The EndoWatch: a smart wearable that serves as *external hypothalamus*

Published: 10-04-2025
Last updated: 28-04-2025

The aim of this study is to determine whether this smart wristband can actually support patients and their parents in managing the consequences of hypothalamic dysfunction. We will investigate what kind of support patients, parents, or caregivers...

Ethical review	Approved WMO
Status	Pending
Health condition type	Hypothalamus and pituitary gland disorders
Study type	Observational non invasive

Summary

ID

NL-OMON57411

Source
ToetsingOnline

Brief title
EndoWatch

Condition

- Hypothalamus and pituitary gland disorders
- Nervous system neoplasms malignant and unspecified NEC

Synonym
Hypothalamic dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Prinses Máxima Centrum voor Kinderoncologie
Source(s) of monetary or material Support: KWF

Intervention

Keyword: Brain tumor, Hypothalamic dysfunction, Monitoring, Smart watch

Outcome measures

Primary outcome

The primary outcome parameter of this study is the score on a 5-point Likert scale as answer to the question posed in the PREM questionnaire at T2:

"The use of the EndoWatch has supported me in the management of the consequences of hypothalamic dysfunction" (for participant) OR

"The use of the EndoWatch has supported me in the management of the consequences of hypothalamic dysfunction of my child" (for parent)

Secondary outcome

Secondary outcome parameters of this study are:

1. Management of hypothalamic dysfunction assessed per domain:

A. Management of temperature dysregulation:

- Score on a 5-point Likert scale in the PREM questionnaire, answered at T2, to the questions in the section 'Managing Body Temperature'.

- Difference in average delta of wrist temperature per day (* = maximum_temp - minimum_temp) measured by the EndoWatch, between the first and last 4 weeks of the study.

B. Management of sleep problems:

- Score on a 5-point Likert scale in the PREM questionnaire, answered at T2, to

the questions in the section 'Managing Sleep'.

- Intraindividual changes of total scores measured by PROMIS Sleep Disturbances Short Form (Appendix C) between T0 - T1 - T2.

- Intraindividual changes of scores measured by PROMIS Sleep Related Impairment Short Form (Appendix D) between T0 - T1 - T2.

C. Management of daily activity:

- Score on a 5-point Likert scale in the PREM questionnaire, answered at T2, to the questions in the section 'Managing daily activity'.

- Difference between average number of steps per day measured by EndoWatch of the first 4 weeks compared to average number of steps per day measured by EndoWatch of the last 4 weeks of the study.

D. Management of hypocortisolism during episodes of increased physical or emotional stress:

- Score on a 5-point Likert scale in the PREM questionnaire, answered at T2, to the questions in the section 'Managing stress or illness'.

E. Management of AVP deficiency:

- Score on a 5-point Likert scale in the PREM questionnaire, answered at T2, to the questions in the section 'Managing desmopressin use'.

2. Explorative comparison of EndoWatch measurements to current home

measurements of patients with hypothalamic dysfunction, assessed per domain:

A. Comparison of EndoWatch measurement of wrist temperature with current home measurement of temperature:

- Difference between EndoWatch measurements of wrist temperature to self-measured ear or rectal thermometer (3 times a day & if otherwise necessary) during two 7-day periods.

B. Comparison of EndoWatch measurement of sleep with self-reported sleep- and wake times:

- Difference between EndoWatch measurements of sleep-onset and -wake times and self-reported sleep-onset and -wake times in the sleep diary, based on two 7-day periods.

C. Comparison of EndoWatch measurements of steps per day with current home measurement of steps per day by smartwatch:

- Difference between EndoWatch measurement of steps per day and the current home measurement of steps per day that was measured by smartwatch, based on two 7-day periods. (Note: only for patients who are already used to wearing smartwatch)

D. Comparison of EndoWatch measurement of changes in physiological metrics with episodes of self-reported increased (physical or emotional) stress:

- Difference in physiological metrics (heart rate (variability), wrist temperature, skin conductance) during self-reported episodes of increased

(physical or emotional) stress (in diary) and during episodes without increased stress, i.e. stress vs non-stress episodes.

3. Required improvements for further development of the EndoWatch, as reported by patients and/or caregiver(s) in semi-structured close-out interviews (at T2).

4. Psychosocial impact of the EndoWatch on patients, caregiver(s) and families, as reported by patients and/or caregiver(s) in semi-structured close-out interviews (at T2).

Study description

Background summary

The hypothalamus is an area in the brain that regulates the *overall bodily balance.* It controls functions such as body temperature, the biological clock, hunger and thirst sensations, energy expenditure, behavior, and the regulation of the pituitary gland (which excretes and controls various hormones in the body). When the hypothalamus no longer functions properly, one or more of these tasks may no longer be performed correctly. This is known as hypothalamic dysfunction. The body is then *out of balance.* This can lead to a variety of symptoms and result in severe obesity, fatigue, and more. Additionally, it requires continuous care from the patient, their parents, or caregivers, which has a significant impact on their daily life.

A smart wristband that continuously monitors body temperature, stress, sleep, and daily activity in patients with hypothalamic dysfunction could help ease the burden for parents, caregivers, and healthcare providers. This wristband is called the EndoWatch. With it, imbalances can be detected and addressed earlier, and more support can be provided in managing hypothalamic dysfunction. Parents can act sooner, take appropriate action, and gain more insight into their child's health (where, in many cases, the child cannot sense or communicate symptoms). A previous pilot study involving 10 patients with hypothalamic dysfunction has shown that wearing this wristband is feasible for both children and adults with hypothalamic dysfunction and that the device and

app are easy to use.

Study objective

The aim of this study is to determine whether this smart wristband can actually support patients and their parents in managing the consequences of hypothalamic dysfunction. We will investigate what kind of support patients, parents, or caregivers experience and what improvements should be made to the wristband. We also want to understand how the use of this smart wristband affects the feelings of patients and parents. The results of this study will be used in further research needed for the further development of this smart wristband, so that it can ultimately be used in the home setting for patients who might benefit from it.

Study design

This is a prospective, longitudinal, observational study.

Study burden and risks

As described in more detail in the study summary in the protocol, and in sections 6.4 and 11.4, the burden of this study is limited to wearing the smart watch, the extra time it takes for the participant and their parents to complete the diaries, and the 3 hospital visits required for this study (2 of which can also take place online if desired).

Some participants may find wearing the smart watch uncomfortable or burdensome, but wearing the wristband itself poses no (health) risks. If the participant decides not to wear the smart watch for this reason, they are free to withdraw from the study.

The ability to access the measurements in the app does not present direct health risks. This is an exploratory, observational study, and the participants are not subjected to any interventions nor will they receive separate instructions based on these measurements. The researchers do acknowledge the potential risk of additional anxiety or stress as a result of continuous health monitoring. However, this risk is considered minimal, as previous pilot studies indicated that many participants reported that the monitoring actually provided a sense of control and reduced feelings of anxiety.

In conclusion, the burden and risks associated with participation in this study are both considered to be minimal, and it is considered that this is proportional to the relevance of the study and the potential benefits for the participants.

Contacts

Public
Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL
Scientific
Prinses Máxima Centrum voor Kinderoncologie

Heidelberglaan 25
Utrecht 3584 CS
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

- Age (at time of study enrolment) between 6-40 years;
- Diagnosed with hypothalamic dysfunction by an endocrinologist. Hypothalamic dysfunction is diagnosed as having at least two of the following symptoms:
*having a decreased resting energy expenditure <80%, as measured with indirect calorimetry OR
*experiencing hyperphagia OR
*overweight or obesity OR
*sleep pattern disturbances OR
*behavioural disorders (defined as presence of obsessive compulsive symptoms, hoarding and/or periods of rage) OR

*temperature regulation disorder OR
*pituitary dysfunction OR
*AVP deficiency with inadequate thirst regulation
- Informed consent has been received.

Exclusion criteria

- Age (at time of study enrolment) <6 or >40 years
- Patients actively undergoing intensive treatment for (supra)sellar tumor
- Illiteracy in patient or caregiver
- Language barrier, despite involvement of interpreter and translation of study information.
- Pre-existing skin conditions to the upper extremities, such as psoriasis, (severe) eczema.
- Informed consent has not been received

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2025
Enrollment:	50
Type:	Anticipated

Medical products/devices used

Generic name:	Corsano CardioWatch 287-2
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO Date:	10-04-2025
Application type:	First submission
Review commission:	METC NedMec

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	NL87495.041.24