What is Evidence and Why Does it Matter?

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Overview

- Why evidence matters
- Evidence as defined across disciplines/topics
- Evidence as a continuum
- Judging the relevancy of the evidence
- Moving programs from evidence-establishing research to the interest of policy makers

Why evidence matters

- Evidence produced from randomized controlled trials has had a profound impact on life and health in America
- Policy makers appear committed to using a similar model to advance health and wellbeing via prevention, education, and psychosocial interventions.
  - CDC: www.effectiveinterventions.org
  - SAMHSA NREPP: www.modelprograms.samhsa.gov

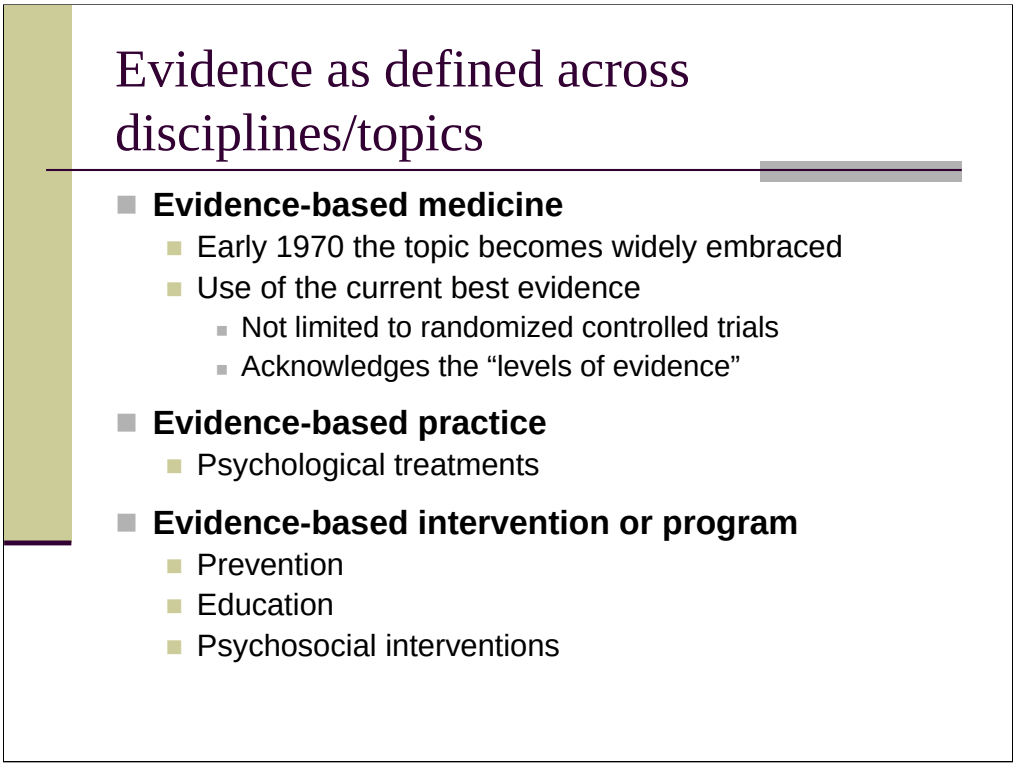
Science has produced knowledge, which has lead to health care innovations and health care policy advances.

Overwhelming positive, but not without some errors. Consider the pharmaceutical industry.

Policy makers appear committed to bring the tools used to provide evidence for medicine into other service arenas.

Here are two example. There are many others.

In sum, there is a clear message coming from Washington and most of the leading non-federal funds that evidence is important and will drive many decisions related to health care.



Evidence-based medicine: freedom from the various biases that beset medical research

We can learn much from the disciplines of Medicine, psychology and education but I caution against mindless adoption of evidence-based standards from these disciplines to the area of caregiving.

For example, consider that medicine typically focuses only well defined diseases and symptoms. There is typically a consensus on the desired outcomes. Treatments can be delineated in concrete terms.

In Caregiving, we move into a different arena that is challenging to defining and treatments that are based on behavior change while navigating numerous social and personal issues.

We need to be careful not to apply standard from one discipline to another without careful review and critique.

Yes, we can learn much from medicine, but caregiving is NOT a disease.

A working definition….

Evidence-based interventions (EBIs)...

-have undergone scientific evaluation,

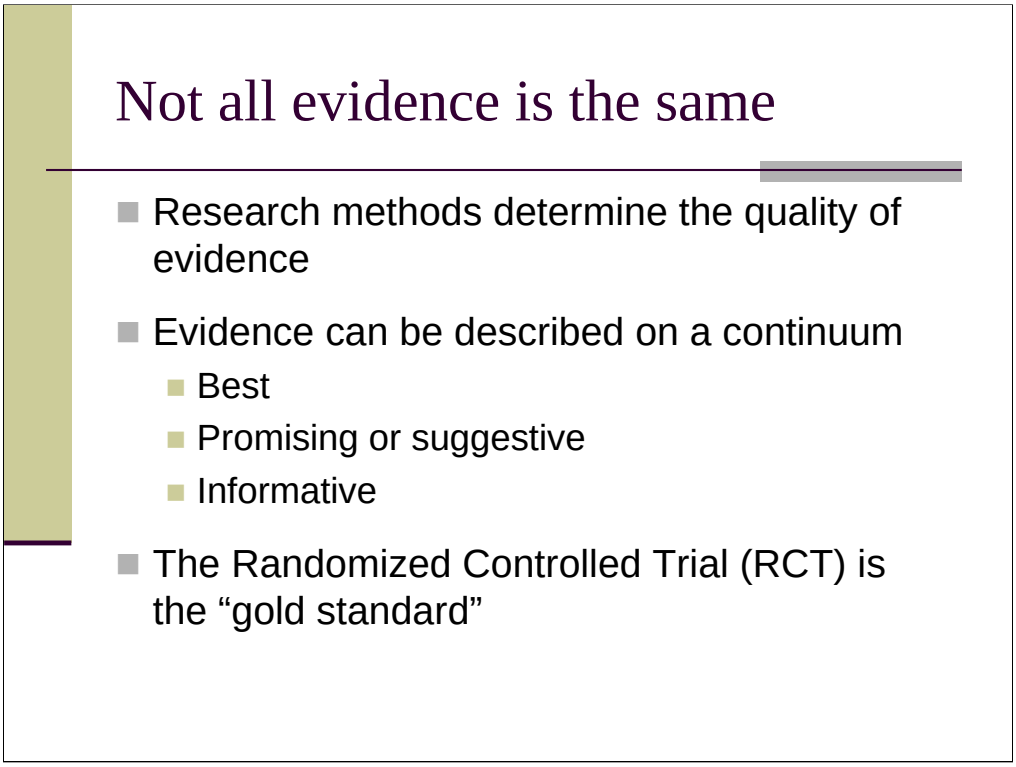
-have defined outcome measures that suggest that the intervention is efficacious or effective,

-and have been thoroughly described, including the intervention, in a peer-reviewed scientific journal

This is the start pointing, the bare minimum.

Think of this as your minimum bet at the CRAPS table.

But is also necessary to judge the strength of the evidence.

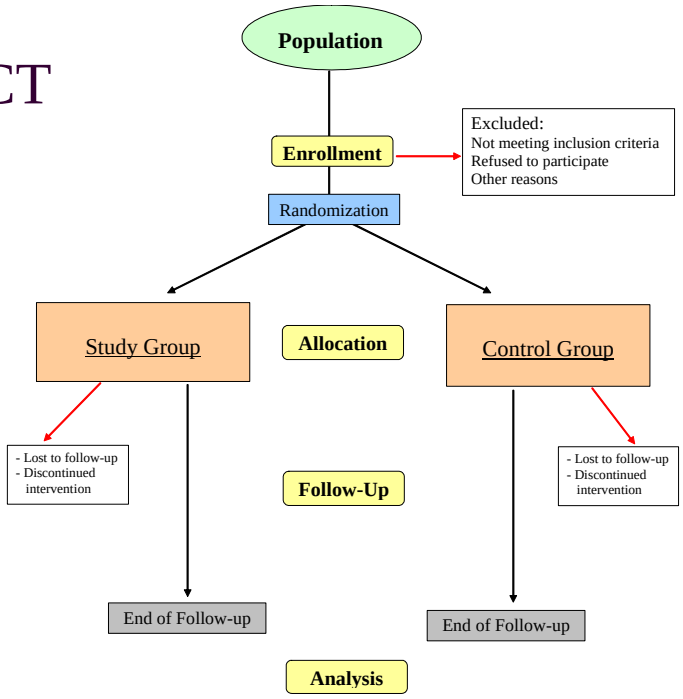


Researchers use a variety of techniques (methods) to gather information on a topic

Methods used can be determined by determined by the
goal of the research,
the availability of the participants or data,
the researcher’s discipline and/or training, etc.

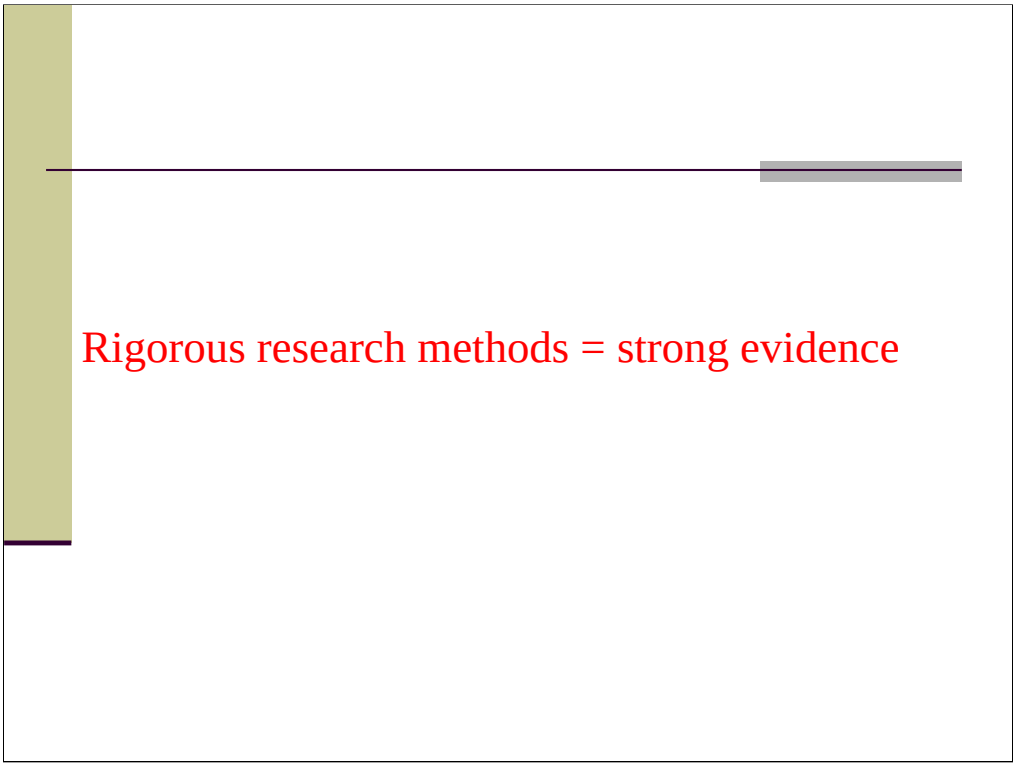
The gold standard in research methods is the randomized control trial.

The RCT


Population
Enrollment
Excluded:
Not meeting inclusion criteria
Refused to participate
Other reasons
Randomization
Study Group
Allocation
Control Group
- Lost to follow-up
- Discontinued intervention
Follow-Up
- Lost to follow-up
- Discontinued intervention
End of Follow-up
End of Follow-up
Analysis

The unique advantage of random assignment

- **One is more likely to conclude that the intervention itself, as opposed to other factors, caused the observed outcome**
  - Randomly assigning a large number of individuals to separate groups dramatically reduces the chance of systematic difference between groups
  - If then the study is carried out properly, differences between groups can be assigned to the intervention
- **The results:** minimize bias and avoid false conclusion



In the next slides, which are same as your handout, I will walk you through the basic elements of research methods that you can consider when evaluating the strength or level of evidence for an intervention.

This checklist is based on several sources focused on the issues of evidence-based programs and interventions from the disciplines of medicine, behavioral medicine, psychology, and education.

This is the basic assumption…rigorous research methods yield strong evidence for the intervention.

Research Methods: Best evidence

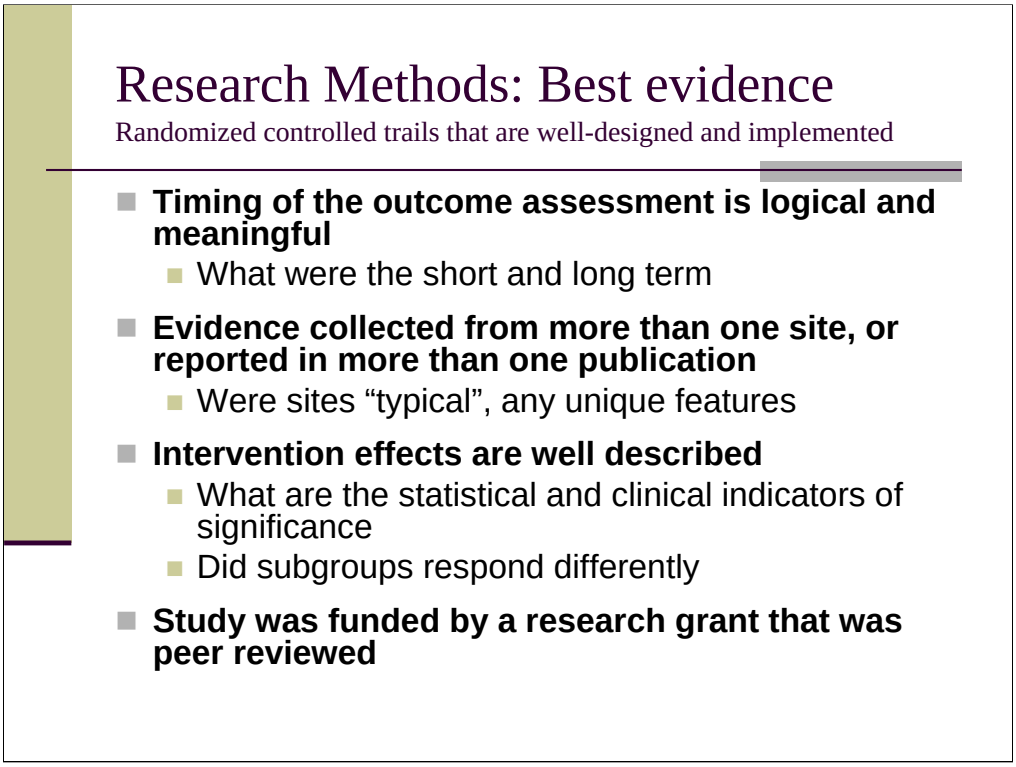
Randomized controlled trails that are well-designed and implemented

- **Participants randomized into groups**
  - Where there systematic differences between groups prior to the intervention
  - At least 20 participants per group, 50 or more is better
  - Eligibility criteria are clearly described
  - Effects were made to “blind” the participant and/or the researcher to group assignment
- **Intervention clearly described**
  - Who administered it, who received it, what it cost
  - How did the intervention differ from the control group
  - Who completed and who dropped out
- **Valid outcome measures**
  - Were multiple measures used and reported
  - Were negative intervention effects discussed

Randomization: FOCUS, stratified by risk level reported at the baseline assessment

Intervention: ESP, the goals and strategies are well delineated

Valid outcomes: NYU included time to nursing home placement



Timing of outcome: Again, NYU had long term follow ups on key outcomes

Evidence from across sites: REACHII , five sites from across the US

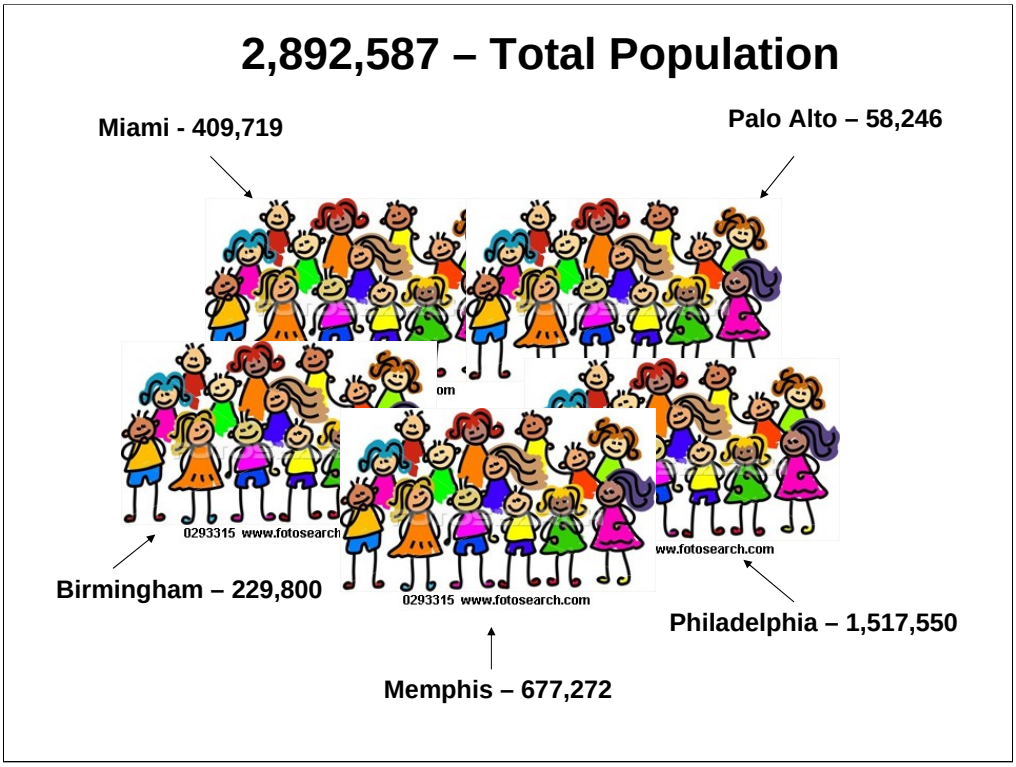
Intervention effects: REACHII, clinical significance and racial/ethnic group difference

Funding: Peer reviewed prior to data collection, and rigorous research methods require resources (time, talent, dollars). You’ll see that in all of today’s presentaitons.

Limitation that are inherent in randomized controlled trails

- **Rigorous research methods are not always possible**
- **Rigorous research methods may distract from the "real world" feel of the study**
  - Was the intervention conducted in a situation that mimics real life
  - Who is signing up for these randomized controlled trials
- **Rigorous research methods may be infeasible or too costly**

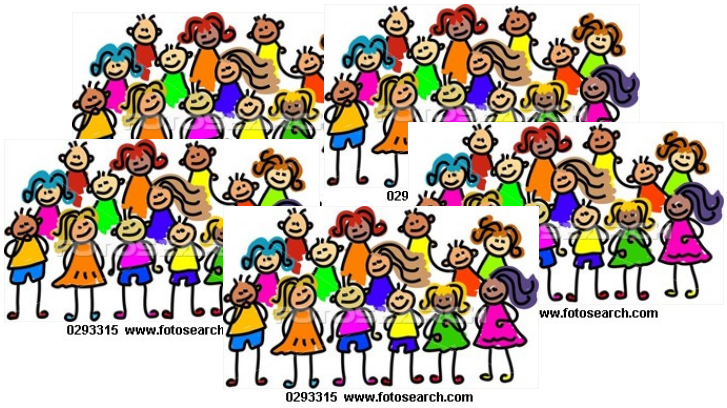
For example, no RCT of the efficacy of condoms in preventing sexual transmission of HIV has been carried out (Stephenson & Imrie, 1998)



This slide shows the total population of each REACH site with the total population (2.9 million) at the top.

2,892,587 – Total Population

231,407 (8%) Caregiver's



Out of that population, 8% are caregiver.

Found from MetLife (2004).

2,892,587 – Total Population

231,407 (8%) Caregiver's

995 persons screened

This slide shows the number of persons screened out of those caregivers.

2,892,587 – Total Population

231,407 (8%) Caregiver's

995 persons screened

642 persons enrolled

0.02% of total population in the 5 site areas
0.3% of total caregivers in the 5 site areas

This slide shows the number of actual study participants out of those screened.

It also shows the percentage of participants out of the total population and caregivers.

Research Methods:
Promising or suggestive evidence

Non-randomized studies provide suggestive evidence

- **Comparison-group studies** make use of "naturally" formed groups of participants (i.e., participants did not agree to be randomized)
  - How were groups formed?
  - Were groups closely matched on important demographic variables and other characteristics prior to the intervention?
- **Theory-based interventions** based on sound behavioral science theory that have some form of process or evaluation data
- Study should adhere to all other research methods expected of "**strong**" evidence studies

Non-randomized studies offer an alternative research methods and can still yield evidence.

Not ideal, but may be all that is available, or may serve as the starting point.

Research methods: Informative

- **Pre-post studies**
  - Measures are done before the study and after the study are threatened by regression to the mean
- **Comparison studies** in which the groups are not well matched
  - Did participants get to choose the intervention they received
- **Meta-analyses** that combine results of individuals studies that did not use rigorous research methods
- **Case Studies**

Some intervention may only be supported by evidence that is “informative”. i.e., gives us an idea of what “may” be.

More studies are needed.

Coleman’s Care Transitions Model – started with a qualitative study, than moved to a randomized controlled trial.

We recently published a case study of a program call Support Teams for Family Caregivers…

Is the evidence relevant to your setting?

- **Requires the simultaneous analyses of research methods used to evaluate the intervention and the condition in which the intervention is to be replicated.**
  - Does the intervention fit your setting, population, culture, etc.
  - Are you **willing** and **able** to replicate as the intervention was reported
- **Moving programs from evidence-establishing arena (academic research) into service or clinical setting implies a change in focus and a change in goals**

So, I have given you three categories of evidence: BEST, Suggestive, Informative.

But is the intervention with the Best evidence really the Best for you??

Maybe not.

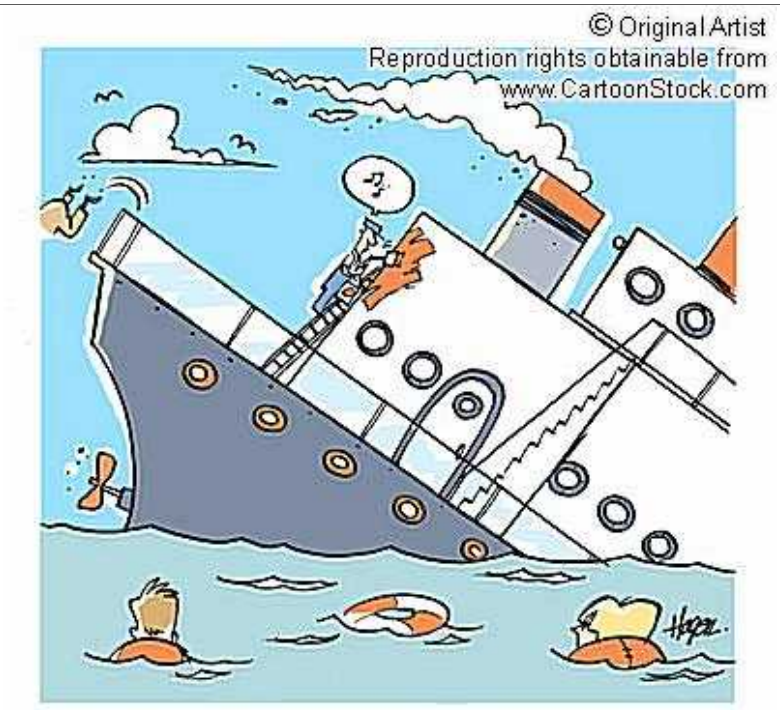
To make this simple, an intervention can have strong evidence, but not be right for your setting, or your desired outcome.

Some examples

Population: Consider using Cash and Counseling – medicaid population

Implementation: Mary Naylor's Care Transitions Model – was implemented by advanced practice nurses (APNs)

Outcomes: Long or short term outcomes, what's important to you. Nursing home placement – NYU caregiving intervention, but not REACHII or Savvy Caregiver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Implementation, Adaptation, Reinvention, and Fidelity

- **Moving from the research arena to the real world to the interest of policy makers is possible**
  - Lorig's Chronic Disease Self-Management Program
  - Coleman's Care Transitions Intervention
- **Adaptations may be necessary and appropriate**
- **Reinvention is a possibility**
- **Fidelity is always necessary**
  - "It's not just what you do, but how you do it"

Fidelity:

Randy Brown, "it's not…"

Effects of Care Coordination on Hospitalization, Quality of Care, and Health Care Expenditures Among Medicare Beneficaiaries: 15 Randomized Trials. JAMA, vol. 301, no 6, 2009, 603-618


Thank you.

Example:
Focus on Youth (FOY) Study

- Naturally formed groups of friends were assigned to intervention group or control group.
- Eligibility included: Youth who were part of a naturally formed friendship group consisting of 3-10 friends of the same gender who varied no more than 3 years in age.
- The intervention consisted of seven 90-minute sessions focused on decision-making, role-playing, and goal-setting to increase abstinence and condom use.
- Theoretical basis: Protection Motivation Theory
- Findings: Sexually active FOY intervention participants were significantly less likely to report unprotected sex compared to those in the comparison at the 18-month follow-up

http://www.cdc.gov/hiv/topics/research/prs/resources/factsheets/FOY.htm

Example:
Meta-Analysis on Nursing Home Predictors

- 77 reports across 12 data sources were included that used longitudinal designs and community-based samples.
- Information on number of nursing home admissions, length of follow-up, sample characteristics, analysis and potential risk factors were looked at from each study with standardized protocols.
- The pooled analysis showed that the strongest predictors of NH admission included needing help with dressing, eating, or bathing, having a cognitive impairment, and prior NH use.

Predicting nursing home admission in the U.S: a meta-analysis.

Gaugler JE, Duval S, Anderson KA, Kane RL. BMC Geriatr. 2007 Jun 19;7:13. Review.

Conclusion slide