

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

Submission date 10/11/2015	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 11/11/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 11/11/2015	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

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 guard 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

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Intentional

Secondary study design

Non randomised study

Study setting(s)

GP practice

Study type(s)

Quality of life

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

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 measure

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

Secondary outcome measures

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

Overall study start date

12/05/2009

Completion date

12/05/2010

Eligibility

Key inclusion criteria

Non-professional, adult caregiver of a person with dementia

Participant type(s)

Carer

Age group

Adult

Sex

Both

Target number of participants

20

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

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Sponsor information

Organisation

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Sponsor type

University/education

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

Publication and dissemination plan

A manuscript has been submitted for publication

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Data sharing statement to be made available at a later date