Efficacy of frequency voiding chart application versus conventional paper version

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23747

Bron
NTR

Verkorte titel
FVC

Aandoening

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

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference of compliance and the number of completely and correctly filled in FVCs in both

the paper version and the FVC application.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Radboudumc
liesbeth de wall

06-15957867

Wetenschappelijk

Radboudumc
liesbeth de wall

06-15957867

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	02-04-2021
Aantal proefpersonen:	122
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	02-04-2021
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9383
CCMO	NL71348.091.19

Resultaten

Samenvatting resultaten
N/A