Growing up with the Young Endocrine Support System (YESS!): innovative e-technology to improve transition from paediatric to adult care

Gepubliceerd: 18-10-2019 Laatst bijgewerkt: 18-08-2022

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

Samenvatting

ID

NL-OMON24682

Bron
Nationaal Trial Register

Verkorte titel
YESS

Aandoening

Congenital adrenal hyperplasia, hypogonadotropic hypogonadism, growth hormone deficiency, combined pituitary hormone deficiency, Turner Syndrome or Klinefelter syndrome.

Ondersteuning

Primaire sponsor: Erasmus Medical Center
Overige ondersteuning: ESPE grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score in group YT compared to group O after 12 months

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Transition from paediatric to adult endocrinology is a challenge for adolescents, their families and their doctors. Up to 25% of young adults with chronic endocrine disorders are lost to follow-up (‘drop-out’) once they move out of paediatric care. Non-attendance and sub-optimal medical self-management can lead to serious and expensive medical complications. In a pilot study, adolescents suggested the use of e-technology to get them more involved in their own transition process. We have designed and developed the YESS! game, a tool to help improve medical self-management in adolescents with chronic endocrine disorders. Our hypothesis is that adolescents playing the YESS! game will show a larger increase in self-management score during the first year of transition and will have a lower drop-out rate at the adult endocrine outpatient clinic (OPC), compared to adolescents who do not play the game.
Objective: 1.To improve medical self-management.
2.To prevent drop-out from the adult outpatient clinic.
Study design: multicentre randomized controlled trial
Study population: 160 transition patients from 15 to 20 years old from the participating countries Spain, The United Kingdom, Belgium and the Netherlands. Patients are diagnosed with a chronic endocrine disorder.
Intervention: The study consists of 4 study arms: receiving the YESS! game and toolkit (group YT), receiving the control game and toolkit (group GT), receiving the toolkit only (group T) and receiving regular transition care (group O). Every group will receive regular transition care. The transition toolkit consists of paper cards with assignments, ideas and tips regarding medical self-management.
Main study parameters: Primary outcome: the Self-management and Transition to Adulthood with Rx (=treatment) (STARx) questionnaire score 12 months after inclusion in group YT compared to group O.
Secondary outcome: the STARx questionnaire 6 and 12 months after inclusion in group YT compared to the other study groups. as well as the drop-out rate to the adult outpatient clinic in the first year after the last visit to the paediatric endocrinologist (i.e. one year after the moment of transfer) in group YT compared to groups GT, T and O.
Nature and extent of the burden and risks associated with participation: The participants are not exposed to any risks. The YESS! and the control game are safe apps played on a mobile phone or tablet. The burden consists of filling out the STARx questionnaires and playing the

YESS! or controle game. The questionnaires will be filled out online at home at the start of the study and after 6 and 12 months. Every 6 months the subject has an appointment at the outpatient clinic. The participant can play the YESS! game for a maximum of 15 minutes a day to prevent game addiction. The control game could be played for an unlimited amount of time, but will unlikely cause game addiction since the game is not considered challenging and exciting enough.

Doel van het onderzoek

Our hypothesis is that adolescents playing the YESS! game will show a larger increase in self-management score during the first year of transition and will have a lower drop-out rate at the adult endocrine outpatient clinic (OPC), compared to adolescents who do not play the game.

Onderzoeksopzet

t=0, t=6 months, t=12 months, t=24 months

Onderzoeksproduct en/of interventie

The study consists of 4 study arms: receiving the YESS! game and toolkit (group YT), receiving the control game and toolkit (group GT), receiving the toolkit only (group T) and receiving regular transition care (group O). Every group will receive regular transition care. The transition toolkit consists of paper cards with assignments, ideas and tips regarding medical self-management.

The intervention (YESS! game):
The YESS! game is a real-life game in which the player has to solve a mystery. The adolescent plays an active role in the course of the story. This results in an interactive experience. During the game, the adolescent is challenged with regard to self-management and responsible behaviour in general life, with parallels to medical self-management and responsible behaviour.
The adolescent has to decide at several different moments whether to take action or not, whether to accept help or not and whether to share (fictive) confidential information or not. Other aspects that are covered are 'taking responsibility' and 'being on time'. The choices the adolescent makes throughout the game are registered in a coded manner, for later analysis. The game is available in Dutch, English and Spanish.

The control game:
The control game is an app called ‘Snake ‘97’. It is free and can be downloaded in the App Store as well. It is a remake of the original snake on the mobile phone in 1997 in which the player moves the snake around and makes it ‘consume food’ (little dots) which causes the snake to grow longer. The goal is to make the snake as large as possible. It has 12 difficulty levels.

Contactpersonen

Publiek

Erasmus Medical University Hospital
Laura de Graaff

+31618843010

Wetenschappelijk

Erasmus Medical University Hospital
Laura de Graaff

+31618843010

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Aged 15 to 20 years old.
- Diagnosed with congenital adrenal hyperplasia, hypogonadotropic hypogonadism, growth hormone deficiency, combined pituitary hormone deficiency, Turner Syndrome or Klinefelter syndrome.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Lack of a mobile phone or tablet.
-Mental disability or language barrier leading to inability to use the YESS! game or the control game.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-12-2019
Aantal proefpersonen:	160
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL8097
CCMO	NL.69953.078.19

Resultaten