**Protocol title:** “Replication of Risen & Gilovich (2008): ‘Why People Are Reluctant to Tempt Fate’”

**Funding:** ASK CHARLIE

**RESOURCES**

*a.) Qualified staff*

*Please state and justify the number and qualifications of your study staff.*

We have three study staff members: (1) protocol director Maya Mathur, who is a biostatistician in the Quantitative Sciences Unit; and (2) co-PD Michael Frank, who is a professor in Department of Psychology; and (3) a graduate student assistant (not yet identified) to administrate the study. All have experience with and current certification for human subjects research.

*b.) Training*

*Describe the training you will provide to ensure that all persons assisting with the research are informed about the protocol and their research-related duties and functions.*

All staff members are well-informed about the protocol. Any necessary changes made by either PD will be discussed and documented thoroughly. No training is necessary to administer this study (the assistant will simply direct subjects to use a Qualtrics link).

*c.) Facilities*

*Please describe and justify.*

We will conduct this study by administering a brief online questionnaire to a lecture hall of undergraduates prior to Psych 1. No special facilities are required.

*d.) Sufficient time.*

*Explain whether you will have sufficient time to conduct and complete the research. Include how much time is required.*

This project will take minimal time to conduct. We expect to finish data collection in 1-2 weeks since it will be administered to a lecture hall of undergraduates simultaneously (in several sessions). We will then spend about 6 months analyzing the data and writing up the results.

*e.) Access to target population.*

Explain and justify whether you will have access to a population that will allow recruitment of the required number of participants.

We will recruit participants from among students attending Psychology 1, which enrolls about 260 students. Even with some non-participation, this is adequate to achieve 80% power for the main endpoint and >80% power for secondary endpoints.

*f.) Access to resources if needed as a consequence of the research.*

*State whether you have medical or psychological resources available that participants might require as a consequence of the research when applicable. Please describe these resources.*

There is no appreciable medical or psychological risk associated with this research.

*g.) Lead Investigator or Coordinating Institution in Multi-site Study.*

*Please explain (i) your role in coordinating the studies, (ii) procedures for routine communication with other sites, (iii) documentation of routine communications with other sites, (iv) planned management of communication of adverse outcomes, unexpected problems involving risk to participants or others, protocol modifications or interim findings.*

(i) The present protocol is part of a multisite replication effort for Risen & Gilovich (2008). MM is coordinating this replication effort by designing the protocols for each site in conjunction with site investigators.

(ii) All sites will stay in communication via regular email and/or phone calls with MM.

(iii) MM will save all email communications.

(iv) There is no appreciable risk of adverse events. Any proposed post hoc protocol changes will be discussed between site investigators and MM.

**PROTOCOL INFORMATION**

**1. Purpose**

*a) In layperson’s language, state the purpose of the study in 3-5 sentences.*

The purpose of the study is to examine the existence and mechanisms of the belief that “tempting fate” is punished with ironic bad outcomes. Specifically, we hypothesize that subjects who complete a challenging mental task (counting backwards by 3s) will show heightened belief that “tempting fate” invites ironic bad outcomes. This study is a direct replication of a previously published study (Risen & Gilovich, 2008) on this topic.

*b) State what the Investigator(s) hope to learn from the study. Include an assessment of the importance of this new knowledge.*

“Magical beliefs”, such as aversions to tempting fate, potentially drive some forms of irrational decision-making that are both personally and societally consequential. The proposed research may help parse mechanisms of a particular magical belief. More broadly, the present protocol is part of a multi-site meta-science study designed to investigate the impact of a priori peer review on scientific replicability; this research will help clarify reasons for widespread non-replicability in the cognitive sciences.

*c) Explain why human subjects must be used for this project. (i.e. purpose of study is to test efficacy of investigational device in individuals with specific condition; purpose of study is to examine specific behavioral traits in humans in classroom or other environment)*

The study is fundamentally about human judgment; thus, we must use human subjects.

**2. Study procedures**

*a) Describe all the research procedures, from screening through closeout, which the human subject must undergo in the research project, including study visits, drug treatments, randomization and the procedures that are part of standard of care.*

Before lecture, the research assistant will invite students to use their personal laptops or mobile devices to access a brief (2-5 minute) online Qualtrics questionnaire involving probability estimation for an imagined scenario and, depending on randomization, a mental arithmetic task (hereafter the “cognitive load” task).

*b) Explain how the above research procedures are the least risky that can be performed consistent with sound research design.*

There is no appreciable risk, beyond everyday risks, associated with participation in this study.

*c) State if deception will be used. If so, provide the rationale and describe debriefing procedures. Since you will not be fully informing the participant in your consent process and form, complete an alteration of consent (in section 13). Submit a debriefing script (in section 16).*

We will not use deception.

*d) State if audio or video recording will occur. Describe what will become of the recording after use, e.g., shown at scientific meetings, erased. Describe the final disposition of the recordings.*

We will not create recordings.

*e) Describe alternative procedures or courses of treatment, if any, that might be advantageous to the participant. Describe potential risks and benefits associated with these. Any standard treatment that is being withheld must be disclosed in the consent process and form. (i.e. standard-of-care drug, different interventional procedure, no procedure or treatment, palliative care, other research studies).*

Since this is a behavioral study targeting normal volunteers, no alternative treatments are relevant.

*f) Will it be possible to continue the more (most) appropriate therapy for the participant(s) after the conclusion of the study?*

Not relevant.

*g) Study Endpoint. What are the guidelines or end points by which you can evaluate the different treatments (i.e. study drug, device, procedure) during the study? If one proves to be clearly more effective than another (or others) during the course of a study, will the study be terminated before the projected total participant population has been enrolled? When will the study end if no important differences are detected?*

Not relevant.

**3. Background**

*a) Describe past experimental and/or clinical findings leading to the formulation of the study.*

As previously mentioned, this is a direct replication of Risen & Gilovich (2008), who found that people believe that tempting fate will provoke bad outcomes and that such tendencies are exacerbated under cognitive load.

*b) Describe any animal experimentation and findings leading to the formulation of the study.*

Not relevant.

**4. Participant Population**

*a) State the following: (i) the number of participants expected to be enrolled at Stanford-affiliated site(s); (ii) the total number of participants expected to enroll at all sites; (iii) the type of participants (i.e. students, patients with certain cancer, patients with certain cardiac condition) and the reasons for using such participants.*

At Stanford, we will enroll approximately n=220-260 undergraduates enrolled in Psych 1. Additionally, 3-10 other universities will each enroll approximately 100-400 subjects, conducting the same protocol. The other sites will be recruited to investigate effects of site-to-site variability on scientific replication.

*b) State the age range, gender, and ethnic background of the participant population being recruited.*

Subjects will be roughly 18-22 years old, roughly 50% female, and will reflect Stanford’s general undergraduate ethnic background (predominantly Caucasian and Asian).

*c) State the number and rationale for involvement of potentially vulnerable subjects in the study (including children, pregnant women, economically and educationally disadvantaged, decisionally impaired, homeless people, employees and students). Specify the measures being taken to minimize the risks and the chance of harm to the potentially vulnerable subjects and the additional safeguards that have been included in the protocol to protect their rights and welfare.*

No vulnerable populations will be recruited.

*If women, minorities, or children are not included, a clear compelling rationale must be provided (e.g., disease does not occur in children, drug or device would interfere with normal growth and development, etc.).*

Among these groups, only children are excluded because they are unlikely to be enrolled in Psych 1.

*State the number, if any, of participants who are laboratory personnel, employees, and/or students. They should render the same written informed consent. If payment is allowed, they should also receive it.*

All participants will be students. Because we are using an online questionnaire, consent will be online rather than written.

*State the number, if any, of participants who are healthy volunteers. Provide rationale for the inclusion of healthy volunteers in this study. Specify any risks to which participants may possibly be exposed. Specify the measures being taken to minimize the risks and the chance of harm to the volunteers and the additional safeguards that have been included in the protocol to protect their rights and welfare.*

Although we will not select for health status, we expect most students to be healthy volunteers. This is because no special populations are needed for this research.

*How will you identify participants for recruitment? (E.g., by: chart review; referral from treating physician; response to ad). Attach recruitment materials in Section #16 (Attachments). All Final or revised recruitment materials, flyers, etc. must be submitted to the IRB for review and approval before use. You may not contact potential participants prior to IRB approval.*

We will recruit participants through the Psychology Department’s standard participant pool. That is, students enrolled in Psych 1 must complete a quota of research participation hours. Our study will be one of several they can choose from in a standardized online interface.

*d) Describe how potential participants will be identified for recruitment (e.g., chart review, referral from individual's treating physician, responses to an ad). Describe how participants will be recruited and how they will initially learn about the research (e.g., clinics, advertising). If this is a clinical trial, indicate the recruitment option selected in registering the trial on the Stanford Clinical Trials web site-whether recruitment is limited to "invitation only" (e.g. your own patients), or whether recruitment will be open to the general public. Attach recruitment materials in Section #16 (Attachments). You may not contact potential participants prior to IRB approval. See guidance Advertisements: Appropriate Language for Recruitment Material.*

We will invite subjects to participate via the standard Psych 1 . This is not a clinical trial.

*e) Inclusion and Exclusion criteria*

*Identify inclusion criteria.*

The single inclusion criterion is that the subject is enrolled in Stanford’s Psych 1 course in Fall 2016.

*Identify exclusion criteria.*

None.

*f) Describe your screening procedures, including how qualifying laboratory values will be obtained. If you are collecting personal health information prior to enrollment (e.g., telephone screening), please request a limited waiver of authorization in section #10.*

Health screening is irrelevant to this survey.

*g) Payment. Explain the amount and schedule of payment, if any, that will be paid for participation in the study. Substantiate that proposed payments are reasonable and commensurate with the expected contributions of participants and that they do not constitute undue pressure on participants to volunteer for the research study. Include provisions for prorating payment. See payment considerations.*

Subjects will not be paid, but will be compensated via accural of study participation credit (an existing requirement for Psych 1 students).

*h) Costs. Please explain any costs that will be charged to the participant.*

No costs to participant.

*i) Estimate the probable duration of the entire study. Also estimate the total time per participant for: (i) screening of participant; (ii) active participation in study; (iii) analysis of participant data.*

The probable duration of the entire study will be 6 months.

i. No time is required for screening.

ii. Active participation will require 2-5 minutes per subject.

iii. Data analysis will require approximately 3 months.

**5. Risks**

*a) Describe risks. Include risks to privacy, confidentiality, etc.*

There are no appreciable risks to privacy or confidentiality.

*b) If you are conducting international research, describe the qualifications/preparations that enable you to both estimate and minimize risks to participants. Also complete the International Research Form and attach it in the Attachments section. If not applicable, enter N/A.*

N/A.

*c) Could any disclosure of the participant's response outside the research reasonably place them at risk of loss of insurability, criminal or civil liability, or be damaging to the participant's financial standing, employability, or reputation?*

No. There is no reasonable way that this could occur.

**6. Benefits**

*a) Describe the potential benefit(s) to be gained by the participants or by the acquisition of important knowledge which may benefit future participants, etc.*

There is no foreseeable benefit to the subjects apart from the accrual of study participation credit.

**7. Privacy and Confidentiality**

*Privacy Protections*

*a) Describe how the conditions under which interactions will occur are adequate to protect the privacy interests of participants (e.g., privacy of physical setting for interviews or data collection, protections for follow-up interactions such as telephone, email and mail communications).*

This study does not involve PHI or any form of sensitive information. We will collect no identifying information.

**\*\* NOTE: If your site is collecting subjects from multiple classes that might have some cross-enrollment, please contact MM so that we can figure out a strategy to avoid subject duplication (e.g. by collecting some identifying information). \*\***

*Confidentiality Protections*

*b) Specify the PHI (protected health information) or other individually identifiable data or specimens you will obtain, use or disclose to others. PHI is health information linked to one or more of the HIPAA identifiers listed above. List BOTH health information AND identifiers.*

N/A.

*c) Describe: (i) how data will be maintained (e.g., paper or electronic spreadsheet, desktop computer, laptop or other portable device); (ii) how you will maintain the confidentiality and data security, (e.g., password protected computer, encrypted files, locked cabinet and office); and (iii) who will have access to the data (e.g., research team, sponsors, consultants)*

Data will be maintained in a .csv file.

*d) If you will be sharing data with others, describe how data will be transferred (e.g., courier, mail) or transmitted (e.g., file transfer software, file sharing, email). If transmitted via electronic networks, describe how you will secure the data while in transit. See http://www.stanford.edu/group/security/securecomputing/ .*

Data will be transferred via regular email or a file-sharing website such as Google Drive or Open Science Framework. This is sufficient given that we will collect no sensitive information.

*e) If you plan to code the data, describe the method in which it will be coded and indicate who will have access to the key to the code.*

N/A.

*f) How will you educate research staff to ensure they take appropriate measures to protect the privacy of participants and the confidentiality of data collected (e.g. conscious of oral and written communications, maintaining paper and electronic data)?*

N/A.

**CONSENT POP-UP WINDOW**

*a.) Not sure what the question was.*

|  |
| --- |
| Describe the informed consent process. Include the following. |
|  | |  |  |  | | --- | --- | --- | |  | (i) | Who is obtaining consent? (The person obtaining consent must be knowledgeable about the study.) | |  | (ii) | When and where will consent be obtained? | |  | (iii) | How much time will be devoted to consent discussion? | |  | (iv) | Will these periods provide sufficient opportunity for the participant to consider whether or not to participate and sign the written consent? | |  | (v) | What steps are you taking to minimize the possibility of coercion and undue influence? | |  | (vi) | If consent relates to children and if you have a reason for only one parent signing, provide that rationale for IRB consideration. | |

(i) The online questionnaire will automatically obtain consent. Students who choose not to participate will be directed not to continue.

(ii) Consent will be obtained online.

(iii) Since the study is online, subjects will read the consent document at their own pace.

(iv) Yes, since the participant can read at his own pace.

(v) The online consent process will inform students that they are under no pressure to participate.

(vi) Not applicable.

*b) What is the Procedure to assess understanding of the information contained in the consent? How will the information be provided to participants if they do not understand English or if they have a hearing impairment? See HRPP Chapter 12.2 for guidance.*

Subjects will be enrolled in an English-language college class, so reasonable fluency is expected.

*c) What steps are you taking to determine that potential participants are competent to participate in the decision-making process? If your study may enroll adults who are unable to consent, describe (i) how you will assess the capacity to consent, (ii) what provisions will be taken if the participant regains the capacity to consent,(iii) who will be used as a legally authorized representative, and (iv) what provisions will be made for the assent of the participant.*

Subjects must have reasonable mental competence in order to be enrolled in Psych 1.