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Group interventions for amyotrophic lateral sclerosis caregivers

Submission date
13/03/2019

Recruitment status
No longer recruiting

Registration date
26/03/2019

Overall study status
Completed

Last Edited
23/09/2019

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Amyotrophic Lateral Sclerosis (ALS) is a rapid and fatal motor neuron disease (MND) marked by progressive physical impairment caused by muscle weakness and muscle wasting. Patients with ALS/MND present with thinking and behavioural difficulties, and caregivers of patients are commonly non-paid immediate family members who take primary responsibility for the complex care needs of patients outside the hospital setting. As a result, many experience a sense of burden, anxiety and/or depression. The aim of this study is to test the usefulness of group-based interventions when compared to each other and to treatment as usual.

Who can participate?
Caregivers (spouse/child/parent) aged 18 and over of patients with ALS

What does the study involve?
This study allocates participants into three groups. The study consists of two intervention groups and a treatment as usual (TAU) group. The interventions consist of 'Mindfulness-based Stress Reduction' and 'Building Better Caregivers', a group-based intervention. Participants' self-reports of anxiety and depression symptoms and caregiver burden and quality of life are measured by questionnaires at the beginning, immediately after the intervention, and after a period of 12 weeks in order to assess if the intervention has worked. The researchers also look at the patient's cognitive and behavioural information, to see if that has an effect.

What are the possible benefits and risks of participating?
This study will provide information on how an intervention may meet the needs of participants, and will inform future practice and research. As with many studies, there is a potential risk that participants will experience tiredness resulting from the intervention programmes. However, there is no strong evidence that negative reactions to the interventions in this study are common. As the aim of this study is to evaluate whether intervention programmes alleviate low mood in the caregivers of people with ALS, participants will be given access to mental health intervention programmes which may alleviate symptoms of depression and anxiety. Potentially, these programmes may alleviate feelings of burden associated with caregiving, benefiting their mood.

Where is the study run from?
Beaumont Hospital (UK)

When is the study starting and how long is it expected to run for?
May 2017 to December 2020

Who is funding the study?
Amyotrophic Lateral Sclerosis Association (USA)

Who is the main contact?
Dr Tom Burke
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
ALSACM396

Study information

Scientific Title

Group interventions for amyotrophic lateral sclerosis caregivers: a randomised controlled trial

Study objectives
With a goal of developing improved clinical service for ALS caregivers, the researchers aim to determine which intervention, if any, within a 6 to 8 week framework leads to a reduction in psychological distress. In doing so, they aim:
1. To evaluate the effectiveness, efficacy and feasibility of low intensity interventions for mild-to-moderate anxiety, depression and burden in caregivers of ALS patients using a cohort of Irish ALS caregivers
2. To inform best practice regarding the mental health needs of caregivers of patients with ALS both nationally, and internationally
3. To evaluate what ALS-specific patient factors predict caregiver outcomes regarding the efficacy and effectiveness of intervention programmes
4. To identify a standard intervention programme suitable for ALS caregivers, which in turn will define a clinic-based pathway for future enrolment to such an intervention

The study is designed not only to meet a gap in the current literature, but to also begin to build a clinically meaningful management strategy for caregivers who experience caregiver burden. An objective of this study is to inform the development of appropriate future management guidelines and strategies for healthcare professionals, both nationally and internationally.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/07/2016 by Beaumont Hospital's Research Ethics Committee, Beaumont Hospital, Beaumont Road, Dublin 9, Ireland, Tel: +353 (0)1 809 2680, Email: beaumontethics@rcsi.com, REC ref: 18/33

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 contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Amyotrophic lateral sclerosis

Interventions

The trial is a 2-arm assessment of effectiveness and efficacy of group-based interventions (Experimental Treatment Arm 1: CBT; Experimental Treatment Arm 2: Mindfulness-Based Stress Reduction [MBSR]) with a treatment as usual (TAU) control arm. The trial will be conducted and reported according to CONSORT guidelines (Schulz, Altman, & Moher, 2010).

The participant information sheet will explain the evidence-based approach of the interventions for mild to moderate anxiety and depression, as well as the nature of the treatment as usual group. Each programme will be briefly described. It will be explained that, in order to evaluate which programme works better, caregivers will be randomly assigned. It will also be explained that participants may withdraw from treatment at any time, and that opting not to participate in the research programme will not affect receipt of services, for them or the person with ALS. Participants will be provided with contact details of members of the research team should they wish to ask any further questions, and participants will be given time to read the information at their leisure. Participants are then asked on the day of consenting if they have further queries or questions. For the purpose of the CONSORT flow diagram, and in the interest of improving future research, participants who discontinue their engagement with the research will be provided with the opportunity to express the reason for this.

Intervention Arm 1: Building Better Caregivers (BBC)

For treatment arm 1, the researchers will run the Building Better Caregivers (BBC; Lorig et al., 2012) programme, as developed by Stanford University. It is described in brief below. In accordance with CBT-based programmes, there is a treatment manual for facilitators to follow – this ensures the standardised delivery of the programme. There is an accompanying workbook in accordance with CBT practice which will incorporate the homework tasks, which are an essential component of CBT. This programme contains six weekly sessions. A detailed breakdown of the intervention structure and content can be seen in Table 1. In this programme, a range of strategies is used to optimize mood management and self-regulation skills through a number of core components such as skill mastery, modelling, exploration of care-partner behaviours, and social support building.

Intervention Arm 2: Mindfulness-Based Stress Reduction (MBSR)

This 8-week class is modelled on the Stress Reduction Clinic and will focus on mindfulness meditation to support a new understanding of how stress affects one's life, and how life can be lived more fully with a mindful mentality. The sessions for the group are broadly categorised as; Being Awake; Ways of Seeing; Being at Home in your Body; Meeting Stress; Responding to Stress; Mindful Communication; Mindfulness in Daily Life; Taking Care of Oneself – Looking Back /Moving Forward. A breakdown of the intervention can be seen in Table 2.

Intervention Arm 3: Treatment As Usual (TAU)

This cohort will act as a control group for the study. On briefing, the potential participants will be informed that they may be assigned to this intervention arm. Should participants be assigned to the TAU arm of the study, they will receive first preference on a group-based intervention should the study show improvement on the primary outcome measures. Participants will be interviewed, as outlined, in order to investigate potential other sources of therapeutic intervention during this research study.

Randomisation

Matching and randomisation will be used when assigning cases to groups. Matching procedures will be used to minimize baseline differences between treatment and control groups. Randomization will be used to prevent bias in assigning cases to groups. groups of three recruited cases will be matched as closely as possible on the following variables: age, gender,

anxiety and depression profile, and patient characteristics (outlined further below) in line with a priori power calculations.

Each case in a group of three will be randomized to an arm of the study with the aid of a computer pre-generated, random number sequence. The demographic and clinical characteristics of cases in treatment and control groups will be presented in a table in the report on the study.

For transparency in reporting, the flow of participants through each stage of the study from appropriate referral, through screening, for Time 0, 1 and 2 assessments (pre-, post-assessment, and follow-up assessment) will be documented in a CONSORT flow diagram for consistency (Schulz et al., 2010). The CONSORT flow diagram allows for greater transparency regarding the recruitment strategy of participants into an intervention study. This will allow for identification of the number of participants who were enrolled, allocated to a treatment group, followed-up, and the reasons why some may have been excluded from analysis e.g., attrition.

Intervention Type
Behavioural

Primary outcome measure
Questionnaires will be administered to participants as a baseline before the intervention, immediately following the intervention, and again after 3 months. The primary aim of the study is to indicate the extent to which an intervention group may lead to improvements in caregiver anxiety and depression (effectiveness), and if these improvements were maintained at 3 months follow-up (efficacy). To do that, the following measures are considered primary outcomes:
1. Depression assessed using Patient Health Questionnaire- 9 (PHQ-9: total score; Kroenke, Spitzer, & Williams, 2001)
2. Anxiety assessed using General Anxiety Disorder Questionnaire-7 (GAD-7: total score; Spitzer, Kroenke, Williams, & Löwe, 2006)
3. Psychological distress assessed using Hospital Anxiety and Depression Scale (HADS: anxiety subscale, depression subscale, and total score; Zigmond & Snaith, 1983)

Secondary outcome measures
Questionnaires will be administered to participants as a baseline before the intervention, immediately following the intervention, and again after 3 months:
1. Caregiver burden assessed using Zarit Burden Interview (ZBI: total score; Zarit, Reever, & Bach-Peterson, 1980)
2. Quality of life assessed using McGill Quality of Life Questionnaire (McGill: total score; Cohen, Mount, Strobel, & Bui, 1995)

Overall study start date
01/05/2017

Completion date
31/12/2020

Eligibility

Key inclusion criteria

1. Caregivers will be included regardless of relationship type (spouse/child/parent), though the patient must have a diagnosis of ALS over another Motor Neuron Disease
2. Caregivers will be aged 18 years and over for consent purposes

Participant type(s)
Carer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
To determine an appropriate sample size for the trial, a power analysis was conducted with G*Power 3.1 (Faul et al., 2007). A power analysis indicated that in order for one-tailed statistical tests with p values of 0.05 and power values of 0.90 to detect small to moderate differences (d = .42) between three groups, a sample size of 75 study-completers (25 cases per cell) will be required. The effect size and drop-out rate in this power analysis are based on results of relevant meta-analyses. The estimated dropout rate of 50% is based on a meta-analysis by Fernadez et al (2015) who found average dropout rates of 39% - 58% respectively. These rates include drop-out before and during treatment. Therefore, participants will be recruited until the expected outcome of n=25 per cell is met.

Key exclusion criteria
1. Co-morbid active psychiatric condition present
2. Capacity to consent is diminished
3. Low levels of literacy would deem the intervention too demanding
4. Neurological or significant healthcare complications
5. Active addiction to state-altering substances

Date of first enrolment
01/07/2019

Date of final enrolment
01/07/2020

Locations

Countries of recruitment
Ireland

Study participating centre
Beaumont Hospital
Beaumont Road

Beaumont
Dublin
Ireland
D09 V2N0

Sponsor information

Organisation
Amyotrophic Lateral Sclerosis Association (ALSA)

Sponsor details
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DC 20005
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Sponsor type
Charity

Website
http://www.alsa.org/research/research-we-fund/project-page.html?appId=1063

ROR
https://ror.org/00mwp5989

Funder(s)

Funder type
Charity

Funder Name
Amyotrophic Lateral Sclerosis Association

Alternative Name(s)
Amyotrophic Lateral Sclerosis Association, The ALS Association, Amyotrophic Lateral Sclerosis Assn., ALS Assoc., AMYOTROPHIC LATERAL SCLEROSIS ASSN, The Amyotrophic Lateral Sclerosis Association, ALSA

Funding Body Type
Government organisation

Funding Body Subtype

Associations and societies (private and public)

Location
United States of America

Results and Publications

Publication and dissemination plan
The researchers intend to submit the full protocol for this RCT for publication prior to the commencement of data collection. They anticipate that they will present the findings of baseline recruitment at international conferences related to ALS. The main results of the main trial will be submitted for publication in a peer-reviewed journal following completion of data collection.

Intention to publish date
31/12/2020

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication, and will be uploaded alongside the manuscript as supplementary material, in line with the research ethics approval.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/09/2019	23/09/2019	Yes	No