

Meditation for people with amyotrophic lateral sclerosis and their caregivers

Submission date 10/12/2015	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 11/12/2015	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/09/2018	Condition category Nervous System Diseases	☐ 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 meditation 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
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Additional identifiers

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Quality of life

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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

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Sponsor information

Organisation

Niguarda Ca' Granda Hospital

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

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