

The effect of prayer therapy on depression and anxiety

Submission date 14/09/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 14/11/2013	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 14/11/2013	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

It is well known that people who have experienced adversity in life are more prone to develop depression and anxiety. Through a research study it became evident that through prayer clients with this adversity experienced a release from the negative emotions and a related decrease in pondering of the hurtful events enabling them to move towards steady mental health more readily. This study aims to document the neural correlates of what is transpiring as the above occurs.

Who can participate?

Adults who are depressed but not on medication and are willing to engage in Christian prayer can participate in the study.

What does the study involve?

Participants are randomly allocated to one of two groups: the intervention group or the wait-list control group. People in the intervention group receive initial evaluation and prayer. Each prayer session lasts for about an hour and is conducted once a week for 6 weeks. Magnetic Resonance Imaging is done at the start and end of the study to record any changes happening in the brain. The wait-list control group will receive all the prayer sessions and evaluations as the interventions group but after 4 weeks.

What are the possible benefits and risks of participating?

This research does not involve major risks. Some clients may be disappointed in the prayer results while others may be encouraged.

Where is the study run from?

Baylor College of Medicine, Houston, Texas, USA.

When is the study starting and how long is it expected to run for?

The study starts in October 2013 and runs until April 2014.

Who is funding the study?

The Institute for Spirituality and Health, USA.

Who is the main contact?
Dr Peter Boelens
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
H-31607-W01

Study information

Scientific Title
Neural correlates of the effect of prayer therapy on depression and anxiety

Study objectives
It is postulated that through prayer a decathexis of emotions from memory enabled patients to change abnormal thought patterns based on these negative emotions more readily. They were no longer bothered by flashbacks. As a result, individuals move from depression to normality.

Further reading:
Boelens PA, Reeves RR, Replogle WH, Koenig HG, A Randomized Trial of the Effect of Prayer on Depression and Anxiety. International Journal of Psychiatry in Medicine 2009;39(4):377-392

Boelens PA, Reeves RR, Replogle WH, Koenig HG, The Effect of Prayer on Depression and Anxiety: Maintenance of Positive Influence One Year After Prayer Intervention. International Journal of Psychiatry in Medicine 2012; 43(1):85-98.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Baylor College of Medicine Institutional Review Board, 23/08/2013

Study design

Randomized wait-listed control study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Emotional disorders

Interventions

Group A receiving immediate evaluation and Christian prayer

Group B wait-listed prior to following the same protocol as Group A

Baseline rating scales and fMRI are performed immediately on entrance into the study. Subjects are then randomized into Group A or B. Group A goes into prayer intervention. Immediately at the conclusion of the prayer sessions both groups are re-evaluated even though Group B had no prayers. Group B is re-evaluated again prior to commencement of their prayers and at the conclusion of their prayers. Wait-list controls will receive their prayers within 4 weeks of the conclusion of prayers in the intervention group. Prayer sessions are 60 minutes in duration and conducted once a week for a duration of 6 weeks.

Intervention Type

Other

Phase

Not Applicable

Primary outcome measure

Brain changes resulting from prayer as documented through fMRI

Secondary outcome measures

1. Clients that meet the requirements of the study are measured for the severity of their depression utilizing the Hamilton Depression Rating Scale (HDRS) with 17 items. Potential

subjects who are not on antidepressant or anti-anxiety medication and have a minimal score of 8 on the HDRS will qualify for the study. The Hamilton Anxiety Rating Scales (HARS) with 14 symptom-related questions will be used to test anxiety.

2. The Life Orienting Test (LOT) will be used to measure the effects of dispositional optimism on self-regulation in a variety of circumstances. It has shown construct validity with other studies demonstrating the effect of optimism health promotion in a variety of circumstances.

3. The Daily Spiritual Experience Scale (DSES) will use 16 questions to assess daily spiritual experiences in six domains

Overall study start date

07/10/2013

Completion date

06/04/2014

Eligibility

Key inclusion criteria

1. The subjects will be adults (male and female) between the ages of 18 and 65 who are depressed but not on medication

2. They will be willing to engage in Christian prayer and be without reservations or contraindications to fMRI scanning

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

24

Key exclusion criteria

1. All children, pregnant women, mentally impaired and those with physically incapacitating problems will be excluded

2. Individuals with other psychiatric disorders and those who have received professional psychotherapy or have been on antidepressants in the 3 months prior to study enrollment. Subjects with severe depression and/or suicidal ideation will be excluded and proper referral made.

3. Those who are unable to respond to the questions or would have difficulty maintaining a focus while responding to the questions during the scanning would also be excluded. Subjects will be allowed to engage in their usual private prayers, devotions and church-related activities. They will not be allowed to participate in any form of psychotherapy during the time period they are in prayer session or are wait-listed. This restraint is lifted for the time period between the

completion of their prayers and the one-year follow-up.

4. Additionally, subjects who are unable to understand and follow the directions involved in the testing will be excluded

For the fMRI portion of this protocol, other exclusion criteria are:

1. Claustrophobia (this would make lying in the scanner very uncomfortable)
2. Pregnant
3. Contraindications to MRI: pacemaker, aneurysm clips, neurostimulators, cochlear implants, metal in eyes, steel worker, or other piercings and implants

Date of first enrolment

07/10/2013

Date of final enrolment

06/04/2014

Locations

Countries of recruitment

United States of America

Study participating centre

213 Redbud Dr

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United States of America

39180

Sponsor information

Organisation

Institute for Spirituality and Health (USA)

Sponsor details

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Sponsor type

Research organisation

Website

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ROR

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Funder(s)

Funder type

Research organisation

Funder Name

Institute for Spirituality and Health (USA)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration