

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

<b>Submission date</b> 21/07/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/07/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/04/2022	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## 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](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  $\geq 4/10$  pain severity sub-scale and  $\geq 4/10$  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

Leeds

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**Sponsor information****Organisation**

University of Leeds (UK)

**Sponsor details**

c/o Medicine and Health Research Governance

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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?
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<a href="#">Results article</a>	results	01/12/2017	Yes	No
<a href="#">Plain English results</a>		04/04/2022	No	Yes
<a href="#">HRA research summary</a>		28/06/2023	No	No