

Title of Study: The Effect of Religious Practices on Mental and Spiritual Health

Date: 11/7/22

Study Protocol

Research Question: What are the effects of using Pray.com on stress in individuals who report high levels of stress?

Hypothesis:

Individuals who report high levels of stress and use the Pray.com app will report lower levels of stress over time compared to individuals in a wait-list control condition.

Outcomes:

Primary outcome: Stress

Secondary outcomes: Anxiety and depressive symptoms, mindfulness, burnout, sleep, religious commitment, spiritual well-being, work progress

Measures:

- Perceived Stress Scale (PSS)
- Hospital Anxiety and Depression Scale (HADS)
- Mindful Attention Awareness Scale (MAAS)
- Copenhagen Burnout Inventory (CBI)-personal subscale
- Pittsburgh Sleep Quality Inventory (PSQI)
- Religious Commitment Inventory (RCI)
- Spiritual Well-Being Scale (SWBS)
- Satisfaction with Life Scale (SWLS)
- Daily Work Progress
- Miscellaneous items
- Demographics

Sample size and inclusion criteria:

N = 300

Participants will be recruited through social media and various organizations. Participants will be over the age of 18 and report at least a moderate level of stress (PSS score of 14 or greater).

Participants also must be willing to participate in a study that involves engaging in a regular Christian religious practice and are willing to download the Pray.com app.

Procedure:

Eligible participants will be randomly assigned into one of three conditions: (1) autonomous use (directed to use the app daily), (2) meditative prayer condition (directed to use this feature of the app daily), or (3) wait-list control condition. Participants will complete measures at baseline (i.e., time 1), four-weeks (i.e., time 2), and eight weeks (i.e., time 3).

Participants will be compensated for their time completing surveys at mid (\$15) and post (\$25) intervention for a total of \$40 at the end of the intervention. Participants who complete all surveys will also be entered in a drawing at the end of the intervention to win one of three \$99 gift cards. Finally, all participants will receive the Pray.com app for free for one year.

Statistical Analysis Plan

Data will be analyzed using longitudinal multilevel modeling. The key analysis will be the condition x time interaction effect. The main hypothesis is that participants in the two Pray.com conditions will report lower levels of stress and psychological symptoms across time, compared to the control condition. Furthermore, we will test whether participants in the two Pray.com conditions (i.e., autonomous use, meditative prayer) differ in outcomes across time. We will also check for moderation with key variables (e.g., days of use).

Informed Consent Form

BIOLA UNIVERSITY CONSENT TO ACT AS A HUMAN RESEARCH PARTICIPANT

The Effect of Religious Practices on Mental and Spiritual Health

Lead Researcher
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Participation is Voluntary

You are being asked to participate in a research study. Participation is completely voluntary. Please read the information below and reach out via email with questions or about anything that you do not understand. A researcher will be available to answer your questions via email.

Study Purpose

The purpose of this research study is to explore the effects of engaging in different types of religious practices on mental health and well-being.

AM I ELIGIBLE TO PARTICIPATE IN THIS STUDY?

You must meet the following criteria to be included in this study:

- 18 years of age or older.
- Have a moderate level of anxiety.
- Own a smartphone and be willing to download a mobile app.
- Willing to engage in a Christian-based religious practice on a mobile app.

WHAT PROCEDURES ARE INVOLVED WITH THIS STUDY AND HOW LONG WILL THEY TAKE?

1. In this study, you will be randomly assigned to one of several conditions. In all conditions, you will be required to complete a monthly online survey at three time points. Each survey will take about 15 minutes of your time. In some conditions, you will also be required to engage in a personal religious practice that will be completed through a mobile app on your phone. You may receive periodic reminders on your phone to engage in the religious practice. We anticipate that this involvement will take about 25 minutes per week.
2. Participation in the study will include 3 monthly surveys as well as the regularly brief religious practice (i.e., a few minutes several times per week) and take a total of about 5 hours over a period of 2 months.

WHAT ARE THE BENEFITS RELATED TO THE STUDY?

Benefits to Participants: Possible benefits to this study include participation in the personal religious practice, as well as feelings of pride and contribution from participating in a research study.

Benefits to Others or Society: Participation in this study may increase our understanding about the effects of engaging in personal religious practices on mental health, spiritual health, and well-being.

WHAT ARE THE POSSIBLE DISCOMFORTS OR RISKS RELATED TO THE STUDY?

There are no known harms or discomforts associated with this study beyond those encountered in normal daily life. The possible risks and/or discomforts associated with the procedures described in this study include feelings of discomfort about sharing information about your mental health, spiritual health, and well-being, as well as a potential for a breach of confidentiality.

ARE THERE ANY ALTERNATIVE TREATMENTS OR PROCEDURES

There are no alternative procedures available. The only alternative is not to participate in this study.

WILL I BE PAID FOR TAKING PART IN THIS STUDY?

You will be asked to complete 3 monthly surveys. You will not receive compensation for completing baseline measures. You will receive a \$15 gift card for completing measures at Time 2. You will receive a \$25 gift card for completing measures at Time 3. If you complete all time points, you will be entered in a raffle for one of three \$99 gift cards. You will also receive a free subscription to a Christian mobile app for one year following completion of the study. Total compensation for participation in this study is \$40. If you decide to withdraw from the study or are withdrawn by the research team, you will receive compensation for the surveys that you have completed.

Reimbursement

You will not be reimbursed for any out-of-pocket expenses.

Costs

There is no cost to you for participation in this study. However, there may be out-of-pocket expenses.

WHAT HAPPENS IF I WANT TO STOP TAKING PART IN THIS STUDY?

You are free to withdraw from this study at any time without loss of benefit for which you are otherwise entitled. **If you decide to withdraw from this study, you should notify the research team immediately.** The research team may also end your participation in this study if you do not follow instructions or if your safety and welfare are at risk.

WHAT INFORMATION WILL BE COLLECTED AS PART OF THIS STUDY

We will collect your name, email address, responses to questionnaires, and usage data from the religious practices mobile app. We will store all responses to questionnaires and app-usage data in a de-identified form (kept separated from any personal identifying information). The data you provide will only be linked to you through a unique participant ID number that will be assigned to you by the research team once you begin the study, except that we may provide Pray.com with your email address to obtain app usage data from the mobile app. We may pair your usage data from the religious practices mobile app with your survey responses (e.g., how often you completed the assigned practices).

HOW WILL MY PERSONAL INFORMATION BE KEPT?

Subject Identifiable Data

Identifiable information collected about you will be used to provide compensation and contact you to complete follow-up surveys. It will be removed at the end of data collection.

Data Storage

Research data will be stored electronically on a laptop computer in an encrypted file and is password protected. Datasets will be maintained in a secure, online survey management system that is password protected.

WHO WILL HAVE ACCESS TO MY STUDY DATA?

The research team, authorized Biola personnel and service providers, the study sponsor, and regulatory entities and other public authorities such as the Office of Human Research Protections (OHRP), may have access to your study records for the purposes described in this consent form, and to protect your safety and welfare or the safety and welfare of others.

Identified (email) data regarding mobile app usage will be shared only between Pray.com and the research team on this study. Identifiable survey responses will not be shared with Pray.com.

While the research team will make every effort to keep your personal information confidential, it is possible that an unauthorized person might see it. We cannot guarantee total privacy.

Aggregate results of this study may be used in reports, presentations, and publications.

Future Research Use

Researchers will use your information to conduct this study. Once the study is done using your information, we may share them with other researchers so they can use them for other studies in the future. We will not share your name or any other private identifiable information that would let the researchers know who you are. We will not ask you for additional permission to share this de-identified information.

ARE THERE OTHER ISSUES TO CONSIDER IN DECIDING WHETHER TO PARTICIPATE IN THIS STUDY?

Investigator Financial Conflict of Interest

The Principal Investigator has equity interests in Pray.com. The Co-Principal Investigators received payment from Pray.com in exchange for helping with this research project.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

If you have any comments, concerns, or questions regarding the conduct of this research, please contact the research team listed at the top of this form.

If you have general questions, have concerns or complaints about the research, have questions about your rights as a research subject, or have general comments or suggestions, please contact the Biola Institutional Review Board by phone at (562) 903-4894, or by e-mail at IRB@Biola.edu.

What is an IRB? An Institutional Review Board (IRB) is a committee made up of scientists and non-scientists. The IRB's role is to protect the rights and welfare of human participants involved in research. The IRB also assures that the research complies with applicable regulations, laws, and institutional policies.

HOW DO I AGREE TO PARTICIPATE IN THIS STUDY?

You will indicate your consent electronically below by typing your name, date, and clicking "I agree to participate in the study." You should not indicate your consent until all of your questions about this study have been answered by a member of the research team listed at the top of this form. You may be given a copy of this signed and dated consent form to keep. **Participation in this study is voluntary.** You may refuse to answer any question or discontinue your involvement at any time without penalty or loss of

benefits to which you might otherwise be entitled. Your decision will not affect your future relationship with Biola University.

Your consent below indicates you (a) are at least 18 years of age or older, (b) have read the information in this consent form, and (c) have had a chance to ask any questions you have about this study.

Typed Name of Participant

Date

I agree to participate in the study.

Yes

No