Trial Description

Title

Userfriendliness and usability of the Dfree ultrasonic sensor to support participation and autonomy of people with detrusor hypotonia: a mixed-method study.

Trial Acronym

Dfree

URL of the trial

[---]*

Brief Summary in Lay Language

Study to evaluate an increase in quality of life and participation in everyday life by using a Japanese ultrasonic sensor, the Dfree. The device promises to solve incontinence problems in everyday life and thus to enable participation.

Brief Summary in Scientific Language

The ultrasound device Dfree is a technical artifact for predicting the need for micturition, to support people having difficulties in controlling micturition. The Dfree sensor is recommended as a new social assistive care technology for accompanying therapy by urinary incontinence. At the moment, however, it is still unclear whether the Dfree offers advantages over previously established therapeutic approaches. The building blocks of conservative therapy for urinary bladder incontinence include, for example, drinking and micturition training, physiotherapy, electrostimulation and drug intervention therapies with cholinergics or alpha blockers or therapy using bladder pacemakers (Bump et al. 1991; Füsgen 2005; Klingler 2007, p. 10; ders., 2014 ; Borello-France et al. 2013; Huang et al. 2019). In addition, the supply of catheter systems in the sense of long-term catheterization as well as operative therapies for bladder emptying disorders and urinary incontinence (Eberhardt and Geissbühler 2000, 44 f .; Jost 2014) are relevant. The Dfree has the potential to minimize problems resulting from urinary incontinence in an uncomplicated and simple manner. However, there is currently no evidence of user-friendliness and usability. In particular, actually there are no studies available to assess the applicability of the Dfree ultrasound device in older people with urinary incontinence, or studies to change or improve the quality of life and improved ability to participate in everyday life. This needs to be evaluated.

Do you plan to share individual participant data with other researchers?

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00020764**
- Date of Registration in DRKS: **2020/02/05**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2019-133 , Ethikkommission der Medizinischen Fakultät der Martin-Luther-Universität Halle Wittenberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **N31.1 - Reflex neuropathic bladder, not elsewhere classified**
- ICD10: **N31.2 - Flaccid neuropathic bladder, not elsewhere classified**

Interventions/Observational Groups

- Arm 1: **20 patients with detrusor hypotension use the Dfree ultrasound sensor 12hours/day during a period of 3 month. At the measurement times T0 (before intervention begins) and T1 (after completion of the intervention period) they will be asked about their OoL using the questionnaire KHQ. In addition, satisfaction with the treatment was assessed by the ZUF-8 questionnaire and supported by a guided interview.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Treatment**
- Assignment: **Single (group)**
-

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Blinding: **[---]***

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Control: **Uncontrolled/Single arm**

Purpose: **Treatment**

Assignment: **Single (group)**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The primary target parameter is the perceived change in the subjectively recognized QoL for the urinary incontinence symptom caused by detrusor hypotonia while using the Dfree sensor. The change in the average scores is considered. The KHQ is helpful to determine the detailed status of the QoL of older men and women [...] who suffer from urinary bladder incontinence (Okamura et al. 2002, p. 411). The KHQ was selected to determine the primary target parameter because it guarantees a comprehensive and valid assessment of micturition satisfaction.

Secondary Outcome

Another secondary target parameter is the number of successful toilet visits without involuntary urination.

The following endpoints are also taken into account as secondary target parameters:

• Reported therapy adherence
• Functional status
• Self-reporting degree of autonomy
• Subjectively perceived improvement in the quality of care

The effect of using the Dfree sensor is observed over time until the end of the observation period or application of another therapeutic intervention.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Martin-Luther-Universität Halle-Wittenberg, Medizinische Fakultät, Dorothea-Erxleben-Lernzentrum, FORMAT-Projekt, Halle Saale**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/06/25**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

• Age ≥18 years
• incontinence
• Urologically confirmed detrusor hypotonia
• Significant suffering

Exclusion criteria

• existing urinary tract infection
• bladder- catheter
• Detrusorhypertonus
• Difficult micturition
• haematuria
• dementia
• Immobility (min. 50 m walking distance).
• Inability to get up from a sitting position
• Life expectancy less than 3 months

Addresses

■ **Primary Sponsor**

MLU Halle-Wittenberg, Med. Fak.; DELH; FORMAT-Projekt
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- **Collaborator, Other Address**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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  Germany

  Telephone: **+4939156701**
  Fax: **[---]***
  E-mail: **esif.mf at sachsen-anhalt.de**
  URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum**
- trial protocol (mandatory for transfer to Studybox) **Studienprotokoll**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*