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

Submission date	Recruitment status	[ ] Prospectively registered
23/04/2012	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
16/05/2012	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/06/2017	Cancer	[ ] 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?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Quality of life

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

Key secondary outcome(s))
No secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
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Sponsor information

Organisation
Department of Biomedical Engineering (Sweden)

ROR
https://ror.org/05ynxx418

Funder(s)

Funder type

Government

Funder Name
Vinnova (Sweden)

Alternative Name(s)
Swedish Governmental Agency for Innovation Systems, Vinnovase

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

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes