Development of an experimental model for continuous measurement of postsurgical patient wellbeing, a pilot study.

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To investigate the effects of disturbing factors during postsurgical hospitalization on participants* wellbeing, in terms of sleep, stress, pain and physical mobility, and how this wellbeing might change during a more personalized hospital stay…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sleep disorders and disturbances
Study type	Observational non invasive

Summary

ID

NL-OMON45404

Source
ToetsingOnline

Brief title
An experimental model for measuring postsurgical wellbeing.

Condition

- Sleep disorders and disturbances
- Therapeutic procedures and supportive care NEC

Synonym
Wellbeing

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Biosensor, Model, Postsurgical, Wellbeing

Outcome measures

Primary outcome

Continuous monitoring with the healthpatch biosensor during both stays:

o Physical activity: number of steps, activity, total activity (cumulative, per time of day, peak)

o Sleep quality: total sleep duration, total duration of rapid eye movement (REM) sleep, number of nightly awakenings

o Stress level: calculated stress index (SI) (average, hourly).

Questionnaires at three moments during both stays:

o State Trait Anxiety Inventory (STAI)

o Visual Analogue Scale (VAS): measuring patient-reported outcomes of energy level and physical mobility

Measurements of pain processing, thresholds and suppression capabilities during both stays:

o Quantative Sensory Testing (QST). QST measurements include pressure pain threshold (PPT), electric pain threshold (EPT) and Conditioned Pain Modulation (CPM).

Secondary outcome

Participants fill in a daily diary of their activities for further validation

and interpretation of the data from the HealthPatch biosensor.

Participants are also invited for a short interview about their personal

experiences and opinions during their hospitalization.

Questionnaire about sleep: Leeds Sleep Evaluation Questionnaire (LSEQ)

Study description

Background summary

In light of innovation project 'Room with a View' of the surgical department of Radboudumc, we aim to investigate the possibilities for improving postsurgical wellbeing of patients. This wellbeing is defined by outcomes in mental stress, pain, physical activity and sleep quality. (the 'BIG 4')

Study objective

To investigate the effects of disturbing factors during postsurgical hospitalization on participants* wellbeing, in terms of sleep, stress, pain and physical mobility, and how this wellbeing might change during a more personalized hospital stay within an optimal healing environment.

Study design

A pilot study, non-randomized

Study burden and risks

The study requires a total time investment of 48 hours, which are spent on the surgical ward of Radboudumc.

Aside from allergic or hypersensitivity reactions to the HealthPatch biosensor, risks are considered minimal.

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

Participants must be at least 18 years old on the day the informed consent form will be signed.
Participants are able to speak, read and understand the local language of the investigational site, are familiar with the procedures of the study, and agree to participate in the study program by giving oral and written informed consent.

Exclusion criteria

History of cardiovascular diseases, arrhythmias or presence of implantable cardiac defibrillator.
History of sleep-related disorders.

History of allergic response or skin irritation in relation to adhesive bandages.
History of a (chronic) pain syndrome that interferes with the interpretation of QST results.
Participant has (a history of) a medical disorder that interferes with the study measurements or may pose a risk for the participant.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-07-2017
Enrollment:	15
Type:	Actual

Ethics review

Approved WMO Date:	06-03-2017
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	25-09-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL59593.091.16