An explorative study to assess the potential impact of the Incosense Smart in Envida

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The aim of this study is to explore the potential impact of the Incosense Smart at the client, professional, care processes and organization.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON44181

Source
ToetsingOnline

Brief title
Incosense Smart in Envida

Condition

- Other condition

Synonym
incontinence; loss of control of the bladder; accidental release of urine

Health condition

urine incontinentie

Research involving
Human

Sponsors and support

Primary sponsor: Zuyd Hogeschool
Source(s) of monetary or material Support: CrossCare (INTERREG);EU

Intervention

Keyword: measurement instrument, urine incontinence

Outcome measures

Primary outcome

Outcome measures include:

- client: experiences, comfort

- care: saturation levels of the incontinence material when changed,

appropriate use of material (size), appropriate time of change (too early,

late, on time).

- Professionals: problems experienced during use of the Incosense Smart,

experiences

- Organisation: use (amount) of incontinence material

Secondary outcome

NA

Study description

Background summary

People in Europe are getting older which is accompanied by increasing health care costs. Healthcare costs rose between 2005 and 2014 from 111,7 million euro to 160 million euro. Partly, this is due to inefficiencies in incontinence care; not saturated incontinence material is being changed. On the other hand incontinence material is being changed while this should have been done

earlier, resulting in leaking incontinence material.

IncoSense Smart is a measurement tool that aims to contribute to solving these inefficiencies. IncoSense Smart consists of a sensor which measures the saturation of the incontinence materials, a notification system and a management dashboard (www.incosensesmart.eu).

In 2016 a small study finished concluding that the incosense has potential in daily practice. The Incosense Smart had been developed further based on the feedback collected from care professionals and clients during the test. In summer 2017, the Incosense Smart was technically validated in a test.

In order to be able to implement the Incosense Smart in future it is essential to better understand the potential added value and impact of this device on the level of the client, care professional, care processes and the organization.

Study objective

The aim of this study is to explore the potential impact of the Incosense Smart at the client, professional, care processes and organization.

Study design

The study concerns an explorative study in two units of elderly care facilities of Envida. 20 to 40 clients will participate in the study. The study will last 10 weeks in total. The study will consist of a baseline measurement (T0) and a period of 9 weeks in which the Incosense Smart is being introduced in a stepwise manner (first notification, following by advise module). During three weeks (T1, T4, T9) data will be collected through registration of incontinence material changes. At the end of the study two focusgroup sessions will be organized. One with care professionals and one with clients of the somatic units.

Intervention

The incosense Smart consists of a sensor, a notification system and a dashboard.

Sensor: The sensor is to be attached to the outside of the Incontinence material. The Incosense Smart is never in direct contact with the skin of the client. By capacitive detection, meaning without direct contact with the wet material, the sensor can measure the presence of fluids in the channels of the incontinence materials. Based on this information the Incosense Smart can determine whether material is saturated or not saturated. When material is saturated the sensor will send a notification to the care professionals.

Attachment: The sensor will be attached by care professional at the front (the outside), the highest point, of the incontinence material.

Dashboard: The dashboard is a tool to advise care professionals on the type and size of the incontinence material that is recommended for a specific client. This advise is based on historical saturation data. Based on an algorithm the dashboard will advise whether lighter or heavier (higher absorption levels) is needed for a specific client.

Study burden and risks

Risks are neglectable for clients and burden is small. At the moment the IncoSense Smart is still in prototype phase. An independent organization confirmed that the Incosense Smart is safe to use. In the upcoming year the Incosense Smart will be CE marked. Clients will be asked to wear the sensor for 24hours a day for 9 weeks. Besides, clients from the unit de Mins (somatic) are asked to participate in a focus group session (max 2 hours). If they prefer to fill out the questionnaire on paper this is possible. If they prefer not to participate in the focusgroup session/questionnaire this will be respected.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Urine incontinence
Use of incontinence material
Willing to let incontinence changes occur on the basis of the incosense smart notifications

Exclusion criteria

There are no exclusion criteria

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	30-10-2017
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	11-10-2017
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 24072
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL63212.096.17
OMON	NL-OMON24072