

Virtual Asthma Clinic for Children.

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The introduction of a virtual asthma clinic may improve the number of asthma free days in children with asthma while the number of visits to the outpatient clinic is decreased by 50%.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27750

Bron

NTR

Verkorte titel

Virtual Asthma Clinic

Aandoening

Asthma, Children, Digital Care, Virtual Clinic, Managment, Self-management

Ondersteuning

Primaire sponsor: UMC St Radboud

Overige ondersteuning: Astmafonds

Innovatiefonds Zorgverzekeraars

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The number of asthma free days during the last 4 weeks of the study.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Pediatric asthma management has evolved considerably over the last decades. In addition to published guidelines and improved modes of administration for medication, much attention is now spent on adherence to treatment, quality of life, and self-management. Web-based digital tools have been shown to improve asthma knowledge, management, and outcome when added to usual care. It has not been investigated whether these tools may substitute regular visits to the outpatient clinic, and still improve asthma outcome in children and adolescents.

Objective:

To assess whether asthma control can be improved through a virtual asthma clinic for children with asthma, while reducing the regular visits to the outpatient clinic by 50%.

Study design:

Prospective, national, multicenter (n=7) randomized trial in which asthma management of children with allergic asthma, aged 6-18 years, through a virtual clinic will be compared with usual care. Children will be randomized into usual care (n=105) or partly digital care (n=105) through the virtual asthma clinic. Asthma treatment is in agreement with Dutch asthma management guidelines, but to correct for subtle differences between centers, randomization will be performed per center.

The primary endpoint is the number of symptom free days per month at the end of the study.

Secondary endpoints are: number of exacerbations, hospital admissions, unscheduled visits, and adherence to treatment, daily dose of ICS, quality of life, asthma control score and patient empowerment. Furthermore, cost-effectiveness will be analyzed.

Doel van het onderzoek

The introduction of a virtual asthma clinic may improve the number of asthma free days in children with asthma while the number of visits to the outpatient clinic is decreased by 50%.

Onderzoeksopzet

1. Start inclusion: September 2011;
2. Stop inclusion: August 2011.

Onderzoeksproduct en/of interventie

Randomized allocation tot usual care (outpatient clinic vist every 4 months) or access to virtual asthma clinic (outpatient clinic visits every 8 months).

The virtual asthma clinic consist of a website, accesible for all patients, their parents and their doctor's. It has three modules:

1. An extended educational/informational module with backgroundinformation on asthma en used medication along with instructive video's;
2. A forum on which questions can be asked and tips can be shared;
3. A shielded privat module on which the personal treatment (maintenance and attack treatment) can be consulted and on which de patient or parent freely, easily and always can communicate with the doctor. Answers are given within 24 hours on working days.

Patients receive an email every 4 weeks requesting to fill in the Astma Controle Test online, a short questionnaire, so doctor's can monitor the degree of asthma. Results are online available for patients. When asthma control is insufficient, the treatment team will contact the patient for discussion and, if necessary, extra measurements are taken. The current contactdetails can also be found in this section.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Children with doctor's diagnosed asthma (based on clinical symptoms, bronchodilator response of FEV1 of > 9% of predicted and/or airway hyperresponsiveness and/or signs of chronic airways inflammation (elevated FENO));
2. At least one allergy for airborne allergens proven by positive skin prick tests and/or blood tests;
3. Between 6 and 18 years of age;
4. Have a computer with internet connection at home.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A history of admission to the intensive care unit for asthma in the preceding 5 years;
2. Difficult to treat asthma (defined as uncontrolled or poorly controlled asthma in spite of maintenance treatment with inhaled corticosteroids with at least 800 micrograms budesonide or equivalent per day, long acting bronchodilators and/or Montelukast®, and/or oral corticosteroids);
3. Use of Omalizumab® for severe allergic asthma;
4. Other chronic diseases;
5. Inability of the parents or older children to understand or read Dutch.

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2011
Aantal proefpersonen:	210
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing	
Soort:	Niet van toepassing

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	NL2298
NTR-old	NTR2689
Ander register	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten

N/A