Chapter 2: Conducting Health Research Chapter Introduction
Book Title: Health Psychology: An Introduction to Behavior and Health
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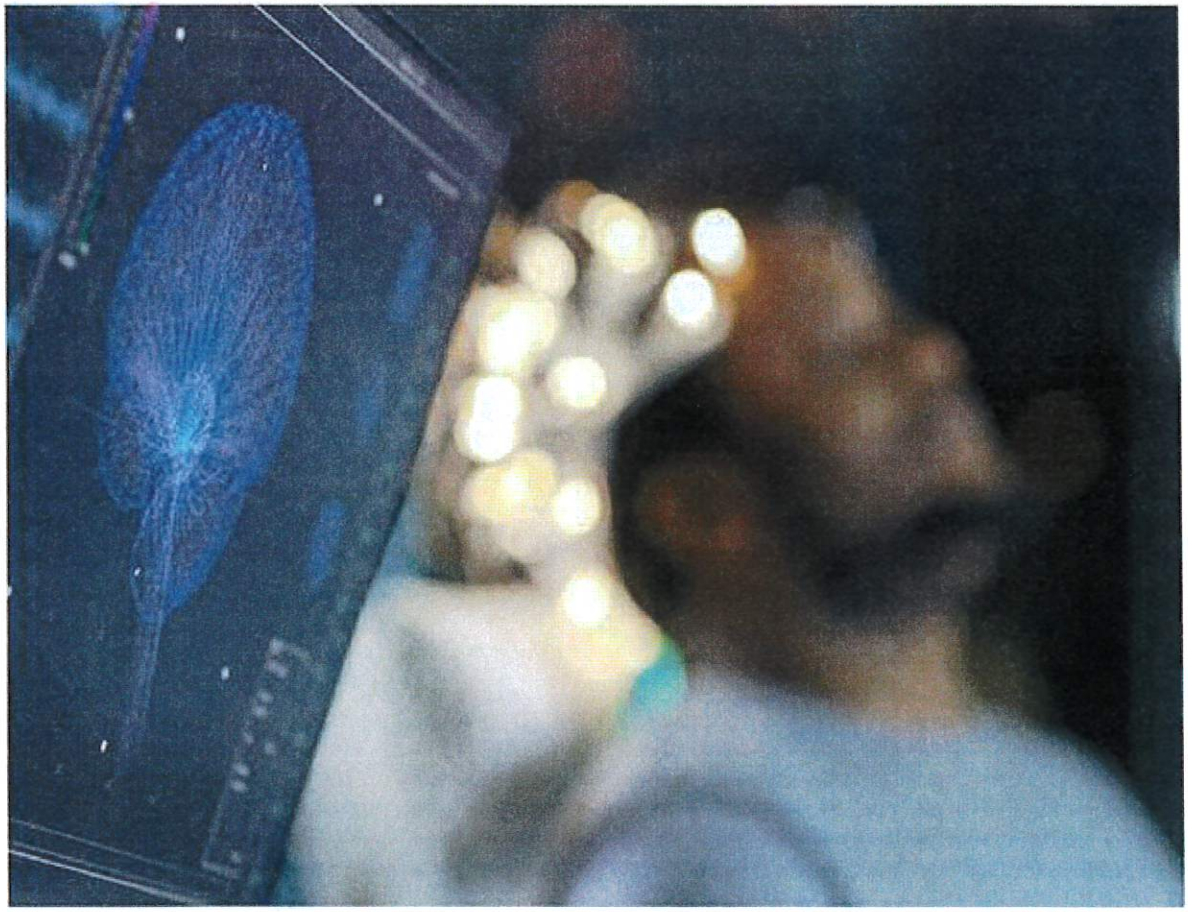
Chapter Introduction



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Learning Objectives

After studying this chapter, you will be able to…

2-1 Understand the placebo effect and how it demonstrates a role of psychological beliefs in health

2-2 Contrast single-blind and double-blind research designs in their ability to control for placebo effects

2-3 Identify the strengths and limitations of correlational, cross-sectional, longitudinal, experimental, and ex post facto research designs

2-4 Understand the difference between disease prevalence and disease incidence

2-5 Identify the strengths and limitations of observational methods, randomized controlled trials, and meta-analyses

2-6 Understand the difference between absolute risk and relative risk

2-7 Identify the seven criteria that can help researchers infer a causal relationship from non-experimental studies

2-8 Recognize the important role of theory in guiding health research

2-9 Understand how reliability and validity improve measurement in health research

Questions

This chapter focuses on five basic questions:

1. What are placebos, and how do they affect research and treatment?
2. How does psychology research contribute to health knowledge?
3. How has epidemiology contributed to health knowledge?
4. How can scientists determine if a behavior causes a disease?
5. How do theory and measurement contribute to health psychology?

Why did Sylvester Colligan get better? Was Moseley negligent in performing a fake surgery on Colligan? Surprisingly, many people do not view Moseley's treatment as negligent. Moseley and his colleagues (2002) were conducting a study of the effectiveness of arthroscopic knee surgery. This type of procedure is widely performed, but it is very expensive, and Moseley had doubts about its effectiveness (Talbot, 2000). So Moseley decided to perform an experimental study that included a placebo as well as a real arthroscopic surgery. A **placebo** (An inactive substance or condition that has the appearance of an active treatment and that may cause improvement or change because of people's belief in the placebo's efficacy. (Chapter 2)) is an inactive substance or condition that has the appearance of an active treatment and that may cause participants to improve or change because of their belief in the placebo's efficacy.

Moseley suspected that this type of belief, and not the surgery, was producing improvements, so he designed a study in which half of the participants received sham—that

is, *fake*—knee surgery. Participants in this condition received anesthesia and surgical lesions to the knee, but no further treatment. The other half of the participants received standard arthroscopic knee surgery. The participants agreed to be in either group, knowing that they might receive sham surgery. The participants, including Colligan, did not know for several years whether they were in the placebo or the arthroscopic surgery group. Moseley discovered, contrary to widespread belief, that arthroscopic knee surgery provided no real benefits beyond a placebo effect. Those who received the sham surgery reported the same level of knee pain and functioning as those who received the real surgical treatment.

Moseley's results suggested that it was the patients' beliefs about the surgery, rather than the surgery itself, that provided such benefits. The placebo effect is a fascinating demonstration of the effect of an individual's beliefs on their physical health. However, the placebo effect presents a problem for researchers like Moseley who want to determine which effects are due to treatment and which are due to beliefs about the treatment.

Check Your Beliefs

About Health Research

Check the items that are consistent with your beliefs.

1. Placebo effects can influence both physical and psychological problems.
2. Patients who expect a medication to relieve their pain often experience a reduction in pain, even after taking a "sugar pill."
3. Personal testimonials are a good way to determine treatment effectiveness.
4. Newspaper and television reports of scientific research give an accurate picture of the importance of the research.
5. Information from longitudinal studies is generally more informative than information from the study of one person.
6. All scientific methods yield equally valuable results, so the research method is not important in determining the validity of results.
7. In determining important health information, studies with nonhuman subjects can be just as important as those with human participants.
8. Results from experimental research are more likely than results from observational research to suggest the underlying cause for a disease.
9. People outside the scientific community conduct valuable research, but scientists try to discount the importance of such research.

10. Scientific breakthroughs happen every day.

11. New reports of health research often contradict previous findings, so there is no way to use this information to make good personal decisions about health.

Items 1, 2, 5, and 8 are consistent with sound scientific information, but each of the remaining items represents a naïve or unrealistic view of research that can make you an uninformed health research consumer. The information in this chapter will help you become more sophisticated in your evaluation of and expectations for health research.

This chapter looks at the way health psychologists conduct research, emphasizing psychology from the behavioral sciences and epidemiology from the biomedical sciences. These two disciplines share some methods for investigating health-related behaviors, but they also have their own unique contributions to scientific methodology. Before we begin examining the methods that psychologists and epidemiologists use in their research, let's consider the situation that Colligan experienced—improvement due to the placebo effect.

2-1 The Placebo in Treatment and Research

Learning Objectives

2-1 Understand the placebo effect and how it demonstrates a role of psychological beliefs in health

2-2 Contrast single-blind and double-blind research designs in their ability to control for placebo effects

As we described in Chapter 1, health psychology involves the application of psychological principles to the understanding and improvement of physical health. The placebo effect represents one of the clearest examples of the link between people's beliefs and their physical health. Like many people receiving treatment, Colligan benefited from his positive expectations; he improved, even though he received a treatment that technically should not have led to improvement.

Most physicians are aware of the placebo effect, and many may even prescribe placebos when no other effective treatments are available (Linde et al., 2018; Tilburt et al., 2008). However, strong placebo effects can pose a problem for scientists trying to evaluate if a new treatment is effective. Thus, the placebo effect may help individuals who receive treatment but complicate the job of researchers—that is, it can have treatment benefits but research drawbacks.

Chapter 2: Conducting Health Research: 2-1 The Placebo in Treatment and Research
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Chapter 2: Conducting Health Research Treatment and the Placebo
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Treatment and the Placebo

The power of placebo effects was nothing new to Moseley, as the potency of "sugar pills" had been recognized for years. Henry Beecher (1955) observed the effects of placebos on a variety of conditions ranging from headache to the common cold. Beecher concluded that the therapeutic effect of the placebo was substantial—about 35% of patients showed improvement! Hundreds of studies have since examined placebo effects. A recent review of this research confirms that placebos can lead to noticeable improvements in health outcomes, especially in the context of pain and nausea (Hróbjartsson & Gøtzsche, 2010). For example, a meta-analysis of migraine headache prevention (Macedo, Baños, & Farré, 2008) shows a placebo effect of 21%. A more recent review (Cepeda et al., 2012) reveals that anywhere from 7% to 43% of patients in pain improve after receiving a placebo, with the likelihood of improvement largely attributable to the type of pain experienced.

Real-World Profile of Sylvester Colligan

Sylvester Colligan was a 76-year-old man who had been having trouble with his right knee for five years (Talbot, 2000). His doctor diagnosed arthritis but had no treatment that would help. However, this physician told Colligan about an experimental study conducted by Dr. J. Bruce Moseley. Colligan talked to Dr. Moseley and reported: "I was very impressed with him, especially when I heard he was the team doctor with the [Houston] Rockets.... So, sure, I went ahead and signed up for this new thing he was doing" (Talbot, 2000, p. 36).

The treatment worked. Two years after the surgery, Colligan reported that his knee had not bothered him since the surgery: "It's just like my other knee now. I give a whole lot of credit to Dr. Moseley. Whenever I see him on the TV during a basketball game, I call the wife in and say, "Hey, there's the doctor that fixed my knee!" (Talbot, 2000, p. 36).

Colligan's improvement would not be so surprising, except for one thing: Dr. Moseley did not perform surgery on Colligan. Instead, Dr. Moseley gave Colligan anesthesia, made some cuts around Colligan's knee that *looked* like surgical incisions, and then sent Colligan on his way home.

Placebo effects occur in many other health conditions. For example, some researchers (Fournier et al., 2010) argue that the placebo effect is responsible for much of the effectiveness of antidepressant drugs, especially among people with mild to moderate symptoms. Furthermore, the strength of the placebo effect associated with antipsychotic

drugs has steadily increased over the past 50 years, suggesting that the effectiveness of these drugs may be in part due to increases in people's beliefs regarding their efficacy (Agid et al., 2013; Rutherford et al., 2014). However, some conditions, such as broken bones, do not respond to placebos (Kaptchuk, Eisenberg, & Komaroff, 2002).

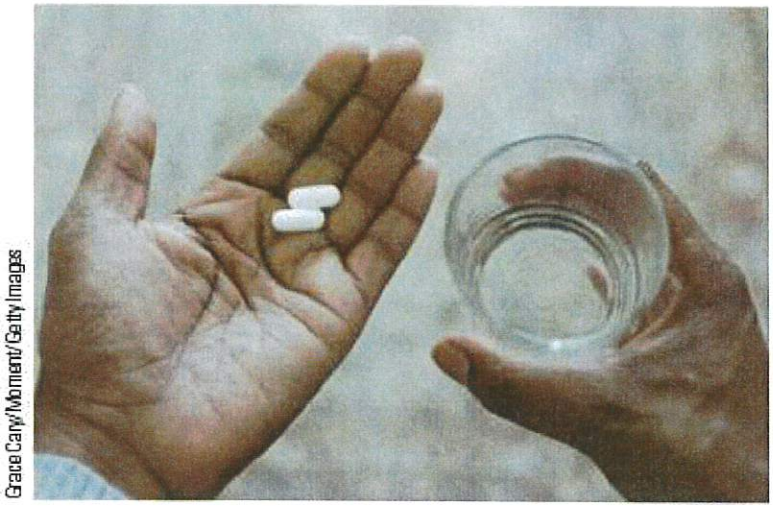
The more a placebo resembles an effective treatment, the stronger the placebo effect will be. Big pills are more effective than little ones, and colored pills work better than white tablets. Capsules work better than tablets, and placebos labeled with brand names work better than generic placebos. Two doses provoke a larger placebo response than one dose. An injection is more powerful than a pill, and surgery tends to prompt an even larger placebo response than an injection does. Even cost matters; more expensive placebo pills work better than cheaper pills (Waber et al., 2008)!

Both physician and patient expectations also strengthen placebo effects. Physicians who appear positive and hopeful about treatment prompt stronger responses in their patients (Moerman, 2003). Placebo responses also relate to the practitioner's other characteristics, such as their reputation, attention, interest, concern, and the confidence they project that a treatment will be effective (Moerman & Jonas, 2002).

Placebos can also produce adverse effects, called the **nocebo effect** (Adverse effect of a placebo. (Chapter 2)) (Scott et al., 2008; Turner et al., 1994). Nearly 20% of healthy volunteers given a placebo in a double-blind study experienced some negative effect because of the nocebo effect. Sometimes, these negative effects appear as side effects, which show the same symptoms as other drug side effects, such as headaches, nausea and other digestive problems, dry mouth, and sleep disturbances (Amanzio et al., 2009). When participants are led to believe that a treatment might worsen symptoms, the nocebo effect can be as strong as the placebo effect (Petersen et al., 2014). The presence of negative effects demonstrates that the placebo effect is not merely improvement; it also includes any change resulting from an inert treatment.

How and why do the placebo and nocebo effects occur? Although many people assume that improvements due to placebos are psychological—"It's in people's heads"—research suggests that they have both a physical and psychological basis (Benedetti, 2006; Scott et al., 2008). For example, a placebo analgesic alters brain activity levels in ways that are consistent with the activity that occurs during pain relief from analgesic drugs (Wager et al., 2004). The nocebo response also activates specific areas of the brain and acts on neurotransmitters, giving additional support to its physical reality (Scott et al., 2008). However, placebos are likely to have unique physiological effects that differ from those attributable to a standard medical treatment. For example, in an antidepressant clinical trial (Zilcha-Mano et al., 2019), participants who believed that they received an antidepressant showed less activity in the amygdala—a brain region associated with processing threat-related emotions of fear, anxiety, and aggression—compared to those were unsure of whether they received an antidepressant or placebo, showing that people's expectations can have unique effects on brain activity.

The more a placebo resembles an effective treatment, the stronger the placebo effect. These sugar pills, which look like real pills, are likely to have strong placebo effects.



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Expectancy is a major component of the placebo effect (Price, Finniss & Benedetti, 2008; Stewart-Williams, 2004). People act in ways that they *think* they should. Thus, people who receive treatment without their knowledge do not benefit as much as those who know what to expect (Colloca et al., 2004). In addition, culture influences the placebo response. For example, cultures that place greater faith in medical interventions show stronger responses to placebos that resemble a medical intervention (Moerman, 2011). Learning and conditioning also factor in the placebo response. Through classical and operant conditioning, people associate a treatment with getting better, creating situations in which receiving treatment leads to improvement. Thus, both expectancy and learning contribute to the placebo effect.

In most situations involving medical treatment, patients' improvements may result from a combination of treatment plus the placebo effect (Finniss & Benedetti, 2005). Placebo effects are a tribute to the ability of humans to heal themselves, and practitioners can enlist this ability to help patients become healthier (Ezekiel & Miller, 2001; Walach & Jonas, 2004). Therefore, the placebo effect can be a positive factor in medical and behavioral therapies, as it was for Colligan, whose knee improved because of sham surgery. However, the placebo effect makes it difficult to separate the effect of a treatment from the effect of people's *beliefs* about the treatment, so researchers often design studies to try to disentangle these effects, as we will describe.

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Research and the Placebo

For researchers to conclude that a treatment is effective, the treatment must show a higher rate of effectiveness than a placebo. This standard calls for researchers to use at least two groups in a study: one that receives the treatment and another that receives a placebo. Both groups must have equal expectations concerning the effectiveness of the treatment. To create equal expectancy, not only must the participants be unaware of whether they are receiving a placebo or a treatment; the experimenters who dispense both conditions must also be "blind" as to which group is which. The arrangement in which neither participants nor experimenters know about treatment conditions is called a **double-blind design** (An experimental design in which neither the subjects nor those who dispense the treatment condition have knowledge of who receives the treatment and who receives the placebo. (Chapter 2)) . As the Would You Believe . . .? box points out, this design strategy creates ethical dilemmas.

Psychological treatments such as counseling, hypnosis, biofeedback, relaxation training, massage, and a variety of stress and pain management techniques also produce expectancy effects. That is, the placebo effect also applies to research in psychology, but double-blind designs are not easy to perform with these treatments. Placebo pills can look the same as pills containing an active ingredient, but providers of psychological or behavioral treatments always know when they are providing a sham treatment. In these studies, researchers use a **single-blind design** (A design in which the participants do not know if they are receiving the active or inactive treatment, but the providers are not blind to treatment conditions. (Chapter 2)) in which the participants do not know if they are receiving the active or inactive treatment, but the providers are not blind to treatment conditions. In single-blind designs, the control for expectancy is not as complete as in double-blind designs; creating equal expectancies for participants, however, is usually the more important control feature. Although health researchers often want to know whether a particular treatment provides benefits beyond placebo effects, health researchers also investigate a variety of other questions with several other research designs, which we will describe in the next section.

Would You Believe...?

Prescribing Placebos May Be Considered Ethical

Cebocap, a capsule available only by prescription, may be a wonder drug. The ingredients in Cebocap can be remarkably effective in relieving many health problems with few serious side effects. Yet, many people would be upset to learn that their doctor prescribed them with Cebocap.

Cebocap is a placebo pill made by Forest Pharmaceuticals. Why would a physician prescribe Cebocap, and could it ever be ethical to do so?

Although it is unclear how often physicians prescribe placebos such as Cebocap, many doctors already report prescribing treatments that they consider to be placebos, such as vitamins or antibiotics for a viral infection (Tilburt et al., 2008). However, nearly three-quarters of doctors who admit to prescribing a placebo describe it simply as "[m]edicine not typically used for your condition but might benefit you" (Tilburt et al., 2008, p. 3). This is truthful and preserves the active ingredient of placebos: positive expectations. However, critics of this practice argue that the physician is deceiving the patient by withholding the fact that the treatment has no inherent medical benefit.

Could a placebo still be effective if the provider fully informed the patient that the treatment was merely a placebo? One team of researchers set out to answer this question, by prescribing placebo pills to patients with irritable bowel syndrome (IBS) (Kaptchuk et al., 2010). IBS is a chronic gastrointestinal disorder, characterized by recurrent abdominal pain. With few other effective treatments available for IBS, many view it as ethically permissible to study the effects of placebos on IBS symptoms.

In one experimental condition of this study, researchers told patients to take placebo pills twice daily, describing them as "made of an inert substance, like sugar pills, that have been shown in clinical studies to produce significant improvement in IBS symptoms through mind-body self-healing processes" (Kaptchuk et al., 2010, p. e15591). Patients in the control condition did not receive any treatment at all. Indeed, the placebo treatment—even when prescribed in this completely transparent manner—led to fewer symptoms, greater improvement, and better quality of life compared with no treatment. Thus, placebos can be both ethically prescribed *and* effective in treatment.

Can placebos be ethically used in research? Typically, clinical researchers do not seek to show that placebos can work. Rather, they seek to show that another treatment performs better than using a placebo. Thus, clinical researchers may have to assign patients to an experimental condition that they know constitutes an effective treatment. How do researchers reconcile this ethical difficulty?

Part of the answer to that question lies in the rules governing research with human participants (American Psychological Association [APA], 2002; World Medical Association, 2004). Providing an ineffective treatment—or any other treatment—may be considered ethical if participants understand the risks fully and still agree to participate in the study. This element of research procedure, known as *informed consent,* stipulates that participants must be informed of factors in the research that may influence their willingness to participate before they consent to participate.

When participants in a clinical trial agree to take part in the study, they receive information about the possibility of getting a placebo rather than a treatment. Those participants who find the chances of receiving a placebo unacceptable may refuse to participate in the study. Colligan, who participated in the study with arthroscopic knee surgery, knew that he might be included in a sham surgery group, and he consented (Talbot, 2000). However, 44% of those interviewed about that study declined to participate (Moseley et al., 2002).

Despite the value of placebo controls in clinical research, some physicians and medical ethicists consider the use of ineffective treatment to be ethically unacceptable because the welfare of patients is not the primary concern. This is a valid concern if a patient-participant receives a placebo instead of the accepted standard of care (Kottow, 2007). These critics contend that control groups should receive the standard treatment rather than a placebo, and that placebo treatment is acceptable only if no treatment exists for the condition. Thus, opinion regarding the ethical acceptability of placebo treatment is divided, with some finding it acceptable and necessary for research and others objecting to the failure to provide an adequate standard of treatment.

In Summary

A placebo is an inactive substance or condition having the appearance of an active treatment. It may cause participants in an experiment to improve or change behavior because of their belief in the placebo's effectiveness and their prior experiences with receiving effective treatment. Although placebos can have a positive effect from the patient's point of view, they are a problem for the researcher. In general, a placebo's effects are about 35%. Its effects on reducing pain may be higher, whereas its effects on other conditions may be lower. Placebos can influence a wide variety of disorders and diseases.

Experimental designs that measure the efficacy of an intervention, such as a drug, typically use a placebo so that people in the control group (who receive the placebo) have the same expectations for success as do people in the experimental group (who receive the active treatment). Drug studies are usually double-blind designs, meaning that neither the participants nor the people administering the drug know who receives the placebo and who receives the active drug. Researchers in psychological treatment studies are often not "blind" concerning the treatment, but participants are, thus creating a single-blind design for these studies.

Apply What You've Learned

1. Think about a time when you received treatment for a health problem. How did your interaction with the treatment provider influence your beliefs about whether the treatment would work?

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2-2 Research Methods in Psychology

Learning Objectives

2-3 Identify the strengths and limitations of correlational, cross-sectional, longitudinal, experimental, and ex post facto research designs

When you stroll through the breakfast food aisle of your supermarket, do you notice how many cereals boast a high-fiber content? Some cereals are intentionally named to highlight fiber: All Bran, Multi-Bran, Fiber One, Fiber 7. This fascination with fiber may have been at its peak in 1989, when the American television show *Saturday Night Live* aired a mock advertisement for "Colon Blow," a cereal with 30,000 times the fiber content as compared to regular oat bran cereals!

Why were Americans so seemingly obsessed with fiber in the 1980s? One reason for this obsession was the belief that a high-fiber diet could reduce one's risk for cancer, particularly colon cancer. This link between fiber and cancer was first suggested in the early 1970s by Denis Burkitt, a British surgeon who worked in sub-Saharan Africa. Dr. Burkitt observed a very low incidence of colon cancer among native Ugandans. At the time, the Ugandan diet differed greatly from the typical Western diet. Ugandans ate plenty of fruits, vegetables, raw grains, and nuts but little red meat. Westerners, on the other hand, ate more red meat and fewer vegetables and nuts, and the grains they consumed were typically processed rather than raw. In short, Ugandans had a high-fiber diet and a low incidence of colon cancer. Dr. Burkitt proposed a seemingly intuitive explanation for this link: Dietary fiber speeds up certain digestive processes, leaving less time for the colon to be exposed to possible carcinogens.

Dr. Burkitt's belief in the benefits of dietary fiber was widely publicized and led to the marketing of fiber in foods and to decades of research on the possible connection between diet and cancer. In this section, we will review some of this research to illustrate a number of important aspects of health research. Most importantly, we will describe the different types of study designs that health researchers can use to investigate a question. We describe the strengths and weaknesses of these designs, as well as how our confidence in study results can depend on the strength of a research design. Additionally, we will show how health

research is a continually evolving pursuit, where old beliefs are often replaced by newer discoveries as researchers acquire and synthesize new evidence.

Chapter 2: Conducting Health Research Correlational Studies
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Correlational Studies

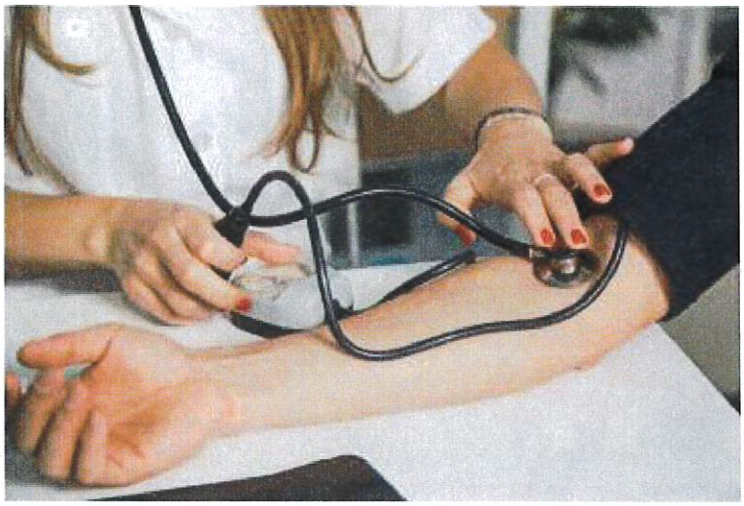
When researchers seek to identify possible factors that predict or are related to a health condition, they use correlational studies. **Correlational studies** (Studies designed to yield information concerning the degree of relationship between two variables. (Chapter 2)) are often the first step in the research process, as they yield information about the degree of relationship between two variables. Correlational studies *describe* this relationship and are, therefore, a type of *descriptive research* design. Although scientists cannot use a single descriptive study to determine a causal relationship—such as whether diet *causes* cancer—the degree of relationship between two factors may be exactly what a researcher wants to know.

To assess the degree of relationship between two variables (such as diet and cancer), the researcher measures each of these variables in a group of participants and then calculates the **correlation coefficient** (Any positive or negative relationship between two variables. Correlational evidence cannot prove causation, but only that two variables vary together. (Chapter 2)) between these measures. The calculation yields a number varying between −1.00 and +1.00. Positive correlations occur when the two variables increase or decrease together. For example, physical activity and longevity are positively correlated. Negative correlations occur when one of the variables increases as the other decreases, as is the case with the relationship between smoking and longevity. Correlations that are closer to 1.00 (either positive or negative) indicate stronger relationships than correlations that are closer to 0.00. Small correlations—those less than 0.10—can be *statistically significant* if they are based on a large number of observations, as in a study with many participants. However, such small correlations, though not random, offer the researcher very little ability to predict scores on one variable from knowledge of scores on the other variable.

In one of the first examinations of the link between diet and cancer, Armstrong and Doll (1975) utilized a correlational design. These researchers examined the correlation between over 20 countries' average meat consumption and the countries' incidence of colorectal cancer. Indeed, the study noted a large and positive correlation of over 0.80, showing that countries with high meat consumption had significantly higher rates of colon cancer than countries with low meat consumption. However, simply knowing this correlation did not allow the researchers to know whether red meat or some other aspect of diet *caused* cancer. High red meat consumption is generally related to other practices, such as low consumption of fiber, fruits, and vegetables, and could be related to environmental factors as well. Thus, this correlational study suggested a link between diet and cancer risk but could not answer questions of causality directly. Nevertheless, it pointed to a strong association between diet and colon cancer, which fueled the public's interest in consuming foods that might prevent

cancer. This finding, together with Dr. Burkitt's highly publicized focus on dietary fiber, led to a widespread public perception of a causal link between fiber intake and colon cancer.

Blood pressure is a risk factor for cardiovascular disease, which means that people with high blood pressure are at increased risk, but not that high blood pressure causes cardiovascular disease.



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Cross-Sectional and Longitudinal Studies

When health researchers seek to understand how health problems develop over time, they use cross-sectional or longitudinal studies. **Cross-sectional studies** (Research designs in which subjects of different ages are studied at one point in time. (Chapter 2)) are those conducted at only one point in time, whereas **longitudinal studies** (Research designs in which one group of participants is studied over a period of time. (Chapter 2)) follow participants over an extended period. In a cross-sectional design, the investigator studies a group of people from at least two different age groups to determine the possible differences between the groups on some measure.

Longitudinal studies can yield information that cross-sectional studies cannot because they assess the same people over time, which allows researchers to identify developmental trends and patterns. However, longitudinal studies have one obvious drawback: They take time. Thus, longitudinal studies are costlier than cross-sectional studies, and they frequently require a large team of researchers.

Cross-sectional studies have the advantage of speed, but they have a disadvantage as well. Cross-sectional studies compare two or more separate groups of individuals, which make them incapable of revealing information about changes in individuals over a period of time. Cancer incidence increases with age, so a cross-sectional study comparing the cancer rates of young adults to those of older adults would undoubtedly show that older adults have higher rates of cancer. However, only a longitudinal study looking at the same people over a long period of time could confirm that age increases cancer incidence. (In a cross-sectional design, it is always possible that the older adults differed from young adults in some important way other than age, such as exposure to carcinogens).

Due to the time and resources needed to conduct longitudinal research, such studies on the link between diet and cancer did not appear until the late 1990s. For example, one study of over 27,000 Finnish males asked about consumption of fat, meat, fruits, vegetables, calcium, and fiber and followed the participants for eight years to track the incidence of colorectal cancer (Pietinen et al., 1999). In this study, colon cancer was linked to some aspects of diet (such as calcium) but was completely unrelated to fiber consumption. Many other longitudinal studies confirmed this lack of relationship. Thus, the results of these longitudinal studies—which provide stronger evidence than the earlier correlational studies—challenged the notion that dietary fiber reduces colon cancer risk.

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Chapter 2: Conducting Health Research Experimental Designs
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Experimental Designs

Correlational studies, cross-sectional designs, and longitudinal studies all have important uses in psychology, but none of them can determine causality. Sometimes psychologists want information on the ability of one variable to cause or directly influence another. Such information requires a well-designed experiment.

An experiment consists of a comparison of at least two groups, often referred to as an **experimental group** (In an experiment or clinical trial, the group of participants who receive an active treatment. (Chapter 2)) and a **control group** (In an experiment or clinical trial, the group of participants who do not receive an active treatment. The control group serves as a comparison to the experimental group. (Chapter 2)) . An experimental group's participants must receive treatment identical to that of the control group's participants, except that those in the experimental group receive one level of the **independent variable** (In an experiment or clinical trial, the variable that represents the presumed cause of an effect or outcome. (Chapter 2)) , whereas people in the control group receive a different level. The independent variable is the condition of interest, which the experimenter systematically manipulates to observe its influence on a behavior or response—that is, on the **dependent variable** (In an experiment or clinical trial, the variable that represents the effect or outcome of interest. (Chapter 2)) . The manipulation of the independent variable is a critical element of experimental design because this manipulation allows researchers to control the situation by choosing and creating the appropriate levels. In addition, good experimental design requires that experimenters assign participants to the experimental or control group *randomly* to ensure that the groups are equivalent at the beginning of the study.

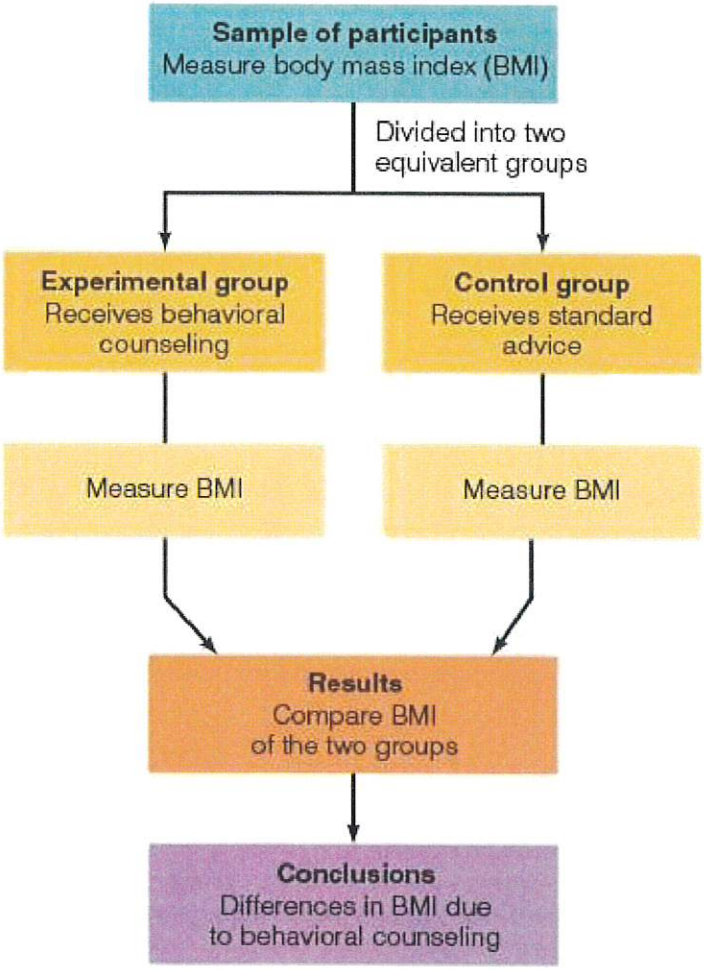
Often the experimental condition consists of administering a treatment, whereas the control condition consists of withholding that treatment and perhaps presenting some sort of placebo. If the experimental group later shows a score on the dependent variable different from the control group, then the independent variable has a cause-and-effect relationship with the dependent variable.

Several large studies have used an experimental design to study the link between diet and cancer (Beresford et al., 2006; Schatzkin et al., 2000). One study randomly assigned nearly 20,000 women to an intervention aimed at reducing fat intake and increasing fruit, vegetable, and fiber consumption (Beresford et al., 2006). Women randomly assigned to the control group were asked to continue eating as usual. Indeed, women in the experimental group changed their diet as instructed, but they did not show any reduced risk of cancer at an eight-year follow-up compared to the women in the control group. Due to its experimental design, this study provided strong evidence of a lack of a causal relationship between dietary fiber and colon cancer risk.

Figure 2.1 shows a typical experimental design comparing an experimental group with a control group, with counseling as the independent variable and body mass index (BMI) as the dependent variable.

Figure 2.1

Example of an experimental method.



Chapter 2: Conducting Health Research Ex Post Facto Designs
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Ex Post Facto Designs

Ethical restrictions or practical limitations prevent researchers from manipulating many variables, such as gender, socioeconomic status, the death of a loved one, smoking, or sexual behaviors. This means that experiments are not possible with many such variables, but these limitations do not prevent researchers from studying these variables. When researchers cannot manipulate certain variables in a systematic manner, they sometimes rely on ex post facto designs.

An **ex post facto design** (A scientific study in which the values of the independent variable are not manipulated but selected by the experimenter after the groups have naturally divided themselves. (Chapter 2)) , one of several types of quasi-experimental studies, resembles an experiment in some ways but differs in others. Both types of studies involve contrasting groups to determine differences, but ex post facto designs do not involve the manipulation of independent variables. Researchers instead choose a variable of interest and select participants who already differ on this variable, called a **subject variable** (A variable chosen (rather than manipulated) by a researcher to provide levels of comparison for groups of subjects. (Chapter 2)) (or *participant variable*). Both experiments and ex post facto studies involve the measurement of dependent variables. For example, researchers might study the link between meat consumption (subject variable) and cancer risk (dependent variable) by recruiting participants from two community groups: one group being a vegetarian/vegan cooking club and the other being the local chapter of Steak Lovers Anonymous. There is no random assignment in this ex post facto design, but the two groups would certainly differ in red meat consumption.

The comparison group in an ex post facto design is not an equivalent control group, because the participants were assigned to groups based on their food preferences rather than by random assignment. Without random assignment, the groups may potentially differ on variables other than food preferences, such as exercise, alcohol consumption, or smoking. The existence of these other differences means that researchers cannot pinpoint the subject variable as the cause of differences in cancer risk between the groups. However, findings about differences in risk between the two groups can yield useful information, making this type of study a choice for many investigations, particularly when random assignment is difficult or impossible.

In Summary

Health psychologists use several research methods, including correlational studies, cross-sectional and longitudinal studies, experimental designs, and ex post facto studies. Correlational studies indicate the degree of association between two

variables, but they can never show causation. Cross-sectional studies investigate a group of people at one point in time, whereas longitudinal studies follow the participants over an extended time period. Although longitudinal studies may yield more useful results than cross-sectional studies, they are more time consuming and more expensive. With experimental designs, researchers manipulate the independent variable so that any resulting differences between experimental and control groups can be attributed to their differential exposure to the independent variable. Experimental studies typically include a placebo given to people in a control group so that they will have the same expectations as people in the experimental group. Ex post facto studies are similar to experimental designs in that researchers compare two or more groups and then record group differences in the dependent variable but differ in that the independent variable is preexisting rather than manipulated.

Apply What You've Learned

1. Rank the research designs described in this section according to their ability to demonstrate a causal relationship between two variables.

Chapter 2: Conducting Health Research: 2-3 Research Methods in Epidemiology
Book Title: Health Psychology: An Introduction to Behavior and Health
Printed By: Bianca Walker (biwalker@claflin.edu)

2-3 Research Methods in Epidemiology

Learning Objectives

2-4 Understand the difference between disease prevalence and disease incidence

2-5 Identify the strengths and limitations of observational methods, randomized controlled trials, and meta-analyses

The field of health psychology benefits not only from the research methods of psychology but also from medical research—in particular, the research of epidemiologists. **Epidemiology** (A branch of medicine that investigates the various factors that contribute either to positive health or to the frequency and distribution of a disease or disorder. (Chapter 2)) is a branch of medicine that investigates factors contributing to health or disease in a particular population (Porta et al., 2014; Tucker et al., 2004).

With the increase in chronic diseases during the 20th century, epidemiologists make fundamental contributions to health by identifying the risk factors for diseases. A **risk factor** (Any characteristic or condition that occurs with greater frequency in people with a disease than it does in people free from that disease. (Chapter 2)) is any characteristic or condition that occurs with greater frequency in a population with a disease than in a population free from that disease. That is, epidemiologists study those demographic and behavioral factors that relate to heart disease, cancer, and other chronic diseases (Tucker et al., 2004). For example, epidemiology studies were the first to detect a relationship between smoking and heart disease.

Two important concepts in epidemiology are prevalence and incidence. **Prevalence** (The proportion of a population that has a disease or disorder at a specific point in time. (Chapter 2)) refers to the proportion of the population that has a particular disease or condition at a specific time. **Incidence** (A measure of the frequency of new cases of a disease or disorder during a specified period of time. (Chapter 2)) measures the frequency of *new cases* during a specified period, usually one year (Tucker et al., 2004). With both prevalence and incidence, the number of people in the population at risk is divided into either the number of people with the disorder (prevalence) or the number of new cases in a particular time frame (incidence). The prevalence of a disorder may be quite different from the incidence of that

disorder. For example, the prevalence of hypertension is much greater than the incidence because people can live for years after a diagnosis. In a given community, the annual *incidence* of hypertension might be 0.025, meaning that for every 1,000 people of a given age range, ethnic background, and gender, 25 people per year will receive a diagnosis of high blood pressure. But because hypertension is a chronic disorder, the prevalence will accumulate, producing a number much higher than 25 per 1,000. In contrast, for a disease such as influenza with a relatively short duration (due to either the patient's rapid recovery or quick death), the incidence per year will exceed the prevalence at any specific time during that year.

Research in epidemiology uses two broad methods:

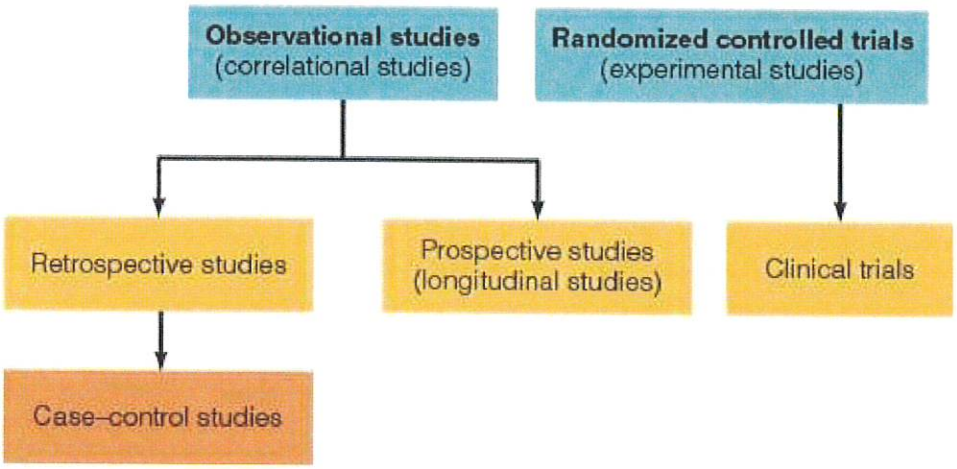
(1) observational studies and

(2) randomized, controlled trials.

Each method has its own requirements and yields specific information. Although epidemiologists use some of the same methods and procedures employed by psychologists, their terminology is not always the same. Figure 2.2 lists the broad areas of epidemiological study and shows their approximate counterparts in the field of psychology.

Figure 2.2

Research methods in epidemiology, with their psychology counterparts in parentheses.



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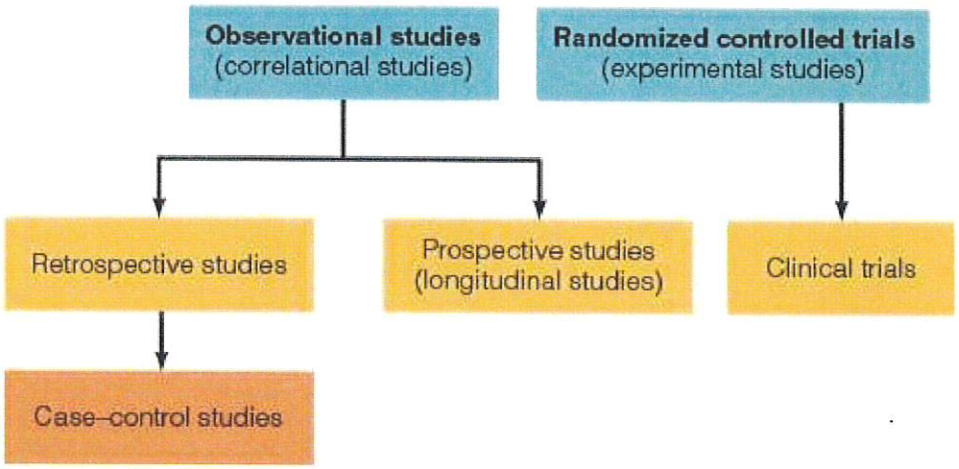

Chapter 2: Conducting Health Research Observational Methods
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Observational Methods

Epidemiologists use observational methods to estimate the occurrence of a specific disease in a given population. These methods do not show causes of the disease, but researchers can draw inferences about possible factors that relate to the disease. Observational methods are like correlational studies in psychology; both show an association between two or more conditions, but neither can be used to demonstrate causation.

Two important types of observational methods are retrospective studies and prospective studies. **Retrospective studies** (Longitudinal studies that look back at the history of a population or sample. (Chapter 2)) begin with a group of people already experiencing a particular disease or disorder and then look backward for characteristics or conditions that marked them as being different from people who do not have that problem. This approach is often used in early stages of research because it is relatively quick and inexpensive but can still yield potentially useful information. Indeed, many of the early studies on diet and cancer were retrospective studies in which cancer patients and healthy individuals provided general information about their past patterns of food consumption. Retrospective studies such as these are also referred to as **case–control studies** (Retrospective epidemiological studies in which people affected by a given disease (cases) are compared with others not affected (controls). (Chapter 2)) , because cases (people who have a health problem) are compared with controls (people who do not have the problem). Interestingly, many of these early retrospective studies from the 1980s *did* find an association between high-fiber intake and lower incidence of colon cancer (Trock, Lanza, & Greenwald, 1990), no doubt fueling the public's belief in the benefits of dietary fiber. However, one of the major drawbacks of retrospective studies is that they rely on people's recollections of past behavior, which are often inaccurate.

In contrast, **prospective studies** (Longitudinal studies that begin with a disease-free group of subjects and follow the occurrence of disease in that population or sample. (Chapter 2)) begin with a population of disease-free participants and follow them over a period of time to determine whether a given factor—such as current cigarette smoking, high blood pressure, or obesity—is related to a later health condition, such as heart disease or death. Prospective studies are longitudinal, making them equivalent to longitudinal studies in psychology: Both provide information about a group of participants over time, and both take a long time to complete. Generally, prospective studies yield stronger evidence than retrospective studies. Prospective studies on diet and colon cancer also led to a different conclusion than retrospective studies. In most prospective studies, which appeared in the 1990s, fiber intake was *not* associated with decreased risk of colon cancer (Pietinen et al., 1999).

Randomized Controlled Trials

A second type of epidemiological research is the randomized controlled trial, which is equivalent to experimental research in psychology. With a randomized controlled trial, researchers randomly assign participants to either a study group or a control group, thus making the two groups equal on all pertinent factors except the variable being studied. (In psychology, this would be called the independent variable.) Researchers must also control variables other than those of primary interest to prevent them from affecting the outcome.

A randomized controlled trial, as with the experimental method in psychology, must avoid the problem of **self-selection** (A condition of an experimental investigation in which subjects are allowed, in some manner, to determine their own placement in either the experimental or the control group. (Chapter 2)) ; that is, it must not let participants choose whether to be in the experimental group or the control group, but rather, it must assign them to groups randomly. The potential for participants to self-select into a study group or a control group can change the results of a study dramatically, underscoring the importance of random assignment. For example, a study of a workplace wellness program's effectiveness found that employees who self-selected into a wellness program had much better outcomes than those who chose not to participate in the program (Jones, Molitor, & Reif, 2019). However, when the researchers compared participants who were randomly assigned to participate in the program with those who were randomly assigned to a control condition, the findings were far different; the program had no effect. The researchers concluded that self-selection was responsible for the promising findings because healthier workers chose to be a part of the program, but less healthy workers chose not to.

A **clinical trial** (A research design that tests the effects of medical treatment. Many clinical trials are randomized controlled trials that allow researchers to determine whether a new treatment is or is not effective. (Chapter 2)) is a research design that tests the effects of a new drug or medical treatment. Many clinical trials are randomized controlled trials that feature random assignment and control of other variables, which allow researchers to determine the effectiveness of the new treatment. Epidemiologists often regard randomized, placebo-controlled, double-blind trials as the "gold standard" of research designs (Kertesz, 2003). This design is commonly used to measure the effectiveness of new drugs, as well as psychological and educational interventions. For example, all drugs approved by the U.S. Food and Drug Administration (FDA) must first undergo extensive clinical trials of this nature, demonstrating that the drug is effective and has acceptable levels of side effects or other risks.

When a controlled clinical trial demonstrates the effectiveness of a new drug or intervention, the researchers often publish and publicize the findings so that others can adopt the treatment. In some cases, a controlled trial may fail to demonstrate the effectiveness of a

new intervention. When trials fail to show a treatment to be effective, researchers may be less likely to publish the findings. By some estimates, studies that fail to find an intervention as effective are three times less likely to be published (Dwan et al., 2008). Thus, researchers, health care providers, and the public are more likely to learn about research showing a particular treatment to be effective but less likely to learn about research showing the same treatment to be ineffective.

Several safeguards are now in place to help ensure that researchers and health care providers can access all available evidence, rather than just the evidence that supports a treatment. For example, major medical journals require that researchers comply with clear guidelines in reporting results of a clinical trial. These guidelines—known as the Consolidated Standards of Reporting Trials (CONSORT) guidelines (Schulz, Altman, Moher, & the CONSORT Group, 2010)—require researchers to register their clinical trial in a registry *prior* to the start of the study. This database allows anybody to locate all clinical trials conducted on a treatment, not simply the trials that found a treatment to be effective.

Meta-Analysis

As we have seen, researchers use a variety of approaches to study behavior and health-related outcomes. Unfortunately, research on the same topic may not yield consistent findings, putting researchers (and everyone else) in the position of wondering which findings are the most valid. Some studies are larger than others, and when it comes to accepting a result, size matters. But sometimes, even large studies furnish results that seem contradictory. However, the statistical technique of **meta-analysis** (A statistical technique for combining results of several studies when these studies have similar definitions of variables. (Chapter 2)) allows researchers to evaluate many research studies on the same topic, even if the research methods differed. The results from a meta-analysis include a measure of the overall size of the effect of the variable under study. The ability to offer an estimate of the size of an effect is an advantage. If an effect is statistically significant but small, then people should not be encouraged to change their behavior based on such findings; doing so would provide too few benefits. On the other hand, if an effect is large, then working toward change would be beneficial, even if it is difficult.

Recently, several meta-analyses have synthesized decades of research on diet and colon cancer. In general, dietary fiber shows a weak association, if any, to colon cancer risk (Vargas & Thompson, 2012; Yao et al., 2017). However, this does not mean that diet is unimportant. A meta-analysis of 19 case-control studies and 6 prospective studies show that a diet high in red meat is strongly associated with greater risk of colon cancer (Aune et al., 2013).

Thus, Dr. Burkitt may have been right all along in speculating that the diet of sub-Saharan Africans protected them against colon cancer. But it wasn't the fiber that mattered; it was the absence of red meat. As researchers used stronger designs and larger samples to investigate the link between diet and colon cancer, the evidence began to show that old beliefs about the role of fiber in colon cancer were inaccurate but pointed to the role of red meat instead.

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