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

Published: 05-12-2019 Last updated: 10-04-2024

Primary Objective: -To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score at t=12 months minus the score at t=0 in group YT compared to group O.Secondary...

Ethical review	Approved WMO
Status	Pending
Health condition type	Endocrine and glandular disorders NEC
Study type	Interventional

Summary

ID

NL-OMON48266

Source ToetsingOnline

Brief title YESS

Condition

• Endocrine and glandular disorders NEC

Synonym chronic hormone disease, endocrine disorder

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

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Source(s) of monetary or material Support: European Society of Paediatric Endocrinology (ESPE)

Intervention

Keyword: Endocrinology, serious game, transition

Outcome measures

Primary outcome

To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score at t=12 months minus the score at t=0 in group YT compared to group O.

Secondary outcome

-To investigate whether there is a difference in the STARx questionnaire score 6 and 12 months after inclusion minus the score at t=0 in group T compared to group O.

-To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score at 12 months minus the score at t=0 in group YT compared to group GT and -T. -To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score at t=6 months minus the score at t=0 in group YT compared to group GT, -T and -O. -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. erto 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

Transition from paediatric to adult endocrinology is a challenge for adolescents, their families and their doctors. Effectiveness of transition varies between patients, the type of endocrine disorders and hospital departments. Up to 25% of young adults with endocrine disorders is lost to follow-up once they move out of paediatric care. This means that up to one in every four young adults with serious endocrine disorders does not attend an adult endocrine outpatients clinic anymore, which causes a deterioration of their clinical condition. Non-attendance (N-A) constitutes a major health risk for young adults since N-A can lead to serious and expensive medical complications. Physical and psychological consequences of suboptimal endocrine treatment can cause absenteeism from school or work.

In a pilot study, we have set out and analysed guestionnaires among adolescents and young adults for their opinion about the transition phase. The improvements they suggested include an up-to-date website, the possibility for attending the outpatients clinic in the evening hours and the use of modern technology, like a personal endocrine health app or a serious game. Playing with the mobile phone is the favourite pastime of many teenagers. In Europe, over 75% of 12-18 year old teenagers and over 90% of 18-25 year old young adults use a smartphone on daily basis [7] and therefore, the ultimate way to reach adolescents is by e-technology. This type of technology, however, is not yet available in the endocrine setting. We have designed and developed a serious game especially for adolescents with endocrine disorders. With this serious game, we aim to get adolescents involved in their disease at an early stage of transition, in order to 1) improve medical self-management and 2) reduce non-attendance (prevent dropout). By playing the YESS! game the adolescent patient learns in an informal and stepwise manner how to be a (medically) responsible young adult. The game is both challenging and entertaining. The concept of a real-life game has not yet been developed elsewhere and is unique in the field of endocrinology. The game has already been developed and is ready for use. In addition to the YESS! game, a transition-toolkit will be implemented to facilitate the transition as well.

Study objective

Primary Objective:

-To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score at t=12 months minus the score at t=0 in group YT compared to group O. Secondary Objectives:

-To investigate whether there is a difference in the STARx questionnaire score 6 and 12 months after inclusion minus the score at t=0 in group T compared to

group O.

-To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score at 12 months minus the score at t=0 in group YT compared to group GT and -T. -To investigate whether there is a difference in the Self-management and Transition to Adulthood with Rx (treatment) (STARx) questionnaire score at t=6 months minus the score at t=0 in group YT compared to group GT, -T and -O. -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. ert 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 design

Randomized controlled trial, a multicenter study, located in Spain, Belgium, The United Kingdom and The Netherlands in paediatric or adult outpatient clinics.

Total duration of study is 3 years (2 years when the first 12 months of patients inclusion are taken into account)

-group YT: participants will play the YESS! game for a maximum of 15 minutes a day for 8 days, between t=0 and t=6 months.

-group GT: participants will play the control game for a maximum of 15 minutes a day for 8 days, between t=0 and t=6 months.

-All 4 groups (YT, GT, T and O): fill out the STARx questionnaires three times during the first year of the transition phase (last questionnaire is filled out at last visit before transfer).

-drop-out rate (i.e. number of missed appointments) will be assessed one year after transfer (t=24 months).

Intervention

The intervention

Group YT: receiving the YESS! game and the transition toolkit.

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 selfmanagement and responsible behaviour. The transition toolkit consists of paper cards with assignments, ideas and tips regarding medical self-management.

The comparator:

-Group GT: receiving the control game and transition toolkit.

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.

-Group T: receiving the transition toolkit only.

-Group O: receiving usual transition care (no game or transition toolkit).

NB! Group YT, group GT, group T and group O will also receive usual transition care.

Study burden and risks

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 or exciting enough.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years) Adolescents (16-17 years) Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

- Aged 15 to 20 years old.

- Diagnosed with congenital adrenal hyperplasia, hypogonadotropic hypogonadism, Turner Syndrome, Klinefelter syndrome, growth hormone deficiency, combined pituitary hormone deficiency, Androgen insensitivity syndrome, thyroid dysgenesis or Addison's disease

Exclusion criteria

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

Study design

Design

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

NL Recruitment status:

Pending

Start date (anticipated):	01-12-2019
Enrollment:	40
Туре:	Anticipated

Ethics review

Approved WMO		
Date:		
Application type:		
Review commission:		

05-12-2019 First submission METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	ID
ССМО	NL69953.078.19
Other	NTR: NL8097, clinicatrials.gov