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Abstract of the Dissertation

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Although the randomized controlled trial (RCT) represents the gold standard of experimental design, its use with human participants can result in threats to both internal and external validity, compromising the intended rigor of randomization. These threats can result from preferences for a particular trial condition, and are most likely to occur in studies in which participants cannot be blinded to their condition, or when certain treatment options are unavailable outside of trials. Although research designs that take participant preferences into account have been developed (i.e., preference controlled trials, or PCTs), little research has been directed at understanding how preferences affect participant experiences and outcomes in RCTs. I designed a trial using a non-patient, undergraduate student population to directly compare participants in a RCT arm of a study to those in a PCT arm of the same study (a Wennberg design). The trial intervention was presented as a treatment that might improve performance on college examinations. This study investigated: (1) the effects of the prospect of being randomized on study accrual; (2) the interaction of participant preferences and treatment assignment on participant feelings about the research, belief in the effectiveness of treatment, intervention contamination, intervention adherence and engagement, trial attrition, and outcomes (examination scores); and (3) the effects of having a choice of treatment on participant feelings, belief in the effectiveness of treatment, intervention contamination, intervention adherence and engagement, trial attrition, and outcomes. Approximately 25% of eligible participants signed up for the study, and among those, 93% enrolled in the trial. Accrual rates did not differ between the RCT and PCT arms of the study. Participants preferred the treatment group to the control group in a 2:1 ratio, and those who were mismatched to their preferred condition had significantly more negative feelings about participating in the research, including greater feelings of anger about the study, regret in having signed up for the study, and envy towards other participants, as

well as less positive feelings about being involved in the study, and were less convinced that the study would provide useful information. These effects were greater among participants holding strong, as opposed to weak, preferences for condition. Being mismatched to preference did not significantly affect belief in the effectiveness of treatment, adherence or engagement in the trial, nor did it affect examination scores. Among participants who were assigned their preferred condition, being matched by choice (as in a PCT) as compared to by chance (as in a RCT) did not affect their feelings about being involved in the trial, belief in the effectiveness of treatment, adherence or engagement, contamination, attrition, or their examination score.

This study provides important information regarding participant feelings about being in a RCT. Negative feelings about being randomized to a non-preferred treatment arose even in this non-patient sample, whereby the outcome of the intervention (examination score) was important to participants, but was not related to their morbidity or mortality. It is quite likely that the effects could be more pronounced in clinical trials with patient samples whereby morbidity or mortality might be affected. Although this study did not find that such negative feelings affected intervention adherence, or outcomes, it is possible that findings would be different in clinical trials of medical interventions, where participants and potential participants may be more invested in having access to a particular treatment condition. This study indicates that, at the very least, participant feelings are affected by the randomization process – which holds potentially important ethical implications for patients participating in clinical trials.

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INTRODUCTION

The basis of much scientific research is to determine what causes something to happen. To determine the cause for effects, scientists perform randomized experiments – the "initial random assignment for inferring treatment-caused change" (e.g., Cook & Campbell, 1979, p. 6). Randomization itself refers to the equal chance subjects have of being assigned to comparison groups (Corrigan & Salzer, 2003, p. 109). For example, if engineers hypothesize that a compressor can alter efficiency in supermarket refrigeration units, they may build multiple refrigeration units identical in structure, and randomly assign refrigeration units to the type of compressor used. Efficiency is monitored, and differences in efficiency are attributed to the type of compressor installed. Because each refrigeration unit had an equal likelihood of being fitted with each compressor, any difference in outcome efficiency can be attributed to differences in compressor and not to another variable.

With humans, trials using such randomization – the randomized controlled trial (RCT) design – have been considered the gold standard for medical and psychosocial treatment studies (Aickin, 2002; Bradley, 1997; Chambless & Hollon, 1998; Lohr & Carey, 1999; Pocock, 1983) because the randomization allows researchers to balance subject-level factors across treatment groups (Aickin, 2002), reducing systematic error that could interfere with trial outcomes (Brewin & Bradley, 1989), and thus eliminating alternative explanations for group differences in outcome variables (Janevic et al., 2003). As illustrated by the refrigeration example, with random assignment a researcher can be certain that differences in outcomes are due to the manipulation (e.g., type of compressor). By randomly assigning compressors to refrigeration units, all preexisting

differences among refrigeration units (known and unknown) are likely to have been equally distributed among groups. This is particularly the case with large samples (Krause & Howard, 2003).

Limitations of Randomized Controlled Trials

Because of the optimized internal validity, that is, the extent to which one can determine whether manipulating one variable causes change in another (Cook & Campbell, 1979), achieved with RCTs, conducting such a study is an important step in determining whether a treatment works, whether it is safe and feasible, and how cost-effective it is (Harrison et al., 2007). However, the randomization process with human beings is more complicated than with objects or animals. Typically, in randomized controlled trials involving humans, researchers recruit potential participants through a number of means including patient registries, advertisements, or physician referral. Interested participants are screened for eligibility, told about the study procedures, including the prospect of being randomly assigned to one of the treatment conditions, and asked for their consent. If consent is given, they are entered into the study and randomized to one of the treatment conditions. Usually, if they withhold consent, they are not enrolled in the study and all potential data – including their reasons for deciding not to enroll – are lost to research.

A new emphasis on evidence-based medicine has led many medical, psychosocial, and behavioral medicine trials to use randomized designs (Davidson et al., 2003) because of widely-accepted view that the RCT is ideal for optimizing internal validity. Yet, because

these trials are conducted with human participants, they can involve behavioral and cognitive nuisance variables (Corrigan & Salzer, 2003) that are brought about *by the randomization process itself* because human beings often have opinions about which condition or treatment they would like to receive. For example, participants may have strong preferences in an experiment designed to determine whether exercise or medication works better to reduce risk of heart disease. Although randomly assigning participants to receive either exercise or medication eliminates confounds from variables such as dietary habits or genetic history, the artifacts raised by assigning participants to randomly receive a treatment they may or may not be amenable to introduce new biases that can alter outcomes and leave researchers with inaccurate conclusions.

Although, in part, the rigor of trials is due to the good internal validity gained from the randomization of participants, this apparent strength is compromised if participants opt out of a trial due to hesitancy to be randomized to a non-preferred condition, or if they remain in the study to complete assessments but fail to adhere to or to be engaged in the treatment. This "non-compliance" is more likely to occur when participants are dissatisfied with their assigned treatment condition (Corrigan & Salzer, 2003; Janevic et al., 2003), and is thus more of a concern in studies in which participants cannot be blinded to their treatment condition or where active participation in treatment is required (Brewin & Bradley, 1989). To continue with our example, if a participant prefers the exercise condition and is assigned to the medication condition, he or she may: (a) fail to take the medication, and/or (b) proceed to exercise on their own, introducing to the study *treatment contamination*, whereby participants gain access to the active ingredients of other treatment conditions (e.g., Courneya et al., 2003). The effect of preference on

treatment outcomes was nicely put by Bradley (1997) when she noted: “Where the success of a treatment depends on patients’ actions … there is scope for patients to make a preferred treatment work better than a treatment they are disappointed to receive (Bradley, 1997, p. 71).

In sum, although the RCT is considered the gold standard for research design, it is apparent that its use with human participants may result in psychological artifacts that may compromise the intended rigor of randomization. Thus far, little research has been undertaken to examine how participant feelings regarding their own participation affect the outcomes of RCTs (Moyer, in press). This is surprising considering that there have been hundreds of thousands of RCTs published (Jadad & Rennie, 1998), and sobering considering that their conclusions can impact health care practices. The need to further our understanding of the psychology of the human participant in research has led to calls to conduct deliberate research on this topic (Moyer, in press).

Although little research has yet investigated how human participants respond to their involvement in RCTs, it has been clear that the use of human participants could be problematic. Two of the first critics of the RCT, Brewin and Bradley, suggest that alternatives to randomization should be developed for trials in which participants must be actively engaged in their treatment and in which they are likely to have strong preferences regarding treatments (Brewin & Bradley, 1989). As Bradley comments, “Where the success of a treatment depends on patients’ actions (even if it is only a matter of taking a tablet at certain times of day), there is scope for patients to make a preferred treatment work better than a treatment they are disappointed to receive” (Bradley, 1997, p. 71).

The potential biases from randomizing human participants filter into two categories: the bias from some participants' unwillingness to enter the study, which has implications for external validity, that is, the extent to which one can generalize conclusions across other populations (Cook & Campbell, 1979), and the bias by artifacts resulting from randomization to an undesired treatment, which has implications for internal validity.

The First Potential Bias: Self-Selection and Threats to External Validity

The first unintentional bias that may result from the prospect of random assignment is that some potentially eligible patients may be unwilling to enter the study. Enrollment rates for clinical trials are typically very low. In the United States, for example, a mere 2-3% of eligible participants enroll in breast cancer clinical trials (Collyar, 2000). The knowledge that one will be randomized to condition may dissuade some people from enrolling in the study, which affects external validity. Eligible patients may not enroll in a study if they fear being randomized to a non-preferred treatment (Bradley, 1993), or if they are uncomfortable with the randomization process itself. Without data on these eligible but not enrolled persons, it is impossible to determine the extent to which results of the study are generalizable to the population of interest.

Few studies have explored potential participants' reasons for refusing to participate in a clinical trial (K. Cox & McGarry, 2003), although some information has been obtained about reasons for *entering* a clinical trial. For example, cancer patients' reasons for enrolling in clinical trials include hope for a cure (K. Cox, 1999), hope of symptom relief, improvement in condition, or longer survival (K. Cox, 1999; Penman et al., 1984; Rodenhuis et al., 1984), feeling honored or privileged to be asked to participate (K. Cox, 1999), influence from family and friends (Rodenhuis et al., 1984), trusting in one's

physician and the information about the trial (Penman et al., 1984), hoping to aid research (Rodenhuis et al., 1984), and feelings of having no choice (Rodenhuis et al., 1984).

Llewellyn-Thomas and colleagues (1991) conducted one of the first studies to understand patients' reasons for electing to not participate in clinical trials. They presented colorectal cancer patients with a hypothetical clinical trial. The study design incorporated a randomization component followed by a trade-off task. The randomization component of the study involved presenting participants with two treatments (here, surgery plus standard care vs. surgery plus chemotherapy), with the explanation that, if they were to enroll in the hypothetical trial, they would be randomized to receive one treatment or the other. If they chose *not* to participate in the trial, they would automatically receive the surgery plus standard care treatment (usual care), and were asked their reasons for deciding not to enroll. If they agreed to participate, they were then asked to complete the trade-off task. For the trade-off task, participants were told the risks and benefits of the two treatments and asked to indicate his or her preferred treatment. Participants were then presented with a scale showing risk/benefit scenarios for the two treatments at varying percentages: a sliding scale in which their indicated preferred treatment becomes less desirable, while the non-preferred treatment becomes more desirable. The percentage point at which the patient switched preference indicated how much more beneficial the originally non-preferred treatment would need to be before the patient would accept the originally non-preferred treatment over the originally preferred treatment. Benefit was defined as increased survival time. Llewellyn-Thomas and colleagues found that 42% of subjects indicated that they would take part in the hypothetical trial, while 58% refused. Refusers indicated less willingness to experience

short term toxicity from chemotherapy for a questionable increase in long term survival (i.e., they had an aversion to one of the treatment options), and were less willing to give the treatment decision-making power to the physician (Llewellyn-Thomas et al., 1991).

Harrison and colleagues (Harrison et al., 2007) conducted a study to understand some of the reasons patients had for not participating in clinical trials. Their study improved upon previous investigations by studying rectal cancer patients being recruited for an actual trial in which they would randomly receive radiotherapy, chemotherapy, chemoradiotherapy, or abdominoperineal resection. Participants unwilling to enroll in the trial were asked to identify their reasons for not entering. The two reasons endorsed most often included not liking the idea of randomization (26-30% of participants) and a desire to make one's own treatment decisions (27-34% of participants).

Challenges to enrollment are not limited to wariness on patients' behalf. Studies have also documented clinicians' failures to enroll potentially eligible patients into trials (Cottin et al., 1999). Reasons clinicians give for this include ethical and philosophical issues regarding the trial, worries about the financial burden of the trial, worry over the risk of the patient receiving a placebo treatment, highly structured protocols, and extra work on behalf of physician and patient (Benson et al., 1991). Physicians have also anonymously admitted to direct subterfuge of the randomization process, attempting to help patients be assigned to conditions that they thought might best suit patients' needs, including engaging in tactics like holding envelopes up to lights to attempt to read the treatment assignment (Schulz, 1995).

In addition to the reasons given for enrollment into trials, such as the hope for potential medical benefits, altruism for science and future patients, and possible honor

attained by participation in a clinical trial, there may be certain personality variables that distinguish those who decide to enroll from those who do not. In particular, when we take note of the issues that non-participants cite as reasons for their lack of interest in enrollment, including not liking randomization and a desire to make their own treatment decisions (Harrison et al., 2007) it may be apparent that deciding to enroll in a RCT takes a certain amount of risk taking, and an ability to venture into something unknown. It is possible that the personality variables Risk Taking as well as Openness to Experiences play a role in the self-selection we see in RCTs, although this has never been investigated.

The Second Potential Bias: Treatment Preferences and Threats to Internal Validity

Although participant and physician refusal to enroll in clinical trials can affect the external validity of a study, the second unintentional potential bias from randomization comes from the introduction of psychological artifacts resulting from randomization to an undesired treatment among those who do enroll (Corrigan & Salzer, 2003; Janevic et al., 2003).

Assigning participants to a non-preferred treatment can deflate the apparent effectiveness of that treatment (Janevic et al., 2003) through participants experiencing "resentful demoralization" (Cook & Campbell, 1979, p. 55) – participants feeling hurt, disappointed, and perhaps betrayed. This can result in decreased motivation to comply (Bradley, 1993), intolerance toward treatment-related challenges that occur during the study (Bradley, 1993), and also through psychological artifacts that result in a *negative placebo* effect, whereby outcomes are affected by the belief that a treatment will not work (Feine, Awad, & Lund, 1998). In describing the nature of dropout from an alcohol

treatment study (B. A. Miller, Pokorny, Valles, & Cleveland, 1970), Adair (1973) speculates that many participants who dropped out "reacted against the procedures" (Adair, 1973, p. 52) of the study, found the protocol a waste of time, did not like their therapist, and/or did not want to participate in group sessions. In short, these participants were not satisfied with their treatment assignment.

If a treatment is unobtainable outside of the trial, participants may decide to enroll mainly due to the chance of gaining access to the treatment. Not receiving that treatment after randomization may be a considerable blow to their hopes for symptom relief or survival. Indeed, disappointment and demoralization from being assigned to a non-preferred treatment may be greatest when the other conditions offer treatments that are new (Brewin & Bradley, 1989) or unavailable elsewhere (Bradley, 1997). The effects of this on outcome measures will likely be greatest in trials in which participants must follow a treatment regimen (Brewin & Bradley, 1989). When study results indicate null findings, but are influenced by these effects, it becomes impossible to know if the results indicate that the treatment itself is ineffective or if it appeared to fail because participants in the treatment group did not believe in the efficacy of the treatment or were unmotivated or unable to adhere (Brewin & Bradley, 1989).

If a treatment *is* obtainable outside of the study, participants dissatisfied with their assignment may not drop out of the study, but simultaneously seek their preferred treatment elsewhere, contaminating the study groups. For example, in studies on the impact of exercise for cancer survivors, 22-50% of control group participants were found to be exercising at the minimum target level for exercise group participants (Courneya et al., 2003; Mock et al., 2001).

Additional threats to validity are posed by participants discontented with their treatment assignment who do not drop out and do not contaminate their treatment, but nevertheless may not be *engaged* in their treatment (Corrigan & Salzer, 2003). Because of the nature of many psychosocial and behavioral medicine interventions, participants often cannot be blinded as they can in a drug trial – participants will necessarily be aware of whether they have been assigned, for example, to the group or the individual therapy, or to the low fat or the high fat diet. In addition, because many psychosocial and behavioral medicine treatments require active participation (exercising a certain number of times per week, being physically and mentally present at group psychotherapy sessions), a disinterest in one's treatment is a serious threat to the validity of RCTs.

When participants discover their assigned condition, the variables assumed to be evenly dispersed by randomization can actually be altered. This effect, coined the "premature disclosure effect" was first officially noted by Shapiro and colleagues (Shapiro et al., 2002). They discovered the effect serendipitously while conducting a study of stress-reduction techniques for breast cancer patients. Due to logistical constraints, they needed to alert participants to their assigned treatments ahead of baseline data collection. Baseline assessments indicated that those who had been assigned to a structured 6-week mindfulness-based stress reduction group had higher scores on distress, and lower scores on quality of life, sense of coherence, and sense of control in comparison to the free choice control group, who were assigned to simply monitor their own stress reduction activities. Because groups were balanced on variables including demographics and health status, the researchers concluded that these differences were a byproduct of participants finding out their treatment assignment.

Why might finding out one's treatment assignment cause one to have different distress, quality of life, coherence, and sense of control scores? Although researchers themselves are familiar with the randomization process and perceive it to be as it is – random – the perception of this process is very different for participants in need of treatment. Participants who are assigned to a treatment condition perceived to be more aggressive than the other conditions may mistakenly assume their condition is worse than it actually is (or, alternatively, better than it actually is). To illustrate, consider a study of British men who participated in a RCT for urinary retention. They expressed during a qualitative study an understanding that the randomization process was like chance, but also described lay theories they had developed to interpret and understand their experience (Featherstone & Donovan, 1998). Some participants thought researchers and doctors must have evaluated the type and severity of their symptoms to decide which treatment they should get, "Well [randomisation] was a bit confusing… They know what's wrong with us… The other consultant would have decided – you know, this lad need [*sic*] medication, or yes, this lad needs the operation" (Featherstone & Donovan, 1998, p. 1179). Although researchers may scoff at this interpretation of the randomization process, as mentioned before, there is sufficient evidence to support the idea that even some doctors in fact try to operate on the methods described by the participants quoted in Featherstone and Donovan's (1998) interviews (Schulz, 1995).

Participants themselves may not have a full understanding of what constitutes a clinical trial or what the purpose of conducting a clinical trial is. For example, Snowdon and colleagues (Snowdon, Elbourne, & Garcia, 1999) used a partially qualitative study to understand parents' responses to Zelen randomization (in which randomization precedes

consent) of their at-risk infants to two types of life support systems: Extra Corporeal Membrane Oxygenation (ECMO) and ventilatory support (conventional management; CM). Authors noted that parents used the terms "trial" and "ECMO" interchangeably, and believed that "infants allocated to the CM condition were not part of the trial" (Snowdon et al., 1999, p. 160). In addition, parents of these infants may have had trouble accepting the idea of randomization being truly random. One parent noted, "I know obviously that they have the baby's welfare at heart but the very word 'trial,' and then the fact that a computer decides [to which condition to allocate the patient] is making it all the more clinical… and very unreal… leaving a very big major decision to a piece of apparatus that's plugged in is just completely wrong" (Snowdon et al., 1999, p. 157). This perspective is quite similar to that expressed by the urinary retention patients in the Featherston and Donovan (1998) study, that someone (perhaps a doctor, or perhaps also something like a higher spiritual power or fate) would take care to place the participant in the best treatment given their symptoms and severity. All these examples of participants' perceptions of the randomization process indicate that they do not understand the difference between clinical trials and clinical research treatment, known as the "therapeutic misperception" (F. G. Miller & Brody, 2003), which holds ethical implications of the use of randomization.

Shapiro and colleagues posit that the effect on baseline data they unexpectedly found in their stress-reduction study (the premature disclosure effect) may occur often, but is usually not detected because baseline assessments in RCTs typically occur before participants learn of their treatment assignment (Shapiro et al., 2002). Detected or not, if the effect occurs – which may be more pronounced in any trial that cannot be blinded and

for which participants may have preferences (Bradley, 1997; Thomas, Croft, Paterson, Dziedzic, & Hay, 2004) – it renders any conclusions derived using the baseline data flawed because the participants are *actually beginning the trial at a different level of the measured variables than indicated by the baseline data collection*.

In an attempt to disentangle some of the effects of randomization and preferences on outcomes, Thomas and colleagues (Thomas et al., 2004) added preference questions to a trial of corticosteroid injections vs. physiotherapy (8 sessions, each 20 minutes) for shoulder pain. Participants were asked to indicate their preferred treatment before randomization, and 6 months post-randomization. Results indicated that having a preference was associated with better improvement at follow-up, but surprisingly, it did not matter whether participants received their preferred treatment. Among participants with good outcomes, their post-randomization preference usually matched with whatever treatment they had been randomized to, and this relationship was more extreme for those who received the treatment for which they had *not* given a preference (Thomas et al., 2004). Thomas and colleagues note that, according to their results, participant preferences may exist and may influence participant outcomes, but these preferences might not be static. It is important to note that these results, especially the result that being matched to one's preference did not impact improvement, may not be generalizable to other trials – especially those for which treatments require more effort on the patients' behalf, or for studies of treatments that are more psychological in nature (e.g., for depression, improving quality of life or well-being, coping with trauma or illness).

Nonrandom Assignment to Preferred Treatment (Having Choice)

The recent debate over the threats to internal validity posed by treatment preferences has led to investigation into how researchers can develop designs that incorporate participant treatment preferences. In addition, the emerging recognition of the ethical need to respect patients and their autonomy while maintaining the expertise of doctors has lead to medical decision making that incorporates patients' choices (Elwyn, Edwards, Kinnersley, & Grol, 2000). There is, however, little empirical study of the effects of patients' decision making on medical outcomes (Elwyn et al., 2000). Several research designs have been developed to incorporate patient choice and counter the threats to validity posed by randomizing participants to undesired treatments. Three of these include the partially randomized preference trial (PRPT, Brewin & Bradley, 1989), Wennberg's doubly randomized preference design (DRPT, Wennberg, Barry, Fowler, & Mulley, 1993), and the Rücker design (Rücker, 1989).

In Brewin and Bradley's PRPT design, participants with some treatment preference are given their preferred treatment, and participants with no preference are randomized to treatment (Corrigan & Salzer, 2003, see Figure 1). PRPTs have very low attrition rates. To illustrate, in a study in which 273 women were entered into either a RCT or PRPT investigating medical or surgical treatment for menorrhagia (abnormally heavy menstrual bleeding), almost all participants in the PRPT arm enrolled, yet 70% of participants in the RCT arm enrolled (Cooper & Grant, cited in Bradley, 1994). Rücker developed a two-stage randomized clinical design in which half of participants are randomized to a choice group (see Figure 2). These participants can choose their preferred treatment if they like, otherwise they are randomized. The other half of participants are randomized from the

beginning (Janevic et al., 2003). The Wennberg design is essentially a PCT vs. RCT design. In this design, participants are randomized to a preference arm, in which all participants choose their treatment, or to a RCT arm (Janevic et al., 2003, see Figure 3). Zelen randomization (Zelen, 1990) involves randomization to the experimental treatment or standard treatment prior to consent (see Figure 4). In this procedure, those randomized to standard treatment do not receive any information of an alternative treatment and do not give consent (i.e., they receive the standard of care as if there were no trial and remain unaware of the trial). Those randomized to the experimental group receive information about the experimental procedure, and, if they give consent, are given the experimental treatment. If they withhold consent, they are given the standard treatment. Zelen randomization is particularly controversial (Marquis, 1986; Snowdon et al., 1999), partially because not all participants are aware that they are taking part in a trial.

Incorporating treatment preferences in trial designs is helpful in addressing the problems that preferences pose for internal and external validity. However, providing a subset of participants their preferred treatment raises questions about the way to appropriately analyze the resulting data. Long et al. (Long, Little, & Lin, 2008) have developed a model to estimate *preference effects*. This model works with designs such as the DRPT, incorporating information gleaned from the preference arm of the trial into the analyses for randomized arm of the trial, which then allows estimates of preference effects and thus causal effects of treatment preference on trial outcomes. However, despite the development and use of nonrandomized PCT designs, including the recent strides made in interpreting the results (e.g., Long et al., 2008; TenHave, Coyne, Salzer, & Katz, 2003), there is still little understanding of what psychological artifacts are

brought about by being matched or mismatched to one's preferred treatment. Ultimately these topics should be tested in clinical trials. Before involving patients who are seeking treatment, however, the RCT and PCT designs should be subject of investigation among individuals not seeking treatment for a serious health condition.

Thus far, however, few studies have used the RCT itself as the subject of investigation. One experimental investigation that did focus on reactions to randomization was conducted by Wortman and colleagues (1976). Researchers compared a desirable treatment (improving students' leisure opportunities by providing information about, and coupons for, activities, sporting events, restaurants, etc.) and a no-treatment control condition. Two experiments were conducted for this study. In the first experiment, participants were randomly assigned to three groups: an unaware group, an aware group, and a becoming aware group. Participants in the unaware group were randomly assigned to receive or not receive the treatment, but neither group was told of the existence of the other condition. Thus, they were not aware that they were being treated differently than were other participants. Participants in the aware group were treated in a way that is consistent with RCT design. They were told about the two conditions (treatment and no-treatment control) and were randomly assigned to one of them. Participants in the becoming aware group were, like the unaware group, randomly assigned to the treatment or to the control and were not told about the other condition. Participants in this becoming aware group, however, *became aware* that other participants were being treated differently in a manner rigged by the researchers to appear accidental. These becoming aware participants had more negative feelings about the research project, and felt that the treatment was more valuable, whereas aware and

unaware participants did not differ on these variables. Overall, control group participants had more negative feelings about the research project than those assigned to the treatment group – but this effect was greater among those in the becoming aware group. Finally, aware group control participants were willing to complete fewer questionnaires, and were more envious of others in the project than aware group treatment participants. There were no differences in feelings about the research project.

Experiment 2 of the Wortman et al. (1976) study investigated if having a choice about whether to participate might have alleviated negative feelings toward the random assignment to conditions. Students enrolled in an undergraduate Psychology course were randomized to either be given a choice about participation in a study that randomized them to receive or not receive a desirable course seminar (the choice group) or were simply randomized to receive the desirable course or not (the no choice group). As the researchers hypothesized, the choice group had more positive feelings about the research project in comparison to the no choice group. In addition, few differences existed between the treatment and control group in the choice condition, whereas the no choice group control participants had less positive feelings toward the research.

This study by Wortman and colleagues is crucial in that it is one of the few studies to investigate how participants react to being assigned randomly to treatment or control in an RCT and how choice can influence effects. The study does leave some unanswered questions that need to be addressed: might it be expected that the results Wortman et al. found could be more pronounced in a study in which the treatment is more desirable than receiving information about leisure opportunities?; how does knowing in advance that one could be assigned randomly to a treatment affect initial enrollment into the study?

A more recent study conducted by Shadish and colleagues (Shadish, Clark, & Steiner, 2008) has also used the RCT as the subject of investigation. They randomized participants to be in either a nonrandomized (PCT) or a randomized (RCT) study. Participants either chose (in the nonrandomized arm) or were randomized to (in the randomized arm) a treatment of vocabulary or mathematics training sessions. They then gave participants their training (either the mathematics or the vocabulary) and later assessed all participants on both mathematics and vocabulary skills. The researchers noted that among the mathematics scores, scores were better for all participants assigned to mathematics in comparison to the vocabulary training. However, scores among those who *chose* the mathematics training were 25% larger than among those who were randomized to receive mathematics training. A similar pattern emerged among the vocabulary scores; scores were better for participants who received vocabulary training in comparison to mathematics training. However, scores among those who *chose* the vocabulary training were 9% larger than those who were randomized to receive the vocabulary training. The study also provided data on what motivated participants in the nonrandomized arm of the study to choose their treatment. Reasons for making their choice included self-improvement (44%), liking mathematics or vocabulary (23%), avoiding the other treatment (16%), and a high sense of self-efficacy that they could do the task (15%). These data indicate that participants given a choice of treatment can exhibit better outcomes in comparison to those randomized to the same treatment. There are several limitations to the Shadish et al. (2008) study that should be noted here. First of all, generalizability to other settings may be limited. This study used participants who entered the study knowing they would be randomized to have a choice or no choice about

their condition. Potential participants not interested in being randomized *at all* were lost to data collection because of this nature of the recruitment process. This type of situation resembles a typical RCT, in which patients uninterested in being randomized opt out of enrollment, which threatens external validity. A limitation that was not discussed by the authors involves the nature of the treatments. The vocabulary and mathematics training may appeal to some people who are motivated for self-enrichment, but any real desire to improve these skills is limited in that the need to improve these skills was only necessary for the experiment itself. This may mean that, although a preference for one treatment over the other may have been indicated (by the participants in the choice arm), realistically, the preference may not have been very strong. Thus, if preferences were also not very strong in the randomized arm of the study, participants may not have been much affected by being randomized to one treatment or another. Any possible artifacts arising from being randomized to a non-preferred treatment would be small, at best, which lack comparability to a true clinical trial. Although treatment preferences were not of specific interest in the study by Shadish and colleagues, it may be that such preferences are one key to understanding why randomized and nonrandomized studies sometimes yield different effect sizes. If preferences are one possible influence on study outcomes in RCTs, using intervention alternatives for which preferences are not very strong may not be very informative. Without data on whether randomized participants received their preferred or non-preferred treatment, and along with the low likelihood of strong preferences on behalf of participants to begin with, the usefulness comparing the PCT to the RCT arm is limited.

One limitation of both the Wortman et al. (1976) and Shadish et al. (2008) studies involves their use of undergraduate subject pool participants in combination with a treatment that may not be greatly desirable. Students who are required to participate in research studies may hold negative attitudes towards participation in research studies (D. E. Cox & Sipprelle, 1971). The implication of this is that, although data are collected on these participants, the data may not reflect accurately what these data would be for one who is actually concerned about performance on the task at hand (Adair, 1973). The data gleaned from the participants of these studies may not generalize to participants in studies who are more concerned about their outcomes, for example, improvement in illness symptoms.

A study by de C Williams and colleagues (1999) that did not use a psychology subject pool sample, but instead a chronic pain patient sample, randomized participants to an inpatient, outpatient, or waitlist control group (an RCT arm) for chronic pain management. Those refusing randomization were then given their choice of inpatient or an outpatient condition (a nonrandomized arm). The inpatient groups met 4.5 days a week for four weeks. The outpatient groups met 3.5 hours once a week for 8 weeks. All participants received an intervention including an education program about pain, disuse, drugs, and sleep, exercise including flexibility and muscle strengthening, and psychology sessions focused on problem solving and behavior modification.

These researchers compared the RCT and nonrandomized arms to determine whether these groups were different at baseline as well as at post-treatment using variables including demographics (baseline comparison only), pain, a 10-minute walk test, depression, self-efficacy, and opioid drug use. They also compared the inpatient and

outpatient groups at one month and one year post treatment. Noteworthy results indicated that inpatients did better than outpatients regardless of whether they were given their choice of condition or were randomized to their preferred condition. Although this indicates that few differences existed in the outcomes of the choice arm and the RCT arm, it is important to note that the treatment these patients received was essentially the same; the difference between groups was only in inpatient vs. outpatient care. Because the conditions were not *qualitatively distinct* from one another in terms of the actual treatment (all participants received information, exercise, and psychology sessions), these results may not generalize to a more common uses of RCT design, which involve comparing different treatments, or comparing a treatment and control group.

In sum, there is growing evidence, often mentioned parenthetically in reports of RCTs, of the existence of psychological artifacts produced by the randomization process. Researchers have developed several alternative designs that might help alleviate any effects created by participant preferences, or at least help researchers factor preferences into their analyses. Still, little research has actually been undertaken to examine how participant feelings affect their experiences as participants, or how these experiences affect the outcomes of RCTs.

The Present Study

The goals of the current study were to investigate: (a) the effects of the prospect of randomization on study accrual, to determine whether personality variables such as risk taking and openness to experiences, or education levels affect willingness to be

randomized; (b) whether participants are more likely to enroll in a preference trial as compared to a randomized trial as well as reasons for deciding to enroll or not enroll; (c) the interaction of participant preferences and treatment assignment on feelings regarding trial participation, belief in the effectiveness of treatment, intervention contamination, intervention adherence, trial attrition, and outcomes; and (d) whether matching participants to their preference condition by *choice*, in comparison to by chance, affects participant feelings regarding participation, belief in the effectiveness of treatment, intervention contamination, intervention adherence, trial attrition, and outcomes.

I designed a trial using a non-patient, undergraduate student population to compare participants directly in a RCT arm of a study to those in a PCT arm of the same study (a Wennberg design). The trial intervention was presented as a treatment that might improve performance on college examinations. Furthermore, the study design aimed to improve upon previously developed studies of RCTs (e.g., de C Williams et al., 1999; Shadish et al., 2008; Wortman, Hendricks, & Hillis, 1976) by:

(1) using a field experiment designed to follow non-participants, that is, following people who were not interested in participating in the randomization study itself, but were willing to fill out some baseline questionnaires;

(2) using a meaningful outcome measure. By using an undergraduate psychology class, I could use performance on a psychology course examination as an outcome measure. This ensured that participants were likely to be invested in their treatment outcome; in that they would be concerned about their exam performance. This scenario more closely resembles a RCT in medical, psychosocial, and behavioral medicine settings, where patients are invested in having a positive outcome;

(3) using a treatment that is truly desirable. By having an outcome measure be something for which participants will seek improvement independent of the study, I was able to offer a treatment that was truly desirable for them. The "treatment" was listening to music composed by Mozart while studying for and taking a college examination. Participants were told that listening to classical music has been shown to improve spatial reasoning tasks (the "Mozart Effect," Rauscher, Shaw, & Ky, 1993), and that we wished to determine whether this effect could be extended to college examination performance. Having a desirable treatment is vital in ensuring that participants will have treatment preferences;

(4) using two conditions that are *qualitatively distinct* from one another. Previous studies of RCTs have used treatments that were similar to one another: vocabulary vs. mathematics training (Shadish et al., 2008) or inpatient vs. outpatient care for the same intervention (de C Williams et al., 1999), which potentially lessens the intensity of participant preferences, and jeopardizes accuracy in interpreting differences between PCT and RCT participant experiences, including outcomes. The present study used conditions that were clearly distinct from one another: in one condition participants listened to a "treatment" of music, in the control condition they received no "treatment" and took their examination under normal testing situations (i.e., usual care); and

(5) observing the differences in outcomes for participants matched to their preferred vs. nonpreferred treatment in the RCT arm of the study.

Basis for Study Design

The study design was based upon the Wennberg DRPT (Wennberg et al., 1993), one of the proposed methods of working with participants' preferences in trials. As in the

Wennberg et al. design, participants were first randomized to have choice or no choice of treatment alternatives (randomized to the PCT arm or RCT arm, respectively; see Figure 5). Those randomized to have a choice of treatment alternatives (PCT; arm A) were then assigned to receive their preferred choice and those randomized to the randomized arm (RCT; arm B) were then randomly assigned to treatment or control. Unlike the Wennberg design, however, I maintained data for non-participants. That is, some participants elected to "enroll in the trial" itself while others elected to be "non-participants" and opted to simply complete a baseline questionnaire. The study design therefore comprised 8 groups in total (see Figure 5).

For the first four groups, preference and actual treatment are matched:

Group 1: Preference for treatment group, assigned to treatment group,

Group 2: Preference for control group, assigned to control group,

Group 3: Preference for treatment group, randomized to treatment group,

Group 4: Preference for control group, randomized to control group,

and

Group 5: Preference for treatment group, randomized to control group, and

Group 6: Preference for control group, randomized to treatment group.

With this design, arm A (G1 and G2) resembles one arm of a preference-based randomized design, whereby participants are assigned to the group reflecting their preference. Arm B resembles a typical RCT. Groups 3, 4, 5, and 6 represent participants who enter a trial preferring a particular treatment and are either randomized to that treatment or not. *These groups probably commonly exist in RCTs but go undetected when participant preferences are not assessed.* Importantly, groups 5 and 6 differed from the

other groups in both arms of the study in not receiving the treatment of their choice; they were *mismatched* to preference. Because four of the groups were within arm B, participants were randomized to arm A and arm B in a ratio of 1:2 to balance group sizes.

There were several reasons why this study represented an ideal model in which to test the interactive effects of preferences and randomization. Prior to running the study, I considered that:

(1) The Mozart Effect is a controversial phenomenon whereby listening to Mozart's Sonata for Two Pianos in D Major K. 448 has been shown to enhance spatial task ability among college-aged students, but has not been successfully replicated in other populations (e.g., preschoolers) or for some tasks (e.g., math). There is thus some evidence for its efficacy but, like most treatments investigated in RCTs, there is no certainty that listening to Mozart would enhance performance on a Psychology course examination. Because my primary research interest was to investigate artifacts related to random assignment to treatment conditions, and not the Mozart Effect itself, I played Sonatas composed by Mozart in addition to Mozart's Sonata for Two Pianos in D Major K. 448. This prevented participants in the treatment condition from habituating to one song or becoming annoyed by listening to the same song for the duration of their exam.

(2) It is likely that participant preferences vary regarding whether they would wish to be assigned to the intervention or the control condition, college students would likely vary in the extent to which they would find Mozart's music appealing.

(3) It is likely that preferences for the intervention and the control condition will be relatively balanced. Zimbardo et al. (2003) conducted a study in which participants could choose an experimental or control condition for an intervention designed to enhance

examination scores (paired testing), and reported that, over several tests, roughly 40% of students choose the experimental examination condition.

(4) Obtaining good grades is attractive for most college students and students doing poorly may feel especially motivated to obtain good grades. This phenomenon of feeling a strong desire to receive a treatment that improves one's situation is most likely experienced in behavioral medicine and psychosocial intervention trials, yet has not been adequately examined in previous studies. By choosing this intervention for the experiment, I sought to achieve superior ecological validity than previous studies of treatment preferences.

METHODS

Participants

Participants (N = 375) were undergraduate students in Psychology courses at Stony Brook University.

Measures (see Appendix A)

There were three main types of factors of interest to this study: (a) predictors of enrollment into the trial such as risk taking and openness to experiences, and reasons for deciding to enroll or not enroll in the trial; (b) reactions to randomization, such as

feelings toward the research project and researcher team, belief in the effectiveness of treatment, intervention contamination, and intervention adherence and engagement; trial attrition; and (c) trial outcome variables such as examination grades.

Demographics

Demographics were collected for all trial participants and all non-participants. In addition to age, gender, ethnicity, and grade point average items, participants were asked about the highest education level attained by a male and female role model. In previous studies about randomization (Helgeson, Cohen, Schulz, & Yasko, 2000; S. R. Sears et al., 2003), education level was related to willingness to be randomized. In our study, because all participants are still in the process of their educational career, these two items were included to assess the education level that best characterized the environment in which they grew up.

Pre-Trial Preferences

Preference for intervention (music listening) condition versus the control or usual care (normal testing) condition was assessed for participants using a 4-point Likert-type scale ranging from 1 (*strongly prefer normal testing*), to 2 (*somewhat prefer normal testing*), to 3 (*somewhat prefer music listening*), to 4 (*strongly prefer music listening*). Thus, participants had to register a preference for one of the conditions, even if it was not a strong preference.

Predictors of Enrollment

Risk Taking

Risk-taking behavior was assessed using four questions adapted from Harrison et al. (2007), assessing physical, financial, social, and health risk-taking. Sample items include:

"Some activities/situations involve a 'physical risk,' where there is a risk of getting injured in an accident or possibly even death. Physical risks can include rock climbing, sky-diving, or occupations such as coal mining or being a police officer;" and "Some activities/situations involve a 'health risk' where there is a risk of harming ones' health. Health risks can include sunbathing with no sun screen or smoking." Items are rated on a 1 (*extremely unlikely*) to10 (*extremely likely*) scale and summed to form a total score. This measure showed good scale reliability in this sample (Cronbach's $\alpha = .64$).

Openness to Experiences

Openness to Experiences was assessed using ten questions excerpted from the Big Five Inventory (John & Srivastava, 1999). Sample items include: "I see myself as someone who… Is ingenious, a deep thinker;" and "I see myself as someone who… Is curious about many different things." Items are rated on a 1 (*disagree strongly*) to 5 (*agree strongly*) scale, and are summed to form a total score. This measure showed good scale reliability in this sample (Cronbach's $\alpha = .78$).

Reasons for Enrollment

Reasons for deciding to not participate in the randomized trial were assessed for non-participants using an adaptation from Harrison et al. (2007). For participants who enrolled into the trial, this questionnaire was adjusted to assess reasons for participation.

Reactions to Randomization

Feelings about Participation in Research

Feelings about participating in the research project were assessed with ten questions used in Wortman et al.'s (1974) prior research. Ratings are made on a 9-point (0-8) scale. Items are: "I feel good about being in the project" (Positive Feelings); "I regret signing

up for the project" (Regret); "I feel angry about the way the project is being conducted" (Anger); "I feel that the project is fair to all participants" (Project Fair); "I feel envious toward others in the project" (Envy); "I feel motivated to help make the project successful" (Motivation); "I respect the people who are running the project" (Respect Researchers); "I believe the people who are running this project are concerned about me. (Researchers Concerned); "I think the objective of this project is worthwhile and important" (Project Worthwhile); and "I think that the project will provide some useful information" (Project Useful).

Belief in Treatment Effectiveness

Belief in the effectiveness of the treatment was operationalized by how desperate participants were for a good grade, their expectations about examination performance, and by Test Anxiety. Participants were queried about how desperate they were to receive a good grade on their next exam, and asked what score they anticipated achieving on the second examination, out of 100 points. Text Anxiety was assessed with (approximations of) the items used in Zimbardo et al.'s (2003) prior research. This involved a "five-question survey with some open-ended items and some fixed-alternative items" (Zimbardo et al., 2003, p. 114). Because correspondence with Dr. Zimbardo indicated that the exact wording of the test items is no longer available, I included an additional, validated measure of state test anxiety. This measure of state test anxiety developed by Hong (Hong, 1998) is a modification of Spielberger's (1980) Test Anxiety Inventory. This measure of state test anxiety showed good scale reliability in this sample (Cronbach's $\alpha = .88$).

Intervention Contamination

Contamination was operationalized as listening to classical music (among control group participants). The number of hours spent studying while listening to classical music was queried in an open-ended fashion. Although the Mozart Effect has been supported only with music composed by Mozart, students unfamiliar with classical music may generalize the effect to all forms of classical music. Therefore, when assessing for contamination it was more effective to inquire about hours spent listening to classical music, as opposed to only music composed by Mozart.

Intervention Adherence and Engagement

Adherence to treatment and engagement in treatment were assessed by recording the number of minutes spent attending study sessions offered by the research staff, as well as collecting responses to a question assessing productivity during the study sessions (developed by the research team), "Was this a productive study session for you for your Psychology exam?", rated on a 1 (*Not really, I daydreamed a lot or worked on something else*) to 4 (*Yes, I think I learned quite a lot*) scale.

Trial Attrition

Trial attrition was operationalized as neglecting to fill out subsequent questionnaires or expressing disinterest in continuing with the research project. Hypothetical willingness to continue in the research project was determined by participants' responses to the invitation to continue to be tested under the same circumstances for the third course examination and to complete more study assessments.

Post-Trial Preferences

Because preferences may shift over the course of a trial (Thomas et al., 2004), participants were asked about their preference; if they were to take part in the trial again, would they prefer the music listening or normal testing condition, using the 4-point Likert-type scale ranging from 1 (*strongly prefer normal testing*), to 2 (*somewhat prefer normal testing*), to 3 (*somewhat prefer music listening*), to 4 (*strongly prefer music listening*). Unbeknownst to participants, this item was a hypothetical question.

Outcomes

Examination Grades

Examination performance was quantified by scores on a multiple-choice examination, which is the standard type of assessment used in the regular conduct of the courses in which the trial was run. Multiple-choice testing of Introductory Psychology course content was used in Zimbardo et al.'s (2003) research utilizing course examination as part of a psychological research design. As part of the consent procedures, participants were asked for permission to use the scores obtained on their course tests in the research. Scores were translated into a 100 point scale for comparison with expected scores.

Manipulation Checks and Additional Probes

A manipulation check was included to make certain that participants were correctly aware of their treatment condition. They were simply asked to indicate which condition they were in.

Knowledge about the existence of other conditions in the study (PCT vs. RCT arms) was probed with the question, "Some participants told us they heard that some students

were given the study condition (music vs. normal testing) that they preferred, while other students were randomly assigned to condition. Did anyone tell you about this?"

Research Design

As mentioned above, I designed an analogue to treatment in a RCT, employing a "trial" on the Mozart Effect to investigate the effects of random assignment on experience as a participant in a research trial. Listening to Mozart's Sonata for Two Pianos in D Major K. 448 has been shown to temporarily increase spatial task performance in college students (Rauscher et al., 1993), and this effect was somewhat supported in a few replication studies (e.g. Jaušovec, Jaušovec, & Gerlic, 2006; Schellenberg, Nakata, Hunter, & Tamoto, 2007) although other studies report failed replication or generalization attempts (e.g. Crncec, Wilson, & Prior, 2006; Hui, 2006). Not coincidentally, this is the context in which clinical trials are launched, whereby there is scientific equipoise with respect to the efficacy of the treatment under study – researchers are not certain which treatment would offer more benefit (Djulbegovic, Cantor, & Clarke, 2003); otherwise, it is considered unethical to test a treatment under randomized conditions (F. G. Miller & Brody, 2003). Thus, our "intervention treatment" was listening to Mozart music while studying for and taking a college course examination.

Procedure

The study was conducted in six psychology courses. For each course used, the procedure was the same, unless otherwise noted (see Figure 6 for a timeline). The study's experimenter (A. F.) or one of the study's research assistants visited the class in their lecture hall one to two weeks prior to their first examination, to present a 3-minute Powerpoint introduction to the study. Students were invited to participate in "an experiment investigating techniques that may lead to improvement in college examination scores." Students were told about the Mozart Effect – the finding that listening to Mozart's Sonata for Two Pianos in D Major causes improved performance on spatial tasks. They were presented with research findings that illustrated the conflicting results about the effect. Students were then informed that we were running a study in which the participants would attend study sessions and take their next examination or quiz in one of two groups: some participants in the experimental group (listening to Mozart Sonatas during organized study sessions and during the examination) and some participants in the control group (attending quiet study sessions and taking their course examination under normal testing conditions). To prevent students from asking in front of the class whether participants would be able to choose their own condition, no questions were taken from students during the presentation itself. Students were instructed to submit any questions to an email to an address dedicated to the study. No students asked whether they would be able to choose their own condition.

Though this study was run in college courses, the professors and teaching assistants were not part of the study, and students' course grades were not affected by their

participation. It was explained to students that their course instructors were not affiliated with the study.

The research team was kept blind to whether participants were allocated to the PCT or to the RCT arm. Though the research team ran study sessions and examinations (i.e., they saw which participants attended these events), the research team did not know participants by name or other identifying information.

Assessment 1: Consent and Baseline Questionnaires

Students were given a flyer during their first examination, with instructions to sign up for the study online. Those who registered were randomized by computer to receive one of the two types of consent forms (see Appendix B), for the two arms of the study (PCT and RCT arms). One-third of the potential participants received consent forms indicating that, should they decide to participate they would be able to choose their condition (listening to music or normal testing), forming a PCT arm; two-thirds of the potential participants received consent forms indicating that, should they choose to participate they will be randomly assigned to their condition, forming a RCT arm (for a flow chart of participant allocation see Figure 5).

Participants who elected to enroll in the trial itself (henceforth referred to as simply "participants") received 2 research credits for completing all assessments. Those who wished to *not* enroll in the trial itself (in both PCT and RCT arms) were given the opportunity to complete a single questionnaire for 1 research credit (these students are henceforth referred to as "non-participants"). This opportunity is outlined on the last page of both consent forms. These non-participants completed only baseline questionnaires

(for questionnaires, see Appendix A). Some students in the classes did not wish to take part in the study at all (henceforth referred to as "true refusers").

The baseline questionnaires assessed demographic information, condition preference, risk taking, and openness to experiences.

Participants had 3 to 5 days to complete the baseline questionnaire online. Once the baseline questionnaire was completed, research staff matched (for the PCT arm) or randomized (for the RCT arm) participants to their treatment condition. The RCT randomization was conducted by ordering participants by their preference in a computer database, then alternating assignment to condition. The course instructors were kept unaware of their students' group assignment.

Assessment 2: Letter of Condition Assignment, Second Questionnaire

Approximately 4 weeks prior to the second course examination date, participants received an email containing information of their assigned condition (see Appendix C). In the *choice* (PCT) arm of the study received "confirmation" of their treatment assignment. Participants in the RCT arm of the study were explicitly told that they were "randomly assigned" to the music listening condition (or to the normal testing condition). Included in this email was information about what classroom to visit to take their examination. The email also contained a web link to the second questionnaire of the study.

This second questionnaire assessed participants' expectations about their performance on the second in-class examination, and feelings about participating in the research study.

The email message participants received also included information about the study sessions. Participants were asked to attend at least 2 hours of study sessions provided by

the research staff. The study session information was also posted on the interactive course website on Blackboard. Study sessions took place simultaneously for treatment as well as control participants, but in separate rooms so that classical music (Sonatas composed by Mozart) could be played during the music listening condition study sessions. For music listening study sessions, the music was played just loud enough that all participants seated in the room could hear the music. Participants logged in to and out of the study sessions by writing their code in a study session log (see Appendix A). They were asked to refrain from cell phone use and from listening to MP3 players while in the study session. When participants left the sessions, they completed a one-item questionnaire to indicate how successful the study session was for them (see Appendix A).

Participants were told that they would receive experiment credit based on completion of assessments, not based upon attending the study sessions. Therefore, participants could receive full credit for the experiment without attending any study sessions. This was intended to be analogous to typical psychosocial and behavioral treatments trials in which study payment (if any) is usually based on assessment, not treatment, completion. Participants were sent a reminder email regarding the study sessions approximately three days prior to the first session.

Intervention and Assessment 3: Final Questionnaire

The final stage of the study took place just after the second psychology course in-class examination itself (or just after the third quiz in one course). Because two rooms were required to accommodate the music listening condition as well as the normal testing condition, information about which classroom to visit was provided in the participants' condition assignment letters, in announcements during class lectures, as well as postings

on the interactive course website on Blackboard. These announcements were posted one to two weeks prior to the examination. In addition, posters were taped to lecture hall doors on the day of the examination reading "Music Listening Condition Exam Room" and "Normal Testing Condition Exam Room." As in the music listening study sessions, for the music listening examination condition, music was played just loud enough for everyone in the room to hear. Care was taken to locate rooms separate from the usual lecture halls for both conditions, however, room restrictions on the part of the university made this impossible for three classes. In these cases, only one additional room could be reserved, and was used for the music listening condition. For these cases, control participants were given sectioned seating in their usual lecture hall. Non-participants, true refusers, and students who for various reasons may not have been aware of the study (this may have occurred for extremely preoccupied students who never attend class lectures and do not utilize the course internet website), took their exam in the usual class lecture hall.

After finishing their examination, participants were given flyers with instructions to complete the final questionnaire online. The third questionnaire contained items assessing participants' anxiety during the examination, and anxiety while studying for the examination. This is similar to previous studies of student examination experiences (e.g., Zimbardo et al., 2003). I also assessed the characteristics of students' studying situations, including whether they listened to music while studying. Finally, participants were asked about their hypothetical: (a) preference to take their next examination under the same testing conditions (music listening or normal testing condition) or not, which allowed me to determine whether preferences shifted over time (e.g., Thomas et al., 2004), and (b)

willingness to continue to participate in the trial by answering additional assessments at the time of the examination. They were also queried as to whether they had heard about the initial randomization to PCT or RCT arms of the study. After this assessment, the trial concluded and participants were debriefed (see Appendix D). All Psychology course students including the study participants were informed of their grade on the second in-class exam in the usual fashion for the course (about three days later).

Participants' scores on the first and second examinations for the course were collected from their instructors (as stated in the consent form).

Hypotheses

Hypothesis 1

Participants unwilling to be randomized (G8, see Figure 5), as compared with participants willing to be randomized (G3, G4, G5, and G6), will be lower in risk taking and in openness to experiences, have higher grade point averages, have higher anticipated scores on the second examination, and have higher parental education levels.

Hypothesis 2

There will be fewer people unwilling to participate among participants assigned to have a choice of treatment condition (G7), compared with those assigned to be randomized to treatment condition (G8). Among participants assigned to have a choice of treatment condition (G7), the most often endorsed reason for enrollment will be related to being able to indicate a preference for one treatment or the other. Among participants

assigned to be randomized to treatment condition (G8), the most often endorsed reason for not enrolling will be a strong preference for one of the conditions.

Hypothesis 3

Participants who are matched by chance to their preferred treatment (G3 and G4), compared with those who are matched by chance to their non-preferred treatment (G5 and G6), will show more positive feelings toward the research project and researcher team, greater belief in treatment effectiveness (higher anticipated examination grade, less desperation for a good grade, lower test anxiety), less contamination, and more study session time and engagement. This effect will be moderated by treatment condition, such that participants assigned to the treatment will have more positive outcomes than those assigned to the control condition. It is also predicted that participants assigned to a preferred condition will be more likely to attend a study session, complete all online follow-up assessments, and be willing to complete an additional questionnaire after their next exam, and have higher examination 2 scores, compared with participants who are mismatched to condition.

Hypothesis 4

Participants who are matched to their preferred treatment by *choice*, compared with those matched by chance (G1 and G2 vs. G3 and G4), will show more positive feelings toward the research project and researcher team, greater belief in treatment effectiveness (higher anticipated examination grade, less desperation for a good grade, lower test anxiety), less contamination, and more study session time and engagement. This effect will be moderated by treatment condition, such that participants assigned to treatment will have more positive outcomes than those assigned to the control condition.

Hypothesis 5: The Mozart Effect

The design of this study allows testing of a separate, but nonetheless interesting, topic – whether listening to music by Mozart does actually affect examination grades. I predicted that participants assigned to the treatment condition will have higher examinations scores on examination 2, compared with participants assigned to the control condition, controlling for scores on examination 1.

Power Analysis

The main effects found in prior research appear to be relatively strong. Zimbardo et al. (2003) reported that the effect size for the superiority of undergraduate collaborative examination testing over individual examination testing on achievement was $d = .80$. Shapiro et al. (2002) found in their "premature disclosure effect" study that the effect sizes for the differences between the experimental and control group after being informed of their group assignment ranged from $d = .42$ to .84 for eight psychological outcomes. The effect size for aware control versus aware treatment participants in Wortman's (1976) study for the number of questionnaires that they were willing to return was $d = -.50$ and for being envious of others in the project was $d = .80$. Therefore, to be conservative I based estimates on a medium effect size of $d = .50$.

For a 2 x 2 MANOVA for Hypothesis 3 (involving groups G3-G6) comparing the effects of matching to preference (match to preference vs. mismatched to preference) and treatment group assignment (treatment vs. control), a cell size of 40 would be required for

a minimum likelihood of .83 of detecting a medium effect size with an alpha of .05 (two-tailed). This would mean a sample of 160 across groups G3-G6. Similarly, a 2 x 2 MANOVA for Hypothesis 4 (involving groups G1-G4) comparing the effects of choice (choice vs. chance) and treatment group assignment (treatment vs. control) would require a cell size of 40, for a total of 240 subjects across groups G1-G6. With 240 participants in the two study arms (participants willing to enter the study), groups G1-G6, a balanced design would require 240 participants outside of arm A and B (participants unwilling to enter the study, groups G7 and G8). This would provide > .95 power to detect a medium effect size difference.

RESULTS

Descriptive Data

Participants (N = 359) were mostly female (59.9%), non-Hispanic (88.0%), freshmen in college (34.8%), and White (48.7), with a number of other races represented (29.8% reporting Asian, 5.0% Black, 1.1% Pacific Islander, and 14.2% indicating a background of Other; see Table 1).

Means and standard deviations for the three categories of main study variables (predictors of enrollment; participant reactions to randomization including feelings about randomization; trial outcomes) are presented in Table 2.

Correlations between the ten indices of participant feelings and other participant reactions to randomization are presented in Table 3. Of particular note: participants' adherence to study sessions (minutes spent in study sessions) was positively correlated with Positive Feelings, $r = .13$, $p = .021$, and their engagement in the sessions, $r = .86$, $p = .000$; participants' adherence to study sessions (engagement in the study sessions) was positively correlated with Positive Feelings, $r = .18$, $p = .002$, Motivation, $r = .13$, $p = .018$, Project Useful, $r = .13$, $p = .025$; and Test Anxiety was negatively correlated with Positive Feelings, $r = -.13$, $p = .033$, Project Fair, $r = -.19$, $p = .002$, Project Worthwhile, $r = -.16$, $p = .009$, and Project Useful $r = -.16$, $p = .008$, and was positively correlated with Respect Researchers, $r = .18$, $p = .003$, Regret $r = .16$, $p = .008$, Anger, $r = .22$, $p = .000$, Envy, $r = .29$, $p = .000$, and Desperation for a Good Grade, $r = .31$, $p = .000$. Grades for Examination 1 and Examination 2 were highly correlated, $r = .58$, $p = .000$.

Preferences

Study participants preferred the treatment condition to the control in a 2:1 ratio, and 41.4% indicated a strong (compared to weak) preference for condition. Specifically, 12% of study participants strongly preferred the control condition, 23.7% somewhat preferred the control condition, 34.8% somewhat preferred the treatment condition, and 29.4% strongly preferred the treatment condition.

Participants' initial preference for treatment condition was associated with their preference if they were hypothetically going to participate again, $r = .59$, $p = .000$. Among those who initially strongly preferred the control condition, approximately 49% maintained that preference post-trial, while 29% switched to somewhat prefer the control, 12% somewhat preferred the treatment, and 10% strongly preferred the treatment.

Among those who initially somewhat preferred the control condition, approximately 56% maintained that preference post-trial, while 9% switched to strongly prefer the control, 24% somewhat preferred the treatment, and 11% strongly preferred the treatment. Among those who initially somewhat preferred the treatment condition, approximately 45% maintained that preference post-trial, while 9% switched to strongly prefer the control, 18% somewhat preferred the control, and 29% strongly preferred the treatment. Among those who initially strongly preferred the treatment condition, approximately 58% maintained that preference post-trial, while 1% switched to strongly prefer the control, and 41% somewhat preferred the treatment. More succinctly; among those that initially preferred the control condition, 71% maintained this preference post-trial, and 29% switched to prefer the treatment. Among those that initially preferred the treatment, 86% maintained this preference post-trial, and 14% switched to prefer the control.

Attrition

The attrition rate was fairly low, regarding completion of the online assessments. All participants completed the baseline questionnaire (without completion of which they would not be participants). Approximately 95% completed the second assessment, and 90% completed the third.

Manipulation Check

When queried about knowledge of the condition to which they were assigned, 3 participants in the control group thought they were in the treatment group and 2 indicated

that they did not know to which group they were assigned. One participant in the treatment group thought he or she was in the control group.

Few participants (4%) indicated that they were aware of the initial randomization (aware that some participants received their choice while some participants were randomly assigned to condition).

Data Analysis

I used a MANOVA to analyze whether participants willing versus unwilling to be randomized differed in risk taking and in openness to experiences, desired examination scores, grade point averages, and parental education (Hypothesis 1). MANOVA was used to determine whether being matched to preference and condition assignment affected feelings about the research project and research team, belief in the effectiveness of treatment, contamination, and study session time and engagement (Hypothesis 3). MANOVA was also used to determine whether being matched to preference by choice or by chance affected feelings about the research project and research team, belief in the effectiveness of treatment, contamination, and study session time and engagement, (Hypothesis 4). All analyses indicating significant effects were followed up with univariate ANOVAs to look at each dependent variable uniquely.

I used an ANCOVA to investigate whether being matched to preference and condition assignment affected examination 2 grade, controlling for examination 1 grade (follow-up to Hypothesis 3). ANCOVA was also used to test whether being assigned to the treatment

group affected examination 2 grade, controlling for examination 1 grade (Hypothesis 5; the Mozart Effect).

Chi-square tests were used to determine whether having a choice of condition affected interest in enrollment into the study (Hypothesis 2), whether being matched to a preferred condition affected the likelihood that a participant would attend a study session (a follow-up to Hypothesis 3), and whether being matched to a preferred condition affected the likelihood that a participant would complete the second or the third online assessments (a follow-up to Hypothesis 3).

I modeled a preference effect analysis based on that conducted by Long et al. (2008, p. 477), using an independent means t-tests to determine whether treatment effects existed based on condition assignment, and an ANOVA to looking at the interaction of preference (treatment vs. control) and condition assignment (treatment vs. control) on examination 2 score.

A Prioi Hypotheses

Hypothesis 1

I conducted a MANOVA to test the hypothesis that participants unwilling to be randomized (G8, see Figure 5), compared with participants willing to be randomized (G3, G4, G5, and G6), would be lower in risk taking and in openness to experiences, have lower desired scores on the second examination, have higher grade point averages, and have higher parental education levels. The hypothesis was not supported, Pillai's Trace $F(5, 213) = 1.56$, $p = .173$.

Hypothesis 2

I conducted a chi-square to test the hypothesis that there would be a smaller proportion of people unwilling to participate among participants assigned to have a choice of treatment condition (G7), compared with those assigned to be randomized to treatment condition (G8). This hypothesis was not supported, $\chi^2(1) = .04$, $p = .837$.

Reasons for Enrollment

The four most commonly endorsed reasons for participating in the trial, among participants in the PCT Arm of the study who enrolled in the trial ($n = 122$), were: liking the concept behind the study (76.2%), needing the research credits offered by participation (73.0%), belief that participation could have a positive impact on exam performance (45.9%), and belief that the results of the study might benefit others (34.4%; see Table 4). The four most commonly endorsed reasons for participating in the trial among participants in the RCT Arm of the study ($n = 211$) were the same: liking the concept behind the study (74.9%), needing the research credits offered by participation (73.9%), belief that participation could have a positive impact on exam performance (49.8%), and belief that the results of the study might benefit others (40.8%).

The four most commonly endorsed reasons for *not* participating in the trial, among participants who declined to participate in the PCT Arm of the study ($n = 9$), were: concern that participation might have a negative impact on their exam performance (55.6%), not wanting to do the extra work involved (22.2%), needing only one more research credit (as opposed to the two credits offered by participation in the trial; 22.2%), and disbelief that either group would help them on their test (22.2%; see Table 5).

The four most commonly endorsed reasons for *not* participating in the trial, among participants who declined to participate in the RCT Arm of the study (n = 17), were: concern that participation might have a negative impact on their exam performance (58.8%), not wanting to do the extra work involved (23.5%), strongly preferring the control condition (23.5%), and needing only one more research credit (as opposed to the two credits offered by participation in the trial; 17.6%).

Chi-square tests were conducted to determine any significant differences in endorsement rates for the reasons for enrolling or not enrolling, depending on participants' allocation to the PCT or RCT arm. Only one item showed a significant difference in endorsement: a disbelief that either group (music or standard testing) would help on the test was endorsed significantly more often for participants allocated to the RCT group, compared to the PCT group, $\chi^2(1) = 4.09$, $p = .043$.

Hypothesis 3

The analysis I conducted for the third hypothesis was modified slightly from the proposed method. I planned to use a MANOVA to test the hypothesis that participants who were matched by chance to their preferred treatment (G3 and G4), compared with those who were mismatched by chance to their preferred treatment (G5 and G6), would show more positive feelings toward the research project and researcher team, greater belief in treatment effectiveness (higher anticipated examination grade, less desperation for a good grade, lower test anxiety), less contamination, and more study session time and engagement with the possible moderation of treatment condition, such that participants assigned to treatment will have more positive outcomes than those assigned to the control condition. The dependent variables of contamination and the ten indices of

participant feelings toward the research project and the research team were excluded from the initial analysis. As proposed, contamination was assessed by asking participants what types of music they listened to while studying. Contamination was considered to occur if participants in the control condition reported listening to classical music while studying. Only five out of the 145 participants in the control condition (3%) reported listening to classical music. This variable was dropped from analysis. The ten indices of participant feelings toward participation were analyzed in a separate MANOVA, as they did not form a reliable scale and they were not used as a unitary scale in prior work (Wortman et al., 1976), making grouping them into one variable unadvisable.

Thus, the independent variables for the first MANOVA were matching (matched to preference vs. mismatched to preference) and condition (treatment vs. control), and the dependent variables were anticipated examination grade, desperation for a good grade, test anxiety, and study session time and engagement. There was no significant main effect of matching, Pillai's $F(5, 168) = .45$, $p = .811$, no main effect of condition, Pillai's $F(5, 168) = 1.14$, $p = .342$, and no interaction effect of matching by condition, Pillai's $F(5, 168) = .32$, $p = .901$.

The independent variables for the second MANOVA were matching (matched to preference vs. mismatched to preference) and condition (treatment vs. control), and the dependent variables were the ten indices of participant feelings toward the research project and research team. There was a significant main effect of matching, Pillai's $F(10, 181) = 2.74$, $p = .004$, no significant main effect of condition, Pillai's $F(10, 181) = 1.61$, $p = .106$, and a significant interaction effect of matching by condition, Pillai's $F(10, 181) = 2.03$, $p = .033$. Closer inspection of the univariate effects revealed a main effect of

matching for Positive Feelings, $F(1, 190) = 12.08$, $p = .001$ such that participants who were matched to their preferred treatment held more positive feelings about being in the study (see Figure 7), and an interaction effect of matching and condition, $F(1, 190) = 7.26$, $p = .008$ such that among participants who were mismatched, those who were mismatched to treatment held lower Positive Feelings ($M = 5.56$, $SE = .25$) as compared to those mismatched to control ($M = 6.83$, $SE = .21$; see Figure 8). For Regret, there was a main effect of matching, $F(1, 190) = 5.66$, $p = .018$, such that participants who were mismatched reported more regret about signing up for the project. For Anger there was a main effect of matching, $F(1, 190) = 6.72$, $p = .010$, such that participants who were mismatched reported more anger about being in the project. For Envy, there was a main effect of matching, $F(1, 190) = 18.04$, $p = .000$, such that participants who were mismatched reported more envy toward other participants in the project. The interaction approached significance, $F(1, 190) = 3.38$, $p = .068$, such that among participants who were in the treatment group, those who were mismatched were more envious ($M = 3.18$, $SE = .30$) as compared to those matched ($M = 2.43$, $SE =. 24$; see Figure 8). There was a main effect of matching for Project Useful, $F(1, 190) = 6.33$, $p = .013$, such that participants who were matched reported higher endorsement of the idea that the project would provide useful information. There were no main effects or interaction effects for Project Fair, Motivation, Respect Researchers, Researchers Concerned, or Project Worthwhile.

Assignment to Condition and Study Session Attendance

Approximately 31% of study participants attended study sessions. I conducted a chi-square test to determine whether participants were more likely to simply *attend* a study

session if assigned to a preferred condition. This analysis revealed no significant effect, $\chi^2(1) = .40$, $p = .529$.

Attrition

For reasons I was not able to assess, 20 participants (5.6%) did not complete the second assessment, and 37 (10.3%) did not complete the third assessment. I used two chi-square analyses to investigate whether participants were more likely to complete the second or the third online assessments if they were assigned to their preferred condition. This analysis revealed no significant effect for completion of the second assessment, $\chi^2(1) = 1.70$, $p = .192$, nor the third assessment, $\chi^2(1) = 2.50$, $p = .114$. Most participants who did complete Assessment 3 indicated in this assessment that they were willing to complete an additional questionnaire after their next exam (76.3%). Their response was not significantly related to whether they were matched to their preferred condition, $\chi^2(1) = .24$, $p = .621$.

Matching and Trial Outcomes (Examination Scores)

I conducted an ANCOVA to determine whether participants' scores on examination 2 were affected by whether they were matched to their preference and their condition assignment. Thus, the dependent variable in this analysis was examination 2 score, the two independent variables were matching and condition, and the covariate was examination 1 score. There was no significant main effect of matching, $F(1, 311) = .22$, $p = .644$, no main effect of condition, $F(1, 311) = .36$, $p = .549$, and no interaction of matching by condition, $F(1, 311) = .05$, $p = .821$.

Hypothesis 4

I conducted a MANOVA to determine whether participants who were matched to their preferred treatment by choice, compared with those matched by chance (G1 and G2 vs. G3 and G4) would show more positive feelings toward the research project and research team, greater belief in the effectiveness of treatment, more study session time and engagement, and less contamination; and whether this effect would be moderated by treatment condition, such that participants assigned to treatment would have more positive outcomes than those assigned to the control condition.

As in the analysis for Hypothesis 3, the variable contamination was dropped. In addition, because the indices of participant feelings toward participation did not form a reliable scale I analyzed these variables in a separate MANOVA.

Thus, for the first MANOVA, the independent variables were matching style (matched to preference by choice vs. matched to preference by chance) and condition (treatment vs. control) and the dependent variables were desperation for a good grade, anticipated grade, test anxiety, study session time and engagement. There was no main effect of matching style, Pillai's $F(5, 191) = .79$, $p = .557$, condition, Pillai's $F(5, 191) = 1.33$, $p = .252$, or their interaction, Pillai's $F(5, 191) = .66$, $p = .655$.

The independent variables for the second MANOVA were matching style (matched to preference by choice vs. matched to preference by chance) and condition (treatment vs. control), and the dependent variables were the ten indices of participant feelings toward the research project and research team. There was no main effect of matching style, Pillai's $F(10, 200) = 1.43$, $p = .168$, no main effect of condition, Pillai's $F(10, 200) =$

1.25, p = .262, and no interaction effect of matching style by condition, Pillai's F(10, 200) = .95, p = .493.

The Mozart Effect

I tested whether being assigned to the treatment group led to improvement in examination scores using an ANCOVA. The dependent variable was examination 2 score, the independent variable was condition assignment (treatment vs. control), and the covariate was examination 1 score. This effect was not significant, F(1, 313) = .399, p = .528.

Post Hoc Analyses

Revisiting Hypothesis 3, Pooling Data from Both Study Arms

Because the results of Hypothesis 4 indicated that there was no effect on the dependent measures based on whether participants were matched to their preference by choice or by chance, I repeated the analysis for Hypothesis 3, this time also including participants from the PCT (choice) arm of the study. The independent variables for the first MANOVA were matching (matched to preference vs. mismatched to preference) and condition (treatment vs. control), and the dependent variables were desperation for a good grade, anticipated grade, test anxiety, and study session time and engagement. There was no main effect of matching, Pillai's F(3, 278) = .81, p =.491, no main effect of condition, Pillai's F(3, 278) = .92, p =.431, and no interaction of matching by condition, Pillai's F(3, 278) = .21, p = .946.

The independent variables for the second MANOVA were matching (matched to preference vs. mismatched to preference) and condition (treatment vs. control), and the dependent variables were the ten indices of participant feelings toward the research project and research team. There was a main effect of matching, Pillai's $F(10, 296) = 3.81$, $p = .000$, a main effect of condition, Pillai's $F(10, 296) = 2.45$, $p = .008$, and an interaction of matching by condition, Pillai's $F(10, 296) = 6.67$, $p = .004$. In looking at the univariate effects, the variable Positive Feelings had a main effect of matching $F(1, 305) = 22.87$, $p = .000$, such that participants matched to their preference had more positive feelings about participation (see Figure 9), a main effect of condition $F(1, 305) = 6.12$, $p = .014$, such that participants in the control group held more positive feelings about participation (see Figure 10), and an interaction of matching by condition $F(1, 305) = 14.93$, $p = .000$ such that among participants who were mismatched to preference, those who were in the treatment group held less Positive Feelings ($M = 5.56$, $SE = .25$) as compared with those in the control group ($M = 6.83$, $SE = .20$; see Figure 11). Regret had a main effect of matching $F(1, 305) = 10.85$, $p = .001$, such that participants who were mismatched to preference held higher feelings of regret, a main effect of condition $F(1, 305) = 7.89$, $p = .005$, such that participants in the treatment group held higher feelings of regret, and an interaction of matching by condition $F(1, 305) = 3.91$, $p = .049$, such that among participants who were mismatched to preference, those who were in the treatment group held more regret ($M = 3.36$, $SE = .26$) as compared with those in the control group ($M = 2.38$, $SE = .21$; see Figure 11). Anger had a main effect of matching $F(1, 305) = 11.53$, $p = .001$, such that participants who were mismatched to preference showed more anger about the way the study was conducted. Project Fair had a main effect of matching

$F(1, 305) = 5.87$, $p = .016$, such that participants matched to preference showed greater levels of belief that the project was fair to all participants. Envy had a main effect of matching $F(1, 305) = 26.03$, $p = .000$, such that participants mismatched to preference showed more envy toward other participants in the study. Motivation had a main effect of matching $F(1, 305) = 5.62$, $p = .018$, such that those matched to preference showed more motivation to participate in the project, and a main effect of condition $F(1, 305) = 4.27$, $p = .040$, such that participants in the control condition showed more motivation to participate in the project. Project Worthwhile had a main effect of matching $F(1, 305) = 6.40$, $p = .012$, such that participants who were matched to preference showed greater belief that the project was worthwhile and important. Project Useful had a main effect of matching $F(1, 305) = 8.70$, $p = .003$, such that participants matched to preference showed greater belief that the project would provide useful information and benefit science. There were no main effects or interaction effects for Respect Researchers or Researchers Concerned (p's .072 and .245, respectively).

Preference Effects

I modeled a preference effect analysis based on that conducted by Long et al. (2008, p. 477). As in their analysis, I focused on adherence (minutes spent in study sessions and engagement in study sessions) and trial outcome (examination 2 score). To replicate their analysis, I first separated the data into two groups based on condition preference (treatment vs. control), and conducted first an independent means t-test with participants who preferred the treatment using the dependent variable of examination 2 score, and the independent variable of condition assignment (see Table 6). I replicated this analysis then with the participants who preferred the control. Once the treatment effects were found for

each of these preference groups, I then calculated the difference between the two effects to find the preference effect (to find the significance of the preference effect I found significance of the interaction, calculated with an ANOVA looking at the interaction of preference (treatment vs. control) and condition assignment (treatment vs. control) on examination 2 score. This process was then repeated using the dependent variable of adherence (minutes spent in the study sessions), and then repeated using the dependent variable of adherence (engagement in the study sessions).

The analysis with the dependent variable of examination 2 score revealed no significant treatment effects for either participants with a preference of the treatment group (p = .914) or the control group (p = .155), and no preference effect (p = .761; see Table 6). The analysis with the dependent variable of adherence (minutes spent in the study session) revealed a significant treatment effect for participants with a preference of the treatment group, such that participants who preferred the treatment group and were assigned to the treatment group spent more minutes in the study sessions (M = 24.76, SD = 41.07), compared with those who preferred the treatment group and were assigned to the control group (M = 14.53, SD = 30.73, F[131] = 9.06, p = .003), and no significant treatment effect for participants with a preference of the control group (p = .333). However, there was no significant preference effect (p = .532). The analysis with the dependent variable of adherence (engagement in the study session) revealed no significant treatment effects for either participants with a preference of the treatment group (p = .614) or the control group (p = .695), and there was no significant preference effect (p = .498).

Study Session Time and Engagement

Visual inspection of the pattern of means by group assignment (G1 through G6) suggested a possible main effect of condition for the dependent variable of adherence (minutes spent in the study sessions; see Figure 12). Thus, I conducted two ANOVAs to investigate the interaction of matching and condition on both measures of adherence: minutes spent in the study session (Figure 12) and engagement in the study sessions (see Figure 13). The independent variables were matching (matched vs. mismatched) and condition (treatment vs. control). The analysis with the dependent variable of minutes spent in the study session revealed no main effect of matching $F(1, 329) = .42$, $p = .520$, a significant main effect of condition $F(1, 329) = 4.74$, $p = .030$ such that those assigned to the treatment group spent more time in the study sessions as compared to those in the control group, and no interaction of matching by condition $F(1, 329) = .33$, $p = .569$.

Strength of Participant Preferences and Reactions to Randomization

Slightly less than half (41.4%) of the study participants indicated a strong (compared to weak) preference for condition. I ran several analyses investigating the effect of strength of preference on outcome variables.

Strength of Preference and Matching

I conducted a MANOVA, exploring the main effects and interactions effects of Strength of Preference and Matching on the ten indices of Participant Feelings. There was a main effect of matching, $F(10, 296) = 4.83$, $p = .000$, no main effect of preference strength, $F(10, 296) = 1.32$, $p = .220$, and an interaction of matching by preference strength, $F(10, 296) = 2.20$, $p = .018$ (see Figure 14).

Univariate tests indicated that, for the main effect of matching, there was a significant effect on Positive Feelings, $F(1, 305) = 23.28$, $p = .000$, Regret $F(1, 305) = 11.28$, $p = .001$, Anger, $F(1, 305) = 13.71$, $p = .000$, Project Fair, $F(1, 305) = 17.02$, $p = .023$, Envy, $F(1, 305) = 36.10$, $p = .000$, Motivation, $F(1, 305) = 4.87$, $p = .028$, Project Worthwhile, $F(1, 305) = 4.47$, $p = .035$, and Project Useful, $F(1, 305) = 7.49$, $p = .007$. For the interaction, there was a significant effect on Positive Feelings $F(1, 305) = 6.21$, $p = .013$, such that, among those with strong preferences, those matched reported more Positive Feelings ($M = 7.45$, $SE = .17$) compared to those mismatched ($M = 6.10$, $SE = .25$; see Figure 14); Regret, $F(1, 305) = 10.417$, $p = .001$, such that, among those with strong preferences, those mismatched reported the most regret, Anger, $F(1, 305) = 9.80$, $p = .002$, such that, among those with strong preferences, those mismatched reported the most anger, and Envy, $F(1, 305) = 9.00$, $p = .003$, such that among those with strong preferences, those mismatched reported the most envy toward other participants.

Hypothesis 3, Selecting Participants with Strong Preferences

I re-explored Hypothesis 3, selecting only those participants who indicated a strong preference. Thus, I ran two MANOVAs. The independent variables for the first MANOVA were matching (matched to preference vs. mismatched to preference) and condition (treatment vs. control), and the dependent variables were desperation for a good grade, anticipated grade, test anxiety, and study session time and engagement. There was no main effect of matching, Pillai's Trace $F(5, 107) = .68$, $p = .637$, no main effect of condition, Pillai's Trace $F(5, 107) = .27$, $p = .930$, and no interaction of matching by condition, Pillai's Trace $F(5, 107) = .51$, $p = .769$.

The independent variables for the second MANOVA were matching (matched to preference vs. mismatched to preference) and condition (treatment vs. control), and the dependent variables were the ten indices of participant feelings toward the research project and research team. There was a main effect of matching, Pillai's $F(10, 113) = 3.90$, $p = .000$ (see Figure 15), no main effect of condition, Pillai's $F(10, 113) = 1.17$, $p = .318$, and an interaction of matching by condition, Pillai's $F(10, 113) = 2.82$, $p = .004$ (see Figure 16). Univariate tests indicated that, for the main effect of matching, there was a significant effect on Positive Feelings, $F(1, 122) = 19.59$, $p = .000$, Regret, $F(1, 122) = 20.41$, $p = .000$, Anger, $F(1, 122) = 24.16$, $p = .000$, Envy, $F(1, 122) = 23.70$, $p = .000$, Motivation, $F(1, 122) = 5.33$, $p = .023$, and Project Useful, $F(1, 122) = 4.27$, $p = .041$. For the interaction, there was a significant effect on Positive Feelings $F(1, 122) = 10.03$, $p = .002$, such that, among those in the treatment condition, those matched reported more Positive Feelings ($M = 7.70$, $SE = .20$) as compared with those mismatched ($M = 7.70$, $SE = .20$; see Figure 16), Regret, $F(1, 122) = 4.52$, $p = .036$, such that, among those in the treatment condition, those matched reported less Regret ($M = 1.98$, $SE = .20$) as compared to those mismatched ($M = 4.23$, $SE = .45$), Anger, $F(1, 122) = 4.13$, $p = .044$, such that, among those in the treatment group, those matched reported less Anger ($M = 2.04$, $SE = .20$) as compared with those mismatched ($M = 4.31$, $SE = .44$); and Project Fair, $F(1, 122) = 7.88$, $p = .006$, such that, among those in the treatment group, those matched to preference reported the more endorsement that the project was fair for all participants ($M = 7.05$, $SE = .24$) as compared to those mismatched to preference ($M = 5.31$, $SE = .52$).

DISCUSSION

The literature on human participation in research suggests that there may be biases created by randomizing human participants that filter into two categories: the bias from some participants' unwillingness to enter the study, and the bias created by psychological artifacts resulting from randomization to an undesired treatment. I sought to investigate both of these biases within the framework of this study, and thus developed a trial design that would allow me to obtain some data from potential participants uninterested in enrolling in the actual trial, and also allow me to compare participants who were matched versus mismatched to their preferred condition within a RCT.

The results of this study suggest that participants, particularly those with strong preferences for condition, have more negative feelings toward their experience as a research participant if they are mismatched to receive their non-preferred condition, as compared with participants who are matched to receive their preferred condition. This study did not find that participants who were mismatched to receive a non-preferred condition had poorer belief in the effectiveness of treatment, adherence, engagement, or greater trial attrition, or contamination, as compared with participants who were matched to their preferred treatment.

Preferences were stable across time, as assessed in this study. Participants' preference for condition at the time of enrollment was highly correlated with preference after the second examination (third assessment). It should be noted that this does not pick up possible fluctuation in preference during other time points in the study, and that

participants reported their post-trial preference after their examination but before receiving their examination scores.

Hypotheses 1 and 2 delved into understanding the first potential bias, self-selection into trials. The results from the investigation into this first bias were not interpretable. Only one-quarter of eligible participants signed up for the study at all, and among those, 93% enrolled into the trial. This left a very small number of participants in the "unwilling" groups. According to the results of the analyses for Hypothesis 1, which focused only on participants in the randomized arm of the study, there were no differences in risk taking, openness to experiences, or education level, between participants who decided to enroll and those who decided not to enroll. However, with such uneven group *n*'s, these results are difficult to interpret. Hypothesis 2 found no difference in enrollment rates between participants assigned to the preference arm of the trial, and those assigned to the randomized arm of the trial. Again, with such a low number of participants in these unwilling groups, interpretation of this result should be considered with care.

Reasons for enrolling in the trial were the same for both PCT and RCT arms – with the main reasons being that the potential participants liked the concept of the study and needed research credits for their psychology course. Interestingly, both groups also indicated that they felt participation would positively impact their examination performance. Reasons for deciding not to enroll were also similar across PCT and RCT arms. The most commonly endorsed reason was concern that participation would have a negative impact on examination performance, along with not wanting to do the extra work involved, and needing only one more research credit for their psychology class.

Some non-participants in the PCT arm reported the reason that they believed neither treatment condition would help them on their examination. Some non-participants in the RCT arm endorsed the reason of preferring the control condition.

Hypotheses 3 and 4 investigated the second potential bias. According to the results from Hypothesis 3, regardless of whether results were for participants only in the RCT arm of the trial, or pooled for both RCT and PCT arms of the trial, participants mismatched to their preferred condition had significantly more negative feelings about participating in the research. However, being mismatched to preference did not significantly affect belief that the treatment would work, adherence or engagement in the trial, nor did it affect examination scores. In addition, being mismatched to preference did not affect the likelihood that a participant would attend a study session at all (regardless of the amount of time spent in the session). According to Hypothesis 4, among participants who were assigned their preferred treatment, being matched by choice (as in a PCT) compared with by chance (as in a RCT) did not affect their feelings about being involved in the trial, belief in the treatment, adherence or engagement, or examination grade.

The advances made by Long et al. (2008) of incorporating preference effects in the interpretation of nonrandomized trial designs are fairly new to the field, and replicating part of their procedure was an exciting addition to the original hypotheses for this study. Although I expected to see preference effects in this sample (that being mismatched to preference would affect outcomes), the results indicated no preference effects among participants in this trial. There was a treatment effect, however, based on this particular analysis. Among participants who preferred the treatment group, those who were

assigned to the treatment group spent more time in study sessions as compared with those assigned to the control group.

Finally, there were significant effects on participants' reactions to being randomized regarding their feelings toward being involved in their project, based on the strength of their preference. Though the effects on participant feelings were strong, it was also the case that strength of preference did not affect other outcome variables including belief in the treatment, adherence, or engagement. It should be noted here, that the analyses for which only participants with strong preferences were selected were underpowered (comprising only 41% of the sample).

Four important issues should be further discussed. First, that few study participants chose to not enroll in the trial itself and only complete the baseline questionnaire, leaving very few participants in the "unwilling" groups (G7 and G8). Second, participants who did enroll in the trial had different emotional reactions toward their experience depending on whether they were matched to their preferred treatment or were mismatched and received their non-preferred treatment. Third, participants' emotional reactions regarding their experience did not significantly affect their participation nor the trial outcomes. Fourth, it made little difference whether participants were matched by choice (as in a PCT) or by chance (as in a RCT).

The First Potential Bias: Self-Selection and Threats to External Validity

Approximately 25% of eligible participants signed up for the study. Among those, most decided to enroll in the trial itself, leaving a very small number of subjects in the

unwilling subgroups. This makes confident interpretation of Hypotheses 1 and 2 unadvisable.

Ethical Issues and Implications Regarding Human Participation

That so few people failed to enroll in the trial, along with such a high percentage preferring the treatment condition (preferred to the control in a 2:1 ratio), mirrors findings from other studies about study accrual (e.g., Harrison et al., 2007; Llewellyn-Thomas et al., 1991). It appears that persons not attracted to the treatment group avoid interacting with the study altogether. In other words, it may be an interest in receiving the treatment that motivates many participants to enroll in a study. Although this appears to be an obvious explanation, the concept is not given proper consideration by researchers who emphasize clinical equipoise (that idea that the medical field is uncertain as to which treatment would offer more benefit) as a justification for the use of randomization (Djulbegovic et al., 2003). Equipoise is considered the cornerstone in the argument of why random allocation to condition is ethical (F. G. Miller & Brody, 2003). However, if participants enter a trial with a belief that one treatment may be more effective over another (presumably seen in participants' preferences), the concept of equipoise that exists from the medical perspective may not exist from the patients' perspective (Moyer & Floyd, 2009). In addition, according to the results of this dissertation, receiving a non-preferred treatment may create feelings of anger, regret and envy (resentful demoralization) which could indicate that randomization be unethical, particularly for patients hoping for potentially life-saving treatments.

The severity of such selective enrollment as seen in this study and others (Harrison et al., 2007; Llewellyn-Thomas et al., 1991) and the qualitative evidence that people do not

really understand the randomization process in the clinical setting (Featherstone & Donovan, 1998; Snowdon et al., 1999), brings up some ethical considerations regarding recruitment of participants to randomized studies. Literature on the ethics of clinical trials posits that potential participants may not understand the difference between clinical practice and clinical research, the "therapeutic misconception" (F. G. Miller & Brody, 2003), and may not understand that within the context of a trial (clinical research) their physician does not exercise any judgment about which treatment may suit the patient best. In addition, the literature describes how participants do not really understand what *randomization* truly means (Morreim, 2009). As Featherstone and Donovan point out in their qualitative study (1998), participants understand that the randomization process is like chance, but also develop lay theories to interpret and understand their experience. Thus, if participants appear to understand euphemisms for randomization such as "flipping a coin" or "drawing numbers out of a hat", it may not be indicative that they are able to really apply this process to their own experience in clinical trials (Brody & Childress, 2009).

In attempt to remain as ethical as possible, two main suggestions are made in the literature dedicated toward research and ethics (Appelbaum, 2002; Appelbaum & Lidz, 2006; Brody & Childress, 2009; Morreim, 2009; Shamoo, 2008): firstly, researchers should be certain that participants understand the distinction between clinical practice and clinical research; and secondly, researchers should be certain that each and every participant understands what *randomization* means, as applied to their personal involvement in a randomized trial.

The Second Potential Bias: Treatment Preferences and Threats to Internal Validity

Participant Feelings about Participation and Matching to Preference

Whether participants were matched to their preferred treatment or mismatched to receive their non-preferred treatment influenced several indices of participant feelings about participation. All of these outcome variables were in the expected direction, with participants who were mismatched to preference experiencing more negative feelings about participation compared with those who were matched to preference. This occurred for almost every aspect of the study about which we inquired, with the exception of items focused on the researchers. That is, significantly more negative feelings were found for items about participants feelings *toward the project* ("I think the objective of this project is worthwhile and important;" "I think that the project will provide some useful information"), toward *their own participation* ("I feel good about being in the project;" "I feel motivated to help make the project successful;" "I regret signing up for the project"), and toward their *comparison with other participants* ("I feel angry about the way the project is being conducted;" "I feel envious toward others in the project;" "I feel that the project is fair to all participants"), but not toward the researchers themselves ("I believe the people who are running this project are concerned about me;" "I respect the people who are running the project").

That participants in an undesirable condition held more negative feelings mirrors findings by Wortman et al. (1976). This study is, however, the first study to investigate the effect of matching to preference among participants in a randomized controlled trial setting.

Participant Feelings about Participation and Treatment Condition

In looking at the main effect of treatment condition on the ten indices of participant feelings about participation, it is interesting to note that these effects only surfaced when data from the PCT arm and RCT arms were pooled, and that they were in the opposite direction as was predicted (with the exception of Envy). That is, participants in the treatment group were *more negative* about their feelings toward participation than were participants in the control group (see Figure 10). Considering that participants preferred the treatment condition to the control condition both before and after the trial, this finding may be primarily driven by a stronger effect among those participants who preferred the control condition but were mismatched to receive the treatment condition (see Figure 11). Although not what I would predict for a clinical trial using a patient population, it may make sense in the context of this particular trial. College students *elect* to be students, and recognize that taking examinations is a product of life as a student. Participants in clinical trials do not choose to have illness or pathology. By electing to be students, our participants have essentially elected from the beginning of their academic careers to be satisfied with conditions identical to what was considered to be the control condition of the study. Because of this, some participants may perceive the treatment condition to be more of a hassle than a benefit.

Outcomes Not Affected By Randomization

It was projected that, if participants had adverse reactions to being assigned a non-preferred treatment, there could be effects on outcome measures relevant to the trial itself (i.e., the internal validity of the trial could be compromised). In this particular study, there was no significant effect of matching (matched to preference vs. mismatched to

preference) or of condition (treatment vs. control) on some of the reactions to randomization (Hypothesis 3). These included belief in the effectiveness of treatment, study session time and engagement, and examination scores. This may be a result of the nature of the study design and not necessarily reflective of what may happen in a true clinical trial. For instance, students taking exams are motivated to do well on their exams regardless of participation in a trial, and they have access to the real treatment that would influence their examination outcomes (actual studying) regardless of condition assignment in the trial. Inspecting this further, one finds that the amount of time students spent studying for their second examination was significantly correlated with their grade on the exam, $r = .14$, $p = .009$, one-tailed. It remains unclear whether these results would generalize to clinical trials, where participants and potential participants may be more invested in having access to a particular treatment condition.

Matching By Choice or By Chance

I also investigated whether matching participants to their preferred treatment by choice as opposed to being matched by chance differentially influenced feelings toward participation as well as outcome variables including belief in treatment, and examination scores. These analyses were not significant, indicating that it is simply the matching itself (match vs. mismatch) and not the style of match (by choice vs. by chance) that affects participant feelings about participation. This result should be taken with caution, as it may simply reflect that the study manipulation of choice versus chance was too subtle. That is, participants may not realize that they were given their preferred treatment or that they were "luckily" randomized to receive it. This manipulation occurred in an email sent to participants (see Appendix C).

Study Limitations and Strengths

The greatest limitation of this study was the inability to obtain information from students who did not enroll into the trial itself, the "non-participants." Although this leaves unanswered the question of what variables differ between eligible participants who decide to enroll and eligible participants who decide not to enroll, it does shed light on the nature of recruitment and offers suggestion about possible solutions to more successfully recruit representative samples.

In this study, and reflective of findings from other studies (e.g., Harrison et al., 2007; Llewellyn-Thomas et al., 1991), a majority of participants preferred the treatment group to the control group. The external validity of studies that recruit only participants interested in one particular treatment is severely compromised. Velicer and colleagues were able to shed some light on this threat to validity by analyzing differences between participants and non-participants. They designed a study in which they first contacted all members of a large medical center for an interview and then (after interviewing them) invited smoking members to participate in an intervention (Velicer et al., 2005). They found that the two groups differed among several variables such as age, marital status, and regarding stage-of-change for smoking cessation. Considering this finding, along with documented evidence of poor enrollment rates, researchers may look into different methods of recruitment for behavioral medicine and other psychological and medical studies. For instance, flyers and other recruitment announcements could be adjusted to appeal to a wider population than only those who are attracted to specific treatments. A flyer advertising a study on "mindfulness meditation for irritable bowel syndrome" will

recruit a much less representative sample than a flyer advertising a study on "treatments for irritable bowel syndrome."

This study is also limited in terms of how well some aspects may generalize to clinical trials. Because this study was the first to investigate participant feelings about randomization, it was advisable to first test a non-patient sample, however, extrapolation from undergraduate samples is controversial (Coulter, 1986; D. O. Sears, 1986). Although we might expect the pattern of results to be similar across other populations (particularly regarding the negative reactions to receiving a non-preferred treatment), it is unclear what the magnitude of the effect would be.

Regarding generalizability, it could be argued that the real treatment for examination grades (my trial outcome measure) is class attendance and simple studying. Studying for one's exam would certainly account for more variance in examination grade than listening to music by Mozart. Studying is a "treatment" for which all participants in my study had access – thus, any failure to find differences in examination grade between matched and mismatched participants may not reflect what could happen in true clinical trials for which participants have no other access to treatment.

It is also important to note here that, although some publications report negative participant responses (e.g., Shapiro et al., 2002), these are often the result of serendipitous findings. The RCT itself has been the subject of investigation in a limited number of studies, and participant responses to being research subjects has had little direct investigation (Moyer, in press). This study was the first to systematically investigate participant reactions to randomization in a RCT for which they could not be blinded to condition, required active participation and engagement, and for which,

importantly, participants could develop condition preferences. This study provides the foundation needed to now apply these empirical questions to patient populations.

Directions for Future Research

In this study, participants were not patients with illness in a clinical trial. Although it was important to use a non-clinical population for this first systematic investigation of participant reactions to randomization in a RCT, this also means that some results may not generalize to a patient population. The answers of importance to medical and psychological researchers will be best addressed by applying the methods used for this study to a clinical trial. This is a unique opportunity for collaboration among clinicians, psychologists, and methodologists to take an actual clinical trial under investigation, to determine the effects of participant reactions to randomization in a field setting. For example, it would be feasible to apply the Wennberg design (Wennberg et al., 1993) used in the present study to a clinical trial investigating the effect of exercise on heart disease. This would allow investigation of a true clinical trial for which participants can not be blinded to condition, require active participation and engagement, and for which, importantly, participants can develop condition preference. This type of investigation would resolve questions about the generalizablity of the present study's results to clinical populations (e.g., do treatment or control participants report more negative feelings about participation in the research study; does randomization to a non-preferred condition affect adherence and outcomes).

The topic matter covered within this dissertation also lends itself well to two other related areas of research. First, it is apparent that further understanding of alternative designs to the RCT (e.g., the Wennberg design, the Rücker design, the Partially Randomized Preference Trial) is needed. Specifically, more research should be carried out to develop methods of analyzing data gathered from such designs. Second, the field of study regarding the ethics of using human subjects has posed as yet unanswered questions about the most ethical ways of explaining the randomization process to participants (e.g., Brody & Childress, 2009; Morreim, 2009). The low enrollment rates into trials, the confusion expressed in qualitative studies by participants, and the evidence that some physicians manipulate the randomization process before allocating their patients, all speak to the underlying ethical issues about randomizing human research participants. Further study of the ethics related to randomization can help future researchers develop methods of randomization that help participants clearly understand randomization and avoid negative reactions to the process (e.g., Goldberg & Kiernan, 2005)

CONCLUSION

Previous articles have noted the limitations of using RCTs with human research participants, particularly when they hold preferences and cannot be blinded to conditions, when treatments require engagement and effort on the participant's behalf, and when trial treatments are not available elsewhere. Yet, there was little understanding of what a participant's psychological experience is like in such trials. The results of this study

indicate that it may not matter if participants are matched to their preference by choice or by chance, but being mismatched to one's preference *does* impact one's feelings about being involved in the trial. In this particular study, having more negative feelings about participation did not accompany compromised trial adherence or other outcomes, although it remains to be seen whether this would be the case in trials using patient populations.

References

Adair, J. G. (1973). *The human subject: The social psychology of the psychological experiment*. Boston: Little, Brown and Company.

Aickin, M. (2002). Beyond randomization. *Journal of Alternative & Complementary Medicine, 8*, 765-772.

Appelbaum, P. S. (2002). Clarifying the ethics of clinical research: A path toward avoiding the therapeutic misconception. *The American Journal of Bioethics, 2*, 22-23.

Appelbaum, P. S., & Lidz, C. W. (2006). Clinical ethics versus clinical research. *The American Journal of Bioethics, 6*, 53-55.

Benson, A. B., Pregler, J. P., Bean, J. A., Rademaker, A. W., Eshler, B., & Anderson, K. (1991). Oncologists' reluctance to accrue patients onto clinical trials: An Illinois Cancer Center study. *Journal of Clinical Oncology, 9*, 2067-2075.

Bradley, C. (1993). Designing medical and educational intervention studies. A review of some alternatives to conventional randomized controlled trials. *Diabetes Care, 16*, 509-518.

Bradley, C. (1997). Psychological issues in clinical trial design. *The Irish Journal of Psychology, 18*, 67-87.

Brewin, C. R., & Bradley, C. (1989). Patient preferences and randomised clinical trials. *British Medical Journal, 299*, 313-315.

Brody, H., & Childress, A. M. (2009). Understanding randomization: Helpful strategies. *The American Journal of Bioethics, 9*, 14-15.

Chambless, D. L., & Hollon, S. D. (1998). Defining empirically supported therapies. *Journal of Consulting and Clinical Psychology, 66*, 7-18.

Collyar, D. E. (2000). The value of clinical trials from a patient perspective. *Breast Journal, 6*, 310-314.

Cook, T., & Campbell, D. T. (1979). *Quasi-experimentation: Design and analysis issues for field settings*. Chicago, IL: Rand McNally.

Corrigan, P. W., & Salzer, M. S. (2003). The conflict between random assignment and treatment preference: Implications for internal validity. *Evaluation and Program Planning, 26*, 109-121.

Cottin, V., Arpin, D., Lasset, C., Cordier, J. F., Brune, J., Chauvin, F., et al. (1999). Small-cell lung cancer: Patients included in clinical trials are not representative of the patient population as a whole. *Annals of Oncology, 10*, 809-815.

Coulter, X. (1986). Academic value of research participation by undergraduates. *American Psychologist, 41*, 317.

Courneya, K. S., Friedenreich, C. M., Sela, R. A., Quinney, H. A., Rhodes, R. E., & Handman, M. (2003). The group psychotherapy and home-based physical exercise (group-hope) trial in cancer survivors: Physical fitness and quality of life outcomes. *Psycho-Oncology, 12*, 357-374.

Cox, D. E., & Sipprelle, C. N. (1971). Coercion in participation as a research subject. *American Psychologist, 26*, 726-728.

Cox, K. (1999). Researching research: Patients' experiences of participation in phase I and II anti-cancer drug trials. *European Journal of Oncology Nursing, 3*, 143-152.

Cox, K., & McGarry, J. (2003). Why patients don't take part in cancer clinical trials: An overview of the literature. *European Journal of Cancer Care, 12*, 114-122.

Crncec, R., Wilson, S. J., & Prior, M. (2006). No evidence for the Mozart effect in children. *Music Perception, 23*, 305-317.

Davidson, K. W., Goldstein, M., Kaplan, R. M., Kaufmann, P. G., Knatterud, G. L., Orleans, C. T., et al. (2003). Evidence-based behavioral medicine: What is it and how do we achieve it? *Annals of Behavioral Medicine, 26*, 161-171.

de C Williams, A. C., Nicholas, M. K., Richardson, P. H., Pither, C. E., & Fernandes, J. (1999). Generalizing from a controlled trial: The effects of patient preference versus randomization on the outcome of inpatient versus outpatient chronic pain management. *Pain, 83*, 57-65.

Djulbegovic, B., Cantor, A., & Clarke, M. (2003). The importance of preservation of the ethical principle of equipoise in the design of clinical trials: Relative impact of the methodological quality domains on the treatment effect in randomized controlled trials. *Accountability in Research, 10*, 301-315.

Elwyn, G., Edwards, A., Kinnersley, P., & Grol, R. (2000). Shared decision making and the concept of equipoise: the competences of involving patients in healthcare choices. *The British Journal of General Practice, 50*, 892-899.

Featherstone, K., & Donovan, J. L. (1998). Random allocation or allocation at random? Patients' perspectives of participation in a randomised controlled trial. *British Medical Journal, 317*, 1177-1180.

Feine, J. S., Awad, M. A., & Lund, J. P. (1998). The impact of patient preference on the design and interpretation of clinical trials. *Community Dentistry and Oral Epidemiology, 26*, 70-74.

Goldberg, J. H., & Kiernan, M. (2005). Innovative techniques to address retention in a behavioral weight-loss trial. *Health Education Research, 20*, 439-447.

Harrison, J. D., Solomon, M. J., Young, J. M., Meagher, A., Hruby, G., Salkeld, G., et al. (2007). Surgical and oncology trials for rectal cancer: Who will participate? *Surgery, 142*, 94-101.

Helgeson, V. S., Cohen, S., Schulz, R., & Yasko, J. (2000). Group support interventions for women with breast cancer: Who benefits from what? *Health Psychology, 19*, 107-114.

Hong, E. (1998). Differential stability of individual differences in state and trait test anxiety. *Learning and Individual Differences, 10*, 51-69.

Hui, K. (2006). Mozart effect in preschool children? *Early Child Development and Care, 176*, 411-419.

Jadad, A. R., & Rennie, D. (1998). The randomized controlled trial gets a middle-aged checkup. *The Journal of the American Medical Association, 279*, 319-320.

Janevic, M. R., Janz, N. K., Dodge, J. A., Lin, X., Pan, W., Sinco, B. R., et al. (2003). The role of choice in health education intervention trials: A review and case study. *Social Science & Medicine, 56*, 1581-1592.

Jaušovec, N., Jaušovec, K., & Gerlic, I. (2006). The influence of Mozart's music on brain activity in the process of learning. *Clinical Neurophysiology, 117*, 2703-2714.

John, O. P., & Srivastava, S. (1999). The Big Five Trait taxonomy: History, measurement, and theoretical perspectives. In L. A. Pervin & O. P. John (Eds.), *Handbook of personality: Theory and research (2nd ed.).* (pp. 102-138). New York: Guilford Press.

Krause, M. S., & Howard, K. I. (2003). What random assignment does and does not do. *Journal of Clinical Psychology, 59*, 751-766.

Llewellyn-Thomas, H. A., McGreal, M. J., Thiel, E. C., Fine, S., & Erlichman, C. (1991). Patients' willingness to enter clinical trials: Measuring the association with perceived benefit and preference for decision participation. *Social Science & Medicine, 32*, 35-42.

Lohr, K. N., & Carey, T. S. (1999). Assessing "best evidence": Issues in grading the quality of studies for systematic reviews. *The Joint Commission Journal on Quality Improvement, 25*, 470-479.

Long, Q., Little, R. J., & Lin, X. (2008). Causal inference in hybrid intervention trials involving treatment choice. *Journal of the American Statistical Association, 103,* 474-484.

Marquis, D. (1986). An argument that all prerandomized clinical trials are unethical. *The Journal of Medicine and Philosophy, 11*, 367-383.

Miller, B. A., Pokorny, A. D., Valles, J., & Cleveland, S. E. (1970). Biased sampling in alcoholism treatment research. *Quarterly Journal of Studies on Alcohol, 31*, 97-107.

Miller, F. G., & Brody, H. (2003). A critique of clinical equipoise: Therapeutic misconception in the ethics of clinical trials. *Hastings Center Report, 33*, 19-28.

Mock, V., Pickett, M., Ropka, M. E., Muscari Lin, E., Stewart, K. J., Rhodes, V. A., et al. (2001). Fatigue and quality of life outcomes of exercise during cancer treatment. *Cancer Practice, 9*, 119-127.

Morreim, H. (2009). The dirty little truth: We want them to understand, but not really... *The American Journal of Bioethics, 9*, 9-11.

Moyer, A. (in press). Psychomethodology: the psychology of human participation in science. *Journal of Psychology of Science and Technology*.

Moyer, A., & Floyd, A. H. (2009). Equipoise may be in the eye of the beholder. *The American Journal of Bioethics, 9*, 21-22.

Penman, D. T., Holland, J. C., Bahna, G. F., Morrow, G., Schmale, A. H., Derogatis, L. R., et al. (1984). Informed consent for investigational chemotherapy: Patients' and physicians' perceptions. *Journal of Clinical Oncology, 2*, 849-855.

Pocock, S. J. (1983). *Clinical trials: A practical approach*. Chichester, UK: Wiley.

Rauscher, F. H., Shaw, G. L., & Ky, C. N. (1993). Music and spatial task performance. *Nature, 365*, 611 - 611.

Rodenhuis, S., van den Heuvel, W. J., Annyas, A. A., Koops, H. S., Sleijfer, D. T., & Mulder, N. H. (1984). Patient motivation and informed consent in a phase I study of an anticancer agent. *European Journal of Cancer & Clinical Oncology, 20*, 457-462.

Rücker, G. (1989). A two-stage trial design for testing treatment, self-selection and treatment preference effects. *Statistics in Medicine, 8*, 477-485.

Schellenberg, E. G., Nakata, T., Hunter, P. G., & Tamoto, S. (2007). Exposure to music and cognitive performance: Tests of children and adults. *Psychology of Music, 35*, 5-19.

Schulz, K. F. (1995). Subverting randomization in controlled trials. *The Journal of the American Medical Association, 274*, 1456-1458.

Sears, D. O. (1986). College sophomores in the laboratory: Influences of a narrow data base on social psychology's view of human nature. *Journal of Personality and Social Psychology, 51*, 515-530.

Sears, S. R., Stanton, A. L., Kwan, L., Krupnick, J. L., Rowland, J. H., Meyerowitz, B. E., et al. (2003). Recruitment and retention challenges in breast cancer survivorship research: Results from a multisite, randomized intervention trial in women with early stage breast cancer. *Cancer Epidemiology Biomarkers & Prevention, 12*, 1087-1090.

Shadish, W. R., Clark, M. H., & Steiner, P. M. (2008). Can nonrandomized experiments yield accurate answers? A randomized experiment comparing random to nonrandom assignment. *Journal of the American Statistical Association, 103*, 1334-1343.

Shamoo, A. E. (2008). The myth of equipoise in phase I clinical trials. *Bioethics, 10*, 254.

Shapiro, S. L., Figueredo, A. J., Caspi, O., Schwartz, G. E., Bootzin, R. R., Lopez, A. M., et al. (2002). Going quasi: The premature disclosure effect in a randomized clinical trial. *Journal of Behavioral Medicine, 25*, 605-621.

Snowdon, C., Elbourne, D., & Garcia, J. (1999). Zelen randomization: Attitudes of parents participating in a neonatal clinical trial. *Controlled Clinical Trials, 20*, 149-171.

Spielberger, C. D. (1980). *Test Anxiety Inventory: Preliminary professional manual*. Palo Alto, CA: Consulting Psychologists Press.

TenHave, T. R., Coyne, J., Salzer, M., & Katz, I. (2003). Research to improve the quality of care for depression: alternatives to the simple randomized clinical trial. *General Hospital Psychiatry, 25*, 115-123.

Thomas, E., Croft, P. R., Paterson, S. M., Dziedzic, K., & Hay, E. M. (2004). What influence participants' treatment preference and can it influence outcome? Results from a primary care-based randomised trial for shoulder pain. *British Journal of General Practice, 54*, 93-96.

Velicer, W. F., Keller, S., Friedman, R. H., Fava, J. L., Gullier, S. B., Ward, R. M., et al. (2005). Comparing participants and nonparticipants recruited for an effectiveness study of nicotine replacement therapy. *Annals of Behavioral Medicine, 29*, 181-191.

Wennberg, J. E., Barry, M. J., Fowler, F. J., & Mulley, A. (1993). Outcomes research, PORTs, and health care reform. *Annals of the New York Academy of Sciences, 703*, 52-62.

Wortman, C. B., Hendricks, M., & Hillis, J. W. (1976). Factors affecting participant reactions to random assignment to ameliorative social programs. *Journal of Personality and Social Psychology, 33*, 256-266.

Zelen, M. (1990). Randomized consent designs for clinical trials: An update. *Statistics In Medicine, 9*, 645-656.

Zimbardo, P. G., Butler, L. D., & Wolfe, V. A. (2003). Cooperative college examinations: More gain, less pain, when students share information and grades. *Journal of Experimental Education, 71*, 101-125.

Figure Caption

Figure 1. The Partially Randomized Preference Trial (Brewin & Bradley, 1989).

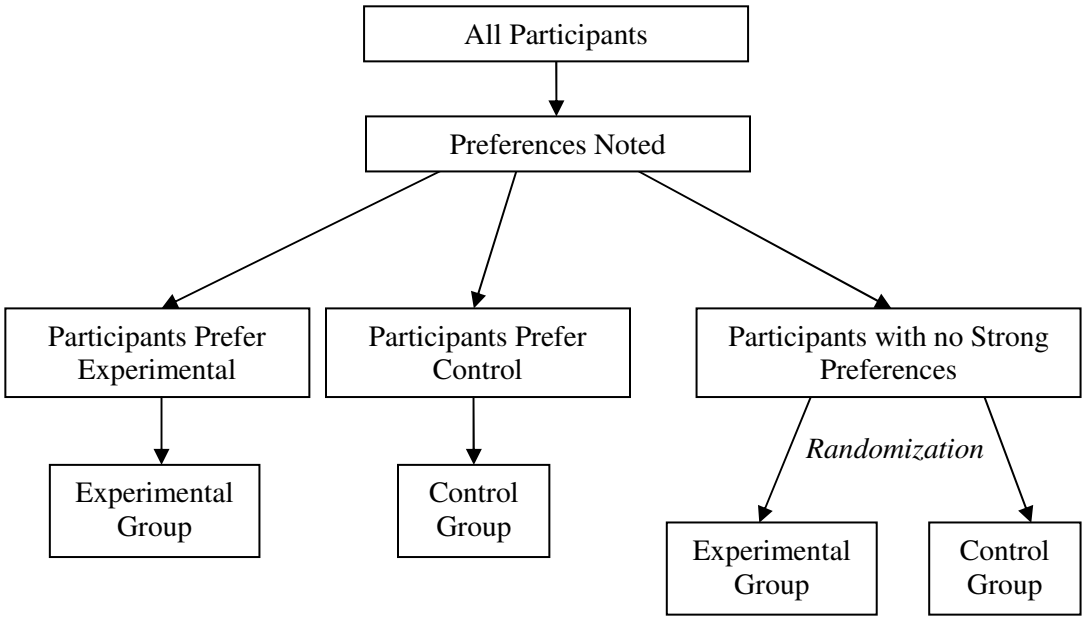

All Participants
Preferences Noted
Participants Prefer Experimental
Participants Prefer Control
Participants with no Strong Preferences
Randomization
Experimental Group
Control Group
Experimental Group
Control Group

Figure Caption

Figure 2. The Rücker Two-Stage Randomized Design (Rücker 1989).

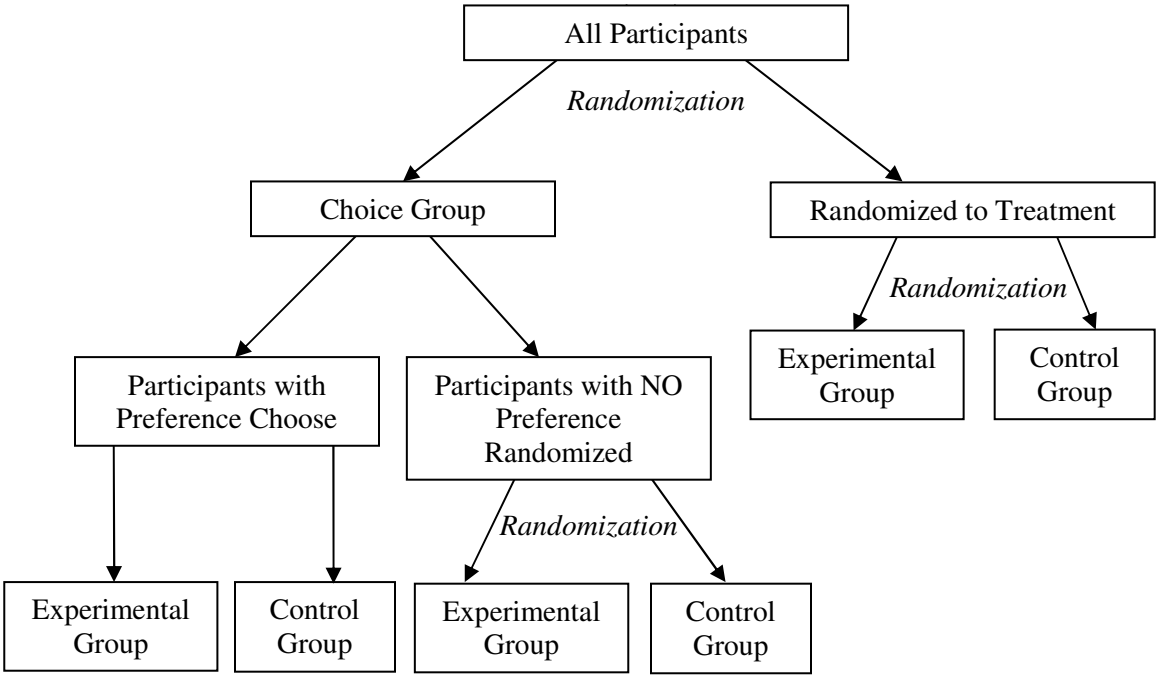

All Participants
Randomization
Choice Group
Randomized to Treatment
Randomization
Participants with Preference Choose
Participants with NO Preference Randomized
Experimental Group
Control Group
Randomization
Experimental Group
Control Group
Experimental Group
Control Group

Figure Caption

Figure 3. The Doubly Randomized Preference Trial (Wennberg Design). (Wennberg, 1993).

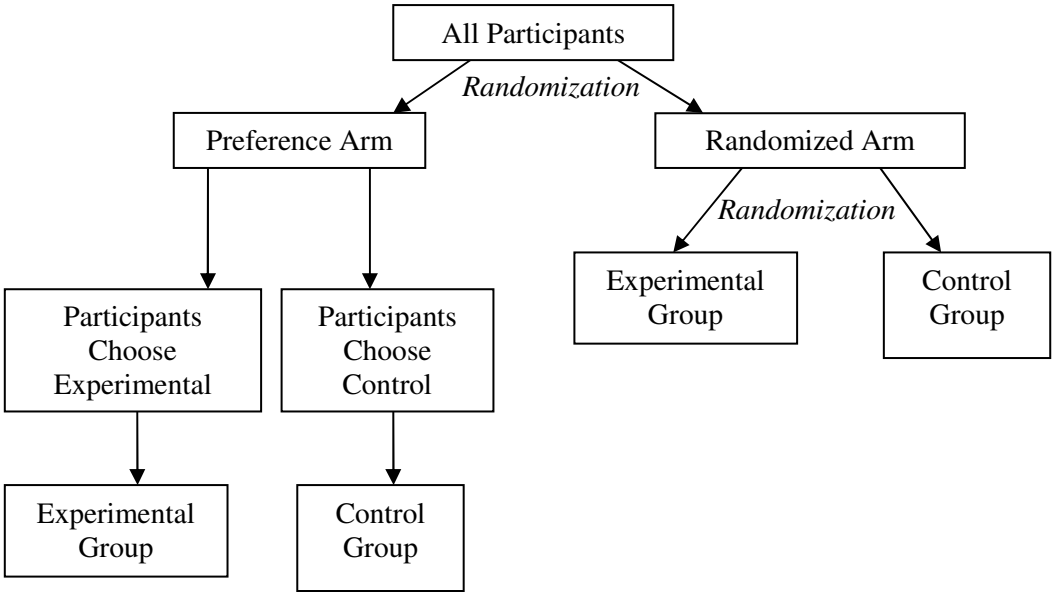

All Participants
Randomization
Preference Arm
Randomized Arm
Randomization
Participants Choose Experimental
Participants Choose Control
Experimental Group
Control Group
Experimental Group
Control Group

Figure Caption

Figure 4. Zelen Randomization (Zelen, 1990).

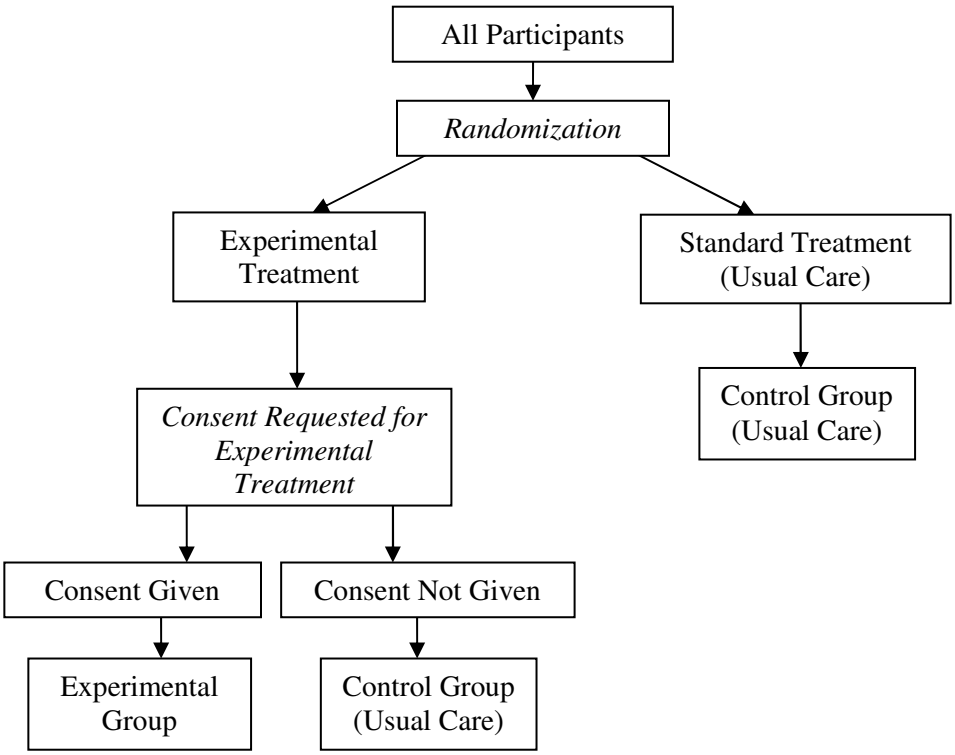

All Participants
Randomization
Experimental Treatment
Standard Treatment (Usual Care)
Consent Requested for Experimental Treatment
Control Group (Usual Care)
Consent Given
Consent Not Given
Experimental Group
Control Group (Usual Care)

Figure Caption

Figure 5. Flow Chart of Participant Allocation.

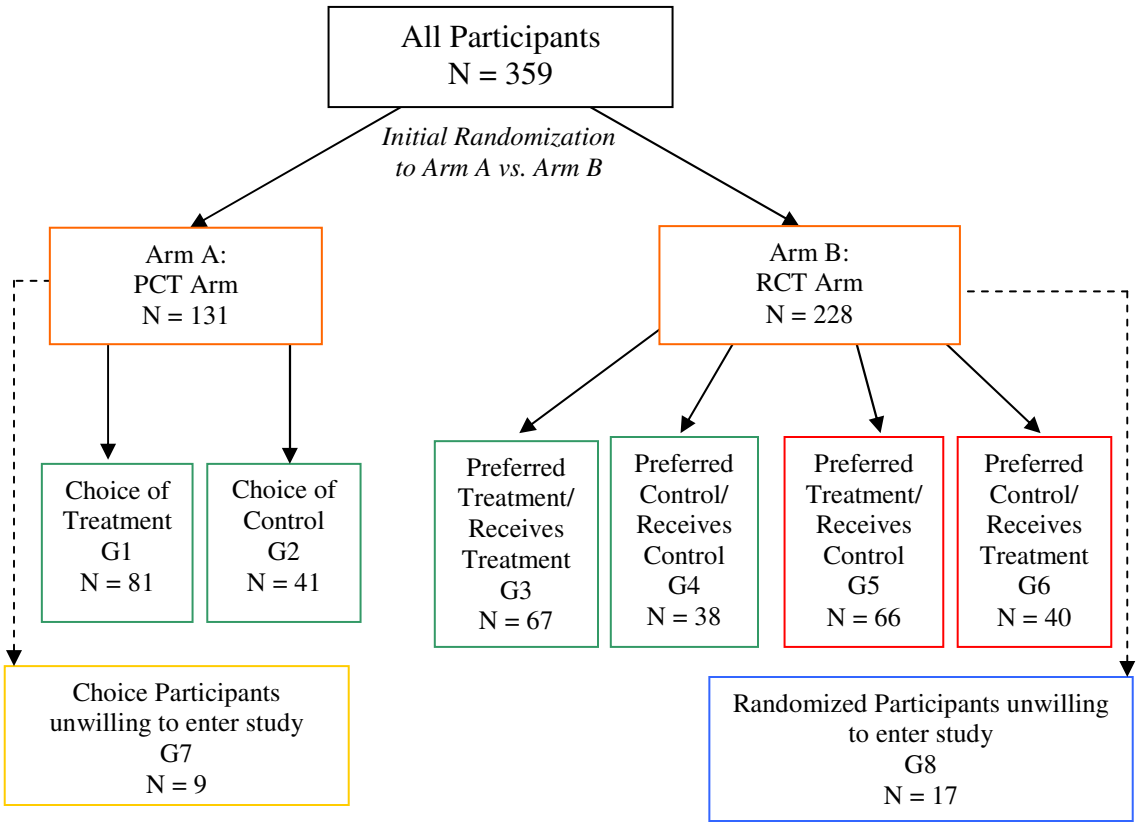

All Participants
N = 359
Initial Randomization
to Arm A vs. Arm B
Arm A:
PCT Arm
N = 131
Arm B:
RCT Arm
N = 228
Choice of
Treatment
G1
N = 81
Choice of
Control
G2
N = 41
Preferred
Treatment/
Receives
Treatment
G3
N = 67
Preferred
Control/
Receives
Control
G4
N = 38
Preferred
Treatment/
Receives
Control
G5
N = 66
Preferred
Control/
Receives
Treatment
G6
N = 40
Choice Participants
unwilling to enter study
G7
N = 9
Randomized Participants unwilling
to enter study
G8
N = 17

Figure Caption

Figure 6. Study Timeline.

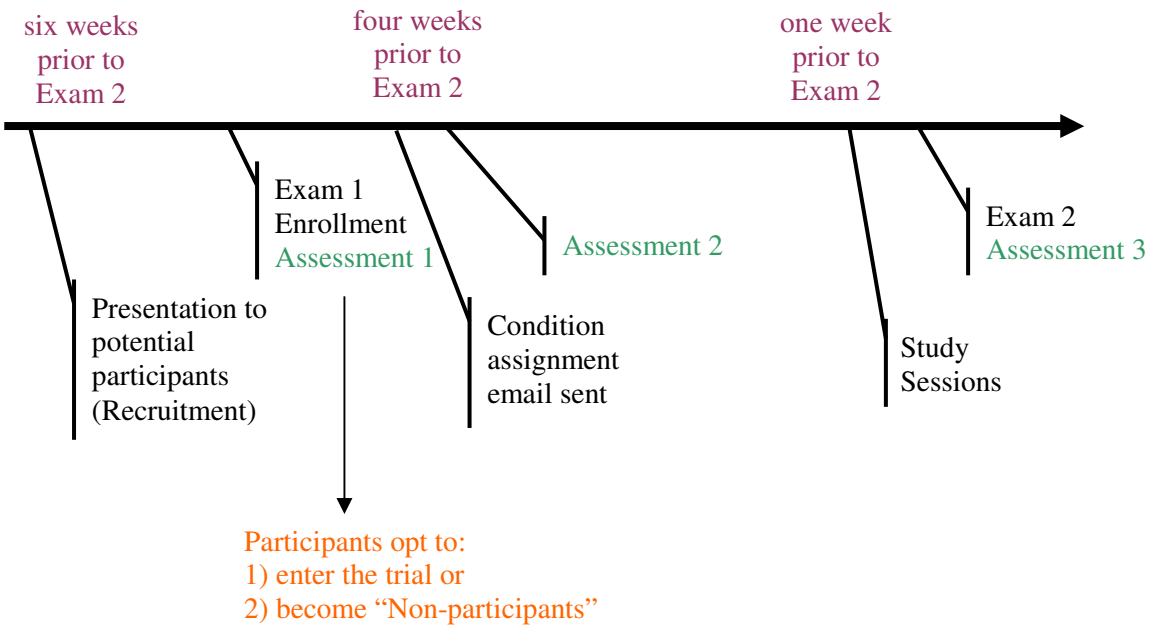
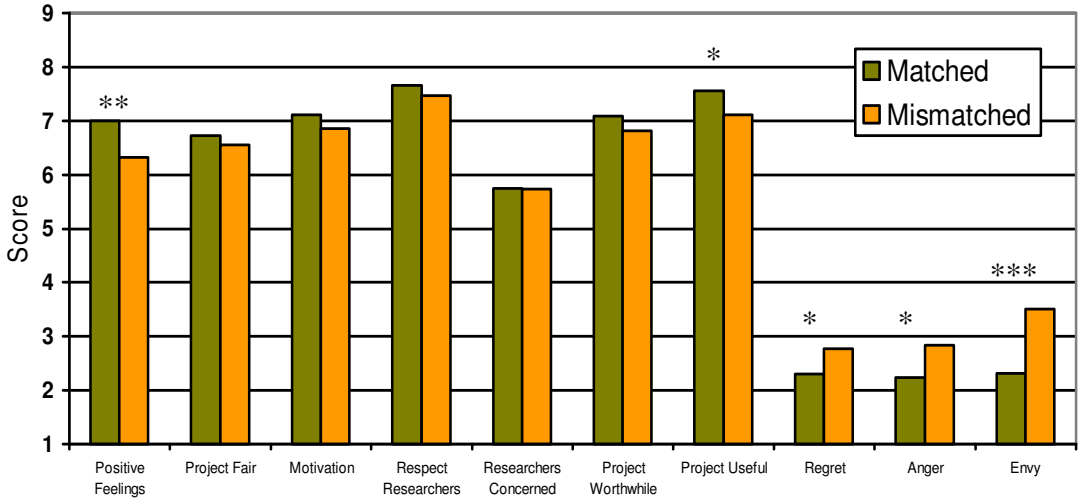

six weeks
prior to
Exam 2
four weeks
prior to
Exam 2
one week
prior to
Exam 2
Exam 1
Enrollment
Assessment 1
Assessment 2
Exam 2
Assessment 3
Presentation to
potential
participants
(Recruitment)
Condition
assignment
email sent
Study
Sessions
Participants opt to:
1) enter the trial or
2) become "Non-participants"

Figure Caption

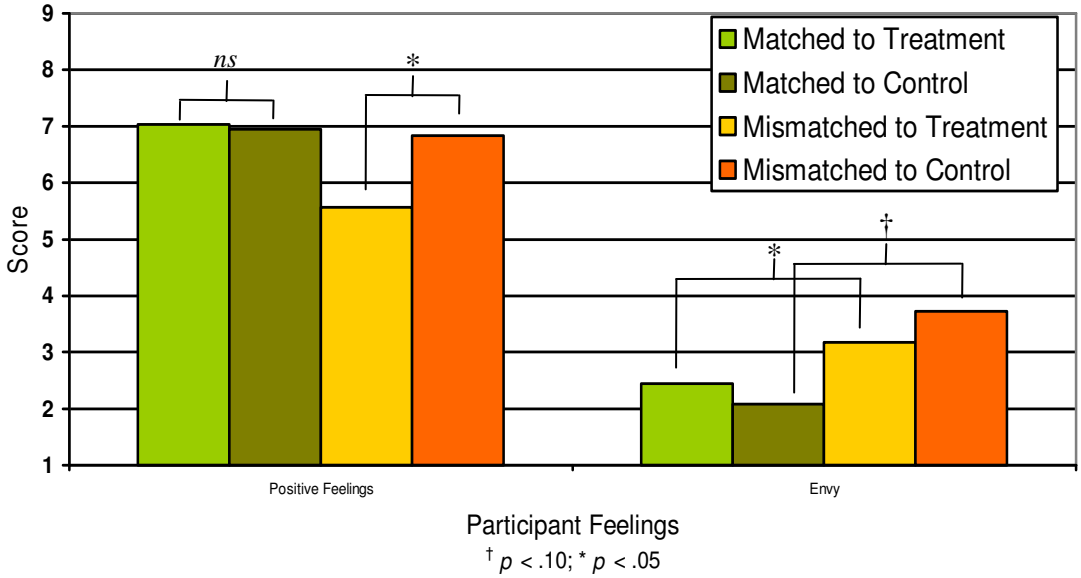
Figure 7. Main Effect of Matching on Participant Feelings About Participation.


9
8
7
6
5
4
3
2
1
Score
**
*
*
*
***
Matched
Mismatched
Positive Feelings
Project Fair
Motivation
Respect Researchers
Researchers Concerned
Project Worthwhile
Project Useful
Regret
Anger
Envy
Participant Feelings

* $p < .05$; ** $p < .01$; *** $p < .001$

Figure Caption

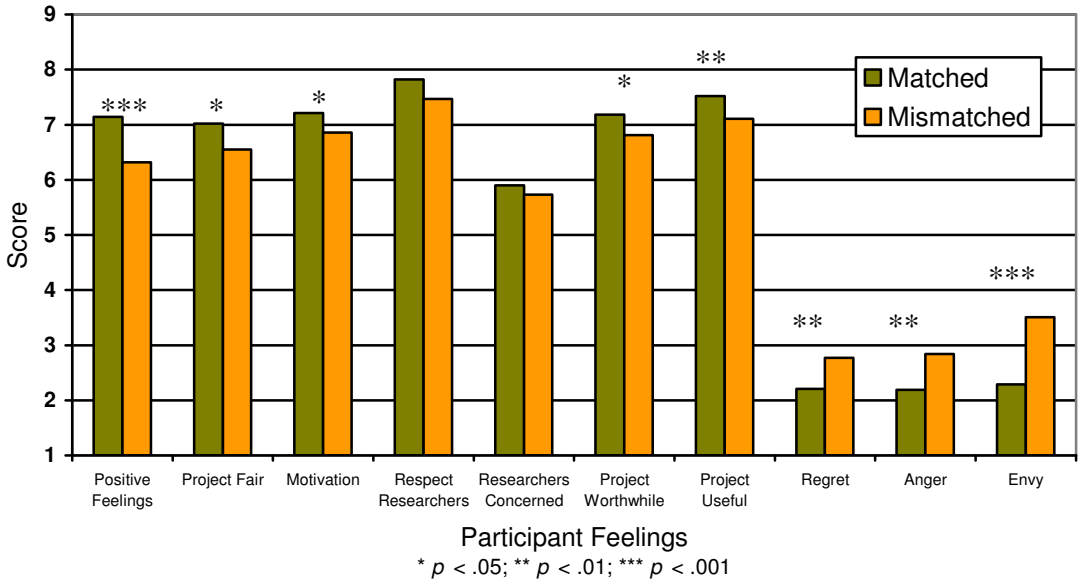
Figure 8. Interaction of Matching by Condition on Participant Feelings about Participation (Only Data for Significant Interactions Shown).



Note: only significant interactions shown.

Figure Caption

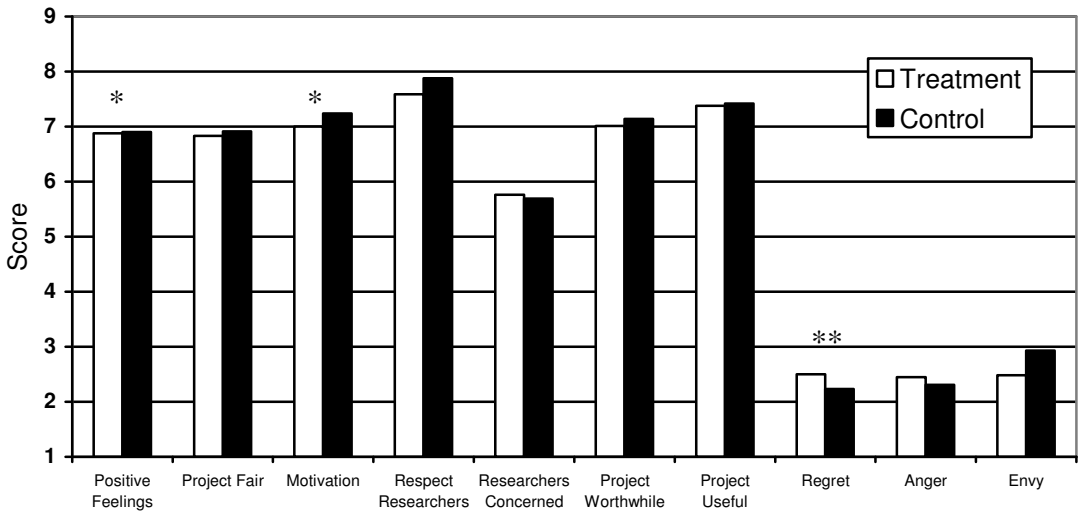
Figure 9. Main Effect of Matching on Participant Feelings About Participation, Pooling RCT and PCT Study Arms.


9
8
7
6
5
4
3
2
1
Score
Matched
Mismatched
***
*
*
*
**
**
**
***
Positive Feelings
Project Fair
Motivation
Respect Researchers
Researchers Concerned
Project Worthwhile
Project Useful
Regret
Anger
Envy
Participant Feelings

* $p < .05$; ** $p < .01$; *** $p < .001$

Figure Caption

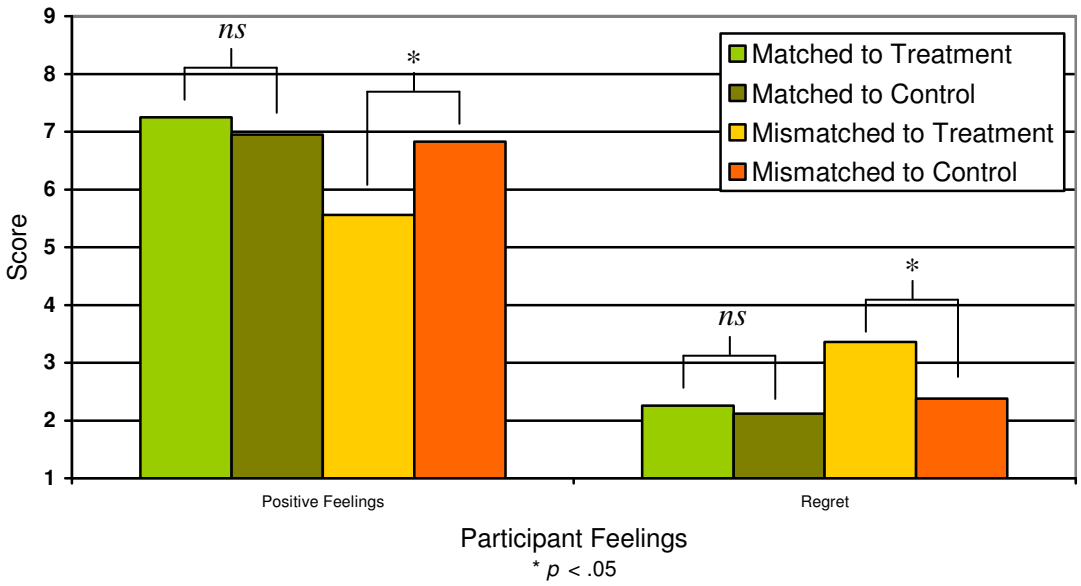
Figure 10. Main Effect of Condition on Participant Feelings About Participation, Pooling RCT and PCT Study Arms.


9
8
7
6
5
4
3
2
1
Score
*
*
**
Treatment
Control
Positive Feelings
Project Fair
Motivation
Respect Researchers
Researchers Concerned
Project Worthwhile
Project Useful
Regret
Anger
Envy
Participant Feelings

* $p < .05$; ** $p < .01$

Figure Caption

Figure 11. Interaction Effect of Matching by Condition on Participant Feelings About Participation, Pooling RCT and PCT Study Arms (Only Data for Significant Interactions Shown).



Note: only significant interactions shown.

Figure Caption

Figure 12. Interaction of Matching and Condition on Adherence (Minutes Spent in the Study Sessions).

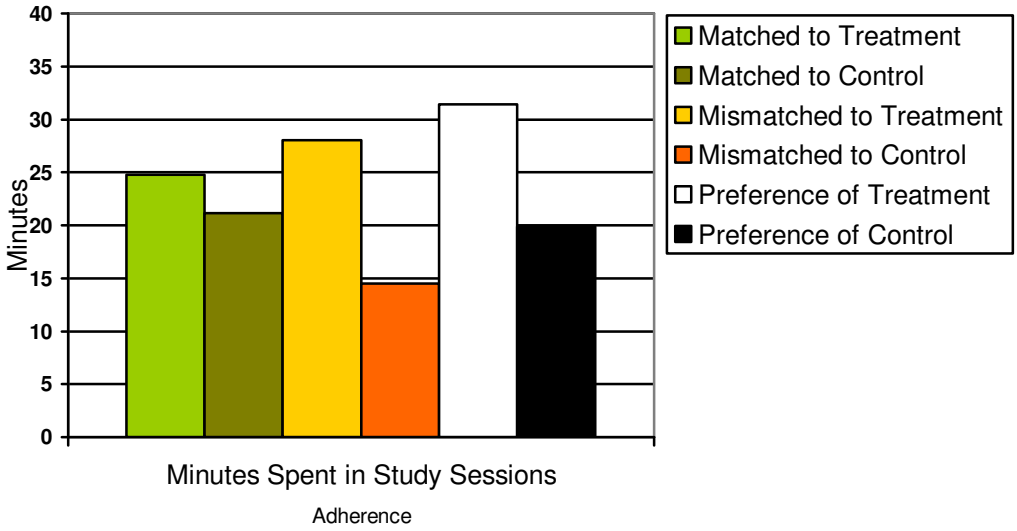

40
35
30
25
20
15
10
5
0
Minutes
Matched to Treatment
Matched to Control
Mismatched to Treatment
Mismatched to Control
Preference of Treatment
Preference of Control
Minutes Spent in Study Sessions
Adherence

Figure Caption

Figure 13. Interaction of Matching and Condition on Adherence (Engagement in the Study Sessions).

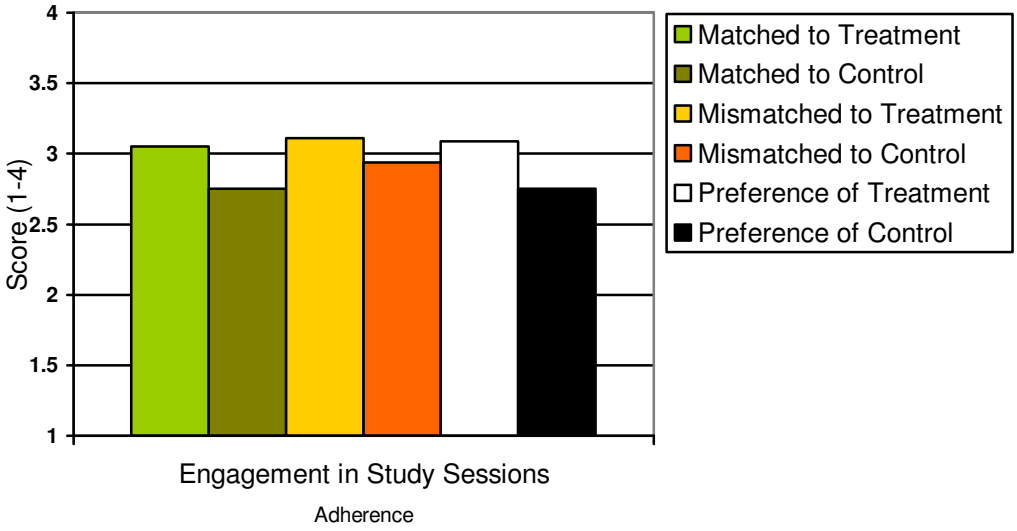

4
3.5
3
2.5
2
1.5
1
Score (1-4)
Matched to Treatment
Matched to Control
Mismatched to Treatment
Mismatched to Control
Preference of Treatment
Preference of Control
Engagement in Study Sessions
Adherence

Figure Caption

Figure 14. Interaction of Preference Strength and Matching.

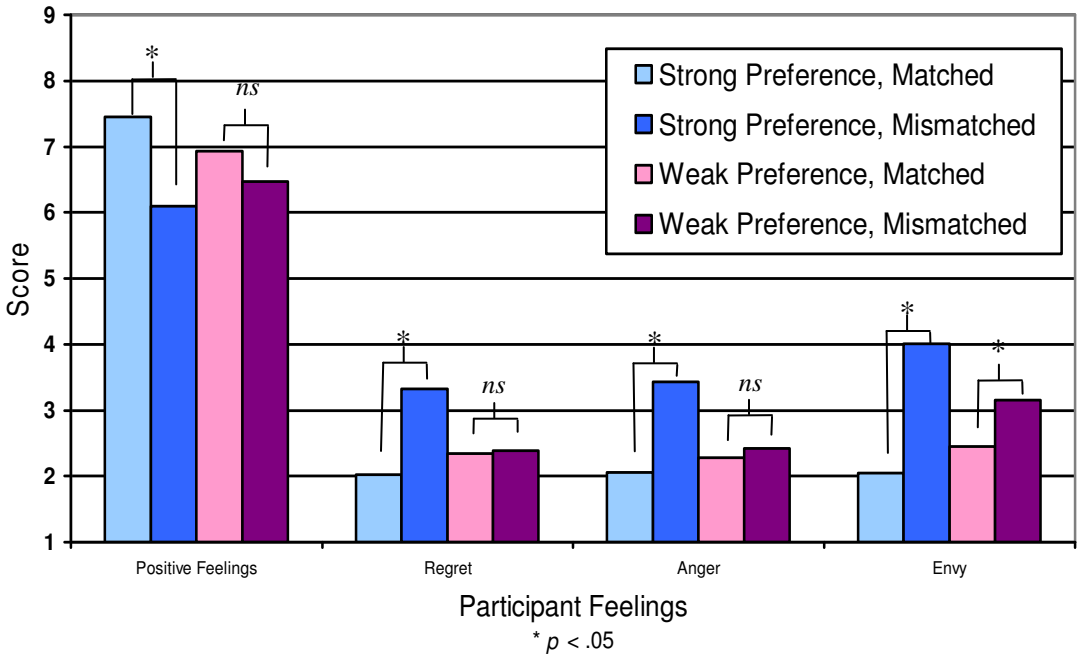
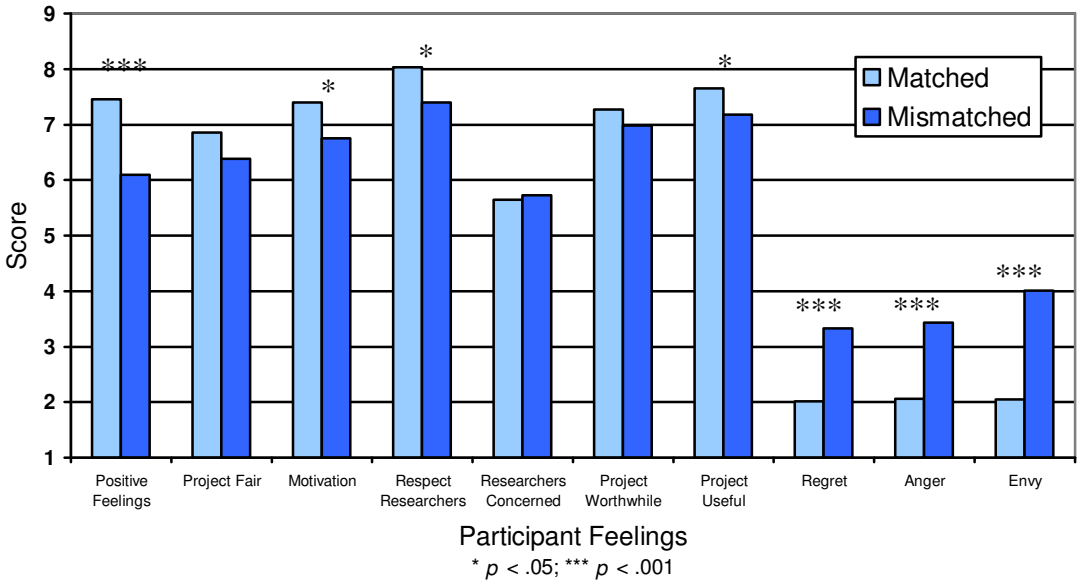

9
8
7
6
5
4
3
2
1
Score
*
ns
*
ns
*
ns
*
*
Strong Preference, Matched
Strong Preference, Mismatched
Weak Preference, Matched
Weak Preference, Mismatched
Positive Feelings
Regret
Anger
Envy
Participant Feelings
* p < .05

Figure Caption

Figure 15. Main Effect of Matching, Selecting Only Participants with Strong Preferences.


9
8
7
6
5
4
3
2
1
Score
***
*
*
*
***
***
***
Matched
Mismatched
Positive Feelings
Project Fair
Motivation
Respect Researchers
Researchers Concerned
Project Worthwhile
Project Useful
Regret
Anger
Envy
Participant Feelings

* $p < .05$; *** $p < .001$

Figure Caption

Figure 16. Interaction of Matching and Condition, Selecting Only Participants with Strong Preferences.

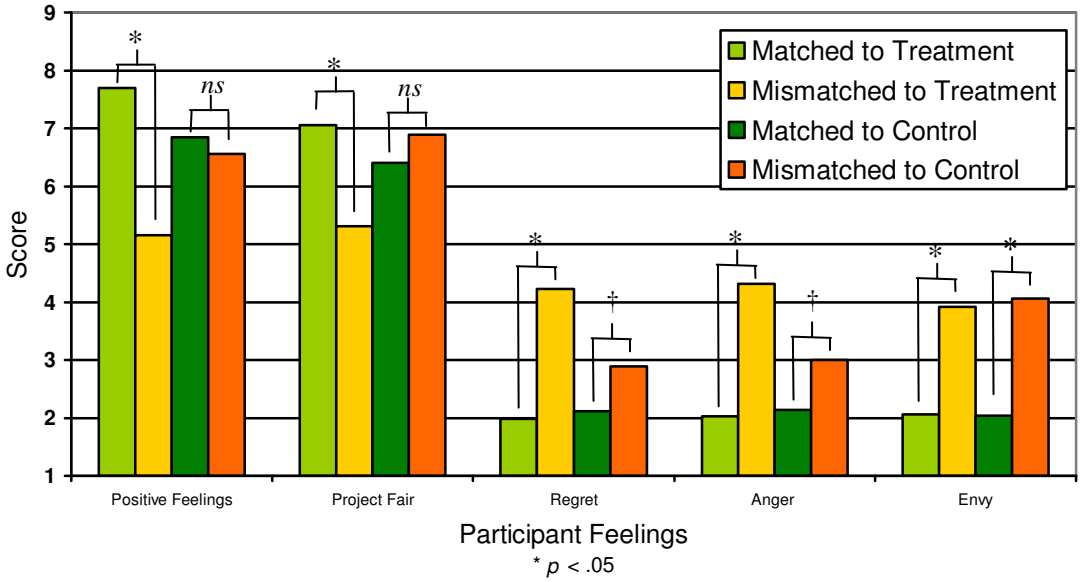

9
8
7
6
5
4
3
2
1
Score
Matched to Treatment
Mismatched to Treatment
Matched to Control
Mismatched to Control
*
ns
*
ns
*
†
*
†
*
*
Positive Feelings
Project Fair
Regret
Anger
Envy
Participant Feelings
* p < .05

Table 1. Participant Demographics.[a]

Variable	All Participants (N = 359)	PCT Arm (n = 131)	RCT Arm (n = 228)
Gender			
Male	40.1	43.5	38.1
Female	59.9	56.5	61.9
Age	M = 20.06 (2.46)	M = 19.92 (2.35)	M = 20.13 (2.54)
Ethnicity			
Hispanic	11.4	10.7	11.7
Non-Hispanic	88.0	88.5	87.9
Race			
Asian	29.8	35.1	26.9
Pacific Islander	1.1	0	1.8
Black	5.0	3.8	5.4
White	48.7	46.6	49.8
Other	14.2	13.7	14.8
Year in College			
Freshman	34.8	34.4	35.4
Sophomore	18.4	19.1	17.9
Junior	26.2	28.2	24.7
Senior	16.2	16.8	15.7
Senior +	4.5	1.5	6.3

[a] in percentages unless noted

Table 2. Means and Standard Deviations of Main Outcome Variables.

Outcome variable	All Trial Participants (N = 333)	Choice of Treatment (n = 81)	Choice of Control (n = 41)	Matched to Treatment (n = 67)	Matched to Control (n = 38)	Mis-matched to Control (n = 66)	Mis-matched to Treatment (n = 40)
Reactions to Randomization							
Adherence							
Study Session Minutes[a]	*N*=102 77.46 (34.30)	*N*=29 87.69 (33.24)	*N*=12 68.00 (32.69)	*N*=21 79.00 (32.69)	*N*=10 80.30 (42.61)	*N*=16 59.64 (34.47)	*N*=14 80.07 (29.59)
Study Session Engagement[a]	*N*=102 2.99 (0.80)	*N*=29 3.09 (0.82)	*N*=12 2.75 (0.75)	*N*=21 3.05 (0.76)	*N*=21 2.75 (0.92)	*N*=16 2.94 (0.85)	*N*=14 3.11 (0.76)
Total Minutes Studied	205.60 (145.31)	187.04 (119.22)	207.97 (146.00)	210.69 (170.77)	196.14 (131.81)	209.63 (142.89)	238.40 (171.00)
Belief in Effectiveness of Treatment							
Anticipated Grade	90.45 (8.01)	90.81 (6.35)	89.52 (12.13)	90.61 (8.46)	90.22 (9.13)	90.37 (6.53)	90.79 (5.81)
Desperation for Good Grade	2.66 (0.97)	2.53 (0.98)	2.63 (0.95)	2.62 (0.93)	3.00 (1.00)	2.76 (0.94)	2.56 (1.05)
State Test Anxiety	15.11 (4.94)	14.82 (5.02)	13.67 (4.18)	15.22 (5.35)	15.66 (4.75)	15.68 (4.68)	15.71 (5.49)
Participant Feelings							
Positive Feelings	6.89 (1.61)	7.43 (1.34)	6.96 (1.62)	7.04 (1.52)	6.95 (1.15)	6.83 (1.87)	5.56 (1.55)
Project Fair	6.87 (1.82)	7.52 (1.82)	7.30 (1.71)	6.76 (1.58)	6.67 (1.84)	6.79 (1.97)	6.18 (1.86)
Motivation	7.10 (1.51)	7.18 (1.50)	7.51 (1.27)	7.07 (1.52)	7.20 (1.39)	7.09 (1.73)	6.52 (1.37)
Respect Researchers	7.72 (1.46)	7.87 (1.26)	8.15 (1.14)	7.53 (1.46)	7.88 (1.21)	7.69 (1.54)	7.15 (1.99)
Researchers Concerned	5.85 (1.76)	5.95 (1.53)	6.20 (1.91)	5.79 (1.81)	5.67 (1.35)	5.98 (1.92)	5.36 (1.95)
Project Worthwhile	7.07 (1.38)	7.26 (1.36)	7.23 (1.24)	7.06 (1.33)	7.15 (1.00)	7.07 (1.57)	6.44 (1.54)
Project Useful	7.39 (1.23)	7.49 (1.09)	7.51 (1.13)	7.57 (1.16)	7.54 (1.00)	7.28 (1.36)	6.85 (1.58)
Regret	2.38 (1.64)	2.08 (1.27)	2.23 (1.62)	2.47 (1.81)	2.00 (1.49)	2.38 (1.52)	3.36 (1.97)
Anger	2.39 (1.69)	2.26 (1.82)	1.96 (1.40)	2.28 (1.48)	2.17 (1.54)	2.66 (1.75)	3.10 (1.90)
Envy	2.67 (1.90)	2.14 (1.56)	2.53 (1.87)	2.44 (1.48)	2.08 (1.55)	3.73 (2.28)	3.18 (2.15)
Trial Outcomes							
Exam 2 Grade	77.83 (12.07)	76.77 (11.28)	79.72 (11.84)	75.84 (12.77)	81.04 (10.69)	76.75 (12.41)	77.71 (12.98)

[a] data only for participants attending study sessions

Table 2. Means and Standard Deviations of Main Outcome Variables (con't).

Outcome variable	All Trial Participants (N = 359)	Choice of Treatment (n = 81)	Choice of Control (n = 41)	Matched to Treatment (n = 67)	Matched to Control (n = 38)	Mis-matched to Control (n = 66)	Mis-matched to Treatment (n = 40)	Un-willing PCT Arm (n = 9)	Un-willing RCT Arm (n = 17)
Predictors of Enrollment									
Risk Taking	20.02 (7.39)	19.74 (6.42)	19.89 (8.29)	20.42 (8.10)	18.08 (8.64)	20.84 (6.57)	20.85 (7.65)	19.89 (4.69)	19.40 (7.50)
Openness to Experiences	37.84 (5.85)	38.72 (5.91)	35.26 (5.55)	39.28 (4.73)	35.63 (5.55)	39.37 (4.92)	36.90 (7.54)	34.44 (6.37)	37.00 (5.77)
Education Level	3.64 (0.81)	3.59 (0.83)	3.56 (0.86)	3.70 (0.80)	3.78 (0.60)	3.67 (0.87)	3.74 (0.73)	3.56 (0.77)	3.26 (0.89)

Table 3. Correlations Among Participant Feelings and Other Reactions to Randomization.

		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
1	Positive Feelings	-															
2	Project Fair	.29**	-														
3	Motivation	.47**	.25**	-													
4	Respect Researchers	-.34**	-.34**	-.56**	-												
5	Researchers Concerned	.27**	.29**	.43**	-.41**	-											
6	Project Worthwhile	.38**	.27**	.46**	-.50**	.46**	-										
7	Project Useful	.41**	.17**	.54**	-.53**	.40**	.77**	-									
8	Regret	-.61**	-.35**	-.37**	.34**	-.23**	-.34**	-.31**	-								
9	Anger	-.37**	-.38**	-.26**	.30**	-.15**	-.25**	-.28**	.58**	-							
10	Envy	-.39**	-.32**	-.33**	.31**	-.16**	-.30**	-.26**	.52**	.54**	-						
11	Adherence (Minutes in Study Session)	.13*	.08	.10	-.03	.01	.09	.10	-.09	-.05	-.04	-					
12	Adherence (Engagement)	.18**	.08	.13*	-.03	.05	.10	.13*	-.08	-.06	-.01	.86**	-				
13	Desperation for a Good Grade	.05	-.08	.05	-.07	-.02	-.00	.04	.00	.05	.14*	.04	.00	-			
14	Test Anxiety	-.13*	-.19**	-.09	.18**	-.10	-.16**	-.16**	.16**	.22**	.29**	.02	-.00	.30**	-		
15	Exam 1 Grade	.06	.04	.07	-.11	-.02	.09	.04	-.11*	-.11	-.18**	-.03	-.02	-.32**	-.24**	-	
16	Exam 2 Grade	.05	-.02	.05	-.08	-.02	.12*	.10	-.08	-.10	-.07	-.02	.06	-.15*	-.22**	.58**	-
	M	6.89	6.87	7.10	7.72	5.85	7.07	7.39	2.38	2.39	2.67	22.32	.86	2.66	15.11	80.03	77.83
	SD	1.61	1.82	1.51	1.46	1.76	1.38	1.23	1.64	1.69	1.90	39.63	1.42	.97	4.94	11.71	12.07

*$p<.05$; **$p<.01$

Table 4. Self-Reported Reasons for Enrolling in the Trial, By PCT Arm and RCT Arm.

Reason for Participating (Participants May Endorse Multiple Items)	Percent Endorsing Response	
	PCT Arm (N = 122)	RCT Arm (N = 211)
I like the concept behind the study	76.2	74.9
I like the idea of being able to indicate my preference for one treatment or the other	25.4	n/a
I like the idea of being randomly assigned to a treatment	n/a	9.0
I think that participation could have a positive impact on my exam performance	45.9	49.8
I think the results of the study will benefit others	34.4	40.8
I like the idea of finding out which group I will be in; this is exciting	n/a	17.1
No real reason/ I just wanted to	10.7	9.5
I need the research credits	73.0	73.9
Other	2.5	3.3

Table 5. Self-Reported Reasons for Not Enrolling in the Trial, By PCT Arm and RCT Arm.

Reason for Not Participating (Participants May Endorse Multiple Items)	Percent Endorsing Response	
	PCT Arm (N = 9)	RCT Arm (N = 17)
I don't like the concept behind the study	11.1	0.0
I don't really want to do the extra work involved	22.2	23.5
I only need 1 more research credit, not 2	22.2	17.6
I'm concerned that participation could have a negative effect on my exam performance	55.6	58.8
I don't think the results of this study will benefit anyone.	11.1	0.0
I don't think either group (music or standard testing) would help me on the test	22.2	0.0*
No real reason/ I just don't want to	11.1	11.8
I strongly prefer the MUSIC group	0.0	5.9
I strongly prefer the NORMAL TESTING group	11.1	23.5
Other	22.2	35.3

** difference significant at the .05 level*

Table 6. Means, Treatment Effects, and Preference Effects.

Outcome	Preference	Condition		Treatment Effect	Preference Effect[a]
		Treatment	Control		
Exam 2 Score	Treatment	75.84	76.75	-.91 (p = .914)	
	Control	77.71	81.04	-3.33 (p = .155)	-2.42 (.761)
Adherence - Minutes Spent in Study Sessions	Treatment	24.76	14.53	10.23 (p = .003)	
	Control	28.03	21.13	6.90 (p = .333)	3.33 (.532)
Adherence - Engagement in Study Sessions[b]	Treatment	3.05 (N=21)	2.94 (N=16)	0.11 (p = .614)	
	Control	3.11 (N=14)	2.75 (N=10)	0.36 (p = .695)	-.25 (.498)

[a] Preference Effect is calculated by subtracting the Treatment Effect of the participants who prefer the control condition from the Treatment Effect of the participants who prefer the Treatment condition.
[b] Engagement calculated only for participants who attended study sessions.

Appendix A:

Measures

note: any red italic text appearing in Appendices is for reviewers and Dissertation committee members, and was not viewed by participants

This is the baseline questionnaire for participants in the PCT group

The Mozart Effect and Student Performance in College Examination (PCT)

Please allow approximately 20 minutes to complete this questionnaire.

Please answer the following questions. This information will allow us to match your data, and still allow you to complete the survey anonymously. This information will also be used to assign your participation credit.

1) Which Psychology Class are you taking (the class you are participating in the Mozart Effect Study for)?

- PSY 103 Introduction to Psychology with Dr. Anne Moyer
- PSY 103 Introduction to Psychology with Dr. Richard Gerrig
- PSY 310 Research and Writing with Dr. Turhan Canli

2) What is your mother's maiden name?

3) What is your birth Month?

4) What is your birthday Day?

5) What do you call/ what did you call your mother's mom (your maternal grandmother)? Examples: Omi, Granny, Nannie, Grandma, Nana, Great Ma, etc.

6) What is your SOLAR ID number?

Baseline Assessment

First, we'd like to ask some questions about you. *(demographics)*

7) What is your age?

8) Are you:

- male
- female

9) What is your ethnicity?

- Hispanic or Latino
- Not Hispanic or Latino

10) What is your race?

- Asian

- Native Hawaiian or other Pacific Islander
- Black or African American
- White/Caucasian
- Other (Please specify)

11) What is your year in college?
- 1 - freshman
- 2 - sophomore
- 3 - junior
- 4 - senior
- 5 +

12) What is your current overall GPA? (if this is your first year of college, use high school GPA)

13) Think about the male figure that is most important to you in your life: your male role-model. Who is this person? (could be an uncle, father, step-father, etc.)

14) What is his highest level of education?
- Elementary School Graduate
- Middle School Graduate
- High School Graduate
- College Graduate
- Advanced Degree (MA, PhD, RN, MBA, etc.)

15) Think about the female figure that is most important to you in your life: your female role-model. Who is this person? (could be an aunt, mother, step-mother, etc.)

16) What is her highest level of education?
- Elementary School Graduate
- Middle School Graduate
- High School Graduate
- College Graduate
- Advanced Degree (MA, PhD, RN, MBA, etc.)

17) How often do you typically listen to classical music?
- Never
- Once or twice a year
- Once or twice a month
- Several times a week

18) Do you often find it interesting to pay attention to the structure of a piece of music?
- Yes
- No

19) What grade do you want to get on your exams in your Psychology Course, out of a 100 point system?

20) What is the absolute lowest grade you would feel OK with getting on an exam in your Psychology Course class, out of a 100 point system? (Note that this could be different from question 19)

--please read carefully—

The Mozart Effect

It has been shown in some studies (Rauscher et al., 1993) that people show enhanced spatial ability when completing tasks while listening to Mozart's Sonata for Two Pianos in D Major (coined "the Mozart Effect"). We would like to investigate whether this Effect holds for college students taking an exam, that is, does listening to Mozart while studying for and taking an exam lead to better test scores? We currently do not know whether this would be the case. It may be that listening to Mozart increases test scores, has no effect whatsoever on test scores, or even decreases test scores.

In this study you will attend study sessions and take your second in-class examination (third quiz if you are in Dr. Canli's class) for your Psychology course either while listening to Mozart (music listening condition) or under normal silent conditions (normal testing condition), depending on your preference.

You will receive an email confirmation of your condition, including information about the study sessions, about 4 weeks before the exam or quiz. Like other examinations in your Psychology course, if this score is the lowest for the semester, it will be dropped in calculating the final grade.

Rauscher, F.H., Shaw, G.L., & Ky, C.N. (1993). Music and spatial task performance. Nature, 365, 611.

(participant preference for condition)

21) With respect to the two alternatives (standard testing situation vs. music testing situation), please indicate your preference:

- ○ strongly prefer Normal Testing condition
- ○ somewhat prefer Normal Testing condition
- ○ somewhat prefer Music Listening condition
- ○ strongly prefer Music Listening condition

22) Do you have any particular reason for your preference?

You indicated to us on your consent form that you are interested in participating in the study situation described above. We would like to ask you a few questions about what led you to your decision.

(Assessment of characteristics related to interest in randomization, adopted from Harrison et al., 2007)

23) Which of these describes your reasons for wanting to participate in the study? (you may check more than one):

- ○ I like the concept behind the study
- ○ I like the idea of being able indicate my preference for one treatment or the other
- ○ I think that participation could have a positive effect on my exam performance
- ○ I think the results of this study will benefit others
- ○ No real reason/ I just wanted to
- ○ I need the research credits
- ○ Other (Please specify)

(adopted from Harrison et al., 2007; assesses risk taking)

The following questions assess how much you are generally inclined or not to accept risk. Please use the scale where 0 is extremely unlikely, and 10 is extremely likely to indicate how likely you would be to do each behavior.

24) Some activities/situations involve a "physical risk", where there is a risk of getting injured in an accident or possibly even death. Physical risks can include rock climbing, sky-diving, or occupations such as coal mining or being a police officer.

Extremely unlikely 1 2 3 4 5 6 7 8 9 10 Extremely likely

25) Some activities/situations involve a "financial risk", where there is a risk of loosing money or assets. Financial risks can involve buying stock in the stock market, gambling in casinos or using slot machines, or betting in sports events.

Extremely unlikely 1 2 3 4 5 6 7 8 9 10 Extremely likely

26) Some activities/situations involve a "social risk", where there is a risk of losing the respect and acceptance of others and harming ones' social status. Social risks can include being very outspoken, giving a controversial speech or violating social norms.

Extremely unlikely 1 2 3 4 5 6 7 8 9 10 Extremely likely

27) Some activities/situations involve a "health risk" where there is a risk of harming ones' health. Health risks can include sunbathing with no sun screen or smoking.

Extremely unlikely 1 2 3 4 5 6 7 8 9 10 Extremely likely

(Assesses Openness to Experience, adopted from The Big Five Inventory, John & Srivastava, 1999)

Here are a number of characteristics that may or may not apply to you.
Please indicate the extent to which you agree or disagree with the statements.

28) I see myself as someone who… Is original, comes up with new ideas
- ○ Disagree strongly
- ○ Disagree a little
- ○ Neither agree nor disagree
- ○ Agree a little
- ○ Agree strongly

29) I see myself as someone who… Is curious about many different things
- ○ Disagree strongly
- ○ Disagree a little
- ○ Neither agree nor disagree
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30) I see myself as someone who… Is ingenious, a deep thinker
- ○ Disagree strongly
- ○ Disagree a little
- ○ Neither agree nor disagree
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31) I see myself as someone who… Has an active imagination
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32) I see myself as someone who… Is inventive
- ○ Disagree strongly
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- ○ Agree a little
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33) I see myself as someone who… Values artistic, aesthetic experiences
- ○ Disagree strongly
- ○ Disagree a little
- ○ Neither agree nor disagree
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- Agree strongly

34) I see myself as someone who… Prefers work that is routine
- Disagree strongly
- Disagree a little
- Neither agree nor disagree
- Agree a little
- Agree strongly

35) I see myself as someone who… Likes to reflect, play with ideas
- Disagree strongly
- Disagree a little
- Neither agree nor disagree
- Agree a little
- Agree strongly

36) I see myself as someone who… Has few artistic interests
- Disagree strongly
- Disagree a little
- Neither agree nor disagree
- Agree a little
- Agree strongly

37) I see myself as someone who… Is sophisticated in art, music, or literature
- Disagree strongly
- Disagree a little
- Neither agree nor disagree
- Agree a little
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38) What is your email address? (This will be used to send to you confirmation of your condition assignment - music listening vs. normal testing - and information about study sessions. Your email address will be erased from our list once the study is complete).

39) Please confirm your email address.

Please click on "Submit"

Submit

This is the baseline questionnaire for participants in the RCT group

The Mozart Effect and Student Performance in College Examination (RCT)

Please allow approximately 20 minutes to complete this questionnaire.

Please answer the following questions. This information will allow us to match your data, and still allow you to complete the survey anonymously. This information will also be used to assign your participation credit.

1) Which Psychology Class are you taking (the class you are participating in the Mozart Effect Study for)?

- ○ PSY 103 Introduction to Psychology with Dr. Anne Moyer
- ○ PSY 103 Introduction to Psychology with Dr. Richard Gerrig
- ○ PSY 310 Research and Writing with Dr. Turhan Canli

2) What is your mother's maiden name?

3) What is your birth Month?

4) What is your birthday Day?

5) What do you call/ what did you call your mother's mom (your maternal grandmother)? Examples: Omi, Granny, Nannie, Grandma, Nana, Great Ma, etc.

6) What is your SOLAR ID number?

Baseline Assessment

First, we'd like to ask some questions about you. *(demographics)*

7) What is your age?

8) Are you:

- ○ male
- ○ female

9) What is your ethnicity?

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino

10) What is your race?

- ○ Asian
- ○ Native Hawaiian or other Pacific Islander
- ○ Black or African American

- White/Caucasian
- Other (Please specify)

11) What is your year in college?
- 1 - freshman
- 2 - sophomore
- 3 - junior
- 4 - senior
- 5 +

12) What is your current overall GPA? (if this is your first year of college, use high school GPA)

13) Think about the male figure that is most important to you in your life: your male role-model. Who is this person? (could be an uncle, father, step-father, etc.)

14) What is his highest level of education?
- Elementary School Graduate
- Middle School Graduate
- High School Graduate
- College Graduate
- Advanced Degree (MA, PhD, RN, MBA, etc.)

15) Think about the female figure that is most important to you in your life: your female role-model. Who is this person? (could be an aunt, mother, step-mother, etc.)

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17) How often do you typically listen to classical music?
- Never
- Once or twice a year
- Once or twice a month
- Several times a week

18) Do you often find it interesting to pay attention to the structure of a piece of music?
- Yes
- No

19) What grade do you want to get on your exams in your Psychology Course, out of a 100 point system?

20) What is the absolute lowest grade you would feel OK with getting on an exam in your Psychology Course class, out of a 100 point system? (Note that this could be different from question 19)

--please read carefully--

The Mozart Effect

.

It has been shown in some studies (Rauscher et al., 1993) that people show enhanced spatial ability when completing tasks while listening to Mozart's Sonata for Two Pianos in D Major (coined "the Mozart Effect"). We would like to investigate whether this Effect holds for college students taking an exam, that is, does listening to Mozart while studying for and taking an exam lead to better test scores? We currently do not know whether this would be the case. It may be that listening to Mozart increases test scores, has no effect whatsoever on test scores, or even decreases test scores.

In this study we will randomly assign you to attend study sessions and take your second in-class examination for your Psychology course (third quiz, if you are in Dr. Canli's class) either while listening to Mozart (music listening condition) or under normal silent conditions (normal testing condition).

You will receive an email to let you know how you have been assigned (music
listening vs. normal testing), including information about the study sessions, about 4 weeks before the exam or quiz. Like other examinations in your Psychology course, if this score is the lowest for the semester, it will be dropped in calculating the final grade.

Rauscher, F.H., Shaw, G.L., & Ky, C.N. (1993). Music and spatial task performance. Nature, 365, 611.

(participant preference for condition)

21) With respect to the two alternatives (standard testing situation vs. music testing situation), please indicate your preference:

- ○ strongly prefer Normal Testing condition
- ○ somewhat prefer Normal Testing condition
- ○ somewhat prefer Music Listening condition
- ○ strongly prefer Music Listening condition

22) Do you have any particular reason for your preference?

You indicated to us on your consent form that you are interested in participating in the study situation described above. We would like to ask you a few questions about what led you to your decision.

(Assessment of characteristics related to interest in randomization, adopted from Harrison et al., 2007)

23) Which of these describes your reasons for wanting to participate in the study? (you may check more than one):

- ○ I like the concept behind the study
- ○ I like the idea of being randomly assigned to a treatment
- ○ I think that participation could have a positive effect on my exam performance
- ○ I think the results of this study will benefit others
- ○ I like the idea of finding out which group I will be in; this is exciting
- ○ No real reason/ I just wanted to
- ○ I need the research credits
- ○ Other (Please specify)

24) Which of the following best describes your feelings?

- ○ I have a "gut feeling" that I will get in the normal testing group.
- ○ I have a "gut feeling" that I will get in the music listening group.
- ○ I have no idea which group I will get in.

(adopted from Harrison et al., 2007; assesses risk taking)

The following questions assess how much you are generally inclined or not to accept risk. Please use the scale where 0 is extremely unlikely, and 10 is extremely likely to indicate how likely you would be to do each behavior.

25) Some activities/situations involve a "physical risk", where there is a risk of getting injured in an accident or possibly even death. Physical risks can include rock climbing, sky-diving, or occupations such as coal mining or being a police officer.

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(Assesses Openness to Experience, adopted from The Big Five Inventory, John & Srivastava, 1999)

Here are a number of characteristics that may or may not apply to you.
Please indicate the extent to which you agree or disagree with the statements.

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40) Please confirm your email address.

Please click on "Submit"

Submit

The following is the baseline (and only) questionnaire for participants randomized to the RCT group who decline to participate in the trial

The Mozart Effect and Student Performance in College Examination (URCT)

Please allow approximately 20 minutes to complete this questionnaire.

Please answer the following questions. This information will allow us to match your data, and still allow you to complete the survey anonymously. This information will also be used to assign your participation credit.

1) Which Psychology Class are you taking (the class you are participating in the Mozart Effect Study for)?

- ○ PSY 103 Introduction to Psychology with Dr. Anne Moyer
- ○ PSY 103 Introduction to Psychology with Dr. Richard Gerrig
- ○ PSY 310 Research and Writing with Dr. Turhan Canli

2) What is your mother's maiden name?

3) What is your birth Month?

4) What is your birthday Day?

5) What do you call/ what did you call your mother's mom (your maternal grandmother)? Examples: Omi, Granny, Nannie, Grandma, Nana, Great Ma, etc.

6) What is your SOLAR ID number?

Baseline Assessment

First, we'd like to ask some questions about you. *(demographics)*

7) What is your age?

8) Are you:

- ○ male
- ○ female

9) What is your ethnicity?

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino

10) What is your race?

- ○ Asian
- ○ Native Hawaiian or other Pacific Islander

- Black or African American
- White/Caucasian
- Other (Please specify)

11) What is your year in college?
- 1 - freshman
- 2 - sophomore
- 3 - junior
- 4 - senior
- 5 +

12) What is your current overall GPA? (if this is your first year of college, use high school GPA)

13) Think about the male figure that is most important to you in your life: your male role-model. Who is this person? (could be an uncle, father, step-father, etc.)

14) What is his highest level of education?
- Elementary School Graduate
- Middle School Graduate
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17) How often do you typically listen to classical music?
- Never
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- Several times a week

18) Do you often find it interesting to pay attention to the structure of a piece of music?
- Yes
- No

19) What grade do you want to get on your exams in your Psychology Course, out of a 100 point system?

20) What is the absolute lowest grade you would feel OK with getting on an exam in your Psychology Course class, out of a 100 point system? (Note that this could be different from question 19)

Here is a description of the study you said you would not like to participate in.

--please read carefully--
The Mozart Effect
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It has been shown in some studies (Rauscher et al., 1993) that people show enhanced spatial ability when completing tasks while listening to Mozart's Sonata for Two Pianos in D Major (coined "the Mozart Effect"). We would like to investigate whether this Effect holds for college students taking an exam, that is, does listening to Mozart while studying for and taking an exam lead to better test scores? We currently do not know whether this would be the case. It may be that listening to Mozart increases test scores, has no effect whatsoever on test scores, or even decreases test scores.

In this study we will randomly assign you to attend study sessions and take your second in-class examination for your Psychology course either while listening to Mozart (music listening condition) or under normal silent conditions (normal testing condition).

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Rauscher, F.H., Shaw, G.L., & Ky, C.N. (1993). Music and spatial task performance. Nature, 365, 611.

You indicated to us on your consent form that you are not interested in participating in the study situation described above. We would like to ask you a few questions about what led you to your decision.
(Assessment of characteristics related to disinterest in randomization, adopted from Harrison et al., 2007)
21) Which of these describes your reasons for not wanting to participate in the study? (you may check more than one):

- ○ I don't like the concept behind the study
- ○ I don't really want to do the extra work involved

- I only need 1 more research credit, not 2
- I don't like the idea of being randomly assigned to a treatment
- I would like to be able to make my own decisions about which group to be in
- I'm concerned that participation could have a negative effect on my exam performance
- I don't think the results of this study will benefit anyone
- I don't think either group (music or standard testing) would help me on the test
- No real reason/ just don't want to
- I strongly prefer the MUSIC group
- I strongly prefer the NORMAL TESTING group
- Other (Please specify)

(adopted from Harrison et al., 2007; assesses risk taking)

The following questions assess how much you are generally inclined or not to accept risk. Please use the scale where 0 is extremely unlikely, and 10 is extremely likely to indicate how likely you would be to do each behavior.

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25) Some activities/situations involve a "health risk" where there is a risk of harming ones' health. Health risks can include sunbathing with no sun screen or smoking.

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(Assesses Openness to Experience, adopted from The Big Five Inventory, John & Srivastava, 1999)

Here are a number of characteristics that may or may not apply to you.
Please indicate the extent to which you agree or disagree with the statements.

26) I see myself as someone who… Is original, comes up with new ideas
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36) What is your email address? (This will be used to confirm that you completed the survey. Your email address will be erased from our list once the study is complete).

37) Please confirm your email address.

Please click on "Submit"

Submit

The following is the baseline (and only) questionnaire for participants randomized to the PCT group, who decline to participate in the trial

The Mozart Effect and Student Performance in College Examination (UPCT)

Please allow approximately 20 minutes to complete this questionnaire.

Please answer the following questions. This information will allow us to match your data, and still allow you to complete the survey anonymously. This information will also be used to assign your participation credit.

1) Which Psychology Class are you taking (the class you are participating in the Mozart Effect Study for)?

- ○ PSY 103 Introduction to Psychology with Dr. Anne Moyer
- ○ PSY 103 Introduction to Psychology with Dr. Richard Gerrig
- ○ PSY 310 Research and Writing with Dr. Turhan Canli

2) What is your mother's maiden name?

3) What is your birth Month?

4) What is your birthday Day?

5) What do you call/ what did you call your mother's mom (your maternal grandmother)? Examples: Omi, Granny, Nannie, Grandma, Nana, Great Ma, etc.

6) What is your SOLAR ID number?

Baseline Assessment

First, we'd like to ask some questions about you. *(demographics)*

7) What is your age?

8) Are you:

- ○ male
- ○ female

9) What is your ethnicity?

- ○ Hispanic or Latino
- ○ Not Hispanic or Latino

10) What is your race?

- ○ Asian
- ○ Native Hawaiian or other Pacific Islander

- Black or African American
- White/Caucasian
- Other (Please specify)

11) What is your year in college?
- 1 - freshman
- 2 - sophomore
- 3 - junior
- 4 - senior
- 5 +

12) What is your current overall GPA? (if this is your first year of college, use high school GPA)

13) Think about the male figure that is most important to you in your life: your male role-model. Who is this person? (could be an uncle, father, step-father, etc.)

14) What is his highest level of education?
- Elementary School Graduate
- Middle School Graduate
- High School Graduate
- College Graduate
- Advanced Degree (MA, PhD, RN, MBA, etc.)

15) Think about the female figure that is most important to you in your life: your female role-model. Who is this person? (could be an aunt, mother, step-mother, etc.)

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17) How often do you typically listen to classical music?
- Never
- Once or twice a year
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- Several times a week

18) Do you often find it interesting to pay attention to the structure of a piece of music?
- Yes
- No

19) What grade do you want to get on your exams in your Psychology Course, out of a 100 point system?

20) What is the absolute lowest grade you would feel OK with getting on an exam in your Psychology Course class, out of a 100 point system? (Note that this could be different from question 19)

Here is a description of the study you said you would not like to participate in.

--please read carefully--
The Mozart Effect

It has been shown in some studies (Rauscher et al., 1993) that people show enhanced spatial ability when completing tasks while listening to Mozart's Sonata for Two Pianos in D Major (coined "the Mozart Effect"). We would like to investigate whether this Effect holds for college students taking an exam, that is, does listening to Mozart while studying for and taking an exam lead to better test scores? We currently do not know whether this would be the case. It may be that listening to Mozart increases test scores, has no effect whatsoever on test scores, or even decreases test scores.

In this study you will attend study sessions and take your second in-class examination for your Psychology course either while listening to Mozart (music listening condition) or under normal silent conditions (normal testing condition), depending on your preference.

You will receive an email confirmation of your condition, including information about the study sessions, about 4 weeks before the exam. Like other examinations in your Psychology course, if this score is the lowest for the semester, it will be dropped in calculating the final grade.

Rauscher, F.H., Shaw, G.L., & Ky, C.N. (1993). Music and spatial task performance. Nature, 365, 611.

You indicated to us on your consent form that you are not interested in participating in the study situation described above. We would like to ask you a few questions about what led you to your decision.

(Assessment of characteristics related to disinterest in randomization, adopted from Harrison et al., 2007)

21) Which of these describes your reasons for not wanting to participate in the study? (you may check more than one):

- ○ I don't like the concept behind the study
- ○ I don't really want to do the extra work involved

- I only need 1 more research credit, not 2
- I don't like the idea of picking one treatment or the other
- I'm concerned that participation could have a negative effect on my exam performance
- I don't think the results of this study will benefit anyone
- I don't think either group (music or standard testing) would help me on the test
- No real reason/ just don't want to
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(adopted from Harrison et al., 2007; assesses risk taking)
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- Agree a little
- Agree strongly

36) What is your email address? (This will be used to confirm that you have completed the study. Your email address will be erased from our list once the study is complete).

37) Please confirm your email address.

Please click on "Submit"

Submit

The following is the second questionnaire for participants in both PCT and RCT groups

Mozart Effect 2nd Assessment

Welcome to the 2nd on-line Questionnaire for the study on the Mozart Effect and Student Performance on College Examination!

Please answer the following questions. This information will allow us to match your data, and still allow you to complete the survey anonymously. This information will also be used to assign your participation credit.

1) Which Psychology Class are you taking (the class you are participating in the Mozart Effect Study for)?

- PSY 103 Introduction to Psychology with Dr. Anne Moyer
- PSY 103 Introduction to Psychology with Dr. Richard Gerrig
- PSY 310 Research and Writing with Dr. Turhan Canli

2) What is your mother's maiden name?

3) What is your birth Month?

4) What is your birthday Day?

5) What do you call/ what did you call your mother's mom (your maternal grandmother)? Examples: Omi, Granny, Nannie, Grandma, Nana, Great Ma, etc.

6) What is your SOLAR ID number?

Now we would like to ask you some additional questions.

(Manipulation check)

7) According to the email you received about the conditions (music listening vs. normal testing), which condition are you in?

- The normal testing condition
- The music listening condition
- I do not know

(Anticipated test performance; assesses ecological validity)

8) Please indicate the score, out of a 100 possible points system, that you anticipate achieving on your next (second) in class examination for this course.

9) Please indicate the score, out of a 100 possible points system, that you need on your next exam to help you achieve the grade you want to get in this course.

10) How desperate do you feel about getting a good grade on the next exam?

- Not At All Desperate – I could get a bad grade and still get the grade I want for the course

- Just a little Desperate
- Pretty Desperate
- Very Desperate- I need that good grade to get the grade I want for this course

(Feelings about participating in the research; adapted from Wortman et al., 1976)
Please rate the extent to which you agree or disagree with the following statements about the research project (listening to music by Mozart testing vs. silent standard testing):

11) I feel good about being in the project.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

12) I regret signing up for the project.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

13) I feel angry about the way the project is being conducted.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

14) I feel that the project is fair to all participants.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree

- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

15) I feel envious toward others in the project.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

16) I feel motivated to help make the project successful.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

17) I respect the people who are running the project.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

18) I believe the people who are running this project are concerned about me.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree

- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

19) I think the objective of this project is worthwhile and important.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

20) I think that the project will provide some useful information.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree
- Very Strongly Agree

Please click on "Submit"

Submit

(participants view this screen if they respond to "I do not know" to question 7)

Mozart Effect 2nd Assessment - Condition Questions

In order to compete the rest of the survey, you will need to know which condition you are in.

This information was sent to you in an email around the date of March 3rd. If you are missing the email, please do the following...

What to do:

Please send us an email (Mozart.Effect.Study@gmail.com) and request information on your condition. To help us do this, please tell us the following:

1. What Psychology class you are taking (103 or 310; and who your professor is: Anne Moyer, Richard Gerrig, or Turhan Canli).

2. Your SOLAR ID number

3. Your birthday (MM/DD/YYY)

Please click on "Submit"

Submit

Study Session Log *(records how long participants attend each study session; assessment of engagement in treatment)*

Birthdate (MM/DD/YYYY)	Mother's Maiden Name	Psych Class Dr. Moyer ? Dr. Gerrig ? Dr. Canli ?	Time in	Time out

What is your birthday? (month/day/year) ____/____/_____

What is your mother's maiden name? _____

What is your SOLAR ID Number? _____

Circle which Professor you have for your Psychology Class:

Dr. Anne Moyer Dr. Richard Gerrig Dr. Turhan Canli

Treatment Study Session Questionnaire

(to be completed after the study session; assesses engagement in treatment)

Was this a productive study session for you for your **Introduction to Psychology** exam or for your **Research and Writing** quiz?

1	2	3	4
Not really, I daydreamed a lot or worked on something else			Yes, I think I learned quite a lot.

The following is the third questionnaire for participants in both the RCT and PCT groups

Mozart Effect Third Assessment

Welcome to the 3rd and final questionnaire for the study "The Mozart Effect and Student Performance on College Examination".

Please allow yourself about 20 minutes to complete this final survey.

Please answer the following questions. This information will allow us to match your data, and still allow you to complete the survey anonymously. This information will also be used to assign your participation credit.

1) Which Psychology Class are you taking (the class you are participating in the Mozart Effect Study for)?

- PSY 103 Introduction to Psychology with Dr. Anne Moyer
- PSY 103 Introduction to Psychology with Dr. Richard Gerrig
- PSY 310 Research and Writing with Dr. Turhan Canli

2) What is your mother's maiden name?

3) What is your birth Month?

4) What is your birthday Day?

5) What do you call/ what did you call your mother's mom (your maternal grandmother)? Examples: Omi, Granny, Nannie, Grandma, Nana, Great Ma, etc.

6) What is your SOLAR ID number?

7) Please confirm your email address (enter the email address you have given us before; the email address with which we
have been in contact with you).

(Anxiety during studying and testing, approximated from Zimbardo et al., 2003)

Please rate the extent to which you agree or disagree with the following statements about Exam 2 (or, if you are in Dr. Canli's class, Quiz 3):

8) I felt anxious about this test while I was studying.

- Strongly disagree
- Somewhat disagree
- Neither disagree nor agree
- Somewhat agree
- Strongly agree

9) I felt anxious about this test while I was taking the test.

- Strongly disagree
- Somewhat disagree

- Neither disagree nor agree
- Somewhat agree
- Strongly agree

(State test anxiety, Hong, 1998)
Please rate the extent to which the following statements are true of you:

10) I was concerned about what would happen if I did poorly.
- Not At All
- Somewhat
- Moderately So
- Very Much So

11) Thinking about my grade in the course interfered with my work on the test.
- Not At All
- Somewhat
- Moderately So
- Very Much So

12) During the test I got so nervous that I forgot the facts that I really knew.
- Not At All
- Somewhat
- Moderately So
- Very Much So

13) I thought about how important the test was for me.
- Not At All
- Somewhat
- Moderately So
- Very Much So

14) While taking the test, I had an uneasy, upset feeling.
- Not At All
- Somewhat
- Moderately So
- Very Much So

15) I felt very panicky when I was taking the test.
- Not At All
- Somewhat
- Moderately So
- Very Much So

16) I felt very jittery when I was taking the test.
- Not At All
- Somewhat

- Moderately So
- Very Much So

17) During the test I felt very tense.
- Not At All
- Somewhat
- Moderately So
- Very Much So

18) I think I would have done better if I had been in the other study condition (music listening vs. normal testing condition).
- Not At All
- Somewhat
- Moderately So
- Very Much So

Please answer the following questions about Exam 2 (if you are in Dr. Canli's class, Quiz 3).

19) How do you feel about your performance on this test?
- Awful, I think I did really bad.
- Not so good.
- I feel alright about it.
- I feel pretty good about it.

20) To what extent do you think being in the condition you were in (music listening vs. normal testing) affected your performance on the exam?
- It hurt my performance tremendously.
- It hurt my performance a little.
- It neither hurt nor helped my performance.
- It helped my performance a little.
- It helped my performance tremendously.

Please rate the extent to which you agree or disagree with the following statements about the research project (listening to music by Mozart testing vs. silent standard testing):

21) I feel good about being in the project.
- Very Strongly Disagree
- Strongly Disagree
- Somewhat Disagree
- Mildly Disagree
- Neither Disagree Nor Agree
- Mildly Agree
- Somewhat Agree
- Strongly Agree

- o Very Strongly Agree

22) I regret signing up for the project.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

23) I feel angry about the way the project is being conducted.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

24) I feel that the project is fair to all participants.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

25) I feel envious toward others in the project.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

26) I feel motivated to help make the project successful.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

27) I respect the people who are running the project.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

28) I believe the people who are running this project are concerned about me.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

29) I think the objective of this project is worthwhile and important.
- o Very Strongly Disagree
- o Strongly Disagree
- o Somewhat Disagree
- o Mildly Disagree
- o Neither Disagree Nor Agree
- o Mildly Agree
- o Somewhat Agree
- o Strongly Agree
- o Very Strongly Agree

30) I think that the project will provide some useful information.

- ○ Very Strongly Disagree
- ○ Strongly Disagree
- ○ Somewhat Disagree
- ○ Mildly Disagree
- ○ Neither Disagree Nor Agree
- ○ Mildly Agree
- ○ Somewhat Agree
- ○ Strongly Agree
- ○ Very Strongly Agree

(Characteristics of study situation)

31) How many minutes did you spend studying for this test? (1 hour = 60 minutes, 1.5 hours = 90 minutes, etc.) If you did not study, indicate N/A.

32) Check what best characterizes your study situation (more than one may apply):

- ○ Alone, in a quiet room
- ○ Alone, in a busy room
- ○ With a study group
- ○ I studied ONLY during the study sessions available through the experiment
- ○ Other (Please specify)

About what percentage of the time you spent studying (on your own, that is, not including the class study sessions) were you:

33) Watching TV?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

34) What type(s) of shows did you usually watch?

35) Listening to music?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

36) What type(s) of music did you usually listen to?

37) Eating?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

38) What type(s) of food did you usually eat?

39) Drinking?

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

40) What type(s) of beverages do you usually drink?

41) Were these study habits typical for you?

- Yes
- No

42) Was there anything you did while studying for this exam that you do not usually do?

43) If you were to participate again, with respect to the two alternatives (standard testing situation vs. music testing situation), which would you prefer?

- Strongly prefer normal testing condition
- Somewhat prefer normal testing condition
- Somewhat prefer music testing condition
- Strongly prefer music testing condition

(Willingness to continue with the intervention and with the trial)

44) Please indicate your preference below:

- I would be willing to complete another brief questionnaire after the next test.
- I would not be willing to complete another brief questionnaire after the next test.

45) Some participants told us they heard that some students were given the study condition (music vs. normal testing) that they preferred, while other students were randomly assigned to condition. Did anyone tell you about this?

- No
- Yes

46) If yes, what thoughts do you have about this?

47) Is there anything at all that you would like to share with us about your experience as a participant in this study? This can be ANYTHING you would like to say. Please tell us what you think and how you feel!

The following question is about your experience in this study. Please be honest! All responses are valid and will not affect your participation credits or your exam grade.

*48) Check which box describes your experience.

- I was assigned to the Music Listening Condition and I attended the Music Listening Condition for the exam.
- I was assigned to the Music Listening Condition but I attended the Normal Testing Condition for the exam.
- I was assigned to the Normal Testing Condition and I attended the Normal Testing Condition for the exam.

- I was assigned to the Normal Testing Condition but I attended the Music Listening Condition for the exam.
- Other (Please specify)

(the following items are viewed by participants who respond that they attended the exam condition for which they were not assigned):

It is not a problem that you attended the examination for the condition that you were not assigned to! We are curious about why you did. Please be honest. Your responses will have no affect on your exam grade.

49) Which condition were you assigned to?
- the Normal Testing Condition
- the Music Listening Condition
- I don't know

50) Which condition did you go to for your exam?
- the Normal Testing Condition
- the Music Listening Condition
- I don't know

51) Do any of the following explain why you attended the wrong session for the exam? (More than one may apply).
- I forgot which group I was in
- I knew what group I was in but I forgot what room to go to
- I forgot which group I was in AND I forgot what room to go to
- I thought I might do better on the exam in the group I went to
- My friend is in this group and I wanted to take the test with my friend
- My friend is in this group and my friend said I might benefit from taking the exam in this group
- Other (Please specify)

Please click on "Submit"

Submit

What is your birth date? (Month/Day/Year): _____/_____/_____
What is your mother's maiden name? _____

Qualitative Assessment

Qualitative Assessments (administered only to participants who approach the research team on their own accord to talk with us about their experience)

1. What would you like to talk about?

2. How would you describe your feelings toward the project?

3. How would you describe your feelings toward the other participants?

4. What do you think about the two conditions in this study? (the music vs. the normal testing condition?)

5. Is there anything you would like to add?

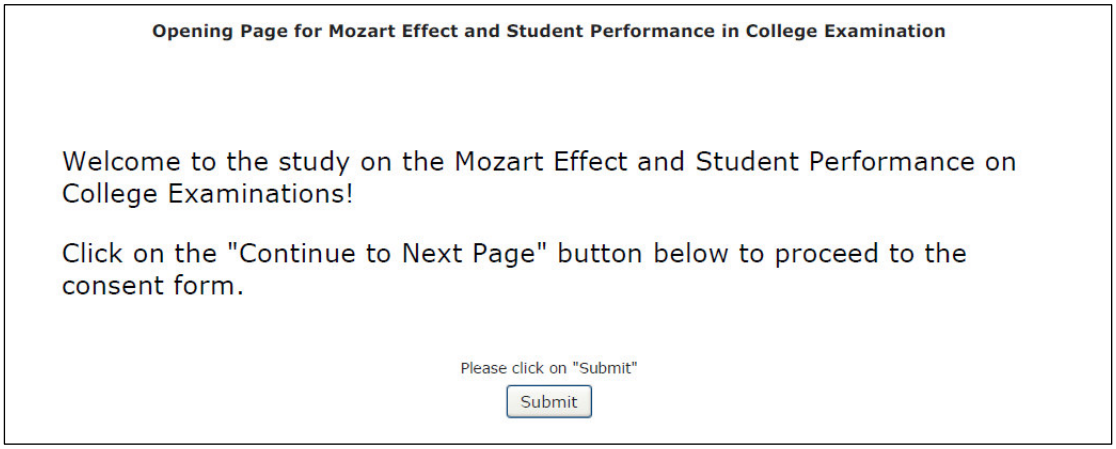
Thank you!

Appendix B

Consent Forms

All potential participants view this screen when they sign up for the study.

Clicking the Submit button randomizes one-third of potential participants to view the Preference Controlled Trial (PCT) consent form, and two-thirds of the potential participants to view the Randomized Controlled Trial (RCT) consent form.



consent form viewed by potential participants randomized to the RCT group

Consent Form for Mozart Effect RCT

Project Title: The Mozart Effect and Student Performance in College Examination (RCT)
Principal Investigator: Anne Moyer, Ph.D., Assistant Professor of Psychology
Co-Investigator: Anna HL Floyd, M.A., Doctoral Candidate

Research Consent Form

You are being asked to be a volunteer in a research study.

Purpose
The purpose of this study is: to examine the effects of listening to music composed by Mozart on student test performance. This involves taking your second course examination (or third course quiz if you are in Dr. Canli's class) possibly while listening to music or possibly under normal testing conditions. We expect 650 people to participate in this research study.

The Mozart Effect

It has been shown in some studies (Rauscher et al., 1993) that people show enhanced spatial ability when completing tasks while listening to Mozart's Sonata for Two Pianos in D Major (coined "the Mozart Effect"). We would like to investigate whether this Effect holds for college students taking an exam, that is, does listening to Mozart music while studying for and taking an exam lead to better test scores? We currently do not know whether this would be the case. It may be that listening to Mozart increases test scores, has no effect whatsoever on test scores, or even decreases test scores.

In this study we will randomly assign you to attend study sessions and take your second in class examination (or third course quiz if you are in Dr. Canli's class) for your Psychology course either while listening to Mozart (music listening condition) or under normal silent conditions (normal testing condition).

You will receive an email to let you know how you had been assigned (music listening vs. normal testing), including information about the study sessions, about 4 weeks before the exam. Like other examinations in your

Psychology course, if this score is the lowest for the semester, it will be dropped in calculating the final grade.

Rauscher, F.H., Shaw, G.L., & Ky, C.N. (1993). Music and spatial task performance. Nature, 365, 611.

Procedures: what you can expect to do in this study

If you decide to be in this study your part will involve: being randomly assigned (randomly, by a computer database) to attend study sessions and to take the second Psychology course in-class examination (or third course quiz if you are in Dr. Canli's class) while listening to music composed by Mozart (music listening condition) or under normal testing conditions (normal testing condition). If you enroll in this study, you will take your second course examination in a location TBA, not the class lecture hall. The score for this examination will be dropped in calculating your final grade for the Psychology course if it detracts from your overall performance in the course (i.e., if it is the lowest of the grades received on all course exams.)

Part 1a: Baseline Assessments

First, you will fill out an online questionnaire of basic demographic information (e.g., age) and your feelings about taking a test while listening to music versus normal testing.

Part 1b: Second Assessments

Later (in a few weeks), you'll learn by email whether or not you were randomly assigned to the music listening condition or the normal testing condition and complete some additional online questionnaire assessments. Completing Part 1a and 1b of the study should altogether take about 30-40 minutes or less.

Part 2: Treatment

You will be asked to attend at least 2 hours of study sessions provided by the research team (there will be several sessions offered, and each study session will be several hours in length; you can attend any 2 hours that you wish).

If you are assigned to the music listening condition, classical music will be played during the study sessions. If you are assigned to the normal testing condition, the study session will be silent (a standard study session). Further information about these study sessions (when, where) will be provided to you by email, and posted on Blackboard. You will receive experiment credit based on completion of assessments (Parts 1 and 3), not based upon attending the treatment study sessions (Part 2).

Part 3: Test Taking and Final Assessments

About four weeks after Part 1b the second Psychology examination (or third course quiz if you are in Dr. Canli's class) will take place. Participants randomly assigned to take the examination in the music listening condition or in the normal testing conditions will have the normally allotted one hour and twenty minutes to complete the exam. They will take the examination in a location TBA, not the class lecture hall. After the exam is finished you will complete some additional follow-up questionnaires online about your feelings about taking the examination. This should take an additional 15 minutes or less. To determine the effect of the type of testing on your performance compared to your prior performance, we will obtain your test scores for the first and second in-class examinations from your course instructor.

Risks/Discomforts

The following risks/discomforts may occur as a result of your participation in the study:

You may be unhappy with your condition. If you have agreed to take part in the study, we will not be able to switch your condition. However, you may talk with us about your experience. In addition, you may drop out of the study at any time.

Benefits

The following benefits to you are possible as a result of being in this study: If you are assigned to the music listening condition, you may find if helpful.

Credit to Subjects / Payment to You

You will receive course research credit based on the time spent participating in the experiment assessments. There are two assessments for the experiment: Initial Assessments outlined in Part 1a and b, which occur at two separate instances and will altogether take 30-40 minutes to complete; and Follow-up questions that will occur just after your second exam for this class and will take about 20 minutes to complete. You will receive 2 credits for completing all assessments.

Confidentiality

- We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too.

- If any papers and talks are given about this research, your name will not be used.

- We want to make sure that this study is being done correctly and that your rights are welfare are being protected. For this reason, we will share the data we get from you in this study with the study team, the sponsor of the study (and those

who work for them), Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices.

- However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this. In a lawsuit, a judge can make us give him the information we collected about you.

- Your information will be kept in a coded format. That is, we will not ask for your name on any of the questionnaire materials. Instead, we will ask you for a code, consisting of your birth-date, and your mother's maiden name. We will, however, need to use your name to match your exam grades to your questionnaire data. After the match occurs, we will destroy the link to your name.

- To assign your research credit, we will need to link the completion of your questionnaires to your name. To do this, we will ask you indicate your birthdate, your mother's maiden name, the high school you graduated from, and what you call your maternal grandmother. We will ask for only your birthdate, your mother's maiden name, the high school you graduated from, and what you call your maternal grandmother on subsequent questionnaires.

- We will ask you for your email address. This will allow us to contact you, to inform you of which condition you will attend (music listening vs. normal testing). Once the experiment is complete, we will destroy the list of email addresses

Costs to You

There is no cost to you in participating in this study.

Alternatives

You do not need to complete this study to fulfill your Psychology course research requirements. Other experiments are available through subject pool (contact Cynthia Zimmerli, Cynthia.Zimmerli@sunysb.edu).

Consequences of Withdrawing

If you withdraw before the completion of the study, you will not receive research credit. However, because you are free to leave the study at anytime, you will not receive a penalty for doing so. If you do withdraw from the study, regardless of whether you were to take the examination while listening to music or under normal testing conditions, you will take the second Psychology in-class exam (or third course quiz if you are in Dr. Canli's class) under normal individual testing conditions.

Subject Rights

Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.

You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.

Any new information that may make you change your mind about being in this study will be given to you.

You will get a copy of this consent form to keep.

You do not waive any of your legal rights by signing this consent form.

Questions about the Study or Your Rights as a Research Subject

If you have any questions about the study, you may contact Dr. Anne Moyer, at telephone number (631) 632-7811.

If you have any questions about your rights as a research subject, you may contact Ms. Judy Matuk, Committee on Research Involving Human Subjects, (631) 632-9036.

As in all psychology studies, please do not discuss the study with other participants.

Option A

If you are interested in completing all questionnaires, and would be willing to have your grades used in the research,

AND you are willing to participate in the experiment of being randomly assigned to attend study sessions and take your second examination (or third course quiz if you are in Dr. Canli's class) in either the music listening condition or the normal testing condition choose option A below.

If you choose OPTION A below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in the full study. This is worth 2 research credits.

(We will let you know by email when it is time for you to attend study sessions and complete the questionnaires).

Option B

If you are NOT willing to take part in the experiment on being randomly assigned to the music listening vs. normal testing,

but if you are interested in only completing the baseline online questionnaire described in Part 1a, and would be willing to have your grades used in the research, choose option B below.

If you choose OPTION B below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this questionnaire-only study. This is worth 1 research credit.

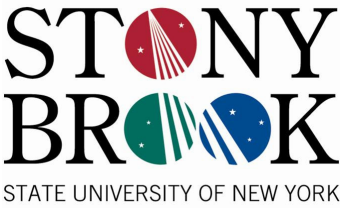
1) Please indicate which option you would prefer:

- Option A - 2 credits - I give consent to participate in the study (music listening vs. normal testing)
- Option B - 1 credit - Do not participate in the study, but give consent to complete a questionnaire
- Option C - do not participate at all

Please click on "Submit"

Submit

consent form viewed by potential participants randomized to the PCT group



Consent Form for Mozart Effect PCT

Project Title: The Mozart Effect and Student Performance in College Examination (PCT)
Principal Investigator: Anne Moyer, Ph.D., Assistant Professor of Psychology
Co-Investigator: Anna HL Floyd, M.A., Doctoral Candidate

Research Consent Form

You are being asked to be a volunteer in a research study.

Purpose

The purpose of this study is: to examine the effects of listening to music composed by Mozart on student test performance. This involves taking your second course examination (or third course quiz if you are in Dr. Canli's class) possibly while listening to music or possibly under normal testing conditions. We expect 650 people to participate in this research study.

The Mozart Effect

It has been shown in some studies (Rauscher et al., 1993) that people show enhanced spatial ability when completing tasks while listening to Mozart's Sonata for Two Pianos in D Major (coined "the Mozart Effect"). We would like to investigate whether this Effect holds for college students taking an exam, that is, does listening to Mozart music while studying for and taking an exam lead to better test scores? We currently do not know whether this would be the case. It may be that listening to Mozart increases test scores, has no effect whatsoever on test scores, or even decreases test scores.

In this study you will attend study sessions and take your second in-class examination (or third course quiz if you are in Dr. Canli's class) for your Psychology course either while listening to Mozart (music listening condition) or under normal silent conditions (normal testing condition), depending on your preference.

You will receive an email confirmation of your condition, including information about the study sessions, about 4 weeks before the exam. Like other examinations in your Psychology course, if this score is the lowest for the semester, it will be dropped in calculating the final grade.

Rauscher, F.H., Shaw, G.L., & Ky, C.N. (1993). Music and spatial task performance. Nature, 365, 611.

Procedures: what you can expect to do in this study

If you decide to be in this study your part will involve: attending study sessions and taking the second Psychology in-class examination (or third course quiz if you are in Dr. Canli's class) while listening to music composed by Mozart (music listening condition) or under normal testing conditions (normal testing condition), whichever you prefer. If you enroll in this study, you will take your second course examination in a location TBA, not the class lecture hall. The score for this examination will be dropped in calculating your final grade for the Psychology course if it detracts from your overall performance in the course (i.e., if it is the lowest of the grades received on all course exams.)

Part 1a: Baseline Assessments

First, you will fill out an online questionnaire of basic demographic information (e.g., age) and your feelings about taking a test while listening to music versus normal testing.

Part 1b: Second Assessments

Later (in a few weeks), you'll receive a confirmation email about receiving your preferred condition (music listening or the normal testing) and complete some additional questionnaires online. Completing Part 1a and 1b of the study should altogether take about 30-40 minutes or less.

Part 2: Treatment

You will be asked to attend at least 2 hours of treatment study sessions provided by the research team (there will be several sessions offered, and each study session will be several hours in length; you can attend any 2 hours that you wish).

If you are in the music listening condition, classical music will be played during the study sessions. If you are in the normal testing condition, the study session will be a standard study session. Further information about these study sessions (when, where) will be provided to you by email and posted on Blackboard. You will receive experiment credit based on completion of assessments (Parts 1 and 3), not based upon attending the treatment study sessions (Part 2).

Part 3: Test Taking and Final Assessments

About four weeks after Part 1b the second Psychology examination (or third course quiz if you are in Dr. Canli's class) will take place. Participants assigned to take the examination according to their indicated preference of either the music listening condition or in the normal testing conditions will have the normally allotted one hour and twenty minutes to complete the exam. They will take the examination in a location TBA, not the class lecture hall. After the exam is finished you will complete some additional follow-up questionnaires online about your feelings about taking the examination. This should take an additional 15 minutes or less. To determine the effect of the type of testing on your performance compared to your prior performance, we will obtain your test scores for the first and second in-class examinations from your course instructor.

Risks/Discomforts

The following risks/discomforts may occur as a result of your participation in the study:

You may be unhappy with your condition. If you have agreed to take part in the study, we will not be able to switch your condition. However, you may talk with us about your experience. In addition, you may drop out of the study at any time.

Benefits

The following benefits to you are possible as a result of being in the study: If you are in the treatment, the music listening condition, you may find it helpful.

Credit to Subjects / Payment to You

You will receive course research credit based on the time spent participating in the experiment assessments. There are two assessments for the experiment: Initial Assessments outlined in Part 1a and b, which occur at two separate instances and will altogether take 30-40 minutes to complete; and Follow-up questions that will occur just after your second exam for this class and will take about 20 minutes to complete. You will receive 2 credits for completing all assessments.

Confidentiality

- We will take steps to help make sure that all the information we get about you is kept private. Your name will not be used wherever possible. We will use a code instead. All the study data that we get from you will be kept locked up. The code will be locked up too.

- If any papers and talks are given about this research, your name will not be used.

- We want to make sure that this study is being done correctly and that your rights are welfare are being protected. For this reason, we will share the data we get

from you in this study with the study team, the sponsor of the study (and those who work for them), Stony Brook University's Committee on Research Involving Human Subjects, applicable Institutional officials, and certain federal offices.

- However, if you tell us you are going to hurt yourself, hurt someone else, or if we believe the safety of a child is at risk, we will have to report this. In a lawsuit, a judge can make us give him the information we collected about you.

- Your information will be kept in a coded format. That is, we will not ask for your name on any of the questionnaire materials. Instead, we will ask you for a code, consisting of your birth-date, and your mother's maiden name. We will, however, need to use your name to match your exam grades to your questionnaire data. After the match occurs, we will destroy the link to your name.

- To assign your research credit, we will need to link the completion of your questionnaires to your name. To do this, we will ask you indicate your birthdate, your mother's maiden name, the high school you graduated from, and what you call your maternal grandmother. We will ask for only your birthdate, your mother's maiden name, the high school you graduated from, and what you call your maternal grandmother on subsequent questionnaires.

- We will ask you for your email address. This will allow us to contact you, to confirm to which condition you will attend (music listening vs. normal testing). Once the experiment is complete, we will destroy the list of email addresses.

Costs to You

There is no cost to you in participating in this study.

Alternatives

You do not need to complete this study to fulfill your Psychology course research requirements. Other experiments are available through subject pool (contact Cynthia Zimmerli, Cynthia.Zimmerli@sunysb.edu).

Consequences of Withdrawing

If you withdraw before the completion of the study, you will not receive research credit. However, because you are free to leave the study at anytime, you will not receive a penalty for doing so. If you do withdraw from the study, regardless of whether you were to take the examination while listening to music or under normal testing conditions, you will take the second Psychology in-class exam (or third course quiz if you are in Dr. Canli's class) under normal individual testing conditions.

Subject Rights

- Your participation in this study is voluntary. You do not have to be in this study if you don't want to be.

- You have the right to change your mind and leave the study at any time without giving any reason, and without penalty.

- Any new information that may make you change your mind about being in this study will be given to you.

- You will get a copy of this consent form to keep.

- You do not waive any of your legal rights by signing this consent form.

Questions about the Study or Your Rights as a Research Subject

- If you have any questions about the study, you may contact Dr. Anne Moyer, at telephone number (631) 632-7811.

- If you have any questions about your rights as a research subject, you may contact Ms. Judy Matuk, Committee on Research Involving Human Subjects, (631) 632-9036.

As in all psychology studies, please do not discuss the study with other participants.

Option A

If you are interested in completing all online questionnaires, and would be willing to have your grades used in the research,

AND you would like to take part in the experiment of attending study sessions and taking your second examination (or third course quiz if you are in Dr. Canli's class) in the music listening condition or the normal testing condition - which ever condition you prefer - choose option A below.

If you choose on OPTION A below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in the study. This is worth 2 research credits.

(We will let you know by email when it is time for you to attend study sessions and complete the questionnaires).

Option B

If you are NOT willing to take part in the experiment on music listening vs. normal testing,

but if you are interested in only completing the baseline online questionnaire described in Part 1a, and would be willing to have your grades used in the research, please choose option B below.

If you choose OPTION B below, it means that you have read (or have had read to you) the information given in this consent form, and you would like to be a volunteer in this questionnaire-only study. This is worth 1 research credit.

1) Please indicate which option you would prefer:

- Option A - 2 credits - I give consent to participate in the study (music listening vs. normal testing)
- Option B - 1 credit - Do not participate in the study, but give consent to complete a questionnaire
- Option C - do not participate at all

Please click on "Submit"

Submit

Appendix C
Email Message for Condition Assignment

Randomly Assigned to Treatment

♫ Mozart Effect Study Announcement
Documentation of Testing Situation Assignment

Thank you again for participating in our study.

This email is to inform you that **you have been randomly, by chance, assigned to take your second Psychology Course examination in the music listening condition.** (You are in the Music Listening Condition.)

Here is what you need to do:

1. It is time to fill out the second on-line questionnaire! You must fill this out BEFORE Monday March 9th at noon. You do NOT need to sign up for this in SONA. There is no separate consent form for this portion. Simply follow this link:

https://www.psychdata.com/s.asp?SID=123368

2. Please make a note that you will take your next Psychology Course exam or quiz on in a different room, not the usual lecture hall. The room location will be posted on Blackboard.

3. We ask that you attend at least 2 hours of the study sessions provided, to study for your exam or quiz. Your attendance does not impact the number of credits you receive for your participation; you will only receive credit based on your completion of the 3 online questionnaires. However, the study sessions are a part of the treatment we are studying and may be important for you in terms of your exam performance. In the table below you will find a study session schedule.

Please bring your text and study materials to the study sessions!

We will be in touch by email and by postings on Blackboard.

Best,
The Mozart Effect Study Staff

Study Session Schedule:
For Participants in Dr. Richard Gerrig's Class
For Participants in Dr. Turhan Canli's Class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
Monday	March 16th	11:00-1:00	PSYC B 248	PSYC A 113
Tuesday	March 17th	10:30-11:30	PSYC A 113	PSYC B 218
Tuesday	March 17th	2:30-3:30	PSYC B 248	PSYC A 113

Wednesday	March 18th	10:00-12:00	PSYC B 116	PSYC A 113
Wednesday	March 18th	2:00-3:00	PSYC B 248	PSYC A 113

Study Session Schedule:

For Participants in Dr. Anne Moyer's class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
Thursday	March 26th	10:30-11:30	PSYC A 113	PSYC B 218
Friday	March 27th	10:00-12:00	PSYC B 248	PSYC B 218
Friday	March 27th	2:00-3:00	PSYC B 248	PSYC A 113
Monday	March 30th	11:00-1:00	PSYC B 218	PSYC A 113

Randomly Assigned to Control

♫ Mozart Effect Study Announcement
Documentation of Testing Situation Assignment

Thank you for participating in our study.

This email is to inform you that **you have been randomly, by chance, assigned to take your second Psychology Course examination in the normal (silent) testing condition.** (You are in the Normal Testing Condition).

Here is what you need to do:

1. It is time to fill out the second on-line questionnaire! You must fill this out BEFORE Monday February 9th at noon. You do NOT need to sign up for this in SONA. There is no separate consent form for this portion. Simply follow this link:

https://www.psychdata.com/s.asp?SID=123368

2. Please make a note that you will take your next Psychology Course exam or quiz in a different room, not the usual lecture hall. The room location will be posted on Blackboard.

3. We ask that you attend at least 2 hours of the study sessions provided, to study for your next exam or quiz. Your attendance does not impact the number of credits you receive for your participation; you will only receive credit based on your completion of the 3 online questionnaires. However, the study sessions are a part of the treatment we are studying and may be important for you in terms of your exam performance. In the table below you will find a study session schedule.

Please bring your text and study materials to the study sessions!

We will be in touch by email and by postings on Blackboard.

Best,
The Mozart Effect Study Staff

Study Session Schedule:
For Participants in Dr. Richard Gerrig's Class
For Participants in Dr. Turhan Canli's Class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
Monday	March 16th	11:00-1:00	PSYC B 248	PSYC A 113
Tuesday	March 17th	10:30-11:30	PSYC A 113	PSYC B 218
Tuesday	March 17th	2:30-3:30	PSYC B 248	PSYC A 113
Wednesday	March 18th	10:00-12:00	PSYC B 116	PSYC A 113
Wednesday	March 18th	2:00-3:00	PSYC B 248	PSYC A 113

Study Session Schedule:
For Participants in Dr. Anne Moyer's class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
Thursday	March 26th	10:30-11:30	PSYC A 113	PSYC B 218
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Friday	March 27th	2:00-3:00	PSYC B 248	PSYC A 113
Monday	March 30th	11:00-1:00	PSYC B 218	PSYC A 113

Assigned to Preference of Treatment Condition

♫ Mozart Effect Study Announcement
Documentation of Testing Situation Assignment

Thank you for participating in our study.

This email is to confirm that you will be taking your next Psychology Course examination **according to your stated preference of the music listening condition.** (You are in the Music Listening Condition).

Here is what you need to do:

1. It is time to fill out the second on-line questionnaire! You must fill this out BEFORE Monday February 9th at noon. You do NOT need to sign up for this in SONA. There is no separate consent form for this portion. Simply follow this link:

https://www.psychdata.com/s.asp?SID=123368

2. Please make a note that you will take your next Psychology Course exam or quiz in a different room, not the usual lecture hall. The room location will be posted on Blackboard.

3. We ask that you attend at least 2 hours of the study sessions provided, to study for your exam or quiz. Your attendance does not impact the number of credits you receive for your participation; you will only receive credit based on your completion of the 3 online questionnaires. However, the study sessions are a part of the treatment we are studying and may be important for you in terms of your exam performance. In the table below you will find a study session schedule.

Please bring your text and study materials to the study sessions!

We will be in touch by email and by postings on Blackboard.

Best,
The Mozart Effect Study Staff

Study Session Schedule:

For Participants in Dr. Richard Gerrig's Class
For Participants in Dr. Turhan Canli's Class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
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Wednesday	March 18th	2:00-3:00	PSYC B 248	PSYC A 113

Study Session Schedule:

For Participants in Dr. Anne Moyer's class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
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Friday	March 27th	2:00-3:00	PSYC B 248	PSYC A 113
Monday	March 30th	11:00-1:00	PSYC B 218	PSYC A 113

Assigned to Preference of Control Condition

♫ Mozart Effect Study Announcement
Documentation of Testing Situation Assignment

Thank you for participating in our study.

This email is to confirm that you will be taking your next Psychology Course examination **according to your stated preference of the normal (silent) testing condition**. (You are in the Normal Testing Condition).

Here is what you need to do:

1. It is time to fill out the second on-line questionnaire! You must fill this out BEFORE Monday February 9th at noon. You do NOT need to sign up for this in SONA. There is no separate consent form for this portion. Simply follow this link:

https://www.psychdata.com/s.asp?SID=123368

2. Please make a note that you will take your next Psychology Course exam in a different room, not the usual lecture hall. The room location will be posted on Blackboard..

3. We ask that you attend at least 2 hours of the study sessions provided, to study for your next exam or quiz. Your attendance does not impact the number of credits you receive for your participation; you will only receive credit based on your completion of the 3 online questionnaires. However, the study sessions are a part of the treatment we are studying and may be important for you in terms of your exam performance. In the table below you will find a study session schedule.

Please bring your text and study materials to the study sessions!

We will be in touch by email and by postings on Blackboard.

Best,
The Mozart Effect Study Staff

Study Session Schedule:
For Participants in Dr. Richard Gerrig's Class
For Participants in Dr. Turhan Canli's Class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
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Study Session Schedule:

For Participants in Dr. Anne Moyer's class

Day	Date	Time	Normal Testing Condition	Music Listening Condition
Thursday	March 26th	10:30-11:30	PSYC A 113	PSYC B 218
Friday	March 27th	10:00-12:00	PSYC B 248	PSYC B 218
Friday	March 27th	2:00-3:00	PSYC B 248	PSYC A 113
Monday	March 30th	11:00-1:00	PSYC B 218	PSYC A 113

Appendix D

Participant Debriefing

Participant Debriefing:
The Mozart Effect and Student Performance in College Examination

The Mozart Effect, the finding that listening to music composed by Mozart enhances spatial reasoning, is a controversial phenomenon that has been supported by some studies (Rauscher, Shaw, & Ky, 1993), but not by others (Crncec, Wilson, & Prior, 2006; Hui, 2006).

The primary aim of this study was to better understand unintentional biases introduced by randomly assigning participants (i.e., by chance, like a coin toss) to treatment conditions, which is common practice in research. Participants in randomized studies may have preferences for the different treatments being compared, but this is not often taken into account. This may lead people with different preferences to not participate in research at all, or drop out, jeopardizing the integrity of research results. Also, people may react to being assigned to their preferred or non-preferred treatment in ways that influence the outcomes of the treatments being compared. Understanding this is critical because randomized studies are important in testing the usefulness of all kinds of treatments.

In this study, half of the participants were randomly assigned (1) to have a choice of the two testing conditions (music listening versus normal) based on their indicated preference or (2) to simply be randomly assigned to the two testing conditions. This was not explicitly indicated to participants because we were interested in how participants would react to having versus not having a choice.

When all of the data are collected, participants who were matched versus mismatched to their preferred treatment will be compared. We are interested in seeing if there will be differences in expectations about whether music listening versus normal testing will be beneficial, how it may have affected scores on the examination, and feelings about being in the research and continuing to be in it. We will also investigate the characteristics of people who decided to not participate in a randomized study.

We will also, incidentally, also test the data to determine whether there is a "Mozart Effect" that enhances student performance on Psychology course examination.

Thank you very much for participating in our study!

References

Crncec, R., Wilson, S. J., & Prior, M. (2006). No evidence for the Mozart effect in children. *Music Perception, 23,* 305-317.

Hui, K. (2006). Mozart effect in preschool children? *Early Child Development and Care, 176,* 411-419.

Rauscher, F. H., Shaw, G. L., & Ky, C. N. (1993). Music and spatial task performance. *Nature, 365,* 611.