Effecten van GroepsconsulTen op zElfmAnageMent en therapietrouw in sikkelcelziekte (TEAM studie).

Gepubliceerd: 13-08-2014 Laatst bijgewerkt: 13-12-2022

We hypothesize that group medical appointments will enhance adherence to treatment and self-efficacy in patients with sickle cell disease, as well as increase quality of life, and satisfaction with the treating physician and nurse. When performing...

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON21649

Bron
NTR

Verkorte titel
TEAM studie.

Aandoening

sickle cell disease, group medical appointments, self-efficacy, adherence.

sikkelcelziekte, groepsconsulten, zelfredzaamheid, therapietrouw.

Ondersteuning

Primaire sponsor: Erasmus Medical Centre- Sophia Children's Hospital (Sickle cell centre).
Overige ondersteuning: -

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Self-efficacy as measured by a validated questionnaire.
2. Adherence to prescribed treatment by the (pediatric) hematologist and measured with two validated self-report questionnaires, out-patient clinic attendance and blood values associated with adherence to medication.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Due to increased immigration to the Western world, sickle cell disease is now diagnosed regularly in the Netherlands, especially in the larger multicultural cities of Rotterdam and Amsterdam. Sickle cell disease is an inherited red cell disorder caused by an abnormal production of the hemoglobin, leading to severe chronic anemia and vaso-occlusive ischemic episodes with long-term organ failure. Sickle cell disease care is often laborious and difficult due to patient-related, socio-economic and cultural factors not easily influenced. These factors negatively influence the quality of care and improvement of overall morbidity. Care is often characterized by late presentation of symptoms and decreased adherence to medical visits and medication. Self-efficacy is defined as confidence in one's own capabilities to manage illness and is an important factor in prognosis and adherence to treatment. Moreover, it is modifiable as reported by various studies. A group medical appointment is a novel form of out-patient contact incorporating an individual appointment within a group consultation, in the presence of fellow patients and other medical professionals. Within a group medical appointment, more time is available for discussion on disease-related topics. In addition, information and social support from fellow patients can improve self-management and quality of life. We hypothesize that group medical appointments may improve self-efficacy and adherence in sickle cell disease.

Objective of the study:

Primary objective

To analyse the effect of group medical appointments on self-efficacy and adherence to medication and outpatient clinic visits in patients with sickle cell disease.

Secondary objectives

To evaluate the effect of group medical appointments on quality of life, morbidity and hospital admissions, and satisfaction with the treating physician and nurse. An economical

analysis with respect to health-related quality of life will be performed to evaluate the cost-effectiveness of the intervention.

Study design:

In this randomized controlled trial, the effects of group medical appointments will be measured and compared to the standard treatment in adults and children with sickle cell disease, during a three year period. Outcome will be measured at t=0 (baseline), t=1.5 years and t=3 years (after four group medical appointments). Adults and children will be analysed separately.

Study population:

Sickle cell patients of all ages and their parents, if applicable, in the Erasmus Medical Centre Sophia Children's Hospital (Sickle cell Centre).

Intervention:

Group medical appointments in the intervention arm, every other visit to the out-patient clinic.

Primary outcome of the study:

1. Self-efficacy measured with a validated questionnaire.

2. Adherence to prescribed treatment by the (pediatric) hematologist and measured with two validated self-report questionnaires, out-patient clinic attendance and blood values associated with adherence to medication.

Secundary outcome of the study:

1. Quality of life as measured with validated generic questionnaires.

2. Medical contacts for sickle cell- related symptoms and complications.

3. Satisfaction with treating physican and sickle cell nurse.

4. Economical analysis of group medical appointments compared to standard treatment with respect to health- related quality of life.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

This study is questionnaire-based and will not require invasive procedures or any extra visits to the out-patient clinic. Questionnaires will take approximately 30 minutes to fill in at each evaluation time point.

Doel van het onderzoek

We hypothesize that group medical appointments will enhance adherence to treatment and self-efficacy in patients with sickle cell disease, as well as increase quality of life, and satisfaction with the treating physician and nurse. When performing an economical analyis, we also believe it may be an important cost-effective innovation in sickle cell disease care.

Onderzoeksopzet

Primary and secondary endpoints will be measured at time points t=0 (baseline), t=1.5 years and t=3 years (after a total of four group medical appointments).

Onderzoeksproduct en/of interventie

A group medical appointment is a novel form of ou-patient contact incorporating an individual appointment within a group consultation, in the presence of fellow patients and other medical professionals. Within a group medical appointment, more time is available for discussion on disease-related topics. In addition, information and social support from fellow patients can improve self-management and quality of life. During three years, every other individual apppointment will be replaced with a group medical appointment (with a total of four group medical appointments).

Contactpersonen

Publiek

Pediatric hematologist
Erasmus Medical Centre - Sophia Children's Hospital
Postbus 2060
M.H. Cnossen
Rotterdam 3000 CB

The Netherlands
+31-107036691

Wetenschappelijk

Pediatric hematologist
Erasmus Medical Centre - Sophia Children's Hospital
Postbus 2060
M.H. Cnossen
Rotterdam 3000 CB
The Netherlands
+31-107036691

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Patients of all ages and parents of children with homozygous or compound heterozygous sickle cell disease.

- Informed (parental) consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients and parents visiting the out-patient clinic for the first time.

- Patients not able to communicate or read adequately in Dutch.

- Patients with hearing or behavioral problems.

- Withdrawal of (parental) informed consent.

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-09-2015
Aantal proefpersonen:	100
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-08-2014
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	NL4591
NTR-old	NTR4750
CCMO	NL42182.000.12

Resultaten