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Clinical and cost- effectiveness of short--term integrated palliative care services to optimise care for people with advanced long--term neurological conditions

Submission date
21/01/2015

Recruitment status
No longer recruiting

Registration date
21/01/2015

Overall study status
Completed

Last Edited
07/06/2023

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

Long-term neurological conditions (LTNCs) are a group of progressive disorders, affecting approximately 10 million people in the UK. People with LTNCs commonly have physical disabilities affecting arms, legs, bladder, bowel, eyesight, or speech, for example, plus other intractable symptoms including pain spasms and fatigue. In addition, there is often a double burden of psychological distress or cognitive dysfunction. Over one third of people with LTNCs are estimated to need help with daily living, and nearly one million informal carers support someone with a neurological disease. Earlier phases of neurological illness can be managed well with medical treatments, rehabilitation, care and support. However, some diseases are or become invariably progressive. In the later stages those affected experience increased problems with greater need for personal, social, psychological and spiritual support. Care needs for those severely affected by LTNCs rise sharply once the disease reaches more advanced stages. Research has shown that these are not managed well by existing standard care; patients live with continuing symptoms, emotional and social problems. Their families also carry increasing burdens. While costs to the NHS increase, not all the care given is experienced as appropriate according to reports from some patients and families, with failures in coordination between acute and community care. Palliative care addresses the needs of the whole person – physical, emotional, social and spiritual. Specialists in palliative care have trained in these specific aspects, and how to communicate well during difficult times. They work in multi-professional teams, in-patient hospices, hospitals, care-homes and in home care. Palliative care has been suggested in NHS policy documents, such as the National Service Framework for LTNCs (quality standard 9) as a way to better help people severely affected by long-term neurological conditions, but it has not been rigorously tested. There is also uncertainty about when to introduce palliative care. Palliative care services are unevenly distributed, many managing on voluntary funding. Primary Care Trust spend on specialist palliative care ranges from £186 to £6,213 per death, with most of their funding supporting cancer patients. Without robust evidence about the best models of providing palliative care for people with long-term neurological conditions, it is very unlikely that palliative care services will be offered appropriately. In this study we aim to find out

whether offering Short-term Integrated Palliative Care Services (SIPC) to people affected by neurological conditions and in several centres can improve their care experience, particularly regarding management of pain and symptoms but also quality of life, anxiety and depression, communication, and caregiver burden. It will also consider whether SIPC may be more cost-effective than standard care, or affects hospital admissions.

Who can participate?
Adults (aged 18 years or over) severely affected by advanced or progressive stages of one of a number of neurological conditions (multiple sclerosis, motor neurone disease, idiopathic Parkinson's disease, progressive supranuclear palsy and multiple system atrophy) and their caregivers.

What does the study involve?
Participants are randomly allocated into one of two groups. Those in group 1 are given standard care plus SIPC. Those in group 2 are given standard care. Participants and their caregivers who agree to take part in the study are asked to participate in a series of interviews to complete questionnaires (about symptoms, quality of life, mood and services received) at the start of the study, then at 6, 12, 18 and 24 weeks into the study. We collect information about hospital admissions, services used and survival from clinical records. Throughout the study about every 6 months we produce a newsletter to keep everyone up to date. We are analysing some results as we go (such as the problems that patients and families have before they start the study) but the main trial analysis is completed at the end of follow-up when we have collected the information. After 12 weeks participants in group 2 are also offered SIPC, so in the end, everyone will receive the SIPC.

What are the possible benefits and risks of participating?
The study is designed to find out whether short-term palliative care offers any clinical benefit to people affected by long-term neurological conditions. It is not known whether those taking part will benefit or not and the results will help to answer that question and help people in the future. Taking part in interviews and completing questionnaires requires some time. Talking about personal experiences can be a relief or a challenge. Sometimes people find it upsetting to share what is happening in their lives. If that happens, interviews can be paused or stopped. Equally, many people find it helpful to talk in confidence about what is happening to them.

Where is the study run from?
Cicely Saunders Institute, King's College London (UK)

When is the study starting and how long is it expected to run for?
January 2015 to January 2019

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Nilay Hepgul
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Contact information

Type(s)
Scientific

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Integrated Research Application System (IRAS)
140633

Protocol serial number
18030

Study information

Scientific Title
Evaluation of the clinical and cost- effectiveness of Short--term Integrated Palliative Care Services (SIPC) to OPTimise CARE for people with advanced long-term Neurological conditions (OPTCARE Neuro)

Acronym
OPTCARE Neuro

Study objectives
The purpose of this study is to determine the effectiveness and cost-effectiveness of Short-term Integrated Palliative Care Services (SIPC) in improving symptoms, selected patient and caregiver reported outcomes and reducing hospital utilisation for people severely affected by long-term neurological conditions (LTNCs).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee London - South East, 09/12/2014, ref: 14/LO/1765

Primary study design
Interventional

Study design

Randomised; Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Dementias and neurodegeneration, Neurological disorders

Interventions
Participants will be randomly allocated to either receiving the intervention immediately or after an (approximately) 12 week waiting period (after the second interview is completed and reviewed). The intervention consists of short-term Integrated Palliative Care (SIPC) offered to patients severely affected by long-term neurological conditions, lasting for 6-8 weeks from referral. SIPC will be delivered by existing multiprofessional palliative care team (MPCT), linked with local neurology and rehabilitation services. All participants are followed up for 24 weeks with interview points at baseline, 6, 12, 18 and 24 weeks.

Intervention Type
Other

Primary outcome(s)
Current primary outcome measures as of 01/02/2017:
A combined score of 8 key items from the Integrated Palliative care Outcome Scale for neurological conditions (IPOS Neuro-S8), measured at 12 weeks post randomisation

Previous primary outcome measures:
A combined score of key symptoms, measured at 12 weeks post randomisation

Key secondary outcome(s)
Current secondary outcome measures as of 01/02/2017:
1. Patients' other symptoms and palliative care needs, measured using the Integrated Palliative care Outcome Scale for neurological conditions (IPOS Neuro)
2. Patients' health-related quality of life and well-being, measured using the EuroQoL (EQ-5D) and the ICEpop Capability measure for Adult (ICECAP-A)
3. Patients' psychological distress, measured using the Hospital Anxiety and Depression Scale (HADS)
4. Patients' satisfaction, self-efficacy and other aspects, measured using the Modified 16-item measure of patient satisfaction (FAMCARE-P16) and the Self-Efficacy to Manage Chronic Disease Scale (SEMCD)
5. Hospital admissions, length of hospital stay, emergency attendance, survival from consent and deaths and other service use during the course of the study, measured using the Client Service Recipient Inventory (CSRI)
6. Caregiver burden and positivity and quality of life, measured using the 12-item Zarit Burden Inventory (ZBI-12) + positivity, the Veterans Rand 12-item Health survey (VR-12) and the Modified 17-item measure of carer satisfaction (FAMCARE2)
7. Caregiver assessment of patients' outcomes, measured using some of the same measures (IPOS Neuro & IPOS Neuro-S8)
8. Observer (completed by the researcher) assessment of the patients' problems, measured using the 6-item Cognitive Impairment Test (6CIT), Modified Fried's Frailty Criteria, the Northwick Park Dependency Scale (NPDS), the Expanded Disability Status Scale (EDSS), the Australian modified Karnofsky Performance Status (AKPS) and the Support Team Assessment

Schedule (STAS)
Patients will be assessed for these outcomes at baseline, 6, 12, 18, 24 weeks

Previous secondary outcome measures:
1. Patients' other symptoms and palliative care needs
2. Patients' health-related quality of life and well-being
3. Patients' psychological distress
4. Patients' satisfaction, self-efficacy and other aspects
5. Hospital admissions, length of hospital stay, emergency attendance, other service use during the course of the study, survival from consent and deaths
6. Caregiver burden and positivity and quality of life
7. Caregiver assessment of patients' outcomes using some of the same measures
8. Observer (completed by the researcher) assessment of the patients' problems
Patients will be assessed for these outcomes at baseline, 6, 12, 18, 24 weeks

Completion date
31/01/2019

Eligibility

Key inclusion criteria
Patients:
1. Adults (aged 18 years or over) severely affected by advanced or progressive stages of the long-term neurological conditions (LTNCs) of either*:
1.1. Multiple Sclerosis (MS) - patients with either aggressive relapsing disease with rapid development of fixed disability or those with advanced primary or secondary progressive disease, often with limitation in a number of areas including gait and upper limb function. We do not define referral based on disability but would expect most patients to have an Expanded Disability Status Scale (EDSS) of at least 7.5
1.2. Parkinsonism & related disorders (PRDs) i.e.
1.2.1. Idiopathic Parkinson's Disease (IPD), Hoehn and Yahr (H&Y) stages 4-5 OR
1.2.2. Progressive Supranuclear Palsy (PSP) Hoehn and Yahr (H&Y) stages 3-5 OR
1.2.3. Multiple System Atrophy (MSA) - Hoehn and Yahr (H&Y) stages 3-5
1.3. Motor Neurone Disease (MND) all stages
AND
2. Who are deemed (by referring/usual care clinicians) to have:
2.1. An unresolved symptom (e.g. pain or another symptom) which has not responded to usual care
2.2. AND at least one of the following: unresolved other symptoms (e.g. breathlessness, nausea /vomiting, spasticity, fatigue); cognitive problems; complex psychological (depression, anxiety, loss, family concerns), communication/information problems and/or complex social needs.
AND
3. Who are able to give informed consent^ OR where their capacity can be enhanced^ (e.g. with information) so they can give informed consent OR where a personal consultee^ can be identified and approached to give an opinion on whether or not the patient would have wished to participate in the study.
AND
4. Are living in the catchment area of the Short-term Integrated Palliative Care Service (SIPC)

Patients are expected to be in the advanced or progressive stages of disease. They may be living at home (most common), in a nursing home or in hospital at the time of recruitment. A proforma

will be developed for referring clinicians to complete (covering contact and clinical information and important reasons for referral/selection).

Caregivers:
1. Adults (aged 18 years or over) identified by the patient as the person closest to them, usually a family member, close friend, informal caregiver or neighbour.
2. Able to give informed consent to complete the questionnaires

Notes:
* Diagnosis must have been established by a specialist neurological assessment
^ When a person lacks capacity to consent for themselves the procedures detailed in the Mental Capacity Act (2005) are adhered to

Participant type(s)
Mixed

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
350

Key exclusion criteria
Patients who meet the inclusion criteria but:
1. Are already receiving specialist palliative care
2. Lack capacity and have no family member, friend or informal caregiver who is willing and available to complete questionnaires about their own and the patient's symptoms and circumstances

Date of first enrolment
09/01/2015

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
United Kingdom

England

Wales

Study participating centre
King's College London & King's College Hospital
London
United Kingdom
SE5 9RS

Study participating centre
The Walton Centre NHS Foundation Trust
Liverpool
United Kingdom
L9 7LJ

Study participating centre
Cardiff & Vale University Health Board
Cardiff
United Kingdom
CF24 0SZ

Study participating centre
Nottingham University Hospitals NHS Trust
Nottingham
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NG5 1PB

Study participating centre
Sussex Community NHS Foundation Trust
Brighton
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BN2 3EW

Study participating centre
Ashford & St. Peter's Hospitals NHS Foundation Trust
Chertsey
United Kingdom
KT16 0QA

Sponsor information

Organisation
King's College London

ROR
https://ror.org/0220mzb33

Organisation
King's College Hospital

ROR
https://ror.org/044nptt90

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Dr Wei Gao (wei.gao@kcl.ac.uk). Data will only be available after publication and for the purposes of secondary analyses or meta-analyses. Data will be shared following the

completion of a data use agreement. Trial participants provided consent for the sharing of their anonymised data with other ethically approved studies.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	03/08/2020	02/09/2020	Yes	No
Results article		01/09/2020	15/02/2023	Yes	No
HRA research summary			28/06/2023	No	No
Other publications		03/08/2017	15/02/2023	Yes	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes