

Protocol Registration Receipt
05/07/2009

Randomized Controlled Trial of Home Telemonitoring for Elderly People (Dreaming)

This study is not yet open for participant recruitment.

Verified by Health Information Management, Belgium, May 2009

Sponsored by:	Health Information Management, Belgium
Information provided by:	Health Information Management, Belgium
ClinicalTrials.gov Identifier:	NCT00893685

► Purpose

The DREAMING clinical trial is part of the DREAMING project, which has the objective to demonstrate that the DREAMING platform consisting of integrated health monitoring, alarm handling and videoconferencing services produces clinical benefits to its users and economic benefits to the health authorities. The study evaluates the long-term (30 months) effect of continuous use of the DREAMING subsystems and is testing the hypothesis that such use is superior to usual care alone in reducing the deterioration of health related quality of life that is associated to age and chronic disease. It also tests the hypothesis that the DREAMING environment is superior to usual care in delaying the transfer to nursing or elderly homes and in reducing the incidence and duration of hospitalisation episodes. The trial will also evaluate the cost-effectiveness of the DREAMING platform. Outcomes are assessed in six different health care systems (Denmark, Estonia, Germany, Italy, Spain and Sweden) and will represent a basis for the adoption of DREAMING services by the respective health authorities.

Condition	Intervention	Phase
Diabetes Mellitus Chronic Heart Failure Chronic Obstructive Pulmonary Disease	Device: Wireless monitors for disease specific clinical parameters.	N/A

Study Type: Interventional

Study Design: Health Services Research, Parallel Assignment, Open Label, Randomized, Safety/Efficacy Study

Official Title: Elderly Friendly Alarm Handling and Monitoring (DREAMING)

Further study details as provided by Health Information Management, Belgium:

Primary Outcome Measure:

- Health related quality of life as assessed by the SF-36 questionnaire, at the beginning, at midterm and at the end of the trial period [Time Frame: 0, 15, 30 months] [Designated as safety issue: No]

Secondary Outcome Measures:

- Time to permanent transfer to elderly homes [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Total and average length of stay in hospital [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of consultations with general practitioners [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of consultations with medical specialists [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of home visits by nurses [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of ambulance transports [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of accesses to emergency rooms [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of falls [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of femur fractures [Time Frame: Measured at month 30] [Designated as safety issue: No]
- HbA1c change over time (only for participants with a diagnosis of diabetes) [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Survival [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Depression as measured by HADS [Time Frame: Measured at months 0, 15 and 30] [Designated as safety issue: No]
- Number of hospitalisations [Time Frame: Measured at month 30] [Designated as safety issue: No]
- Number of permanent transfers to elderly homes [Time Frame: Measured at month 30] [Designated as safety issue: No]

Estimated Enrollment: 300

Study Start Date: May 2009

Estimated Study Completion Date: December 2011

Estimated Primary Completion Date: November 2011

Arms	Assigned Interventions
Experimental: Home telemonitoring	<p>Device: Wireless monitors for disease specific clinical parameters.</p> <p>Homes of participants will be equipped with wireless monitors for blood pressure, blood oxygen, blood glucose, peak expiratory flow, electrocardiogram, body weight. All vital parameters are monitored on a continuous, at least daily basis and obtained values are transmitted to a monitoring centre. Abnormal values are classified for their health risk and health</p>

Arms	Assigned Interventions
	alarms and/or intervention of health professionals is triggered.
No Intervention: Usual care (control group)	

Homes of participants are equipped with environmental sensors, motion detection, and with wireless sensors for blood pressure, blood glucose, body weight, blood oxygen saturation, peak expiratory flow and electrocardiogram. Disease related parameters are monitored at least daily and the measured values are transmitted to a central monitoring unit. In case of abnormal values, health alarms are generated and transmitted to the local health authorities to trigger eventual intervention by the physicians and nurses who normally follow the participants. Participants and health professionals can stay in contact via an easy to use, home television based videoconferencing system. Participants are also equipped with a personal alarm and GPS-enhanced localisation system.

Eligibility

Ages Eligible for Study: 65 Years and older

Genders Eligible for Study: Both

Accepts healthy volunteers.

Inclusion Criteria:

Inclusion criteria:

- Diagnosis of chronic heart failure
- Diagnosis of diabetes mellitus
- Diagnosis of chronic obstructive pulmonary disease

Only in the case that the number of recruited participants is not sufficient, inclusion criteria can be extended to one or more of the following conditions:

- History of myocardial infarction
- History of stroke (brain ischemia or hemorrhage)
- History of falls within the last two years
- Hospitalization during the last two years (for every reason)

Exclusion Criteria:

- Not willing to participate (e.g non signing informed consent)
- Inability to use the DREAMING equipment
- Significant impairment of language comprehension or expression (aphasia)
- Diagnosis of dementia
- Completely dependent on others for the activities of daily living
- Living without access to ISDN or DSL service

Contacts and Locations

Contacts

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Locations

Denmark

Langeland Municipality
Langeland, Denmark, 5900

Estonia

East Tallin Central Hospital
Tallin, Estonia, 10123

Germany

Pflegwerk Berlin, Mediplus
Berlin, Germany, 10439

Italy

Azienda per i Servizi Sanitari ASS N.1
Trieste, Italy, 34128

Spain

Servicio Aragones de Salud
Barbastro, Spain, 22300

Sweden

GP Surgery
Heby, Sweden, 74432

Investigators

Study Director:	Reinhard W Prior, M.D.	Health Information Management, Brussels, Belgium
Principal Investigator:	Helmut Prior, Prof. Dr.	Institute for Experimental Psychology, University of Düsseldorf, Germany (H.Prior is head of the data monitoring committee)

More Information

DREAMING official project website
<http://www.dreaming-project.org/>

Responsible Party: Health Information Management Sa, Belgium (Marco D'Angelantonio)

Study ID Numbers: European Commission, European Commission, ICT support policy program, Contract Number 225023

Health Authority: Denmark: The Regional Committee on Biomedical Research Ethics;

Estonia: The State Agency of Medicine; Germany: Ethics
Commission; Italy: Ethics Committee; Spain: Ethics Committee;
Sweden: Regional Ethical review board