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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24682

Source

Brief title YESS

Health condition

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

Sponsors and support

Primary sponsor: Erasmus Medical Center Source(s) of monetary or material Support: ESPE grant

Intervention

Outcome measures

Primary outcome

1 - Growing up with the Young Endocrine Support System (YESS!): innovative e-technol ... 13-05-2025

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

Secondary outcome

-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 GT and -T after 12 months.

-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 GT, -T and -O after 6 months.

-To investigate whether there is a difference in the drop-out rate to the adult outpatient clinic in group YT compared to group GT, -T and -O during the first year after the last visit to the paediatric endocrinologist (i.e. one year after the moment of transfer, t=24 m).

Study description

Background summary

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

2 - Growing up with the Young Endocrine Support System (YESS!): innovative e-technol ... 13-05-2025

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.

Study objective

Our hypothesis is that adolescents playing the YESS! game will show a larger increase in selfmanagement 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.

Study design

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

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.

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:

3 - Growing up with the Young Endocrine Support System (YESS!): innovative e-technol ... 13-05-2025

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.

Contacts

Public Erasmus Medical University Hospital Laura de Graaff

+31618843010 Scientific Erasmus Medical University Hospital Laura de Graaff

+31618843010

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

-Lack of a mobile phone or tablet.

-Mental disability or language barrier leading to inability to use the YESS! game or the control game.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-12-2019
Enrollment:	160
Туре:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable Application type:

Not applicable

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	
ССМО	

ID NL8097 NL.69953.078.19

Study results