

Trial Description

Title

The FeverApp Registry - Ecological Momentary Assessment (EMA) of fever management in families regarding conformity to up-to-date recommendations.

Trial Acronym

The FeverApp-Registry

URL of the trial

<https://www.feverapp.de>

Brief Summary in Lay Language

Fever is a most common symptom and its mismanagement is a health care burden. A FeverApp, based on current guidelines, guiding parents and carers to handle and document fever, will be developed with family pediatricians and recommended for all parents in Germany

Brief Summary in Scientific Language

Fever is a most common symptom and its mismanagement is a health care burden. A FeverApp, based on current guidelines, guiding parents and carers to handle and document fever, will be developed with family pediatricians and recommended for all parents in Germany. A registry will anonymously document features, management and outcomes of febrile episodes: basic sociodemographic and medical information, course of fever, initial symptoms, pharmacological and non-pharmacological interventions, consultation with doctors, outcomes, fever fear, and app satisfaction. Primary objective is to assess and increase parental confidence and guideline adherence and reduce overuse of antipyretics, antibiotics and healthcare providers. To calculate guideline adherence with $\pm 2\%$ precision, 2,400 fever episodes will be guaranteed by Reference Practices. Data analysis is expected to enable optimization and culturally sensitive individualization of registry, app and guidelines, reducing discrepancies between guidelines and reality. This may improve communication quality and health, e.g. asthma and antimicrobial resistance. Results will be published per website and app (FeverMap and FeverStats).

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

No

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00016591**
- Date of Registration in DRKS: **2019/02/07**
- 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.: **139/2018 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

- BfArM-No.: **01GY1905**

Health condition or Problem studied

- ICD10: **R50 - Fever of other and unknown origin**

Interventions/Observational Groups

- Arm 1: **Observation unit: the parent as primary care-giver of the minor in Germany using the FeverApp (in German, English, Greek, Turkish or Arabic language modes). Target population: all parents with at least one fever event in at least one child. Source population: those persons who document the presence or absence of fever in the FeverApp during the registry period. Fever is a most common symptom and its mismanagement is a health care burden. A FeverApp, based on current guidelines, guiding parents and carers to handle and document fever, will be developed with family pediatricians and recommended for all parents in Germany. A registry will anonymously document features, management and outcomes of febrile episodes: basic sociodemo-graphic and medical information, course of fever, initial symptoms, pharmacological and non-pharmacological interventions, consultation with doctors, outcomes, fever fear, and app satisfaction. Primary objective is to assess and increase parental confidence and guideline adherence and reduce overuse of antipyretics, antibiotics and healthcare providers. To calculate guideline adherence with $\pm 2\%$ precision, 2,400 fever episodes will be guaranteed by Reference Practices. Data analysis is expected to enable optimization and culturally sensitive individualization of registry, app and guidelines, reducing discrepancies between guidelines and reality. This may improve communication quality and health, e.g. asthma and antimicrobial resistance. Results will be published per website and app (FeverMap and FeverStats).**

Characteristics

- Study Type: **Non-interventional**

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- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Other**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Is to assess and increase guideline adherence (primary outcome) and parental confidence in managing fever, and reduce overuse of antipyretics, antibiotics and healthcare providers.

Secondary Outcome

- **To create a “FeverApp” that will enable parents to handle fever safely, and use the FeverApp Registry as symptom and fever management diary.**
- **To develop and test a symptom-led (fever) registry model by app-based acquisition of parental entries of febrile illness cycle data.**
- **To develop and test models of how an interactive app-based registry can enable nationwide EMA information to inform science, guideline (DGKJ e.V, BVKJ e.V.) and policy makers, and the public (via FeverMap and FeverStats).**

Countries of recruitment

- **DE Germany**

Locations of Recruitment

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/09/01**

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- Target Sample Size: **2400**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **17 Years**

Additional Inclusion Criteria

Pediatric fever in parental view

Exclusion criteria

not applicable

Addresses

■ Primary Sponsor

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■ **Collaborator, Other Address**

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Germany

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Fax: [---]*

E-mail: [---]*

URL: **<https://bvkj.de>**

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.)**

Bundesministerium für Bildung und Forschung Dienstsitz Bonn
Heinemannstr. 2

**Public funding institutions financed by tax money/Government funding body
(German Research Foundation (DFG), Federal Ministry of Education and
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E-mail: [---]*

URL: <https://www.gesundheitsforschung-bmbf.de/de/fieberapp-register-aufbau-eines-registers-zur-information-und-selbstdokumentation-der-9014.php>

■ **Private sponsorship (foundations, study societies, etc.)**

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64297 Darmstadt
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URL: <https://www.sagst.de/en/>

Status

■ Recruitment Status: **Recruiting ongoing**

■ Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

■ Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum FieberApp Register**

* 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.