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Self-Management of Analgesia and Related Treatments at the End of life

Submission date 21/07/2014	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/07/2014	**Overall study status** Completed	
Last Edited 04/04/2022	**Condition category** Signs and Symptoms	

Plain English summary of protocol
http://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-to-develop-a-tool-to-help-people-better-manage-their-cancer-pain-smarte

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 12/188/05

Study information

Scientific Title
Self-Management of Analgesia and Related Treatments at the End of life: a pre-post observational study

Acronym
SMARTE

Study objectives
We aim to develop a support tool to improve the management of medications for pain relief, nausea, constipation and drowsiness in patients with significant pain approaching the end of life. Ultimately we aim to establish the acceptability and up-take of our prototype SMST and determine the feasibility of evaluating this intervention within a larger trial.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/1218805
Protocol can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0018/130671/PRO-12-188-05.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Lancaster Research Ethics Committee, 27/10/2015, ref: 15/NW/0797

Study design
Phase I - development; design: evidence synthesis
Phase II - modelling; design: focus groups
Phase III - assessing feasibility; design: pre-post observational study

Primary study design
Interventional

Secondary study design

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Significant pain experienced by patients approaching the end of life living within the community

Interventions

We aim to develop a support tool to improve the management of medications for pain relief, nausea, constipation and drowsiness in patients with significant pain approaching the end of life.

A patient decision aid or SMST should help patients make informed choices about managing their healthcare by taking into account their values and preferences and those of their informal carer(s). We have defined an SMST as a set of materials and coaching procedures which delivers knowledge, facilitates the generation of specific action plans and enhances the users capacity to monitor and reflect on their actions. Ideally patients and their carers using our SMST should feel empowered with increased knowledge and skills to recognise worsening symptoms, be able to self-initiate therapeutic adjustments and know how and when to access help from their local healthcare system. We envisage that our SMST will include the following four components.

Initial assessment
At the initial meeting the Clinical Nurse Specialist (CNS) will discuss with the patient and their informal carer what strategies they already use to manage their medications for pain relief, nausea, constipation and drowsiness. The CNS will discuss what roles and tasks are required by each person to engage patients and their informal carer in self-management and encourage behaviour change. This initial assessment may also include a discussion about: 1. Concerns and fears about using opioids
2. Barriers and fears about self-management
3. Prioritising symptoms to self-manage
4. Providing the necessary information to support self-management
5. Trade-offs between symptom management and side-effects and how they will deal with the outcomes.

Information provision
The CNS will provide relevant information about managing medications for pain relief, nausea, constipation and/or drowsiness. This information will present benefits and burdens of medications in verbal, written, or audio-visual formats and will encourage a conversation about the trade-offs between symptom management and side-effects and how the consequences of these compromises might be dealt with.

Competencies based action plan (assessing capabilities)
Following provision of information, the CNS will undertake a competency-based assessment of the patients ability to self-manage, with support from a carer where appropriate. The purpose of this assessment is to identify the issues and situations that patients and carers feel they would like to self-manage. The CNS work with the patient and their carer to identify and record the self-management tasks that are required. This will form the basis of the self-management action plan. The CNS will help patients to develop their self-management action plan by balancing their values and preferences with the tasks and requirement of medication management alongside the possible side-effects.

Coaching, monitoring and modification
Strategies to encourage self-management require patients and their informal carers to change their behaviour and adopt new roles. Patients and carers must shift from a position of passively receiving medical information to actively engaging with supported decision making about their healthcare. For patients to successfully fulfil this new role they must feel that they can legitimately occupy it, understand what is required of them to fulfil this role and receive role support from a professional. This process of legitimisation begins with the initial assessment and provision of information and it continues through the collaborative development of the self-

management action plan. Finally, to maintain and encourage this behaviour change a timetable of regular monitoring of self-management progress must be established between the CNS, patient and carer.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Average pain intensity measured using the Brief Pain Inventory (BPI)

Secondary outcome measures
1. Neuropathic pain: Self-administered Leeds Assessment of Neuropathic pain Symptoms and Signs (S-LANSS)
2. Self-efficacy: Patient Activation Measure (PAM)
3. Cognitive representation of medications: Beliefs about Medicines Questionnaire (BMQ)
4. Intensity of common symptoms: Edmonton Symptom Assessment System (EASA)
5. Carer experience: Family Pain Questionnaire (FPQ)
6. Health-related quality of life: European Quality of life - 5 Dimensions (EQ-5D) questionnaire
7. Satisfaction with information: Satisfaction with Information about Medicines Scale (SIMS)
8. Patient records: We will ask patients to give their consent for us to check their patient and pharmacy records. From these records we will collect data on healthcare resource use, date and place of death

Overall study start date
01/09/2014

Completion date
30/08/2016

Eligibility

Key inclusion criteria
Patients will be included if they are:
1. Approaching the end of life - defined as patients with an incurable advanced disease, considered to be within the last year of life
2. Experiencing significant pain: assessed using Brief Pain Inventory (BPI) and defined as a score of =>4/10 pain severity sub-scale and =>4/10 pain impact sub-scale
3. Treated with, or starting, opioid analgesia
4. Experiencing, or anticipating, adverse effects of nausea, constipation and drowsiness
5. Living at home and being cared for by specialist palliative care services in West Yorkshire and Hampshire.

Staff will be included if they are:
1. Clinical Nurse Specialists (CNSs) part of a community palliative care team
2. Service providers or managers of specialist palliative care services
3. Local commissioners of palliative care services
4. Working within palliative care services in West Yorkshire and Hampshire

Participant type(s)
Mixed

Age group
Adult

Sex
Both

Target number of participants
Phase 1: n=16. Phase 2: n=35. Phase 3: n=30. Total n=81

Key exclusion criteria
Patients will be excluded if they lack capacity to consent to inclusion

Date of first enrolment
23/11/2015

Date of final enrolment
21/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Leeds Institute of Health Sciences
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Sponsor information

Organisation
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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
01/03/2017

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	results	01/12/2017		Yes	No
Plain English results			04/04/2022	No	Yes
HRA research summary			28/06/2023	No	No