ISRCTN16603570 https://doi.org/10.1186/ISRCTN16603570

Useability of the robot ZORA in pediatric rehabilitation

Submission date	Recruitment status	[ ] Prospectively registered
06/11/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
11/01/2017	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/07/2017	Cancer	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Zora is a robot developed to help people recover from medical treatments by motivating them to do interactive therapeutic exercises. This study is looking at whether this sort of interactive robot can motivate both healthy children and children with cancer to exercise more than another human (for example, a physical therapist) can.

Who can participate?
Children with cancer aged 3-15 and hospitalized die to a low number of neutrophils (a type of white blood cell) and healthy children aged 4-13.

What does the study involve?
The study is split into two parts. In the first part, the healthy group of children are randomly allocated to one of four groups. Those in group 1 do exercises demonstrated by a physical therapist. Those in group 2 do exercises demonstrated by a physical therapist with music playing. Those is group 3 do texercises demonstrated by Zora. Those in group 4 do exercises demonstrated by Zora with music playing. In part 2, the children in the hospital are also split into the four groups and do the same exercises. All children are assessed to see whether they enjoyed the sessions and would do them again.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
University Hospital Ghent (pediatric cancer ward) and a nearby primary school (Belgium)

When is the study starting and how long is it expected to run for?
October 2014 to September 2016

Who is funding the study?
Agency for Innovation by Science and Technology, Flanders, IWT (Belguim)

Who is the main contact?
Dr Pieter Meyns

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2015/0888

Study information

Scientific Title

Useability of a humanoid robot to increase the motivation to perform physical activity in typical developing children and hospitalized children in neutropenia

Study objectives
A humanoid robot will motivate healthy typical children and hospitalized children in neutropenia more to perform physical activity exercises than a human (e.g. physical therapist)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee - University Hospital Ghent (Commissie voor medische Ethiek - Universitair Ziekenhuis Gent), 07/10/2015, ref: 2015/0888

Study design
Single-centre randomised cross-over study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Childhood cancer with neutropenia (i.e. low concentration of neutrophils in the blood).

Interventions
The protocol of the study comprises 2 parts:

Part 1 includes about 90 healthy typical children from the elementary school “De Vierklaver” in Temse, Belgium. Per grade (from kindergarten until the sixth year), about 10 children will be recruited at random. During physical education class every child will perform sets of exercises individually in four conditions:

Condition A consisted of an exercise set demonstrated by a human (therapist).
Condition B was similar to condition A but with music added.
Condition C consisted of an exercise set demonstrated by the humanoid robot.
Condition D was similar to condition C but with music added

The sets of exercises are similar between conditions. In order to avoid a learning effect and prevent monotony, the sequence of movements was different in every condition. Each condition

will last about 1-2 minutes. The sets of exercises and music are age-appropriate. After each condition the child will be asked whether they would want to perform the exercise again, and using a visual analogue scale they are asked how much fun they had. After all conditions they will be asked to order the conditions from the most fun to the least fun. The total testing time for one individual is estimated at 15 minutes. From the results it will be determined whether the different conditions (robot versus human & music versus no music) showed an effect on the motivation to perform the sets of exercises.

Part 2 of the study takes place at the University hospital Ghent. Maximum 30 children with an oncological disorder in the same age range, which suffer from neutropenia, will be asked to perform the same exercise sets in the same conditions (the level of difficulty will be adjusted to the patient's abilities). The same outcome parameters will be measured as in part 1. During the rehabilitation of these children, the humanoid robot will be present as well (for children to get used to the robot). After one week the same exercise sets and conditions will be performed in these children, to check whether motivation will be affected when the robot is not as new anymore.

Intervention Type
Behavioural

Primary outcome measure
Motivation, using Again Again table immediately after each exercise session. Three different aspects if motivation were measured:
1.1. How many times does the participants want to repeat the exercise
1.2. How much fun did they experience
1.3. Compared to the other exercises, where do they rank this exercise
2. Degree of fun experienced, assessed using the Smileyometer immediately after each exercise session.
The Smileyometer is a visual analogue scale based on a 1 to 5 Likert scale using smileys developed for children
3. Most fun exercise session, assessed using the Funsorter once all exercise sessions were completed.
Each child was asked to rank the conditions (A, B, C, D) from "least fun" (at the left of the grid) to "most fun" (at the right of the grid) on an empty grid

Secondary outcome measures
N/A

Overall study start date
01/10/2014

Completion date
12/09/2016

Eligibility

Key inclusion criteria
Children with cancer
1. 3 to 15 years old
2. Hospitalized at the pediatric cancer ward of the Ghent University Hospital
3. In neutropenia (i.e. low concentration of neutrophils in the blood)

Children without cancer
1. 4 to 13 years old
2. In an elementary school in Flanders, Belgium (BS De Vierklaver, Temse)

Participant type(s)
Mixed

Age group
Child

Lower age limit
3 Years

Upper age limit
15 Years

Sex
Both

Target number of participants
Children with cancer; n=20, children without cancer; n=90

Key exclusion criteria
1. Insufficient knowledge of the Dutch language
2. Does not understand the instructions
3. Unable to perform the movements
4. No signed informed consent

Date of first enrolment
01/10/2015

Date of final enrolment
04/12/2015

Locations

Countries of recruitment
Belgium

Study participating centre
University Hospital Ghent (pediatric cancer ward)
De Pintelaan 185
Ghent
Belgium
9000

Study participating centre
Basisschool De Vierklaver (a primary school)
Azalealaan 101
Temse
Belgium
9140

Sponsor information

Organisation
University Gent (UGent) - Faculty Medicine and Health Sciences - Department Rehabilitation Sciences and Physiotherapy

Sponsor details
Campus Heymans (UZ Ghent)
Building B3 - Second floor
De Pintelaan 185
Gent
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9000

Sponsor type
University/education

Website
http://www.ugent.be/ge/revaki/en

ROR
https://ror.org/00cv9y106

Funder(s)

Funder type
Government

Funder Name
Agentschap voor Innovatie door Wetenschap en Technologie

Alternative Name(s)
Agency for Innovation by Science and Technology, Flanders, IWT

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
Belgium

Results and Publications

Publication and dissemination plan
Results of the current study are planned to be disseminated in a scientific publication in 2017.

Intention to publish date
12/09/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary
Not expected to be made available