

The psychological health benefits of mindfulness-based stress reduction in family caregivers of patients with dementia

Submission date	Recruitment status	<input type="checkbox"/> Prospectively registered
10/11/2015	No longer recruiting	<input type="checkbox"/> Protocol
Registration date	Overall study status	<input type="checkbox"/> Statistical analysis plan
11/11/2015	Completed	<input type="checkbox"/> Results
Last Edited	Condition category	<input type="checkbox"/> Individual participant data
11/11/2015	Mental and Behavioural Disorders	<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

A caregiver or carer is an unpaid or paid person who helps another individual with an impairment with his or her activities of daily living. Caregiving for a dementia patient is associated with increased risk of psychological and physical health problems. Mindfulness Based Stress Reduction (MBSR) may help to reduce stress among non-professional caregivers of patients with dementia. This study was designed to investigate the effectiveness of and the mechanisms by which a MBSR-based training course may reduce stress in non-professional caregivers of patients with dementia.

Who can participate?

Adult children or grandchildren, spouses, and non-professional caregivers (age over 21) of persons with dementia.

What does the study involve?

Participants attend an eight-week Mindfulness Based Stress Reduction-based training course designed to better accommodate the needs of non-professional caregivers. Participants complete psychological questionnaires and provide blood samples before and after completion of the MBSR training course to evaluate the effects of the course.

What are the possible benefits and risks of participating?

Participants do not benefit directly from being in this research study. The researchers hope to learn more about how the Mindfulness for Caregivers class benefits caregivers in both their psychological and physical health. This might help caregivers in the future. There is a slight risk associated with blood sampling, which includes a brief sense of pain with the needle stick, possible bruising of the skin, and a very small risk of infection. There is a small risk that answering the psychological assessments may cause emotional distress. To guide against the risk of loss of privacy, all results from psychological assessments and blood tests will be identified using non-identifiable codes not linked to any personal information such as name or social security number.

Where is the study run from?

Martha Stewart Center for Living, the geriatrics outpatient practice of the Brookdale Department of Geriatric and Palliative Medicine at the Icahn School of Medicine at Mount Sinai in New York, NY (USA).

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

May 2009 to May 2010

Who is funding the study?

Icahn School of Medicine at Mount Sinai Pilot Grant

Who is the main contact?

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Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

The development of clinically accessible biomarkers for predicting the health benefits of mindfulness-based stress reduction for caregivers of patients with dementia

Study objectives

We hypothesise that a Mindfulness-Based Stress Reduction training course that was designed to better accommodate the needs of non-professional caregivers may help reduce stress among non-professional caregivers of patients with dementia

Ethics approval required

Old ethics approval format

Ethics approval(s)

Institutional Review Board, Icahn School of Medicine at Mount Sinai, approval number 090354

Study design

Single-center prospective single-arm behavioral intervention study

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Self-perceived stress, depression, burden and grief in non-professional caregivers of dementia patients

Interventions

Mindfulness Based Stress Reduction (MBSR) has been shown to reduce stress and improve chronic disease outcomes for many different medical problems. This study was designed to investigate the effectiveness of, and the mechanisms by which a MBSR-based training course that is designed to better accommodate the needs of caregivers may reduce stress in non-professional caregivers of patients with dementia. Our MBSR training course for caregivers is closely modeled after the MBSR curriculum originally established by the Center of Mindfulness at the University of Massachusetts. Caregivers generally have a difficult time getting away to attend Mindfulness training. Based on evidence demonstrating that the length of classes is not correlated with mean effect, our MBSR course is especially modified to reduce class duration from 2.5 hours to 1.5 hours to accommodate the needs of caregivers. The course consists of a series of eight weekly classes meeting for 1.5 hours each, plus a four-hour retreat during week six. During the sessions, participants learn and practice several mindfulness exercises, such as the body scan, sitting meditation, mindful yoga postures, and walking meditation, which aim to develop mindfulness and the ability to attend to the present moment "without judgment".

Intervention Type

Behavioural

Primary outcome(s)

1. Overall score from the Caregiver Self-Assessment Questionnaire, a validated self-administered tool for assessing caregivers' own perceived depression, burden, stress and grief
2. Overall score from the Five Facet Mindfulness Questionnaire, a validated self-administered tool for assessing the acquisition of mindfulness skills
3. Gene expression profiles in peripheral blood mononuclear cells

Key secondary outcome(s)

1. Self-perceived depression assessed using the Center for Epidemiological Studies Depression Scale
2. Self-perceived stress assessed using the 10-Item Perceived Stress Scale
3. Self-perceived burden assessed using the Rapid Screen for Caregiver Burden
4. Self-perceived grief assessed using the Inventory of Traumatic Grief Pre-Loss

Completion date

12/05/2010

Eligibility

Key inclusion criteria

Non-professional, adult caregiver of a person with dementia

Participant type(s)

Carer

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

Acute psychiatric illness or active substance abuse which precludes active participation in the course and commitment to practice

Date of first enrolment

12/05/2009

Date of final enrolment

12/05/2010

Locations

Countries of recruitment

United States of America

Study participating centre

Icahn School of medicine at Mount Sinai

1428 Madison Ave

New York

United States of America

10029

Sponsor information

Organisation

Icahn School of Medicine at Mount Sinai (USA)

ROR

<https://ror.org/04a9tmd77>

Funder(s)

Funder type

University/education

Funder Name

Icahn School of Medicine at Mount Sinai Pilot Grant (USA)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Participant information sheet</u>	Participant information sheet	11/11/2025	11/11/2025	No	Yes