ISRCTN11845385 https://doi.org/10.1186/ISRCTN11845385

Comparing hypnosis and supportive counselling as psychological treatments for Amyotrophic Lateral Sclerosis (ALS)

Submission date
10/04/2019

Recruitment status
No longer recruiting

Registration date
09/05/2019

Overall study status
Completed

Last Edited
10/05/2019

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) is a fatal neurological disease currently lacking any efficacious cure. The disease imposes a huge burden on the psychological health of patients, leading to high level of anxiety and depression, as well as extreme distress and burnout in their caregivers.

Until a cure is discovered, the principal therapeutic intervention for ALS is palliative care, aimed to reduce psychological distress and improve patients' quality of life. Indeed, psychological status is strongly related to outcome in ALS patients, and research showed that improved psychological wellbeing is associated to higher survival rates.
Notwithstanding this important role of psychological care, there is still a lack of literature on the efficacy of psychological/psychopharmacological treatments for ALS patients' psychological health.

The present study compares two different psychological interventions in people with ALS, a supportive counselling treatment and a hypnosis-based treatment. The two treatment-groups were compared to a control group receiving only routine medical care.

The aim of the trial is to present a first comparison between eligible psychological treatments for ALS patients, toward the goal of identifying efficacious and cost-effective gold-standard treatments.

Who can participate?
People suffering from Amyotrophic Lateral Sclerosis who attend the Motor Neuron Disease Centre at the Padova University Hospital.

What does the study involve?
Participant volunteered in the study and they were assigned to two groups, according to the time of their enrollment. One group received a supportive counselling treatment, based on a person-centered approach, acceptance and empathy and aimed to facilitate patients' active and

aware coping with negative thoughts and emotions associated with the physical progression of the disease. A second group received a hypnosis-based treatment, focused on achieving relaxation and coping with the disease symptoms through guided imageries and individually-tailored metaphors. Participants who could not be assigned to the treatment groups for logistical reasons were assigned to the control group and received only routine medical care.

Both treatments consisted of 4 weekly domiciliary sessions lasting 60 minutes each. Participants filled outcome questionnaires 2 weeks before their first treatment session, after the last session, and at two follow-ups at 3 and 6 months. Outcome questionnaires measured anxiety, depression and quality of life.

What are the possible benefits and risks of participating?
At the time of study, ALS patients cured at the Motor Neuron Disease Centre at the Padova University Hospital received no routine psychological treatment. For this reason, patients enrolled in this study had the same expected risks as patients who did not participate in the research.

On the other side, supportive counselling and hypnosis-treatment are established psychological interventions that may provide care and support to enrolled patients, as was observed in the case of other neurological diseases.

Where is the study run from?
The Motor Neuron Disease Centre at the Padova University Hospital has run the study, and the psychological treatment took place in the homes of the participating patients.

When is the study starting and how long is it expected to run for?
March 2012 to June 2018

Who is funding the study?
The authors received no specific funding for this study. ASLA ONLUS non-profit organization provided partial financial support.

Who is the main contact?
Prof. Arianna Palmieri from the University of Padova (arianna.palmieri@unipd.it)

Contact information

Type(s)
Public

Contact name
Prof Arianna Palmieri

ORCID ID
https://orcid.org/0000-0003-0453-001X

Contact details
Via Venezia, 14
Padova
Italy
35131

+39 049 8276672
arianna.palmieri@unipd.it

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Psychological Intervention in Amyotrophic Lateral Sclerosis: Comparing Hypnosis and Supportive Counselling

Acronym
PIALS-HySuCo

Study objectives
We investigate the differences between the efficacy of supportive counselling treatment and a hypnosis-based treatment in reducing psychological symptoms and improving quality of life in persons affected by Amyotrophic Lateral Sclerosis (ALS). We hypothesize that patients in both groups will show a better outcome than an untreated control group. We had no apriori hypothesis on the superiority of one of the two treatments.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/06/2012, the Ethical Committee of the University of Padova (Dipartimenti/Sezione di Psicologia, Università degli Studi di Padova, Via Venezia 8, 35131 Padova, Italy; +39 49 827 6600; comitato.etico17@gmail.com), ref: 46FAFF0A5274E64103D324EEB6D47BEA.

Study design
Pragmatic single-centre interventional longitudinal study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Amyotrophic Lateral Sclerosis

Interventions
Treatment 1: Hypnosis-based intervention
Treatment 2: Supportive Counselling Treatment
Both treatments consisted of 4 weekly domiciliary sessions lasting 60 minutes each.

The control group received routine medical care without further psychological treatment.

Arms were not randomized.

Two groups were compared with two different treatments and an untreated control group at different time points before and after treatment and in 3- and 6-month follow-ups.

Due to design constraints, no formal allocation ratio was employed and no masking of participants or experimenters was present. Control participants were people with ALS who could not enroll in the treatment protocols for logistical reasons. Assignment to groups was based on the time of enrollment.

The study was single-centre.

Both Supportive Counselling and Hypnosis treatments consisted of 4 domiciliary session of about 1.5 hours. The outcome data was collected by telephone and by clinical interviews after the treatment and at 3 and 6 months follow-ups.

Supportive Counselling Treatment: The supportive counselling treatment is inspired by Rogers's person-centred approach using as the main tools the therapist's unconditional positive regard, and acceptance of the patients while helping them to achieve their potential and genuine empathic understanding. The aims of the treatment were: to facilitate patients' active and aware coping of negative thoughts and emotions associated with the physical progression of the disease; and to help them accept their feelings, and share them with family and friends, counting on their empathic reactions and support. Psychoeducational aspects were included in the intervention sessions and tailored to the patients' needs.

Hypnosis-based Treatment: The hypnosis-based treatment is inspired by the Ericksonian approach, in which hypnotherapeutic communication strategies are individual. The core part of the hypnotic sessions consisted of administering therapeutic metaphors, guided visual imagery, and direct and indirect suggestions tailored on a per-patient basis, although the four weekly sessions were based on common themes. These themes concerned suggestions and imagery of relaxing, awareness of individual thoughts and emotions, and bonding with loved ones.

Intervention Type
Behavioural

Primary outcome(s)
1. Anxiety and depression are measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, at the end of treatment (only for the treated groups), and 3 and 6 months after the treatment.
2. Global quality of life is measured using the Amyotrophic Lateral Sclerosis Specific Quality of Life – Revised (ALSSQOL-R) at baseline, at the end of treatment (only for the treated groups), and 3 and 6 months after the treatment.

Key secondary outcome(s))

none

Completion date
08/06/2018

Eligibility

Key inclusion criteria
1. Probable or confirmed sporadic ALS according to the revised El Escorial criteria

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
51

Key exclusion criteria
1. Significant neuropsychological impairments
2. Concomitant psychiatric disorders
3. Concomitant neurological disorders
4. Using high-dose psychoactive drugs

Date of first enrolment
11/06/2012

Date of final enrolment
01/12/2017

Locations

Countries of recruitment
Italy

Study participating centre
Motor Neuron Disease Centre at the Padova University Hospital
via Giustiniani 2, Dipartimento di Neurologia
Padova
Italy
35128

Sponsor information

Organisation
ASLA Onlus

Funder(s)

Funder type
Charity

Funder Name
ASLA Onlus

Results and Publications

Individual participant data (IPD) sharing plan
The raw and anonymized dataset generated and analyzed during the current study are publicly available in the OSF repository https://doi.org/10.17605/OSF.IO/E2C97 in order to provide full publication transparency. Data availability has no end date. Data can be used for any purpose. Any further use of the dataset must report a full citation of the data origin.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	16/06/2015	11/04/2019	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes