1. Understand methods of administration; seek objectivity, avoid bias

2. Retain purity in measurement to avoid tautology in associations; be careful with “spirituality scales”

3. Understand the strengths & weaknesses of each scale, and how commonly it is used in R-H research; understand the different dimensions of religiousness

4. Take time choosing a scale, think about what R dimension the scale is measuring & why it should be related to health outcome

Questions and Discussion

(9:35 conclude)

10 min break

9:45-11:15

Highest and Lowest Priority Studies

Developing a Research Question

Observational Studies

Randomized Clinical Trials

Highest and Lowest Priority Studies

1. Need to focus efforts
2. Mental health
3. Physical health
4. Disease prevention, health promotion
5. Clinical application
6. Importance of collaboration
7. Lowest priority studies
8. **Dead ends**

Need to Focus Efforts

1. Limited time
2. Limited funding support
3. No need to expend limited resources on research that will not advance the field or provide new information

Priority Studies in Mental Health

1. Common mental disorders (course over time)

2. Chronic mental disorders (huge gap in literature); especially as relates to course & exacerbations

3. Emotional & behavior disorders in children (including substance abuse & delinquency)

4. Mental disorders in the elderly (depression, bipolar disorder, anxiety, substance abuse)

5. Adaptation and coping by family caregivers

6. **Interactions** with biological and psychological treatments for mental or emotional disorder (especially psychotropic medications)

Priority Studies in Physical Health

1. Studies of **common** medical illnesses with psychosomatic influences (heart disease, cancer, hypertension/renal disease, stroke, chronic fatigue syndrome, fibromyalgia, irritable bowel syndrome, peptic ulcer disease, asthma, Alzheimer's)
   [cross-sectional and longitudinal studies]

2. Outcomes following surgery; tremendous potential based on physiology of healing

3. Interactions with biological treatments such an antibiotics in infections or chemotherapy in cancer [to see whether religious people heal more quickly]

4. Studies on immune parameters (cytokines, NK cells, CD-4 counts, t-lymphocytes) (C/S and longitudinal)

Disease Prevention, Health Promotion

1. Studies of health behaviors involving diet, exercise, weight control in religious vs. non-religious (longitudinal)

2. Studies of disease screening and detection in religious vs. non-religious people

3. Studies of outcome effectiveness of health ministries in faith communities, in terms of disease detection and health promotion (especially in minority communities)

Clinical Applications

1. Receptiveness of patients to spiritual history taking
   - whether upsetting or comforting, and for whom
   - effects on doctor/nurse-patient relationship
   - effects on patient & clinician satisfaction with care
   - effects on mental health, coping, quality of life
   - effects on physical health & medical outcomes
   (cross-sectional and longitudinal)

2. Receptiveness of patients to physicians/nurse prayer vs. chaplain-led prayer, and comparison of effectiveness on outcomes above (cross-sectional, longitudinal, interventions)

3. Cost-benefit analysis of spiritual history taking, prayer with patients, or other spiritual interventions by health professionals ($$, other) (longitudinal)

Importance of Collaboration

1. Priority must be given to collaboration
2. Team approach is essential to being competitive
3. Multi-center studies more positively reviewed; greater potential for generalization

Lowest Priority Studies

1. Cross-sectional studies on mental health states, such as depressive symptoms
2. Cross-sectional studies on well-being or life-satisfaction
3. Cross-sectional studies on substance abuse
4. Cross-sectional studies in general, except if done in non-Christian religions or in other countries

Dead Ends (academically)

1. Distant intercessory prayer studies
2. Distant intercessory prayer studies
3. Distant intercessory prayer studies
4. Any study that seeks to prove the supernatural, the paranormal, or whose mechanism lies outside of known scientific pathways (psychosocial, behavioral, or physiological)

Identifying the Research Question

Importance of Research Question

1. Directs everything that follows
2. All other aspects of research design must flow naturally from it
3. Protects against a “lack of focus”
4. Spend time choosing the “right” question
5. Discuss with your colleagues and experts

Identifying the Research Question

1. Your interest
2. Feasibility
3. Novelty
4. Ethical
5. Relevant

Will discuss each of these

What Are You Interested In?

1. Do you passionately want to know the answer to this question?

2. Are you willing to devote the energy and time necessary to seek the answer?

3. How much are you willing to give up to pursue this answer?

4. Is it really worth it? Will the answer make a difference that is worth the sacrifice and effort?

Is Your Research Question Feasible?

1. Is there a research design capable of answering your research question? (not all questions can be answered by scientific methods)

2. Is it feasible in terms of $ cost? Can you successfully carry out the study based on the funds you can raise?

3. Do you have the time to carry this project out?

4. Do you have access to a large enough sample needed to answer your question? [sample size estimates]

5. Do you have the skills & resources to recruit the subjects, measure the variables, manage project, and analyze the data?

Novelty?

1. Is your research question a new one?

2. Is your research question a creative one likely to capture the imagination of others? Is it likely to excite others?

3. Might answering you research question buttress previous important work that had a less stringent design?

Ethical?

1. Can the study to answer your question be designed in a way that will not violate the rights or well-being of participants in the study?

2. Among clinicians, particularly chaplains, there is often over-sensitivity to this issue, preventing important research from being done (or leaving it to be done by those insensitive to spiritual issues)

3. Check with your IRB early on (today, regulations are so strict that most ethical concerns must be taken care of before they will even consider a protocol)

Relevant?

1. Will answering your research question provide information that is relevant to the health of others?
2. Will it advance the field?
3. Will it influence the care of patients?
4. Will it affect the cost of services?
5. Will it influence health care policy?

Next, State your Research Question

Make it specific – very specific:

YES:
"What is the relationship between frequency of church attendance and diastolic blood pressure in Southern Baptists from North Carolina?"

NO:
"What is the relationship between religion and blood pressure?"

State Your Hypothesis

1. Say what you expect to find.

   "We hypothesize that Southern Baptists from North Carolina who attend church weekly or more will have an average 5 mmHg lower diastolic blood pressure than those who attend services less than weekly")

2. Base this statement on what is known in the literature, and be sure there is solid rationale based on existing data.

3. This determines how you conduct your power analysis, which will determine how large a sample you need (which will determine the size of your research team & funding needs)

How Many Research Questions?

1. Only <u>one primary overarching research question</u>

2. May have one or two other research questions, but these must be directly related to the primary question. For example:

"Does gender influence the relationship between church attendance and diastolic blood pressure?" (i.e., is relationship stronger in Southern Baptist women than in men?)

or / and

"Does race influence the relationship between church attendance and diastolic blood pressure?" (i.e., is the relationship stronger in African-American Southern Baptists than in White Southern Baptists?)

Summary

1. Formulating a research question is critical and takes time

2. Research question depends on the burning question inside of you

3. Research question will determine the design of your study, your type of sample, sample size needed, and funds needed

4. All depends on your research Q, access to subjects, and funds available to conduct the research

Observational Studies

What Observational Studies Can Tell You

1. That two variables are associated (if cross-sectional)

2. That one variable precedes changes in the other variable (if prospective)

3. Can provide evidence for causality (next slide)

4. Cannot “prove” causality. Only a randomized clinical trial can do that.

Criteria for Causation

(i.e., that variable A affects variable B)

(1) a significant association between variable A and variable B

(2) the relationship is not "spurious" (i.e., there is no alternative cause or third variable C that explains the relationship) [most difficult to establish]

(3) variable A precedes variable B in terms of temporal order

Source:
Kenny, DA (1979). *Correlation and Causality*. NY, NY: Wiley-Interscience

Types of Observational Studies

(will discuss each one separately)

1. Case reports (qualitative)
2. Case series (qualitative)
3. Case-control studies
4. Cross-sectional studies
5. Retrospective cohort studies
6. Prospective cohort studies

(Research programs will often develop in this order, and followed by the development of interventions tested in randomized clinical trials)

Cross-sectional (80-90% of studies)

(assessment occurs at one point in time)

1. Strengths
   - large numbers
   - quick, relatively easy, low cost
   - can generalize results
   - example: General Social Survey, Gallup Polls

2. Limitations
   - no information on causality or direction of effect
   - limited information about nature of relationship or how it came about over time (i.e., prayer and pain relationship)
   - if large study, information often relatively superficial
   - cannot measure/control for all factors affecting relationship

3. Comments: Sampling method and response rate most important; need to account for non-participants (info critical)

Prospective Cohort Studies

(collect data and look forward over time - longitudinal)

1. Strengths
   - adds element of time
   - can provide evidence for causation (though not proof)
   - can help to "explain" a relationship
   - can measure what you want & how you want
   - more generalizable than RCT

2. Limitations
   - more expensive, time consuming, complex
   - dropouts can affect generalizability

3. Comments
   - may change the system by observing and interacting with it (to avoid dropouts & keep in study)
   - need as much info on dropouts as possible

Summary

1. Observational studies may be either cross-sectional (CS) or longitudinal (prospective)

2. There are strengths and weaknesses of each approach, although prospective studies always preferred if possible

3. For CS studies, focus is on systematically identifying a sample, using validated measures to assess variables, maximizing the response rate, & collecting info on non-responders

4. For prospective studies, focus is on using validated measures of predictors and outcomes at baseline & follow-up, ensuring interviewer consistency and reliability, maximizing follow-up of subjects recruited at baseline, & accounting for all dropouts

Randomized Controlled Trial (RCT)

Overview of Clinical Trials

1. Definition
2. Advantages and disadvantages
3. Basic features
4. Patient selection
5. Measuring variables
6. Standardize intervention
7. Types of control groups
8. Randomization
9. Blinding

Definition of a Clinical Trial

A prospective study comparing the effect and value of an intervention against a control in human subjects. A randomized clinical trail is when subjects are randomly allocated to treatment groups.

1931 first double-blind randomized clinical trial that tested the efficacy of gold treatment in TB (didn't work)

Pros and Cons

- Advantages – why important
- Disadvantages – limitations

Why Important

1. Given the uncertain knowledge about disease course, factors that affect it, and low precision in measuring psychosocial variables, it is usually impossible to say whether a variable (religion/spirituality) affects an outcome (health) outside of a randomized clinical trial

2. A randomized clinical trial can determine whether religion/spirituality actually leads to or causes changes in health. If so, this justifies the development of religious/spiritual intervention to prevent or treat the illness.

Strength of Evidence Hierarchy

1. Systematic review of randomized trials
2. Single randomized trial
3. Systematic review of observational studies addressing patient-important outcomes
4. Single observational study addressing patient-important outcomes
5. Qualitative research
6. Unsystematic clinical observations

Limitations

1. RCT do not translate easily into real world:
   I.e., they are staged
   - due to stringent inclusion/exclusion criteria
   - nature of subjects (volunteers)

2. Long-term effects are often not known

3. There is no such thing as a perfect study or clinical trial - all clinical trials involve compromise between ‘ideal’ & ‘doable’

Limitations

4. Poorly designed/conducted clinical trials can be misleading

5. Well-run clinical trials, especially those involving religious or spiritual interventions are costly and involve a tremendous amount of effort

Basic Features of Clinical Trials

1. Subjects are followed forward in time

2. Need not all be followed from an identical calendar date, although each subject must be followed from a well-defined point and followed for the same amount of time (ideally)

3. Intervention must be defined, documented, and applied in the standard fashion directed at changing some aspect of the subject

4. Clinical trial must contain a *control* group, against which the intervention is compared (otherwise, it is called a single-group experimental study)

Basic Features of Clinical Trials

5. At baseline the control group must be similar on all relevant characteristics to the intervention group, so any differences in outcome can be ascribed to the intervention. This is usually achieved by randomization.
6. Subjects in both control and intervention groups can and usually are receiving *other* interventions (self-administered, family, friends, etc.)
7. But, there is an attempt to limit these other interventions that could affect outcomes (or at least measure them and control for them during analysis phase)

Basic Features of Clinical Trials

8. Potential subjects must be fully informed about the trial (informed consent), including what they might or might not get [but there are ways of consenting subjects so that they are not aware of what others are getting (later)]

9. Investigator cannot force subjects to comply; thus must consider magnitude to which subjects will fail to comply with the protocol & measure this

Basic Features of Clinical Trials

11. Random assignment is necessary and indicated -– removes bias in allocation, produces comparable groups, guarantees validity of statistical tests

12. Objective in many clinical trials is to see if the new intervention plus standard care is better or worse than a control condition plus standard care

13. The control condition should include equal amounts of human attention as participants in the intervention are receiving, but…much easier to show an effect if comparing to standard care alone

Patient Selection

- Inclusion criteria define the study population and affect generalizability

- Balance between homogeneous and heterogeneous selection
  - Homogeneous
    1. Easier to detect effect
    2. Harder to enroll patients
    3. Less generalizable
  - Heterogeneous
    1. dilution of effects
    2. easier to enroll patients
    3. more generalizable

Standardize Intervention

- Document protocol
- Describe activities and sequence of different parts of the intervention in detail
- Ensure administered in same way each time (videotape or audiotape to ensure this) (called treatment "fidelity")

Types of Control Groups

1. *Randomized control* – usual [RCT]

2. *Non-randomized concurrent control* – subjects treated without the intervention at approximately same time as intervention group is treated (i.e., compare survival or health outcomes of a religious hospital with that of a non-religious hospital) [not RCT]

3. *Historical controls* –intervention is used in a series of subjects and results compared to outcome in previous series of comparable subjects (outcomes of 10 CABG patients receiving prayer from a chaplain with outcomes of 10 previous comparable CABG subjects without prayer from chaplain) [not RCT]

Types of Control Groups

4. *Wait-list control* – patients randomized to control group eventually get intervention (but interferes with long-term follow-up and comparison of outcomes) (RCT)

5. Crossover trial - subjects in the control group are crossed over to the intervention group at the end of the trial (RCT)

6. *Withdrawal studies* – examine effect of discontinuation or reduction in an intervention (i.e., stop praying or meditating) [not RCT]

Randomization

A. Simple

1. toss an unbiased coin (but, there could be substantial imbalance and "looks bad")
2. random number table
3. random number producing algorithm (computer)
4. alternate assignment (ABABABAB) is not random

B. Blocked

1. avoid imbalance in number of subjects assigned to intervention (A) vs. control groups (B)
2. block size 4 ensures that for every 4 subjects 2 subjects will get into A group and 2 subjects will get into B group

Randomization

C. Stratified

designed to achieve between group comparability of certain characteristics known to be prognostic factors (for example, gender, race, religiousness)

Randomization

Procedure:

An independent central unit should develop randomization process and make the assignment of subjects to the appropriate groups (envelope system or telephone system). Primary investigative team should not be involved, because of potential for bias.

Types of Blinding

1. *Un-blinded* (investigator/subject know identity of the Rx) (also called “open-label” trial)
2. *Single-blind* (only investigator knows)
3. *Double-blind* (neither subject nor investigator knows)

Double blind:
- removes bias in application of intervention or subject treatment
- removes bias in assessment
- removes bias by subject’s preconceived notions about benefit Rx

Double-blind impossible with religious or spiritual interventions, except with intercessory prayer studies [not research]

Summary

1. Clinical trials are important for many reasons, although they also have serious weaknesses

2. In the design of RCTs, careful attention must be paid to inclusion/exclusion criteria, selection of control group, randomization method, blinding, and consenting of patients

3. RCTs are expensive and difficult to carry out, but the power of this method is its unique ability to (a) show that R/S affects health & (b) identify effective interventions

Questions and Discussion

(11:15 conclude)

10 min break

Where to Obtain Funding for Research

(1) Conducting research without funding
(2) Funding your own research
(3) Feasibility of obtaining outside funding
(4) Getting started
(5) Locating sources of funding
(6) NIH
(7) Other government (military, VA)
(8) National organizations
(9) Institutional grants
(10) Private foundations
(11) Individual donors

Conducting Research Without Funding

1. **Most published research on religion and health**

2. **Time, data, and statistical skills are needed**

Time:
lunch hour, late nights, weekends, vacations, summer

Data:
Piggy back religious variables onto other funded research
Use existing datasets with religious variables (King lecture)

Statistical skills:
Learn basic skills in statistics
Convince statistician to donate time

3. **And learn how to write**

Data sets with religion variables:

• The Association of Religion Data Archives (ARDA):
•http://www.thearda.com/
The ARDA website has much interesting information.

• Links re: religion from U.S. Census Bureau
http://www.census.gov/prod/www/religion.htm

National Center for Health Statistics Public-Use Data Files (includes NHANES, NHCS, etc.)
(http://www.cdc.gov/nchs/data_access/ftp_data.htm)

• National Archive of Computerized Data on Aging: (at ICPSR) http://www.icpsr.umich.edu/NACDA/welcome.html

• Soon, many of the large longitudinal data sets in the US and around the world will be including religious variables that researchers can analyze:
Shields, A. (2016-2019). National spirituality and health consortium. Retrieved from https://www.templeton.org/grant/national-spirituality-and-health-consortium

Funding Your Own Research

1. Fund your research with your own money
2. All donations to non-profits are tax-deductible
3. Allocate 10% of your salary to a special research fund
4. Take on extra work for 6 mos, do research for 6 mos
5. Get your parents, spouse, and children involved
6. Consider this a mission field
7. Most investigators unable to do this (others may be)

Enroll in Post-doc Fellowship

1. Provides salary support
2. Provides training
3. Provides access to ongoing studies of mentors
4. Often provides small amounts $$ for your research

Spirituality and Health post-docs:
Duke post-doc in Spirituality, Theology & Health (ended 7/10)
David B. Larson Fellowship in Health & Spirituality
Baylor Institute for Studies of Religion (ISR)
Post-doc in a traditional area, with side-focus on spirituality

Feasibility of Obtaining Outside Funding

1. Convincing record of success (grants, publications)
2. Academic affiliation
3. Research team and environment
4. Connections (you must know people)
5. Time and energy
6. Tolerance for rejection

Getting Started (to be covered in depth in grants lecture)

1. Need innovative research question, solid proposal
2. Be sure grant time frame meets with your time frame
3. Learn about the grant agency and their priorities
4. Prepare a 1-2 page proposal summary
5. Contact program staff and discuss project with them
6. Review previous successful proposals
7. Contact your Office of Research Support
   - may offer special workshops or seminars

Example of Grant Writing Workshop

Path to Independence Program

For Duke faculty who wish to have hands-on guidance in writing their first independent R01 grant application

Provides personal advice on writing R01 grant application from Duke faculty experienced preparing and reviewing successful NIH application

See website:
http://medschool.duke.edu/faculty/office-faculty-development/path-to-independence-program

Locating Sources of External Funding

- **NIH Office of Extramural Research**
  -- website that outlines all NIH grant mechanisms
  -- http://grants.nih.gov/grants/oer.htm

- **NIH Guide Archive**
  --provides NIH program announcements and RFPs
  -- http://grants.nih.gov/grants/guide/index.html

Locating Sources of External Funding

- **Community of Science***
  -- provides an e-mail every week with all grants (private and government)
  -- http://fundingopps.cos.com

- **Grantsnet***
  -- http://www.grantsnet.org

- **Illinois Researcher Information Service (IRIS)***
  -- http://library.uiuc.edu.iris/

*Researchers can establish customizable searches for grant info in specific areas

Locating Sources of External Funding

- **Foundation Center**
  -- as information on independent, nonprofit organizations
  -- a comprehensive source of information on foundations and corporate giving programs
  -- http://fdncenter.org

- **GrantSelect**
  -- http://www.grantselect.com

Source: Grant Application Writer's Handbook
[contains many other sources of grants]

NIH as a Source of Funding

1. **NCCAM**
   a) most religion/spirituality grants sent here
   b) traditional religious interventions often not reviewed well

2. **NIA**
   a) several grants given (Levin, Chatters, Ferraro, Krause)
   b) 1995 consensus conference (Fetzer); 1998 measures consensus conference (Fetzer)

3. **Other Institutes (NCI, NINR)**

4. **NIMH** (mental health) (?)

NIH as a Source of Funding

Types of grants

a) **Training**: K series (academic awards), 50-75% effort. 3-5 yrs

- K07 (Academic Career Award)
- K99/R00 (Pathway to Independence)
- F31 (enable promising pre-doctoral students to obtain individualized, mentored research training from outstanding faculty sponsors while conducting dissertation research

b) **Small grants** (R03) ($100,000 DC for 2 yr project)

c) **Exploratory** (often new investigator) (R21) ($275,000 DC for 2 yr project)

d) **Investigator initiated**: R01 (up to $250,000-500,000/year x 3-5 years for DC)

e) **Conference grants**: R13, U13

f) **Others** (loan repayment programs, research contracts, P series, U series)

In 2016 at NCCIH, success rate was 13.9%; NIMH 22.9%; overall 19.1%

(see: http://report.nih.gov/success_rates/Success_ByIC.cfm)

Other Government (Military, VA)

1. Congressionally Directed Medical Research Programs (CDMRP)
2. Consortium to Alleviate PTSD (CAPS)
3. VA Merit Review Research Program
   (only VA employees, 5/8th time)
4. Others?

National Organizations

1. American Federation on Aging Research (AFAR) ($50,000/year x 2-3 years)
2. American Federation for AIDS Research (AmFAR)
3. Alzheimer's Association
4. American Cancer Society
5. American Diabetes Association
6. March of Dimes

*these may involve career, project or pilot grants ($20,000-$50,000 typical)

Institutional (intramural) Grants

Young investigators grants (Mellon foundation)

Pilot grants from Center grants

-- General Clinical Research Center

-- Older Americans Independent Centers

-- Diabetes Center

Others (typically $10K-20K)

Contact your grants office for list

Industry/Corporation Grants

Drug companies

- Lilly Endowment (Louisville Foundation)
- Pfizer
- Kings Pharmaceuticals (Bristol, TN)

Cigarette makers

- R.J. Reynolds Foundation
- Liggett-Meyers

Health Insurance Company grants

1. Aetna
2. AmeriHealth
3. Blue Cross-Blue Shield
4. Health Insurance Corporation of America
5. Humana
6. Nationwide Health
7. Partners Health Plan
8. The HMO Group
9. United Healthcare
10. Worldwide Health Partners

Local/Community/State grants

- Churches and denominational offices
- Hospital auxiliaries
- State departments of aging, health, emergency management, etc.

Foundation Grants

1. Contact your Office of Corporate and Foundation Relations
   or your Development Office

2. Services sought:
   - targeting right foundation for your need
   - provide foundation background research
   - foundation contact info and introduction
   - proposal development, guidance

3. Be careful when working with Foundation Relations
   - they have their own priorities
   - you may not be one of them

Foundation Grants

1. Fetzer Institute
2. Arthur Vining Davis Foundation
3. Retirement Research Foundation
4. Robert Wood Johnson Foundation (Faith in Action)
5. Greenwall Foundation
6. Institute of Noetic Sciences
7. Samueli Institute
8. Nathan Cummings Foundation
9. Kellogg Foundation
10. Ford, McArthur, Rockefeller, etc.
11. Local foundations
12. Duke Endowment
13. Mary Biddle Duke Foundation
14. Lilly Foundation (not health-related)
15. F.I.S.H. Foundation

Foundation Grants

16. John W. Kluge Foundation (hosting Larson post-doc fellowship at Library of Congress)

17. James LeVoy Sorenson Foundation (Utah – Mormon connections)

18. Z. Smith Reynolds Foundation (sabbatical grants in the order of $25,000; Winston-Salem, 336-725-7541)

Templeton Foundation

1. Primary funding source for spirituality & health research

2. Small Grants are defined as requests for $217,400 or less. OFI deadlines for small grant requests at August 31 (once yearly)

3. Large Grants are defined as requests for more than $217,400. The Foundation has only one deadline per year for OFIs related to large grant requests on August 31st.

4. Spirituality & health is not their priority

5. In Feb-Apr 2012 LOI submission window, they received 152 LOI, of which they approved 18 (11.8%) for submission of a full proposal

6. Of full proposals, 42% are likely to be funded (**thus less than 6% of all LOI will be funded**; compare to NIH funding line of 19%);

Individual Donors

1. Develop personal connections
2. Excite individuals with your vision
3. Publicize your needs (GoFundMe.com [??])
4. Conduct a fund raising campaign
5. Enlist a professional fund-raiser
6. Contact alumni (but watch out for development office!)

Individual Donors

The Rich Register (Austin, Texas, SBN 0-9633933-2-4) ($360)

1. John W. Henry - 301 Yomato Rd. Boca Raton, FL
2. Daniel C. Searle - 400 Skokie Blvd, #300, Northbrook, IL
3. Jack A. Belz - 100 Peabody Place, #1400, Memphis, TN
4. Richard T. Aab - 200 Meridian Center, Rochester, NY
5. Isaac Arnold, Jr. - 601 Jefferson Street, Houston, TX
6. J. Carter Bacot - Bank Of New York, 1 Wall Street, NY,NY
7. Larry R. Benaroya - 1001 4th Avenue, #4700, Seattle, WA
8. Christopher H. Brown - 350 Park Avenue, 9th Fl, NY, NY
9. Charles M. Cawley –1100 N. King Street, Wilmington, DE
10. John R. Stafford - 5 Giralda Farms, Madison, NJ
11. David A Jones –500 West Main Street, Louisville, KY
12. Alfred E. Mann –12740 San Fernando Road, Sylmar, CA

Individual Donors

13. Genevieve Gore –555 Papermill Road, Newark, DE
14. Phillip H. Morse - Boston Scientific, Pruyn's Island, Glen Falls, NY
15. David Schwartz - 1000 Alfred Nobel Drive, Hercules, CA
16. Robert J Bosh – Robert Bosch GmbH (Germany)
17. Laurence Freedman (Australian) – Equitiilink
18. David C. Auth - 17425 NE Union Hill Road, Remond, WA
19. Denise Debartolo York– 7620 market Street, Youngstown, OH
20. Peter A Morton –510 N. Robertson Blvd. Los Angeles, CA
21. Burton P. Resnick –110 East 59th Street, New York, NY

North Carolina

1. Vera Davis - W.D. Charities, Inc., P.O. Box 19366, Jacksonville, FL
2. F. M. Kirby, 17 DeHart St., P.O. Box 151, Morristown, NJ
3. Foundation for the Carolinas, 217 S. Tryon St., Charlotte, NC
4. Salisbury Community Foundation, Inc., 217 S. Tryon St. ,Charlotte, NC

Summary

1. Funding is scarce, but not impossible to get
2. Try to do as much research as possible without funding
3. Develop a good protocol and then shop it around
4. Conduct thorough search of existing funding opportunities
5. Consider linking research ideas with high priority areas of NIH or private foundations
6. Don’t forget individual donors

Summer Research Workshop

August 12-16, 2019

Durham, North Carolina

5-day intensive research workshop focus on what we know about the relationship between spirituality and health, clinical applications, how to conduct research, and how to develop an academic career in this area. Faculty includes leading spirituality-health researchers at Duke, Yale University, Emory, and elsewhere.

-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 tuition Scholarships are available

If interested, contact Dr. Koenig: Harold.Koenig@duke.edu

Questions and Discussion

(12:00 conclude)