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A resource for advance care planning in multiple sclerosis

Submission date
26/03/2021

Recruitment status
No longer recruiting

Registration date
30/03/2021

Overall study status
Completed

Last Edited
18/06/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
Advance care planning (ACP) is advocated to provide better care at the end-of-life (EOL) for people suffering from chronic progressive diseases, included severe, progressive multiple sclerosis (pwPMS). However, ACP uptake is low, and healthcare professionals (HPs) appear hesitant to engage with these discussions. A recent guideline on palliative care in pwPMS found no evidence of the effects of ACP in this population.

Multiple sclerosis (MS) is the most common cause of non-traumatic disability in young adults. The progressive form of the disease is caused by loss of the protective insulation around nerves and nerve damage and can lead to complex needs and severe disability for a variable period.

Previously an ACP booklet has produced involving: pwPMS, pwPMS' significant others (SOs), such as family members, and HPs. This booklet explains the concepts of advance directives and ACP according to the Italian Law 219/2017, describes why ACP is important in Multiple Sclerosis, and provides guidance for pwPMS considering an ACP.

This study aims to set up and evaluate the effectiveness of an ACP intervention in pwPMS in different MS care settings in Italy. This intervention will involve a conversation between pwPMS and their physician about the ACP using the ConCure-SM booklet. The physician and other HPs will also be provided with training in order to conduct these conversations.

Who can participate?
Adult pwPMS where an advance care plan (ACP) is relevant and has not already been completed

What does the study involve?
This study will involve the training of HPs at the participating centers on ACP for pwPMS and have focus group meetings with HPs to investigate their experiences. Then the safety and effectiveness of conducting a conversation between the pwPMS and their physician about the ACP using the ConCure-SM booklet will be tested over 6 months at six centers (MS centers and rehabilitation centers) across the three geographic areas of Italy.

Participants and their carers will be invited to personal semi-structured interviews and asked to complete questionnaires and the study will assess for how many participants an advance care plan document is completed. The study will investigate the differences in treatment preferences between pwPMS and their carers, pwPMS mood symptoms, and caregiver burden. Participants will also be asked about the quality of communication about future medical treatment and EOL care by physicians.

What are the possible benefits and risks of participating?
Expected benefits include increased pwPMS autonomy and shared decision-making through early conversations and planning ahead, increased congruence in treatment preferences between pwPMS and their carers, increased satisfaction of SOs, and increased competencies and satisfaction of HPs.

As far as risks are concerned, since a study-related increase in emotional burden cannot be excluded, pwPMS mood symptoms will be carefully monitored.

Where is the study run from?
Istituto Neurologico Carlo Besta (Italy)

When is the study starting and how long is it expected to run for?
From August 2020 to February 2024

Who is funding the study?
Fondazione Italiana Sclerosi Multipla (Italy)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
FISM 2020/R-Multi/024

Study information

Scientific Title
Advance care planning intervention for people with multiple sclerosis: pilot and feasibility trial

Acronym
ConCure-SM Phase 2

Study objectives
The ConCure-SM intervention which includes the HP training program and an advance care plan (ACP) conversation using the ConCure-SM booklet, will produce higher completion of an ACP document, increased congruence in treatment preferences between people with progressive multiple sclerosis (pwPMS) and their carers, and an increase in the quality of communication about end of life (EOL) care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 14/04/2021, Comitato Etico Regione Lombardia Sezione Fondazione IRCCS Istituto Neurologico “Carlo Besta” (Segreteria Amministrativa Comitato Etico, Fondazione IRCCS Istituto Neurologico "Carlo Besta", via Giovanni Celoria 11, 20133 Milano, Italy; +39 (0)2 23942321 2020 3568; comitatoetico@istituto-besta.it), ref: 83

All other centres sought and received ethics approval before recruiting the first participant

Study design
Multi-center pilot and feasibility single-arm trial with a nested qualitative study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)

Quality of life

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
People with severe progressive multiple sclerosis (pwPMS) across various health care settings in Italy

Interventions
The ConCure-SM intervention consists of an advance care plan (ACP) conversation involving the people with progressive multiple sclerosis (pwPMS), and their specially trained caring physicians, using the ConCure-SM booklet.

The Italian Law 219/2017 prescribes that ACP involves the patient, the referring physician, and, when applicable, the trustee. In this study, it was decided to train healthcare professionals (HPs) other than physicians (MS nurses, therapists, psychologists, social workers) in order to promote ACP knowledge within the caring team. Trainers will be a panel of neurologists, psychologists, a palliative care physician, a palliative care nurse, and a bioethicist. All have consolidated experience in leading training courses and workshops on patient-clinician communication and shared decision-making (SDM), and four on ACP and end of life (EOL) conversations. These four researchers will support physicians at the centers for issues concerning the conduction of the ACP conversation during the pilot trial. The training program will be CME accredited, residential, and will last one-and-half days/12 h. It consists of: one 2.5 h theoretical session on the clinical, ethical and statutory principles of SDM and ACP; two 4 h empirical sessions (one each day) on conducting ACP conversations in various clinical scenarios using the ConCure-SM booklet through guided role-play exercises; and two 45 min self-evaluation sessions (at the beginning and at the end of the training program).

The ACP conversation involves the pwPMS, the ACP-trained physician involved in their care, and, when applicable, the significant other (SO) such as a family member. In addition, if the pwPMS agrees, the non-physician ACP-trained HP at the center will participate. The conversation takes place in a dedicated room at the center, using the ConCure-SM booklet, and is audio-recorded.

The ConCure-SM Booklet was developed in Phase 1 of the project, from the ACP booklet of the National ACP programme for New Zealand (https://www.hqsc.govt.nz/home/). It consists of an introduction, ‘guidance’, and the advance care plan document. The introduction explains the concepts of advance directives and ACP according to the Italian Law 219/2017 and describes why ACP is important in MS. The guidance sections inlcude ‘My Advance Care Plan’, ‘What matters to me’, ‘What worries me’, ‘Why I'm making an Advance Care Plan’, ‘How I make decisions’, ‘If I were no longer able to make decisions: my trustee’, ‘Thinking about my end of life’, ‘My treatment and care choices’, ‘Signatures’, ‘Acronyms’. If the advance care plan document is completed (during the ACP conversation or in the following six months), the pwPMS (and, when applicable, the pwPMS trustee) sign the document, which is scanned and stored, together with the completed booklet, in the pwPMS (electronic) medical record.

A qualitative process evaluation will be used to explore organizational and environmental arrangements and participant experiences to understand the factors likely to influence future implementation and scalability of the intervention.

Intervention Type

Behavioural

Primary outcome measure
Completion of (dated and signed) advance care plan (ACP) document during the six months of the study measured using between baseline and 6 months

Secondary outcome measures
1. Advance care plan (ACP) engagement measured using the 4-item ACP engagement questionnaire on the trial web platform at baseline, 1 week, and 6 months
2. Quality of communication about future medical treatment and end of life (EOL) care (physician's skills) measured using the following after the ACP conversation:
2.1. The unobtrusively audio-taped and verbatim-transcribed ACP conversation rated by a specially trained third observer using the Observing Patient Involvement in Shared Decision Making (OPTION) scale, an observer-based scale that evaluates the behavior of the physician in terms of patient involvement in decision-making
2.2. The Quality of Communication Questionnaire (QOC) completed by participants after the ACP conversation
2.3. The QOC significant other (SO) version completed by SOs after the ACP conversation
2.4. The QOC physician version (last two items) completed by physicians after the ACP conversation
3. Quality of life measured using the Multiple Sclerosis Quality of Life 29-item questionnaire (MSQOL-29) electronic version at baseline and 6 months
4. Mood symptoms measured using the Hospital Anxiety and Depression Scale (HADS) at baseline, 1 week, and 6 months
5. Caregiver burden measured using the Zarit Burden Interview (ZBI) at baseline, 1 week, and 6 months
6. Safety measured from the incidence of Serious Adverse Events (SAE) (defined as an emotional breakdown resulting in hospitalization, suicidal attempt, or death) which will be monitored using the implementation of a thorough safety data monitoring plan and assessed at 6 months
7. Feasibility of the study, and sample size estimation for a subsequent phase III trial, should this be feasible, measured using the following between baseline and 6 months:
7.1. The number of pwPMS who accept the invitation to participate in the study
7.2. The number of pwPMS who receive the intervention
7.3. The rate of recruitment and refusal to participate
7.4. The rate of attendance of 6-month follow-up
7.5. Acceptability of the recruitment processes, assessments, intervention delivery, and secondary outcome measures with key stakeholders measured through interviews
7.6. Barriers and facilitators to implementing ACP in pwPMS, and the influence of the clinical setting

Overall study start date
01/08/2020

Completion date
29/02/2024

Eligibility

Key inclusion criteria
1. Aged ≥18 years
2. Diagnosed with primary or secondary progressive multiple sclerosis from ≥1 year before

inclusion
3. Able to communicate in Italian
4. Gave written consent
5. Advance care plan (ACP) relevant as has ≥1 of the following conditions:
5.1. Expressed desire for ACP
5.2. Questions about own future
5.3. Thoughts about hastening death or medically assisted suicide
5.4. High risk for death within two years measured using the 'Surprise Question'
5.5. High risk for development of severe cognitive compromise/dementia within two years
5.6. High risk for development of impairments preventing communication within two years
5.7. Significant suffering (such as uncontrolled physical symptoms, psychosocial issues, or existential issues)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
38

Key exclusion criteria
1. Severe cognitive compromise, a score of <19 on the Mini-Mental State Examination (MMSE)
2. Impairments preventing communication
3. Psychosis or other serious psychiatric conditions
4. Advance care plan (ACP) document completed

Date of first enrolment
30/11/2021

Date of final enrolment
03/03/2023

Locations

Countries of recruitment
Italy

Study participating centre

Fondazione IRCCS Istituto Neurologico Carlo Besta
via Celoria 11
Milan
Italy
20133

Study participating centre
Azienda USL-IRCCS di Reggio Emilia
Reggio Emilia
Italy
42122

Study participating centre
Borgo Roma Hospital
Azienda Ospedaliera Universitaria Integrata Verona
Verona
Italy
37134

Study participating centre
IRCCS Istituto delle Scienze Neurologiche di Bologna
Bologna
Italy
40139

Study participating centre
M. L. Novarese Hospital
Moncrivello (Vercelli)
Italy
13040

Study participating centre
IRCCS S. Lucia Foundation
Rome
Italy
00179

Study participating centre

University Hospital Policlinico Vittorio Emanuele
Catania
Italy
95124

Sponsor information

Organisation
Istituto Neurologico Carlo Besta

Sponsor details
Fondazione IRCCS Istituto Neurologico Carlo Besta
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Sponsor type
Hospital/treatment centre

Website
https://www.istituto-besta.it

ROR
https://ror.org/05rbx8m02

Funder(s)

Funder type
Charity

Funder Name
Fondazione Italiana Sclerosi Multipla

Alternative Name(s)
Italian Multiple Sclerosis Foundation, Italian MS Foundation, FISM

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
Italy

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Protocol to be submitted for publication by April 2021.

Intention to publish date
31/12/2024

Individual participant data (IPD) sharing plan
The datasets generated and analysed during the current study will be available in a publically available repository: https://zenodo.org/communities/besta/

Added 24/10/2023:
The type of data stored: general and clinical data, PROMs at T0, T1 and T2 (patients and significant others)
The process for requesting access (if non-publicly available): publicly available
Dates of availability: at trial publication (early in 2024)
Whether consent from participants was required and obtained: data are anonymized
Any additional comments: audio recordings (interviews, focus group meetings, and first ACP consultations) will be not made available as they contain personal data

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v1.0	15/03/2021	31/03/2021	No	No
Protocol article	protocol	13/08/2021	16/08/2021	Yes	No
Participant information sheet			24/10/2023	No	Yes
Other unpublished results			18/06/2024	No	No