

Trial Description

Title

inContAlert: Identifying Adoption Factors and Design Principles Affecting the Intention of Incontinent Patients to Adopt Mobile Health Applications

Trial Acronym

[---]*

URL of the trial

<https://incontalert.de/>

Brief Summary in Lay Language

Urinary incontinence (UI) is a urological health issue affecting hundreds of millions of individuals worldwide, bringing manifold consequences on both the individual and societal level. While conventional aids have unhygienic and cumbersome attributes, mobile health (mHealth) interventions have the potential to significantly improve the quality of life of those affected. However, knowledge of determinants affecting patients to adopt mHealth interventions and how these solutions should be designed to support their adoption is scarce. In this study, we aim at developing an adoption model and hence deriving design principles to support the adoption of mHealth solutions by chronic disease patients, such as UI patients. Built upon our findings, we also develop a mHealth device for supporting UI management.

Therefore, we initially reviewed and analyzed literature. Subsequently, we developed the adoption model and the mHealth solution and conducted 32 expert interviews to evaluate, revise, and refine both the model and the device. Ultimately, we conducted a survey with 387 participants to test and validate our adoption model in a larger setting.

Brief Summary in Scientific Language

Urinary incontinence (UI) is a urological health issue affecting hundreds of millions of individuals worldwide, bringing manifold consequences on both the individual and societal level. While conventional aids have unhygienic and cumbersome attributes, mobile health (mHealth) interventions have the potential to significantly improve the quality of life of those affected. However, knowledge of determinants affecting patients to adopt mHealth interventions and how these solutions should be designed to support their adoption is scarce. In this study, we aim at developing an adoption model and hence deriving design principles to support the adoption of mHealth solutions by chronic disease patients, such as UI patients. Built upon our findings, we also develop a mHealth device for supporting UI management.

Therefore, we followed an Action Design Research approach, which initially held a systematic literature review resulting in the identification and analysis of 67 relevant papers. Subsequently, we developed the ex-ante model and an initial version of the mHealth solution and conducted 32 expert interviews to evaluate,

revise, and refine both the model and the device. Ultimately, we conducted a confirmative survey with 387 participants to test and validate our adoption model in a larger setting. As a result, we introduce the ex-post model consisting of five categories (User Factors, Perceived Benefits, Hardware and Software, Data Factors, and Environment) and 28 sub-categories (e.g., Perceived Convenience and Perceived Unobtrusiveness) of mHealth adoption. We also illustrate our final mHealth intervention including a sensor device, a monitoring app, and an additional drinking protocol app and present 26 specific principles for designing mHealth solutions (e.g., Miniaturization, Clearness, and Readability).

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00021103**
- Date of Registration in DRKS: **2020/05/12**
- 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.: [---]* , **Ethikkommission der Universität Bayreuth**

Secondary IDs

Health condition or Problem studied

- Free text: **Urinary incontinence as well as similar functional and sensory disorders of the urinary bladder**
- ICD10: **R32 - Unspecified urinary incontinence**
- ICD10: **N39.3 - Stress incontinence**
- ICD10: **N39.4 - Other specified urinary incontinence**
- ICD10: **F98.0 - Nonorganic enuresis**
- ICD10: **N31 - Neuromuscular dysfunction of bladder, not elsewhere classified**
- ICD10: **N32.8 - Other specified disorders of bladder**
- ICD10: **G95.8 - Other specified diseases of spinal cord**

Interventions/Observational Groups

- **Arm 1: In this study, we aim at developing an adoption model and hence deriving design principles to support the adoption of mHealth solutions by chronic disease patients, such as urinary incontinence patients. Built upon our findings, we also develop a mHealth device for supporting urinary incontinence management. Therefore, we followed an Action Design Research approach, which initially held a systematic literature review resulting in the identification and analysis of 67 relevant papers. Subsequently, we developed an ex-ante model and an initial version of the mHealth solution.**
- **Arm 2: Within the alpha cycle of our Action Design Research approach, we conducted 16 expert interviews to evaluate and revise both the model and the device. Here, we conducted ten interviews with urinary incontinence patients and six with practitioners from urinary incontinence related fields and organizations.**
- **Arm 3: Within the beta cycle of our Action Design Research approach, we conducted 16 further expert interviews to evaluate and refine both the model and the device. Again, we conducted ten interviews with urinary incontinence patients and six with practitioners from urinary incontinence related fields and organizations. Ultimately, we conducted a confirmative survey with 387 participants to test and validate our adoption model in a larger setting.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Other**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Supportive care**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

We identified adoption factors of urinary incontinence patients regarding the adoption of mHealth solutions and derived design principles regarding the development of such mHealth. We focused on factors that foster the adoption by patients. Finally, we developed an adoption model and a catalog of specific design principles.

Secondary Outcome

Furthermore, we developed a sensor system that noninvasively determines the filling level of the urinary bladder and displays the filling level to a digital end device.

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- other **Universität Bayreuth, Bayreuth**
- other **Projektgruppe Wirtschaftsinformatik des Fraunhofer-Instituts für Angewandte Informationstechnik (FIT), Bayreuth**
- other **Kernkompetenzzentrum Finanz- & Informationsmanagement (FIM), Bayreuth**
- other **Netzwerk und Kontakt-Empfehlungen, deutschlandweit**
- other **Selbsthilfegruppen, Gesellschaften, Vereinigungen und Vereine, deutschlandweit**
- other **Soziale Medien und sich darin befindende Gruppen, deutschlandweit**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/05/22**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

**Urinary incontinence;
majority age**

Exclusion criteria

**No urinary incontinence;
exclusive fecal incontinence;
no majority age**

Addresses

■ Primary Sponsor

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Sources of Monetary or Material Support

■ Institutional budget, no external funding (budget of sponsor/PI)

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Status

■ Recruitment Status: **Recruiting complete, follow-up complete**

■ Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]*

■ Reason, if Reason for Recruiting Stop "Other": [---]*

■ Study Closing (LPLV): **2020/09/10**

■ Number of Participants in Germany after Recruiting complete: **419**

■ Total Number of Participants (all Sites worldwide) after Recruiting complete: **419**

Trial Publications, Results and other documents

■ Paper **Burkard, Michael; Lockl, Jannik; Zürl, Tristan; and Ruhland, Nicolas: "Managing My Bladder Dictates My Daily Routines - A Model for Design and Adoption of mHealth in Chronic Disease Management" (2021). Wirtschaftsinformatik 2021 Proceedings. 12.**

■ Paper **Paper (en), Burkard et al. 2021, Wirtschaftsinformatik 2021 Proceedings**

■ Paper **Poster (en), Burkard et al. 2021, Wirtschaftsinformatik 2021 Proceedings**

■ Abstract **Abstract (de), Burkard et al. 2021**

■ Trial results **Studienergebnisse (de), Burkard et al. 2021**

* 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.