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Meditation for people with amyotrophic lateral sclerosis and their caregivers

Submission date
10/12/2015

Recruitment status
No longer recruiting

Registration date
11/12/2015

Overall study status
Completed

Last Edited
05/09/2018

Condition category
Nervous System Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease (after a famous baseball player who suffered from it), is a serious condition which affects the nervous system. When a person is suffering from ALS, the nerve cells in the brain and spinal cord which control the movement of muscles (motor neurons) are gradually lost (neurodegeneration). The disease often begins with muscle twitching and weakness in the arms or legs, leading to paralysis and death, when the main muscle involved in breathing (diaphragm) is also paralysed. A diagnosis of ALS can be extremely distressing for patients, and people who are diagnosed often experience worry about their future to such an extent that they experience mental health problems such as anxiety and depression. Mindfulness is a concept designed to help people to be more aware of their thoughts and feelings in order to become more self-aware and accepting of the current moment. Its use in the treatment of people suffering from mental health problems is steadily increasing, and new techniques are being developed to help people with different problems. Mindfulness-based stress reduction (MBSR) is a programme which has been developed using the concept of mindfulness in order to help people living with pain and long-term health conditions. The aim of this study is to find out whether a MBSR programme involving mediation exercises specifically designed for people with ALS can help to improve quality of life.

Who can participate?
Adults suffering from ALS who are able to speak and are in control of their mental faculties.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the first group being an 8-week course of Mindfulness-Based Stress Reduction. This involves weekly sessions run by two trained facilitators, teaching meditative exercises such as breathing and relaxation training, group discussions about how to accept emotions and increasing awareness of the body. Participants in the second group continue to receive standard care throughout the 8 weeks. These participants are also given the option of receiving counselling sessions for additional support. At the start of the study, and then again at 3, 6 and 12 months, participants in both groups complete a number of questionnaires in order to test their quality of life, any feelings of anxiety or depression and mindfulness.

What are the possible benefits and risks of participating?
Participants may benefit from feeling better emotionally thanks to the mindfulness training. There are no notable risks of taking part in this study.

Where is the study run from?
Niguarda Ca' Granda Hospital (Italy)

When is the study starting and how long is it expected to run for?
December 2011 to November 2015

Who is funding the study?
Ministry of Health (Italy)

Who is the main contact?
Dr Francesco Pagnini

Contact information

Type(s)
Scientific

Contact name
Dr Francesco Pagnini

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effect of a psychological intervention for people with amyotrophic lateral sclerosis and their caregivers on their quality of life: Mediation compared to usual care

Study objectives
Meditation training designed for people with ALS can improve their quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Niguarda Hospital Ethics Committee, 30/05/2012, ref: 190_05/2012

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Amyotrophic lateral sclerosis (ALS)

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: Participants take part in weekly sessions of Mindfulness-Based Stress Reduction adapted for people with ALS for 8 weeks. Each sessions lasts for 1.5-2 hours, and involves meditative exercises such as body scan, breathing and relaxation training, group discussions about emotions and how to accept them and other cognitive tasks that facilitated the awareness of being in the moment with no judgement.

Control group: Participants receive standard care throughout the 8 week study period. Standard care referred to a multidisciplinary approach, which also included the chance of psychological support when needed. Depending on the patient's needs, psychological support can include up to 8 counselling sessions.

After the 8 week study period, all participants joined post-intervention assessments and follow-up, at 6 and 12 months from the recruitment.

Intervention Type
Behavioural

Primary outcome measure
Quality of life is assessed using the ALS-Specific Quality of Life Revised (ALSSQoL-r) at baseline, 3, 6 and 12 months.

Secondary outcome measures
1. Anxiety and Depression measured using the Hospital Anxiety and Depression Scale at baseline, 3, 6, and 12 months
2. Mindfulness is measured using the Five Facet Mindfulness Questionnaire at baseline, 3, 6, and 12 months

Overall study start date
01/12/2011

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Probable or definite ALS diagnosis within 6 months of recruitment
3. Ability to speak and comprehend
4. A caregiver identified as the person who provided the most of care and assistance (e.g. a close relative)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Co-morbidity
2. History of psychiatric illness

Date of first enrolment
30/05/2012

Date of final enrolment
30/11/2014

Locations

Countries of recruitment
Italy

Study participating centre
Niguarda Ca' Granda Hospital (Ospedale Niguarda Ca' Granda)
Centro Clinico NEMO
Piazza dell'Ospedale Maggiore 3
Milan
Italy
20123

Sponsor information

Organisation
Niguarda Ca' Granda Hospital

Sponsor details
L.go Ca' Granda 3
Milan
Italy
20123

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00htrxv69

Funder(s)

Funder type
Government

Funder Name
Ministero della Salute

Alternative Name(s)
Italian Ministry of Health, Italy Ministry of Health, Ministry of Health of Italy, Ministry of Health - Italy, Ministry of Health, Italy

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Italy

Results and Publications

Publication and dissemination plan
Planned submission of results for publication in a peer reviewed journal.

Intention to publish date
28/02/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2017		Yes	No