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

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Country

United Kingdom

Title of project or programme

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

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NIHR

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4.0

The project/programme is most relevant to:

Alzheimer's disease & other dementias|Motor neurone diseases|Parkinson's disease & PD-related disorders

Keywords

Research Abstract

DESIGN: Follows MRC guidance for evaluation of complex interventions: (i) set up, feasibility, mapping; (ii) randomised pragmatic trial of Short-term Integrated Palliative Care (SIPC) offered from a Multiprofessional Palliative Care Team compared to best usual care; (iii) a qualitative component, explores change process, how SIPC might be improved, interprets quantitative results, plus survey of health professionals; (iv) economic modelling. Methods build on those tested in our phase II randomised trial for MS patients, and longitudinal, economic and qualitative studies with patients and caregivers severely affected by these and other longterm conditions. SETTING: Five areas from across the UK; South London, Cardiff, Brighton and Sussex, Liverpool and Nottingham, all with palliative care, neurology/rehabilitation services and sufficient catchment population – representative of people with longterm neurological conditions in mixed urban, suburban and rural areas. TARGET POPULATION: Patients severely affected by advanced or progressive stages of the longterm neurological conditions (LTNCs) of either: • Multiple Sclerosis (MS) – primary or secondary progressive or aggressive relapsing remitting disease • Parkinson's Plus (PP) i.e. Idiopathic Parkinson's Disease(IPD) and related movement disorders of Progressive Supranuclear Palsy(PSP) or Multiple System Atrophy(MSA) – stages 3-5 Hoehn and Yahr(H&Y) or related measures for PSP/MSA • Motor Neurone Disease (MND) All are assessed (by clinicians) to have to have a least one unresolved symptom (e.g. pain, breathlessness, nausea/vomiting) which is continuing despite usual care and at least one of the following: 2nd unresolved symptom, cognitive problems; complex psychological (depression, anxiety, loss, family concerns) and/or complex social needs. INTERVENTION: SIPC runs from existing palliative care teams, linked with local neurology and rehabilitation services. Following referral a SIPC keyworker visits and makes a comprehensive palliative care assessment and proposes treatments, within 5 working days. There are 2-4 follow-up visits and referral to other services as appropriate. SIPC is offered in addition to usual services. CONTROL: Best usual services, including nurse specialists, neurology and rehabilitation. DATA COLLECTION: Face to face interviews at baseline (pre-randomisation), and follow up at 6, 12, 18 and 24 weeks. MEASUREMENT OF COSTS AND OUTCOMES: Recorded in face to face interviews with trained interviewers. Primary outcome is combined score of POS-S5 a validated measure of 5 core symptoms: pain, nausea, vomiting, sleeping difficulty and mouth problems at 12 weeks. Costs are estimated at baseline, and at 12-and 24-week follow-up from service use during the previous 12 weeks, recorded using an adapted version of the Client Service Receipt Inventory(CSRI). Secondary outcomes are: caregiver burden, caregiver experience, patient's psychological distress, quality of life, palliative needs and symptoms recorded by patient, caregiver, presence of future care plans and a short observer (researcher) assessment. We survey health professionals on their views of SIPC. QUALITATIVE COMPONENTS: Interviews and focus groups with patients, families and staff in the set up to explore ways to: enhance recruitment; improve documentation; hone the components of SIPC and how introduced. During the trial: study the recruitment progression; consider any improvements. In order to understand the effects of SIPC we will conduct qualitative interviews with patients, caregivers and professionals to explore their experience of SIPC; explore change process; interpret the quantitative data, ascertain whether other aspects of their care need addressing. SAMPLE SIZE: We recruit 356 patients for the main trial. In view of the advanced illness in this patient

group we have allowed 20% attrition (phase II trial attrition from death or illness: 3/52) to the primary 12-week outcome, giving 296 patients, or 148 in each arm with both baseline and 12-week outcome data. Each centre will recruit 70-90 patients over 27 months. Qualitative interviews are with 7 patients / caregivers and 6 staff per centre. The survey of health professionals is of 40 per centre, 200 total. ANALYSIS: Quantitative trial data follows CONSORT guidance on an intention-to-treat basis using generalised linear mixed model with centre as a fixed effect, adjusting for baseline score of POS-S5 and for variables from the baseline assessment for which treatment-group imbalance is found. Confidence intervals and test statistics are calculated using cluster robust estimates to account for therapist effects. The comparative effectiveness of the SIPC and standard care is explored and analysed within and across centres. The missing data are imputed using appropriate imputation techniques, depending on missing mechanisms. Robustness of findings is assessed, further uncertainties are addressed by sensitivity analysis. Secondary outcomes(hospital admissions, POS, ZBI, HAD, EQ-5D) are analysed using similar framework with that of primary outcome. The economic evaluation is conducted from(i) the health/personal social services perspective and (ii) a societal perspective. Qualitative data are analysed using the framework approach, in relation to aspects of study design and care. PROJECT TIMETABLE: Months 1-5 -Map current practice, set up trial, qualitative exploration, training, database preparation. Month 6-Trial commences. Monitor recruitment with feedback to centres. Months 6-33 – Recruitment of patients into study at rate of 8-15 patients per month (ie 1-3 patients per centre). Qualitative data collection. Months 11, 18, 24, 30-Formal reviews of recruitment rates. Data checking and cleaning. Months 12, 18, 24, 30-Interim dissemination of study, including mapping, qualitative exploration and trial recruitment and baseline needs, at conferences and with a six monthly e-newsletter. Months 33–Recruitment of new patients to trial ends, follow up continues for 6 months. Month 33-36-Analysis of all baseline data–Continued collection follow-up data Month 36-39 – Main trial analysis. Month 39–42 Analysis of final follow up data in both arms. Dissemination. PATIENT/PUBLIC INVOLVEMENT: 3 or more representatives (one is co-applicant), plus recruitment of individuals locally and from national groups on the Project Steering Committee, and integrated in all phases.

Lay Summary
Further information available at:

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Investments > €500k

Member States:
United Kingdom

Diseases:
Alzheimer's disease & other dementias, Motor neurone diseases, Parkinson's disease & PD-related disorders

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