

PallPen - IT support for home healthcare: reporting of symptoms and messages with a digital pen

Submission date 23/04/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 16/05/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 12/06/2017	Condition category Cancer	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This aim of this study is to find out whether the use of Information Technology (IT), specifically a digital pen, can improve symptom control in patients with end-stage cancer who are receiving advanced palliative home care.

Who can participate?

Patients with end-stage cancer receiving advanced palliative home care, who are experiencing at least moderate pain or decreased well-being

What does the study involve?

Participants are randomly allocated into two groups. One group receives an IT system to be used for symptom reporting while the other group uses traditional ways of symptom reporting. The IT system consists of a Symptom Diary form together with digital pen technology to capture symptom assessments in the home of the patient. The Symptom Diary includes assessment of pain intensity and well-being, a question about consumed extra doses of analgesics (painkillers), and the possibility to write free text messages to the care providers. Participants use a digital pen to fill in the diary and data is transmitted using the cell phone network to a server system. The server system includes possibilities for visualizing data and for sending text messages to care providers when symptoms increase.

What are the possible benefits and risks of participating?

Participants may benefit from a richer participation in their own care and an increased sense of security. Every piece of information stored in the information system is protected from unauthorized access. Participants using the IT system shall use traditional routines if the IT system fails.

Where is the study run from?

The study is run from Linköping University, with participating home healthcare clinics from Östergötland, Sörmland and Kalmar counties (Sweden).

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

February 2008 to December 2009

Who is funding the study?

1. VINNOVA, the Swedish Governmental Agency for Innovation Systems
2. Santa Anna IT Research Institute AB/Swedish ICT Research

Who is the main contact?

Dr Leili Lind

leili.lind@liu.se

Contact information

Type(s)

Scientific

Contact name

Dr Leili Lind

Contact details

IMT

Linköpings Universitet

Linköping

Sweden

58185

-

leili.lind@liu.se

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

n/a

Study information

Scientific Title

PallPen - IT support for home healthcare: reporting of symptoms and messages with a digital pen - a randomized controlled trial

Acronym

PallPen

Study objectives

The use of Information Technology (IT) in palliative home healthcare has the ability to reduce the time span of the patients assessed and reported symptoms until these reports were received by the professional caregiver.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Regional Ethical Review Board in Linköping, Sweden, 20/06/2007, ref: M101-07

Study design

Randomized controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

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

Patients with end-stage cancer receiving advanced palliative home care

Interventions

One group receives an IT system to be used for symptom reporting while the other group uses traditional ways of symptom reporting.

The intervention consisted of a Symptom Diary form together with digital pen technology to capture symptom assessments in the home of the patient. The Symptom Diary included the assessment of pain intensity and well-being using 10 cm visual-analogue scales (VAS). Further, the diary included a question about consumed extra doses of analgesics and the possibility to write free text messages to the care providers. Participants in the intervention arm used a digital pen to fill in the diary and data was transmitted using the cell phone network to a server system. The server system included possibilities for visualizing data and for sending text messages to care providers when the symptom level increased.

Intervention Type

Device

Primary outcome measure

The time span of the patients assessed and reported symptoms until these reports were received by the professional caregiver

Secondary outcome measures

No secondary outcome measures

Overall study start date

16/02/2008

Completion date

31/12/2009

Eligibility

Key inclusion criteria

1. Patients assessing their pain to Visual Analogue Scale (VAS) 3 (VAS 1-10 cm) or higher, or well-being to VAS 4 or higher
2. Participants were required to be mentally clear
3. Swedish-speaking to the level of understanding the study form and to be able to perform symptom assessments

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

Given that 220 assessments were needed and an estimation of patients using the system for on average 7 days x 2 assessments daily, the estimated number of participants was 16

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

16/02/2008

Date of final enrolment

31/12/2009

Locations

Countries of recruitment

Sweden

Study participating centre
Linköpings Universitet
Linköping
Sweden
58185

Sponsor information

Organisation
Department of Biomedical Engineering (Sweden)

Sponsor details
IMT
Linköpings Universitet
Linköping
Sweden
58185
-
daniel.karlsson@liu.se

Sponsor type
University/education

Website
<http://www.imt.liu.se/>

ROR
<https://ror.org/05ynxx418>

Funder(s)

Funder type
Government

Funder Name
Vinnova (Sweden)

Alternative Name(s)
Swedish Governmental Agency for Innovation Systems

Funding Body Type
Government organisation

Funding Body Subtype

National government

Location

Sweden

Funder Name

Santa Anna IT Research Institute AB/Swedish ICT Research (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration