A SOCIAL, BEHAVIORAL, & EDUCATIONAL RESEARCH (SBER) CASE STUDY OF DECEPTION IN RESEARCH

ASSESSING ADHERENCE TO A HYBRID TAI-CHI/YOGA REGIMEN IN ANXIETY DISORDER RESEARCH

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OVERVIEW

The social, behavioral, and educational research (SBER) case studies provide education and guidance on how to identify and mitigate risks associated with SBER. These studies may be used by both IRB administrators and investigators when reviewing and designing research studies that involved SBER components.

Case studies follow a standard format that includes: 1) a fact pattern, 2) regulatory, cultural, and ethical issues, and 3) a risk/benefit analysis and risk management options. This format was created to allow for flexibility in applying the case studies.

By identifying common themes, linking them directly to federal regulations and guidance, and outlining risk mitigation options, the case studies can be used in a variety of ways, which include: 1) as an education tool for training individuals in human subjects research, 2) as a basis for developing reviewer checklists/worksheets, and 3) as a tool in designing research projects.

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CASE STUDY

SCENARIO/FACT PATTERN:
An area fitness club has developed a new tai-chi/yoga hybrid in partnership with a local psychiatry practice with the aim of treating a specific kind of anxiety disorder that can result in hospitalizations of acute patients. A research team led by a senior psychiatrist and comprised of an additional two psychiatrists and two certified instructors from the fitness club will collaborate to evaluate the effectiveness of the regimen.

A trial of the program requires subjects attend a daylong introductory workshop to learn the basic steps. Subjects will then participate in two one-hour sessions per week (for 16 weeks) during which they will learn new moves, discuss their progress with a support group (composed of other subjects), and undergo psychiatric and biofeedback evaluations to measure their progress. These sessions will be co-led by a fitness instructor and psychiatrist. Subjects are also instructed to complete two 30-minute workouts per day, one in the morning and one just before bed.
The researchers worry that some subjects will not truthfully comply with the prescribed regimen of self-directed workouts. Because of this, they also want to measure compliance. They will give each subject a special yoga mat fitted with a hidden chip that can detect temperature changes as well as motion and sunlight. The chip will record when the mat is unrolled, moved, opened in a lit space, or stood upon. The entrance to the room where the biweekly sessions are held is equipped with Wi-Fi receivers that will download the data from each mat’s chip as the mat enters the room. In this way the researchers can know who is compliant with the regimen and account for lapses when they analyze their data. Patients will not be told about the chip or tracking of usage because the researchers don’t want to influence their behavior or cause them to try and “trick” the device into recording a fake workout.

Subjects must be age 19 or older and physically able to perform the necessary regimen. Participants will be recruited from the psychiatry practice; clinicians will identify patients who qualify for participation and will provide these patients with information about the study and procedures.

Hoping to curb medical expenses, the patients’ health insurance company has agreed to subsidize each subject’s membership in the fitness club as a way to help sponsor the research. Fitness club membership (valid for six months) will not be cancelled should a subject withdraw from the study.

Questions/Comments for the researcher:

- Who will approach potential subjects to provide information about the study? Their treating clinician? The PI?
- Will subjects undergo a fitness evaluation prior to the first session?
- What instruction will be provided to participants regarding confidentiality among the support group members?
- Would one 30-minute session per day be sufficient, or is the full regimen required?
- Will participants be debriefed at the end of the study? Provided with results?
- What markers would trigger subject removal from research? Hospitalization?

REGULATORY, ETHICAL, & CULTURAL ISSUES:

45 CFR 46.116
An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct
8.07 Deception in Research
(a) Psychologists do not conduct a study involving deception unless they have determined that the use of deceptive techniques is justified by the study's significant prospective scientific, educational or applied value and that effective non-deceptive alternative procedures are not feasible.
(b) Psychologists do not deceive prospective participants about research that is reasonably expected to cause physical pain or severe emotional distress.
(c) Psychologists explain any deception that is an integral feature of the design and conduct of an experiment to participants as early as is feasible, preferably at the conclusion of their participation, but no later than at the conclusion of the data collection, and permit participants to withdraw their data.

8.08 Debriefing
(a) Psychologists provide a prompt opportunity for participants to obtain appropriate information about the nature, results, and conclusions of the research, and they take reasonable steps to correct any misconceptions that participants may have of which the psychologists are aware.
(b) If scientific or humane values justify delaying or withholding this information, psychologists take reasonable measures to reduce the risk of harm.
(c) When psychologists become aware that research procedures have harmed a participant, they take reasonable steps to minimize the harm.

Questions for the IRB:
• Does use of the chip constitute use of an investigative device; is an IDE required? Consult with an IND/IDE expert.
• Does participation in the research (two sessions per week, plus 30-minute sessions twice per day) place too much burden on research subjects? Increase risk of non-compliance?
• Are sufficient plans in place should a subject experience severe anxiety and/or require hospitalization?
• Is the coverage of the club membership by the health insurance company too coercive?
• Will results of the study be shared with the health insurance company? Aggregate results? Individual results? Compliance (chip) data?

RESOLUTION & DISCUSSIONS:
Risk/Benefit Analysis:
• What special challenges does this research pose for this population?
• What information will each research site/group (the psychiatry group and the fitness center) receive? Does this pose additional risks? What about sharing data with the health insurance company?
• Does the recruitment process pose unnecessary risks?
• Consider the following risks: loss of confidentiality, disclosure of mental illness/seeking treatment, risk to insurability.
• Debriefing:
  o If participants will be debriefed, might a participant feel he/she has been coerced and might not have chosen to participate if fully informed?
  o Might a subject feel his/her privacy has been invaded? Could this cause increased anxiety in the population?
Could debriefing result in damage to a subject’s self-esteem; could it result in a subject feeling ashamed, guilty, stressed, embarrassed, distrustful or suspicious, or a loss of control/autonomy?

Does the cohort suffer from paranoia? If so, might debriefing cause subjects to be more paranoid and experience increase anxiety?

Mitigation/Management of Risks:

- The study should be designed so that participants’ compliance data is protected from disclosure where they could be harmed by others knowing that they were less than truthful (to avoid embarrassment, lowered esteem of family/colleagues, or loss of insurance coverage).
- The insurance company should only receive aggregate, de-identified research data.
- Each session should begin with a confidentiality reminder to all participants (in a similar manner to focus groups).
- All research team members should have an understanding of procedures should a subject experience an anxiety attack during a session.
- A plan should be in place, and instructions communicated to subjects and research team members, should a subject experience severe anxiety at any time during the research.

REFERENCE(S):
American Psychological Association's (APA) Ethical Principles of Psychologists and Code of Conduct

45 CFR 46.116
http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.116

Partners IRB Deception and Incomplete Disclosure in Research Guidance for Investigators