

Efficacy of frequency voiding chart application versus conventional paper version

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23747

Source

NTR

Brief title

FVC

Health condition

Paediatric patients with an indication to evaluate voiding and drinking habits with an FVC

Sponsors and support

Primary sponsor: Radboudumc

Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Difference of compliance and the number of completely and correctly filled in FVCs in both the paper version and the FVC application.

Secondary outcome

Applicability, feasibility and child's participation of the FVC application.

Other objectives:

Appealing, clarity, feedback-mechanism and educational part of the FVC application.

Study description

Background summary

Introduction

A frequency voiding chart (FVC) is an essential tool for diagnosis, treatment, evaluation and follow-up for paediatric patients with voiding disorders or to evaluate micturition and drinking habits in general. However, compliance with regard to completely and correctly filled in FVCs is moderate, leading in unnecessary delay in diagnosis and follow-up. One potential method to improve this compliance might be the development of a mobile FVC application. In the Radboudumc a newly developed application is realized in collaboration with patients and healthcare providers.

Purpose

The purpose of our study is to test the compliance and the number of completely and correctly filled in FVCs in both the paper version and the developed FVC application. Furthermore, we will test the applicability, feasibility and child's participation of this application.

Objectives

Difference in compliance and the number of completely and correctly filled in FVCs in both the paper version and the FVC application. Furthermore, applicability, feasibility and child's participation will be tested as secondary objectives.

Study design

Prospective randomized controlled trial in 122 patients.

Study population

Paediatric patients with voiding disorders or need for evaluation of voiding and drinking habits from 5-12 years old and their parents.

Methods

Eligible patients are asked for participation during regular outpatient visits. After informed consent patients are randomized into two groups. Group one will receive a paper FVC, group two a mobile FVC application. Every participant will get a study number.

The treating physician or nurse specialist will ask permission to share the patient's data with the principal investigator. The data are anonymous and can only be traced back to the patient by the principal investigator. Either paper or digital FVC will be filled in for 2 x 24

hours. Data are collected after 4-8 weeks in the next regular visit and a short interview is conducted afterwards with a maximum of 10 minutes in which applicability, feasibility and other parameters are scored.

Statistical analysis

The significance of the results for the difference in compliance will be tested with the help of an exact Fisher test.

The secondary objectives will be analyzed with the use of an independent T-test.

Study objective

The expectations are that the FVC application will provide a higher completion rate and more correct and legible data than the conventional paper FVC.

Study design

Patients and their parents are asked to participate during the regular appointment at the outpatient clinic where information is given orally and in writing by the treating physician or nurse specialist, including informed consent. After at least 14 days the patients will be contacted by telephone by the treating physician or nurse specialist and upon participation and signed informed consent the patients will receive by post either the conventional paper FVC or a word document with instructions of how to download the application or a paper FVC, depending on their randomisation.

After 4 to 8 weeks, a regular check-up appointment with the treating physician follows, in which completeness and correctness of the FVCs will be evaluated. Afterwards, a short-term interview of up to 10 minutes takes place to request the user-friendliness of the application.

Intervention

The investigational product in this study will be a newly developed FVC application. The application was realized in collaboration with patients, health care providers from the Radboudumc Amalia Children's Hospital and the technical professionals from B302.

Contacts

Public

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Eligibility criteria

Inclusion criteria

Age 5-12 years old
Treated in the Radboudumc Amalia children's Hospital
FVC indicated for diagnosis or treatment of their condition
Speaking Dutch language
Signed informed consent
o legally authoritative parents by all patients

Exclusion criteria

Age <5 or >12 years old
Not in the possession of a mobile phone or tablet

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	02-04-2021
Enrollment:	122
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Plan description

N/A

Ethics review

Positive opinion

Date: 02-04-2021

Application type: First submission

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

NTR-new

CCMO

ID

NL9383

NL71348.091.19

Study results

Summary results

N/A