Research Protocol - Example 1

Purpose:

To adapt and pilot Attachment-based family therapy for depressed and suicidal adolescents for repairing attachment ruptures between non-depressed, non-suicidal lesbian, homosexual and bisexual (LGB) adolescents and young adults and their parents.

Sample:

20 LGB adolescents/young adults ranging in age from 15-35 who report that their parents have known definitively of their minority sexual orientation for at least 6 months and that at least one parent rejects their sexual orientation. Both the adolescent/adult child and his/her parent(s) must consent in order to be included in the study. Exclusion criteria include use of drugs, history of psychosis, impaired mental capacity (e.g., retardation), current or recent (last 6 months) significant suicidal ideation or behavior.

Procedure:

Recruitment and inclusion/exclusion criteria. Potential participants will be recruited through ads placed on the internet and on bulletin boards, as well as through word of mouth. Individuals who call will receive general information about the study on the phone. Those interested will be invited in for an intake evaluation. The intake will include a structured diagnostic interview (i.e., SCID) and a more detailed description of the study. Those individuals meeting criteria will be consented (see attached consent form).

Measurement. Adolescents/adult children will complete a set of self-report questionnaires at the end of the intake evaluation, after 6 weeks of therapy and after 12 weeks of therapy. The questionnaires include a measure of depressive symptoms (BDI), general symptoms (Brief Symptom Inventory; BSI), measures of perceived parenting behaviors (CRPBI), attachment (PBI and ORI), quality of child-parent relationship, child-parent conflict (Parent Child Tactic Scale), internalized homophobia/lgb development (LGIS) and four open-ended questions about parental acceptance of their LGB status. Parents will complete a measure of personality symptoms (PDQ), a measure of attachment toward their own parents, prior to treatment (i.e., during the intake evaluation). In addition, parents will complete four open-ended questions regarding their level of acceptance of their child's LGB status before and after treatment. Finally, both adolescents/young adults and their parents will participate in a qualitative interview about their experience in treatment at the end of treatment.

Therapy. Therapy will be given on a once-weekly basis. Sessions will last approximately one hour. All therapy will be administered by Gary M. Diamond, Ph.D., a licensed clinical psychologist and family therapist and one of the primary developers of ABFT or Maya Shpigel, M.A., a clinical psychology intern supervised by Dr. Diamond. The course of therapy will be between 12 and 24 weeks, depending on the unique clinical demands of the case. The first sessions involve meeting alone with the adolescent/adult child separately and parent separately. These sessions involve alliance building. In the mid-stage of therapy,

conjoint sessions focus on repairing attachment. The final stage of therapy involves consolidation and commitment to relationship in future. This therapy has been successfully tested for LGB suicidal adolescents in previous trials funded by the American Foundation for Suicide Prevention and the US Center for Disease Control. The procedures and results for these studies have been published in detail elsewhere (see Diamond et al., 2010 for example). All therapy sessions will be videotaped.

For those clients needing or requesting additional therapy after their course of treatment in the study, referrals will be made to area mental health clinics, family therapy clinics and private therapists. All clients will receive at least one referral to each type of setting mentioned above.

Safety procedure: Since this is not a depressed population, and since individuals with significant suicidal ideation will be excluded from the study, we do not expect any medical emergencies. However, to err on the side of precaution, clients will have access to Dr. Diamond's cell phone number, which is active 24 hours a day. Moreover, any indications of severe psychological distress during the therapy will be explored and, if necessary, appropriate referrals for concurrent therapy/psychiatric consultation will be made.

Research Protocol - Example 2

1. Research Design

The goal of this research is to gain some insight into the role of rationality in decision making. The research to be conducted under this protocol falls under the general heading of behavioral economics (experimental economics), which contrasts behaviors in simple computerized environments with predictions of classic economic theory. Examples of the experiments include the ultimatum game, the dictator game, and the prisoner dilemma game.

Games rules will be manipulated to identify factors that influence people to make decisions that are either more or less rational. For example, in dictator games the first of two players, the proposer, divides an amount of money (the pie or cake) between the two players. The other player, the responder, can only accept the decision and amount of money allocated to him or her. This game can be manipulated by varying the social distance between the two players, by repeating the game with the same two players multiple times, or by asking players to first write down how they would respond if they were the other player. As another example, the participant might hear a high-pitched sound for 10 seconds and be asked how much they would have to be paid to spend 30 seconds listening to this sound again (we have used these sounds for years and they are low intensity but slightly annoying).

The protocol will be implemented in two setting: 1) decision making lab, or 2) in public places. The lab-based experiments will be the more complex and longer experiments, while the experiments executed at public places will be simpler and shorter (about 10 min). All of the information about the particular games, including rules of the game and payment will be provided to participants before they begin playing.

Lab-based protocol:
The first screen of the computer will present the consent form with a button at the bottom of the screen that indicates that the participant has read the instructions and would like to continue. Once the participants move to the next screen, they will be presented with the exact rules for the game they are about to play.

Games are incentive compatible, which means that all participants will know in advance what the rules for payment are, and how different outcomes of the games will be translated into different levels of payment. At the end of a game, participants will be paid according to the pre-specified payment rule, and thanked for their participation.
Examples of games that will be played are the prisoner dilemma game, the ultimatum game, the matrix game, etc. For example, in the ultimatum game, one individual is given $10 and is asked to allocate any amount from this $10 to a second player. If the second player accepts the offer they both get their allocation, and if the second player rejects the offer the money returns to the experiments (and of course all the rules are known in advance). In the matrix game, the respondents are given a set of shapes and within a short time are asked to find the two that match best. Correct answers are

rewarded by a known $ amount and wrong answers are punished by a known $ amount.

Public spaces protocol
For very short games (about 10 min) the protocol will be carried out in public spaces, such as the Student Center, with a large sign announcing the experiment and the expected pay (for example "make up to $5 for 5 min of your time"). These experiments will be all computer-based with almost no intervention from the experimenter – who will simply point the potential participants to the computer, answer questions if any arise, and pay the participants the amount shown on the screen at the end of the experiment.
The first screen of the computer will present the consent form (see below) with a button at the bottom of the screen that indicates that the participant has read the instructions and would like to continue. At the end of a game, participants will be paid according to the pre-specified payment rule and thanked for their participation.

2. Subject Selection
For the studies in the decision making lab, subjects will be recruited through standard procedures including fliers around campus and emails to students who are listed in subject pools.
Subjects recruited in public spaces will include anyone interested in participating as long as they are at least 18 years old.

3. Risks and Benefits
There are no potential risks and no anticipated benefits to individual participants.

Research Protocol - Example 3

Research protocol

The present study evaluates hazard perception training programs for young-inexperienced drivers. All young-inexperienced drivers will undergo a training session. In the training session, each participant will be designated to one of four experimental conditions based on his or her gender, demographics and sensation seeking score (Zuckerman M, 1994).

Approximately a week later participants will undergo a hazard perception test session. The test includes two sections: 1) a computer based session; 2) simulated driving session.

In the computer based test session participants will be asked to observe various traffic scenarios and to press a response button each time they detect a hazard. The drivers will then observe six additional hazard perception movies and will be asked to classify them into an arbitrary number of groups according to the similarity in their hazardous situations. During this section drivers they are connected to an eye tracking system

In the simulated driving session, drivers will first have a short adaptation experience to the simulator in order to get familiar with the driving simulator's steering wheel and pedals. Then, drivers will be asked to drive several traffic-scenarios of approximately 20 minutes.

Participants

Participants will be **52** young-novice drivers (17-18 year-olds with an average) with less than three months of driving experience.

High school students will be randomly recruited from the city of Beer-Sheva (via newspapers ads and mouth-to-ear) where our labs are located.

Each participant will be asked to sign a consent form and parental agreement if the participant is under the age of 18.

In addition, each participant will be asked to fulfill a demographic questionnaire in which data regarding his or her socio economic status will be collected (such as, does he or she have a car, do their parents own one, amount of driving they did, etc.)

Participants will receive monetary compensation of 60NIS for the training phase (1.5 hours) and 80 NIS for the testing phase (two hours).

Apparatus

Facilities

Two main locations will be used: (1) the eye movements' laboratory in which drivers will be trained and then tested on their HP abilities while connected to an eye tracking system and

(2) the driving simulator in which drivers will be further evaluated on their performance in actual driving.

- The eye movements' laboratory includes an ASL D6 heads-free (the participant is not wearing any equipment on himself) eye tracking system. D6 is able to track a user's eye movements at a rate of 60Hz without any limitation on the user's head movement. The D6 is designed to track eye movements on a single plane. The D6 meets with all safety standards (see appendix 3.4)
- The STISIM is a non-moving base driving simulator. The Driving simulator Lab consists of a brand-new Cadillac and a 180 degrees rounded screen to display a wide field of view of the driving scenarios.