

# Meditation for people with amyotrophic lateral sclerosis and their caregivers

<b>Submission date</b> 10/12/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 11/12/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/09/2018	<b>Condition category</b> Nervous System Diseases	<input type="checkbox"/> 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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**Contact details**  
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## Additional identifiers

**Protocol serial number**  
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

**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

20123

**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?
<a href="#">Results article</a>	results	01/04/2017		Yes	No