“Hé James”

A study on the use of a social assistive humanoid robot in paediatric patients during post-operative tonsillectomy treatments

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Abstract

Objective. This pilot study aimed to evaluate the safety, feasibility, acceptability, potential effectiveness and implementation process of a Social Assistive Humanoid Robot (SAHR) in a paediatric hospital setting, to assess whether a SAHR can improve the performance of post-operative tonsillectomy treatments in terms of improved cooperation as well as reduced inpatient anxiety and nursing staff interventions. **Method.** The study used a triangulated mixed-method design. We observed and interviewed 26 children and their parents during the performance of a postoperative tonsillectomy treatment. First, in the control period, 10 children and their parents (n=13), receiving standard treatment, were observed (for any side effects, cooperation and signs of distress) and interviewed about experiences and any perceived distress. Subsequently, during the implementation period, 16 children and their parents (n=25) were observed and interviewed in a similar way. Additionally, interviews were held with eight healthcare professionals about their experiences with the robot, its feasibility and their views on (future) implementation, by using the Consolidated Framework for Implementation Research (CFIR). All participants were recruited via a convenience sampling method. **Results.** No serious adverse events occurred, and (technical) problems were mostly related to Wi-Fi disconnection and mapping problems. On average, one person is needed to incorporate the SAHR into treatment. The total time of a treatment in which the SAHR was implemented remained low (setup time 68.4 sec over 71.9 sec clean-up time). The acceptability of the SAHR can be considered positive as 75 per cent of the participants experienced the robot as enjoyable to use. Thereby, 82 per cent would or maybe want to use the robot during a future treatment. Although there were no differences in anxiety scores, the SAHR caused a shift of focus when recalling a hospital admission as often participants referred back to the robot instead of an unpleasant experience when they were asked how they experienced the admission. Moreover, the SAHR is considered to have a positive effect on cooperation as participants of the control group scored 5.9 compared to 7.6 when looking at results reported by the nursing staff. Barriers of the implementation were mostly related to the inner and outer setting of the implementation. **Conclusion**. The SAHR was well accepted and the implementation is considered as safe, as no adverse events did occur. Feasibility measures, despite mapping issues are realistic. To confirm initial findings, important recommendations for further research are to include a larger sample from different hospitals, to include appropriate medical treatments for both motivation and distraction, and to include more detailed information about the treatment environment and patient information.

Content

Introduction

The use of technology in healthcare is increasing, as is the use of social robotics. In particular, Socially Assistive Humanoid Robots (SAHRs) are starting to be widely used, especially in elderly and paediatric healthcare settings (Kachouie, Sedighadeli, Khosla & Chu, 2014; Taylor et al., 2021; Rossi, Larafa, & Ruocco, 2020). According to Feil-Seifer & Mataric (2005), SAHRs can be defined as robots aiming to assist human users through social interaction and to interact closely and effectively in order to achieve measurable improvements in for example recovery, rehabilitation or education.

So far, the effectiveness of SAHRs in health care has generally been insufficiently studied (Schüssler et al., 2020). Different studies show that SAHRs may have a positive effect on a person's behaviour, motivation, well-being, physiological parameters, social contacts, cognitions, and quality of life (QoL) (van der Drift et al., 2014; Abdi, Al-Hindawi, & Vizcaychipi, 2018; Pu, Moyle, Jones & Todorovic, 2019; Rossi, Larafa, & Ruocco, 2020). One example is robot Nao who, through interacting with children, could reduce pain and distress during vaccinations (Beran, Ramirez-Serrano, van der Kooi & Kuhn, 2013). Another study of van der Drift et al., (2014) shows results that patient motivation and adherence increased by implementing robot NAO in the treatment of diabetes. However, a recent review by Trost et al. (2019), on the use of SAHRs in healthcare settings emphasises the fact that although satisfaction levels are high, there is limited evidence supporting that the use of SAHRs can reduce distress in children, as well as a lack of clear evidence on the reduction of pain.

A reason for insufficient research on the use and the effectiveness of SAHRs in healthcare settings may be related to the number of associated feasibility problems. Different studies indicated feasibility problems such as robot disconnection failure, start-up problems and non-responsive screens (Ali et al., 2021; Taylor et al., 2021). Despite the feasibility issues, safety issues may also be related to insufficient research on the effectiveness of SAHRs, as this may hinder the adoption process among users. Issues related to ensuring the safety and security of the use of robots in healthcare are recognised as critical issues in practice when using healthcare robots in institutional settings (Betriana., et al 2021). Although studies on the use of social robots have shown that the chance of a (serious) adverse event is minimal, this possibility can never be completely avoided due to internal defects or external failures affecting the robot (Mengoni et al., 2017; Olivieri, Henze, Braghin & Roa, 2019). Consequently, additional data is needed on the effectiveness, feasibility and safety of SAHRs in healthcare settings.

Attracting children's attention and distracting them from painful and/or fearful stimuli has been shown to have a positive effect on patient motivation during treatment and on health-related outcomes (de More & Cohen, 2005; Cohen, 2008). The use of distraction is a frequently used technique to improve patient motivation in cooperation and to reduce fear, distress and pain in short (invasive) medical treatments in paediatric patients (Hoffman et al., 2004; Sinha, Christopher, Fenn & Reeves, 2006; Wang, Sun & Chen, 2008; Gates et al., 2020). The ideal process of distraction and patient motivation includes persuasion as well as engaging the child's different senses including vision, hearing and touch, as well as involving the child's emotions effectively (Wismeijer & Vingerhoets, 2005). A supportive tool should therefore include a minimal capacity of persuasion and amount of attention where multisensory modalities (visual, auditory and kinaesthetic) are involved, the child is actively emotionally involved and participates to compete with the signals from the negative stimuli (Fogg, 2002; Wismeijer & Vingerhoets, 2005). Consequently, immersive technologies, such as Virtual Reality (VR) and SAHRs, can be considered as a supportive tool for children in case of (potential) fear or pain to improve the patient's motivation to cooperate during medical treatments, and to reduce potential anxiety as a SAHR can provide the necessary features to act as a distractor. (Feil-Seifer & Mataric, 2005).

In this study, a SAHR was tested during post-operative tonsillectomy treatments among paediatric patients in a hospital setting. Tonsillectomy is a very common surgical procedure. For instance, in the Netherlands, 30,860 children aged between 0 and 20 years received the procedure over a five-year period (CBS, 2014). One post-operative challenge is a pattern of significant pain (Stewart, Ragg, Sheppard & Chalkiadis, 2012). Acute pain causes discomfort, anxiety, behavioural problems and is also associated with sleep disorders, inadequate oral fluid intake, readmissions for pain management, (Power, Howard, Wade & Franck, L. S. 2012; Sutters & Miaskowski, 1997; Stanko et al., 2013). Acute pain in paediatric patients can even lead to long-term anxiety, even in the form of post-traumatic stress (PTSD) (Hildenbrand et al., 2016). However, according to Lauder & Emmott (2014), good cooperation, meaning drinking sufficiently, can improve recovery and reduce the risk of complications such as post-operative bleeding Nevertheless, taking fluid often appears to be challenging, requiring additional nursing support frequently (Lauder & Emmott, 2014).

In order to determine the ability of a SAHR in motivating and distracting paediatric patients during post-operative tonsillectomy treatments to increase cooperation and decrease inpatient anxiety, the SAHR can be scored in terms of safety, feasibility, acceptability and

potential effectiveness. The **safety** of a SAHR can be expressed in terms of the number of adverse events and refers to preventing harm to the patient and protecting or promoting the patient's emotional, physical, cognitive and social wellbeing (Ienca, Jotterand, Vică, Elger, 2016). From previous studies with social robots, it is known that the possibility of the occurrence of a (serious) adverse event or reaction is remote (Mengoni et al., 2017). Secondly, the **feasibility** of a SAHR as a distractor in post-operative tonsillectomy treatments includes different outcomes to estimate what is required to implement a SAHR. Outcomes contain the time to set up and clean up the SAHR in seconds, the number of personnel needed to incorporate the SAHR within the treatment, the type and frequency of (technical) problems observed as well as the experiences of the professionals (Appel et al, 2020; Ali et al., 2021; Taylor et al., 2021). Thirdly, the **acceptability** of a SAHR as a distractor in post-operative tonsillectomy treatments can be evaluated via semi-structured satisfaction interviews where participants' and parental experiences of the SAHR can be defined (Wren et al., 2021). Lastly, to measure **potential effectiveness,** the SAHR must provide some degree of distraction, even if minimal, to improve the performance of a post-operative tonsillectomy through improved fluid intake as well as reduced patient anxiety and numbers of nursing interventions which are the three effectiveness measures chosen for this study. Through an observational study, types and numbers of nursing interventions as well as cooperation levels during treatment can be assessed. Nevertheless, anxiety is an internal state that cannot be fully measured by an observer, therefore perceived inpatient anxiety is best measured by self-reported anxiety scales (Venham and Gaulin-Kremer, 1979).

Ultimately, several elements of an implementation determine whether an implementation succeeds or fails. A useful tool to identify facilitators and barriers that were beneficial or detrimental to the implementation of an intervention is the Consolidated Framework for Implementation Research (CFIR) (CFIR Research Team-Center for Clinical Management Research 2022). The following five domains are part of the evaluation according to CFIR: *Intervention characteristics*, the aspects of an intervention that can influence the success of its implementation; *Outer setting*, external impacts on the implementation of the intervention; *Inner setting,* characteristics of the organisation; *Characteristics of individuals*, beliefs, knowledge, self-efficacy, and personal characteristics, and *Implementation process*, the stages of implementation.

This study will test a SAHR in a hospital setting in terms of safety, feasibility, acceptability, potential effectiveness and implementation processes to determine if a SAHR as a distractor can improve the performance of a post-operative tonsillectomy treatment in terms

of improved cooperation and reduced anxiety in paediatric patients. Research questions for this study are:

- To what extent is an implementation of a SAHR during a postoperative tonsillectomy treatment among paediatric patients safe in terms of the number of adverse events?
- To what extent is an implementation of a SAHR during a post-operative tonsillectomy treatment among paediatric patients feasible in terms of (technical) feasibility problems and time to set up and clean up the SAHR as well as the number of personnel needed?
- To what extent is an implementation of a SAHR during a post-operative tonsillectomy treatment among paediatric patients acceptable in terms of patient and parental satisfaction?
- Is an implementation of a SAHR during a post-operative tonsillectomy treatment among paediatric patients potentially effective in terms of improved cooperation, reduced perceived anxiety in paediatric patients and reduced number of nursing interventions during post-operative tonsillectomy treatments?
- What have been promoters and barriers of the implementation process of the SARH and what are suggestions for future use?

Methods

Design

The present study used a triangulated mixed-method design. In this study, a control group was used, consisting of participants who received a standard tonsillectomy postoperative treatment as well as a trial group consisting of participants who received a standard tonsillectomy postoperative treatment but with the addition of a SAHR.

The study was conducted first among the participants in the control group, after which the SAHR was implemented allowing the study to be conducted among the participants of the trial group. The data in this study includes observations of adverse events and feasibility, dual interviews with parents and children focusing on experiences, and questionnaires from patients, parents and health care professionals focusing on degree of anxiety and cooperation of treatments with or without the use of a SAHR. Furthermore, this study also includes data from focus group evaluation interviews with health professionals aimed at implementation experiences and possibilities for future implementation. The study was performed at the Paediatric Department of Rijnstate Arnhem-Noord, a public hospital in the Netherlands located in the province of Gelderland (Rijnstate n.d.). The study design received ethical approval from

the internal scientific ethics of Rijnstate (case no. 21/1996) as well as by the BMS Ethics Committee of the University of Twente (case no. 22/220117).

Zorabot James

The SAHR used within this study is James, a SAHR from Zorabots, see Figure 1. This study includes James his functionalities in information provision, motivation and distraction in the form of social interaction through speech, videos and images. A pre-programmed set (composition) was programmed in James, including information about the post-operative treatment, motivating statements, and entertaining videos. For an example composition, see Appendix B.

The treatment starts when James enters the participant's room under the instructions of a nurse. Subsequently, the nurse manually starts the composition by clicking on the composition option on the screen. The composition starts with the first component in which James introduces himself as a new colleague in the paediatric department. Subsequently, the second component starts, where James gives an explanation of the performance of the post-operative treatment. Eventually, the third component starts, consisting of a combination of motivational statements and distraction techniques in the form of YouTube videos. James invites the patient to start the treatment (sipping a small amount of fluid) by using motivational statements (e.g. "I'm sure you can do it!") while the application YouTube starts, allowing patients to watch a video of their choice. After exactly fifteen minutes, the YouTube video stops after which James invites the patient to take again a few sips while the YouTube video continues to play. Again, after fifteen minutes, the application stops and James again reminds the patient to drink. Finally, James indicates that his " assistance time " is over and gives instructions on how to continue the treatment without his presence. The session with James ends with him asking for a high-five, after which he automatically leaves the room and returns to his starting point.

Figure 1 Zorabot James

Note. By Zora Robotics n.d., Robot James, specifications.

Participants & Procedure

In total, twenty-six participants were involved in this study, distributed into ten participants (mean age 5 years) in the control group and sixteen participants in the study group (mean age 4.1 years). Parents or caregivers (N= 38) of each participant as well as nursing staff (N= 8) were also included in the study. All participants had to be between three and eight years old. Including children less than three years old would have limited the study, as they might not have fully understood the situation and, additionally, the procedure would have been affected by communication difficulties. On the contrary, above the age of eight, James' presence would have lost its efficacy, due to the rational development of the patients (Ahmad, Mubin & Orlando, 2017). The exclusion criteria of this study were not being able to manage the Dutch language and hearing or visual impairments.

All patients who received a postoperative tonsillectomy were recruited via a convenience sampling method. Participants from the control group as well as from the study group were patients who were treated for tonsillectomy in the hospital in the first quartile of 2022. Given that participants were no older than eight years, consent from caregivers was required. Handing over and discussing the informed consent (Appendices A-I and A-II) with both, caregivers and patients, was accomplished by the nursing staff during the anamnesis. Subsequently, verbal consent was documented within the electronic patient record system to guarantee anonymity. Final participation depended on the clinical situation and the patient's condition which was estimated by a health care professional since the impact of the study on the participant had to remain minimal. All participants who were asked for participation decided to participate in the study and completed the full study.

The observational study was performed by a member of the research team. After 30 minutes of observation, short semi-structured dual interviews were conducted with participants, which were conducted directly after each observation study by a researcher from the team and took place in the participants' room. Additionally, the nursing staff was required to complete a questionnaire after each 30 minutes of observation in order to collect data focussed on their perception of treatment performance. Subsequent to the research period, the evaluation period took place in which health care professionals from the paediatric department were interviewed by a researcher from the team in the form of focus group sessions consisting of three, to a maximum of four, health care professionals.

Instruments

In total, four sub-studies were conducted, for an overview of the data collection and components linked to each sub-study, see Table 1.

Table 1 Method table

Sub-study	Safety	Feasibility	Acceptability	Potential effectiveness	Implementation & future use
1	X	X			
2			X		X
3				X	
4		X	X	X	X

Sub-study 1: Observational study on safety & feasibility

To measure safety, the occurrence of an adverse event in patients during treatments that included the SAHR, was observed by the nursing staff using an observation format, see Appendix C. The observation format contains a pre-settable including two safety components, namely pain or discomfort as well as physical (mechanical) injury, and there was an open option to record if 'other' side effects occurred (Ienca, Jotterand, Vică, Elger, 2016). The pre-set table was filled right after the session with the SAHR, by ticking an adverse event when it occurred. Additionally, there was an option to mark that no adverse events occurred.

To measure the practical feasibility, feasibility measures were observed by a research worker in a predetermined feasibility questionnaire, see Appendix D. The feasibility questionnaire included the following measures: James performs the treatment successful and comprehensive in which answers varied in 'yes, without any problems' (A), 'yes, with some problems' (B), 'yes, with many problems' (C) and 'no, it did not work out' (D). Other feasibility measures were time to set-up and clean-up time of James in seconds, the number of professionals needed, and the frequency of observed (technical) problems (Appel et al, 2020; Ali et al., 2021; Taylor et al., 2021).

Sub-study 2: Interview study among children & parents on acceptability and future use

Satisfaction interview questions were used to assess the acceptability of the SAHR. One of the aims of the semi-structured dual interviews was to gain more insight into the experiences and satisfaction of using the SAHR. The satisfaction interview questions of this study were based on satisfaction questionnaires from different studies (Chai et al., 2021; Wren et al., 2021). Participants were asked about their experiences by using 3-point Likert-scale satisfaction interview questions, after which caregivers were asked for supplementary in-depth experiences,

see Appendix E-II. Questions were about the patients' overall experiences of the SAHR, the patient's opinion of the used distraction strategy, in which answers varied in 'fun' (1) 'little fun' (2), and 'not fun' (3). Additionally, patients were asked if they would like to use the SAHR in a subsequent medical treatment, in which answers varied in 'yes' (1), 'maybe' (2) and 'no'(3). Smiley emoticons showed which number represented what emotion (Kilic, Uysal & Kalkan, 2021). Lastly, in addition to acceptability, patients and their parents were asked to name some ideas on future use of the SAHR.

Sub-study 3: Before and after-implementation questionnaires on anxiety and cooperation

First, to measure perceived patient anxiety, 5-point Likert-scale questions were included in the dual interviews (Appendices F-I and F-II). A good anxiety scale for this study needed to be clinical-friendly, time-consuming, engaging, and suitable for younger children that have limited cognitive and linguistic skills, therefore the Facial Image Scale (FIS) was included in this study. The FIS contains a series of five faces, ranging from very happy to very unhappy (Buchanan & Niven, 2002). Participants were asked to select the face that they felt most associated with at that moment. The scale was scored as 1 for the most positive face which represents 'not frightening at all' and 5 for the most negative face which represents 'very frightening'. After each question, caregivers were asked to elaborate on the answer given by the patient.

Secondly, a 10-point Likert scale was incorporated within the dual interview scheme to measure cooperation among participants in caregivers, where 1 was 'very poor cooperation' and 10 'very good cooperation', see Appendices E-I and E-II. Moreover, to validate, the cooperation related 10-point Likert scale was also included within the nursing staff questionnaire as well as within the protentional effectiveness observation scheme (Appendices F-G). Furthermore, (the intention to) refuse to drink, crying, other (negative) emotions and other forms of resistance in participants were the remaining constructs of cooperation used within this study, which were measured via a pre-set observational scheme, filled in by a research worker, see Appendix G. This pre-set table has been developed in cooperation with nursing staff, who did consolidate common behaviours and emotions during a post-operative tonsillectomy treatment.

Sub-study 4: Evaluation study among healthcare professionals on experiences and future implementation

To measure promoters and barriers of the implementation process, a semi-structured interview scheme was used, see Appendix H. All questions are based upon the earlier mentioned constructs of the CFIR (CFIR Research Team-Center for Clinical Management Research, 2022). In addition to evaluation, there was also a focus on further implementation of the SAHR in which participants were asked for ideas on future use of James.

Analysis

Means, standard deviations and medians were provided for the safety, feasibility, acceptability, anxiety and cooperation constructs of the different included questionnaires. SPSS.27 was used to record data and determine descriptive statistics. Types and numbers of adverse events, (technical) issues and behavioural and emotional constructs of the potential effectiveness, were categorized and counted in Excel.

Dual interviews as well as evaluation focus-group interviews were recorded by using an audio recorder, and were transcribed in Atlas.ti version 22. The analysis of both interview studies was done by one researcher. For the analysis of the dual interviews, first relevant fragments were dived into positive and negative comments. In a second step, all fragments were further categorized into themes, using inductive analysis, meaning that the analysis starts with a focus on the study area and lets the theory emerge from the data (Strauss & Corbin, 1998, p. 12). In contrast, a deductive approach was used while analysing the focus-group interviews in which the CFIR was applied in creating categorisations of the codes created. All data involved in this study got stored anonymously on a protected drive of Rijnstate.

Results

Description of the study group

The characteristics of the included children and their caregivers in the control and trial group, are displayed in table 2.

Table 2 *Demographics of participants & caregivers*

Characteristics	Control group (n=10)				Study group (n=16)			
child	n	M	SD	%	n	M	SD	%
Age (years)	10	5	1		16	4.1	.9	
Gender								
Male	6			60	7			44
Female	4			40	9			56
Other	-				-			
Caregivers	13				25			
Mother	5			50	6			38
Father	2			20	1			6
Both	3			30	9			56
Other	-				-			

Note. M = Mean. SD = Standard Deviation.

Sub-study 1. *Observational study on safety & feasibility*

Safety. Overall, during post-operative tonsillectomy treatments with the SAHR, no serious adverse events occurred that would be a consequence of the presence of the SAHR. However, 'pain or discomfort' was one of the components which emerged in eight out of sixteen participants, see table 3. Additional comments from the nursing staff showed that discomfort was the biggest factor involved. All additional comments regarding this component were focused on James' voice, which was described as 'robot-like' and 'low', which subsequently was experienced as harsh: *"While James was introducing himself I saw that the patient was a bit scared for a moment."* and *"I saw the patient felt uncomfortable since he huddled underneath his blanket."* However, it was noted that this form of discomfort occurred only during introduction moment, as the treatment including the SAHR progressed, and as the SAHR keeps socially interacting with the participant, the feeling of discomfort disappeared in most of the participants.

Table 3 *Safety components of the SAHR*

Safety components	Occurrence (in total numbers)	%
Pain or discomfort	7	44
Physical (mechanical) injury	-	
Other adverse events	-	
No adverse events	9	56

Feasibility. Table 4 provides the results on each of the feasibility measures including an overview of the identified (technical) feasibility problems. The required number of nursing staff, averages between one and two members needed to perform the treatment including the

functioning of the SAHR. The mean set-up time of the SAHR was 68.4 seconds, which is time required of the healthcare professionals. The SAHR clearance time averaged 71.9 seconds. However, this clean-up time does not require any time from healthcare professionals, as James leaves the room independently and returns to his starting point or, if necessary, returns to his recharging point.

The treatment in collaboration with the SAHR was completed in all sixteen cases. In eight out of sixteen times, it was stated that the performance of the composition of the SAHR was successful, but that problems did occur. Problems that often occurred were mainly technical problems such as running into an object, see table 4. Objects that were frequently mentioned, were beds located in the hallway or the computer on wheels (COW) that were located in the hallway. A consequence of such a driving "crash", was often a mapping problem, since after a crash, the route on the internal map was lost, which made driving on to a final destination last longer or even impossible without a manual reset. Other defined patient related problems which occurred, were patient incapacity and a decrease in interaction and interest since. For instance, some patients were not able to click or type on the display of the robot. Besides, the interaction between the child and the SAHR stopped in some cases because of the child which lost attention to other aspects.

Table 4 *Feasibility measures and (technical) feasibility problems (n=16)*

Number of staff needed (in total numbers)		Set-up time (sec)		Clean-up time (sec)	
M	SD	M	SD	M	SD
1.3	.5	68.4	18.9	71.9	63.4

Did you manage to start the composition during the treatment?	Occurrence (in total numbers)	%
Yes, without any problems (a)	7	44
Yes, with some problems (b)	8	50
Yes, with many problems (c)	1	6
No, it did not work out (d)	-	

(technical) Feasibility issues	
Technical	Occurrence (in total numbers)
Runs into an object	7
Mapping problems	3
Composition stop	1
Volume problems	3
WIFI disconnection	3
Patient	
Incapacity	2
Decrease in interaction and interest	2

Note. M = Mean. SD = Standard Deviation. number of times a (technical) problem occurred was tallied per time of occurrence

Sub-study 2. ***Interview study among children & parents on acceptability and future use***

Acceptability. Twelve out of sixteen participants liked the SAHR (table 5). One of the caregivers stated: *"We like James very much, he is a good-looking, very helpful robot."* Some participants could answer individually, citing: *"James is my new best friend."* In general, parents indicated that all videos were helpful in distracting their child from the situation, "*James has many Opportunities to play with children, It is also useful that children can choose which video should be played so that it is automatically tailor-made for each person.*" Moreover, the SAHR seems to have something human which seems to have a positive effect on the performance of treatment, as was stated: *"because he has a human touch, he is very helpful in supporting actions."* In addition, the majority of the participants would like to have or would maybe like to have the support of a SAHR again during a future medical treatment.

In addition to the high degree of positivity, there are also points of dissatisfaction, which include: speech levels that are frequently too loud or too harsh, low levels of interaction and a poor mobility, citing: *"James' speech his is a bit harsh."* Or, *"James doesn't drive very smoothly, he sometimes drives into a bed."* See Appendix I for an overview of the final coding schemes.

Table 5 *Satisfaction scores of patients on the SAHR*

Satisfaction related question	Study group (n=16)	
	N	%
What do you think of James?		
I like it (1)	12	75
Like it a little (2)	2	12.5
Do not like it (3)	2	12.5
Did you like de videos?		
I like it (1)	11	73
I like it a little (2)	3	20
I do not like it (3)	1	7
Does James help you during the treatment?		
Yes (1)	8	50
A little (2)	6	38
Not at all (3)	2	12
Would you like to use James again during a future medical treatment?		
Yes (1)	7	44
Maybe (2)	6	38
No (3)	3	18

Future use. Table 7 shows the results of future use obtained from the dual-interviews and the evaluation focus-group sessions. A total of seven ideas were themed. Although James does not have arms, he would be suitable as a mobiliser as he would be able to show pictures

or videos of physical exercises. In addition, his availability on the application YouTube would be very helpful in giving information or tutorials about (aftercare) treatments.

Table 6 *List of ideas on future use by patients & parents*

Ideas
Mobilisation
Providing information about (after-care) treatments
Providing general information about the department
Functioning as a department host
Assisting in nebulisation treatments
QR code for PREM evaluations
Video call buddy

Sub-study 3. *Before and after-implementation questionnaires on anxiety and cooperation*

Potential effectiveness. Results on patient anxiety show that the mean value of the study group is not significantly lower than the control group mean, see table 7. However, results do indicate that verbal explanations of the overall experience of being in the hospital, were often directed at James and also framed in a more positive way, as one of the participants stated *"I found it a bit exciting here, but James is my best friend now."*

Table 7 shows that the mean cooperation scores of the study group from each source are higher than the mean values of the control group. Besides these differences in cooperation mean scores, table 7 shows that there are noticeable differences in behaviour and emotions between both research groups. Participants of the control group showed for instance more crying behaviour compared to the trial group. Additionally, it was seen that children who performed the treatment by using the SAHR laughed more often than children who did not make use of the SAHR.

Between both research groups, there was no major difference in the mean number of nursing interventions provided during each treatment, see table 7. However, something striking about the data is that compared to the control group, the nursing staff performed extra monitoring moments in order to check whether the SAHR was performing well. Lastly, the majority of nursing interventions were facilitator-oriented.

Table 7 *Patient anxiety using an independent t-test to compare means, results of cooperation levels & nursing interventions*

	Control group (n=10)		Study group (n=16)		
	M	SD	M	SD	p
Patient anxiety 1. What did you think of the drinking?	3.9	1.4	3.3	.6	.134
	N	%	N	%	
Not frightening at all(1)	2	20	-		
Not rightening(2)	-		1	6.2	
Neutral(3)	2	20	9	56.3	
Frightening (4)	2	20	6	37.5	
Very frightening (5)	4	40	-		
	M	SD	M	SD	p
2. What did you think of being here in the hospital?	2.8	1.1	2.2	.7	.122
	N	%	N	%	
Not frightening at all(1)	2	20	2	12.5	
Not rightening(2)	2	20	11	68.8	
Neutral(3)	5	50	2	12.5	
Frightening (4)	-		1	6.2	
Very frightening (5)	1	10	0		
Cooperation scores					
Parents	5.7	2.3	7.6	1	
Nursing staff	5.9	2.9	7.6	1.2	
Research team	6.3	2.3	7.9	1	

Coded behaviour/emotion		Occurrence (in total numbers)		Occurrence (in total numbers)
	Refusal to drink	8	Refusal to drink	5
	Crying	12	Crying	3
	Fatigue	4	Avoiding eye contact	2
	Avoiding eye contact	2	Laughing	18
	Laughing	3	Relaxation	1
	Relaxation	1		
	Enthusiasm	1		
	Anger	2		
Coded nursing interventions		Occurrence (in total numbers)		Occurrence (in total numbers)
	Giving information	4	Giving information	3
	Stimulating	2	Stimulating	1

Reassuring	1	Reassuring	1
Facilitating drinks/food	3	Facilitating drinks/food	13
		Intervention monitoring	6

Note. M = Mean. SD = Standard Deviation. Patient anxiety ranges from 1(not exiting at all) to 5 (very exiting). Cooperation score ranges from 1 (very poor cooperation) to 10 (very good cooperation). Types of interventions were tallied by number of times they occurred.

Sub-study 4. *Evaluation study among healthcare professionals on experiences and future implementation*

Evaluation. Regarding the five main elements of the CFIR, barriers and facilitators were found, see Appendix J. Frist, looking at the intervention, results show that the SAHR is experienced as user-friendly. There is also a degree of satisfaction with regard to its appearance as well as its mobility. However, there is still a need for more interaction options and improvement of the friendliness of its voice, as was indicated: *"James knows the way, it is a nice sight to see a robot driving through the corridor like that. His face is friendly, it is true though that his voice is a bit harsh."*. Access to Knowledge & Information can be seen as a facilitator, as it was stated that there was sufficient space and opportunity to ask questions during the implementation of the SAHR. This sufficient space for questions contributes to the ease of access to required information and knowledge during the implementation of the SAHR. However, concerning Evidence, Strength & Quality, there was a lack of information on how the implementation of the SAHR is organised and why a SAHR was chosen, as the following was stated by one of the focus-group members *"We hadn't really received an explanation why we should start with robot James."* This lowers the perception of the quality and validity of the evidence that supports the belief that the implementation of the SAHR will have desired outcomes.

Secondly, regarding the outer setting of the implementation, the needs of the patients are known by the health professionals, as they know about the importance of good and sufficient support while drinking water during the post-operative tonsillectomy treatment. Furthermore, considering the Available Recourses, a barrier that was mentioned frequently, was the lack of training. Prior to the implementation, the healthcare professionals would have preferred more training on how to work with the SAHR, as it was stated: *"I would have liked to have some more, perhaps individual, training on how to work with James"*.

Thirdly, the inner setting of the implementation, the context in which the implementation took place, lacked stability. A reduced number of team members were available at the time of the implementation, as well as colleagues from other departments had to give

support. This caused, in some situations, health professionals without any knowledge of the SAHR, to be asked to work with the SAHR, resulting in confusion, additional requests for help and reduced confidence in implementation among the health care professionals. Moreover, this has also resulted in a large proportion of the health care professions not being actively involved in the implementation, as some of them did not use the SAHR at all.

Next, during the focus group sessions, self-efficacy levels of health care professionals were frequently mentioned as being low. Often these professionals have the self-image of not being "technical", and certainly not being able to work with a robot: *"I am not technical at all, I find it rather scary or am afraid to fail".* On the other hand, there are also professionals, that are enthusiastic about having a robot around in the department and about the opportunities it offers.

Lastly, during the implementation process, it was ensured that health professionals were constantly involved in the various process steps of implementing the SAHR, such as setting up the compositions, what has led to the SAHR being engaged in the department and specifically with the working style of the health professionals, as was stated: *"James is a perfect fit for us as colleagues, but even more so for our patients*."

Future use. Ideas on future use mentioned by the healthcare professionals were mainly focused on four ideas, namely: a supportive tool in patient mobilisation, a department guide function, an (general) information provider and an interactive playmate in which the SAHR can be seen as a robotic friend as a supportive tool for mental health.

Discussion

This triangulated mixed-method pilot study on getting a first impression of a SAHR as a distractor during postoperative tonsillectomy treatment assessed the SAHR in terms of safety, feasibility, acceptance and potential effectiveness. Furthermore, facilitators, barriers to implementation and ideas for future use were defined.

Main findings

During implementation, no serious adverse events did occur, which is in line with what was expected prior to the study, given that literature states that the possibility of the occurrence of a (serious) adverse event or reaction when using a SAHR, is remote (Mengoni et al., 2017). Good robotic interventions prevent any harm to patients and protect or promote the emotional, physical, cognitive, and social well-being of the patient (Ienca, Jotterand, Vică, Elger, 2016).

Yet, a recommendation for further implementation of James, is changing its voice to being more child friendly to prevent user discomfort.

Regarding the feasibility, our study showed that the incorporation of SAHR James into the post-operative treatment, can be done by one person, the average time required of a nurse for this is one minute and eight seconds. However, the length of the route to the patient's room must be taken into account. In fact, with each observation, the mean time varied because if the distance to the patient's room was increased, the start-up time also increased as James' driving speed is low. In addition, clean-up time does not involve time spent by the nurse, although when a mapping problem occurs, it does involve extra time spent by the nurse in order to correct the mapping issue. A mapping problem was often caused by hospital interiors placed randomly in the hallway. Other (technical) problems varied from WiFi and mapping issues to patient-related incapacities. Apart from mapping issues, these results are consistent with feasibility issues in comparison to other studies on the implementation of a SAHR (Ali et al., 2021; Taylor et al., 2021). In terms of practical outcomes, it can be concluded that the SAHR is feasible, although follow-up steps should include reducing mapping problems. This can be done, for instance, by improving internal mapping settings or by creating fixed areas for hospital interiors, using, as an example, shadings on the floor.

In general, satisfaction scores of both patients and parents were high, indicating a high acceptability. The distraction videos were well-received due to the use of the YouTube application, which makes it possible to select a video of own interest. In addition, 88 per cent of the users indicated that the SAHR helped them either a little or good during treatment. Although, there was also some dissatisfaction with the SAHR. In addition to this dissatisfaction of the SAHR itself, the discrepancy can be related to either not understanding the SAHR or lack of efficacy due to rational development of the patient (Ahmad, Mubin & Orlando, 2017). Overall, it can be concluded that the implementation of a SAHR during a postoperative tonsillectomy treatment in paediatric patients is acceptable in terms of patient and parent satisfaction, in which it is important to continue in tailoring the content of the SAHR (information, interaction levels and amusement) to age limits of the users during further implementation to maintain satisfaction among users.

In an attempt to get insight in the potential effectiveness of the SAHR, we compared pre- and post-implementation scores on children’s anxiety, their corporation and the number of nurse interventions needed. The results revealed that we did not find significant pre-post differences in anxiety, and nursing interventions, but we did find differences in the mean cooperation scores provided by parents, nursing staff and the research team. Results of

improved cooperation are in line with results from previous research. Results of improved cooperation are in line with results from previous research. As mentioned earlier, robot NAO appears to increase the motivation of paediatric diabetes patients (van der Drift et al., 2014). During the standard post-operative tonsillectomy treatments, often parents are expected to motivate their child, however, drinking water often remains difficult (Lauder & Emmott, 2014). The SAHR can be considered a supportive tool that includes the by Fogg et al., (2002) mentioned minimal capacity of persuasion to improve cooperation, as was stated that due to the human aspect involved, the SAHR provides the impression that there is monitoring of the treatment's performance due to the human aspect.

In contrast to our expectations, based on previous studies, the use of the SAHR did not lead to reduced anxiety among patients (Hoffman et al., 2004; Sinha, Christopher, Fenn & Reeves, 2006; Wang, Sun & Chen, 2008; Gates et al., 2020). There are various explanations possible here. First, a reasons may be that the SAHR does not perform sufficiently as a distractor. Here the question can be asked whether simply playing a YouTube video is a sufficient distracting tool, as this could also be done on, for example, an iPad, a device that was already frequently used in the department for distraction purposes. In addition, it can also be considered whether a proper treatment was chosen to apply distraction from a SAHR. In previous studies, a SAHR was used for invasive or threatening treatments such as vaccinations or wound care (Beran, Ramirez-Serrano, van der Kooi & Kuhn, 2013). However, this study involves a medical treatment in which the patient is asked to actively perform an action, namely drinking three sips of fluid every 15 minutes. Furthermore, the questionnaire consisted of only two anxiety-related questions on which patient anxiety results were based, whereas other studies did use more extensive anxiety questionnaires (Jeong et al., 2015; Rossi, Larafa, & Ruocco, 2020). Despite, responses to the question of what patients felt about their experience of admission differed. Answers here were framed more positively. A cause may be related to shifting focus since the presence of a SAHR during treatment could ensure that unpleasant memories of the treatment, such as fear or pain, will be shifted to the background or even taken over by memories of a SAHR which turns out to make a big impression on paediatric patients.

The number of nursing interventions did not differ compared to the control group. In fact, extra interventions occurred in the form of checking moments for the execution SAHR intervention itself. Because additional support from a nurse is often needed during post-operative tonsillectomy treatment, it was thought that a SAHR might provide a reduction in nursing interventions (Lauder& Emott, 2014). Additionally, it appears that observed interventions, were not specific to fluid intake, but more facilitative focused such as facilitation

in eating or drinking. Overall it can be concluded that the implementation of a SAHR during a post-operative tonsillectomy treatment, leads to increased patient motivation resulting in improved cooperation. Furthermore, the SAHR can lead to a shift of focus in a patient's memory regarding a hospital admission. a follow-up study should include a larger anxiety questionnaire to measure patient anxiety.

Finally, we were interested in potential barriers and facilitators as well as opportunities for future implementation. The CFIR was a helpful tool to find these facilitators and barriers, while its comprehensiveness is an advantage when considering factors that facilitate and hinder implementation, it also makes the framework cumbersome to use. Facilitators of the intervention, the SAHR, are mainly appearance, mobility and usability. This high level of satisfaction can be caused due to the fact that the robot was programmed in cooperation with the nursing staff prior to the study. The SAHR was set up in a way that was as user-friendly as possible by creating one internal environment in which all user options were visible. However, the SAHR has limited interaction skills as well as the voice is seen as not user-friendly. Concerning the outer and inner setting of the implementation, the barriers found were related to insufficient evidence, (background) information, training and instructions in the form of videos or instruction cards. This could be related to the fact that the research design had to be changed in a period of one week from the target group and therefore also from the department due to a lack of participants. Moreover, due to COVID-19, there was a reduced capacity in nursing staff, which resulted in reduced time among the health professionals for being engaged in the implementation. Looking into the healthcare professionals themselves, a barrier is their low self-efficacy, which might be related to a lack of training, as some do not feel capable enough to use the SAHR. Next, as was already mentioned, the healthcare professionals helped in programming the SAHR as well as helped in planning and choosing the medical treatment in which the SAHR was implemented. This cooperation has led to a high degree of commitment to the implementation of the SAHR. Lastly, four realistic ideas for future use are defined, namely, as a SAHR as a: patient mobilisator; department guide; (general/treatment) information provider; interactive playmate. It can be concluded that the implementation of the SAHR was successful. Although in further implementation more attention should be paid to available resources, in the form of training, evidence, and background information , as well as ensuring a stable inner setting.

Strengths & Limitations

The results of this study should be interpreted with care, as it has a number of limitations. First, the small sample size (n=26) limits the possibility of being a representative sample and to generalise. The number of participants required for an expected 95 per cent confidence interval of the intra-class correlation coefficient for this study was calculated to be at least 20 participants using the intervention (Giraudeau & Mary, 2001). However, it was decided to use this number of participants as a reference, hence an attempt was made to get as many participants as possible within the available timeframe. A follow-up study should include larger sample size and if possible, different hospitals.

Secondly, both conducting the study, and analysing the data were done by the same researcher, resulting in the researcher may be being biased in interpreting the data but also because it could be that there was a desire to please health professionals. During a subsequent study a larger research team will be required in which different components are mutually assessed.

Thirdly, the repetitive performance of a treatment as well as previous hospital admissions may affect the performance and experiences of a treatment. For example, a patient who is already familiar with the treatment may find it less exciting and will perform the treatment better than a patient for whom everything is new, or who has already had a previous admission which was experienced as unpleasant. During the study, there was no data collected regarding previous admissions and or previous performance of treatment, which is something that should be included within follow-up research.

Lastly, not all situations while performing the treatment were the same. For example, some treatments took place in a one-person room and others in a two-person room, where sometimes both patients received the same aftercare treatments. Seeing and hearing a fellow patient, in addition to performing the treatment, could also influence answering questions since interview answers could be heard by other participants. No data was collected regarding a description of the setting. Even though the difference in rooms is always present in a hospital setting, it can influence the results. In a follow-up study, it is necessary to obtain information regarding the research setting, as example, a single or double room.

Conclusion

This pilot study provides preliminary evidence on the safety, acceptability, feasibility, potential effectiveness and implementation process of a SAHR in paediatric patients receiving

a post-operative tonsillectomy treatment. The SAHR was well accepted by its users. Furthermore, the SAHR implementation is considered as safe as no adverse events did occur. Feasibility measures, despite mapping problems, have also been evaluated as realistic. Important recommendations for further implementation of the SAHR, are mostly related to improvements of the interactive and mapping skills, as well as the inner and outer settings of the implementation process, such as providing training and instruction to healthcare professionals. Important recommendations for further research are, to include different hospitals, and to include appropriate medical treatments for both motivation and distraction, and in which more detailed information about the treatment environment and patient information is included. Based on this study, there seems to be sufficient grounds to initiate follow-up research on a large scale to confirm these initial findings.

Literature list

Abdi, J., Al-Hindawi, A., Ng, T., & Vizcaychipi, M. P. (2018). Scoping Review on the Use of Socially Assistive Robot Technology in Elderly Care. BMJ open, 8(2), e018815. http://dx.doi.org/10.1136/bmjopen-2017-018815

Ahmad, M. I., Mubin, O., & Orlando, J. (2017). Adaptive social robot for sustaining social engagement during long-term children–robot interaction. International Journal of Human–Computer Interaction, 33(12), 943-962. https://doi.org/10.1080/10447318.2017.1300750

Ali, S., Sivakumar, M., Beran, T., Scott, S. D., Vandermeer, B., Curtis, S., … & Hartling, L. (2018). Study protocol for a randomised controlled trial of humanoid robot-based distraction for venipuncture pain in children. BMJ open, 8(12), e023366. https://doi.org/10.1136/bmjopen-2018-023366

Appel, L., Kisonas, E., Appel, E., Klein, J., Bartlett, D., Rosenberg, J., & Smith, C. (2020). Introducing virtual reality therapy for inpatients with dementia admitted to an acute care hospital: learnings from a pilot to pave the way to a randomized controlled trial. *Pilot and Feasibility Studies*, *6*, 1. https://dx.doi.org/10.1186%2Fs40814-020-00708-9

Beran, T. N., Ramirez-Serrano, A., Vanderkooi, O. G., & Kuhn, S. (2013). Reducing children's pain and distress towards flu bers: A novel and effective application of humanoid robotics. Vaccine, 31(25), 2772-2777. https://doi.org/10.1016/j.vaccine.2013.03.056

Betriana., et al (2021). Interactions between healthcare robots and older people in Japan: A qualitative descriptive analysis study. Japan Journal of Nursing Science: JJNS, e12409-e12409. https://doi.org/10.1111/jjns.12409

Buchanan, H., & Niven, N. (2002). Validation of a Facial Image Scale to assess child dental anxiety. International journal of paediatric dentistry, 12(1), 47-52. https://doi.org/10.1046/j.0960-7439.2001.00322.x

CBS (5 februari, 2014). Operaties in het ziekenhuis; soort opname, leeftijd en geslacht, 1995-2010. CBS statline.
https://opendata.cbs.nl/statline/#/CBS/nl/dataset/80386ned/table?ts=1643900795381

Chai et al., (2021). Assessment of the Acceptability and Feasibility of Using Mobile Robotic Systems for Patient Evaluation. JAMA Network Open, 4(3), pp.e210667-e210667. https://doi.org/10.1001/jamanetworkopen.2021.0667

CFIR Research Team-Center for Clinical Management Research (2022). Constructs. Accessed at 1-6-2022, via https://cfirguide.org/constructs/

Cohen, L. L. (2008). Behavioral approaches to anxiety and pain management for pediatric venous access. Pediatrics, 122(Supplement 3), S134-S139. https://doi.org/10.1542/peds.2008-1055f

DeMore, M., & Cohen, L. L. (2005). Distraction for pediatric immunization pain: A critical review. Journal of Clinical Psychology in Medical Settings, 12(4), 281-291. http://dx.doi.org/10.1007%2Fs10880-005-7813-1

Giraudeau, B., & Mary, J. Y. (2001). Planning a reproducibility study: how many subjects and how many replicates per subject for an expected width of the 95 per cent confidence interval of the intraclass correlation coefficient. *Statistics in medicine*, *20*(21), 3205-3214.

Feil-Seifer, D., & Mataric, M. J. (2005, June). Defining socially assistive robotics. In 9th International Conference on Rehabilitation Robotics, 2005. ICORR 2005. (pp. 465-468). IEEE. https://doi.org/10.1109/ICORR.2005.1501143

Fogg, B. J. (2002). Persuasive technology: using computers to change what we think and do. Ubiquity, 2002(December), 2. https://doi.org/10.1145/764008.763957

Gates, M., Hartling, L., Shulhan-Kilroy, J., MacGregor, T., Guitard, S., Wingert, A., … & Ali, S. (2020). Digital technology distraction for acute pain in children: a meta-analysis. Pediatrics, 145(2). https://doi.org/10.1542/peds.2019-1139

Groeneveld, van Vliet & Vlieger (2020). Positief taal-gebruik in de gezondheidszorg. Nurse Academy, number 3.

Hoffman, H. G., Patterson, D. R., Magula, J., Carrougher, G. J., Zeltzer, K., Dagadakis, S., & Sharar, S. R. (2004). Water-friendly virtual reality pain control during wound care. Journal of clinical psychology, 60(2), 189-195. https://doi.org/10.1002/jclp.10244

Hildenbrand, A. K., Marsac, M. L., Daly, B. P., Chute, D., & Kassam-Adams, N. (2016). Acute pain and posttraumatic stress after pediatric injury. Journal of pediatric psychology, 41(1), 98-107. https://doi.org/10.1093/jpepsy/jsv026

Ienca, M., Jotterand, F., Vică, C., & Elger, B. (2016). Social and Assistive Robotics in Dementia Care: Ethical Recommendations for Research and Practice. International Journal of Social Robotics, 4(8), 565-573. http://dx.doi.org/10.1007%2Fs12369-016-0366-7

Jeong et al., (2015). A social robot to mitigate stress, anxiety, and pain in hospital pediatric care. In Proceedings of the Tenth Annual ACM/IEEE International Conference on Human-Robot Interaction Extended Abstracts (pp. 103-104). https://doi.org/10.1145/2701973.2702028

Kachouie, R., Sedighadeli, S., Khosla, R., & Chu, M. T. (2014). Socially assistive robots in elderly care: a mixed-method systematic literature review. International Journal of Human-Computer Interaction, 30(5), 369-393. https://psycnet.apa.org/doi/10.1080/10447318.2013.873278

KILIÇ, A. F., UYSAL, İ., & KALKAN, B. (2021). An Alternative to Likert Scale: Emoji. Eğitimde ve Psikolojide Ölçme ve Değerlendirme Dergisi, 12(2), 182-191. https://doi.org/10.21031/epod.864336

Lauder, G., & Emmott, A. (2014). Confronting the challenges of effective pain management in children following tonsillectomy. International journal of pediatric otorhinolaryngology, 78(11), 1813-1827. https://doi.org/10.1016/j.ijporl.2014.08.011

Lin, C., MacDorman, K. F., Šabanović, S., Miller, A. D., & Brady, E. (2020). Parental Expectations, Concerns, and Acceptance of Storytelling Robots for Children. In Companion of the 2020 ACM/IEEE International Conference on Human-Robot Interaction (pp. 346-348). https://doi.org/10.3389/frobt.2021.579993

Mengoni et al., (2017). Feasibility Study of a Randomised Controlled Trial to Investigate the Effectiveness of Using a Humanoid Robot to Improve the Social Skills of Children With Autism Spectrum Disorder (Kaspar RCT): A Study Protocol. BMJ open, 7(6), e017376. https://doi.org/10.1136/bmjopen-2017-017376

Olivieri, N., Henze, B., Braghin, F., & Roa, M. A. (2019). Experimental evaluation and 26odelling of passive falls in humanoid robots. In 2019 IEEE-RAS 19th International Conference on Humanoid Robots (Humanoids) (pp. 1-7). IEEE. https://doi.org/10.1109/Humanoids43949.2019.9034995

Power, N. M., Howard, R. F., Wade, A. M., & Franck, L. S. (2012). Pain and behaviour changes in children following surgery. Archives of disease in childhood, 97(10), 879-884. http://dx.doi.org/10.1136/archdischild-2011-301378

Pu, L., Moyle, W., Jones, C., & Todorovic, M. (2019). The effectiveness of social robots for older adults: A systematic review and meta-analysis of randomized controlled studies. The Gerontologist, 59(1), e37-e51. https://doi.org/10.1093/geront/gny046

Rossi, S., Larafa, M., & Ruocco, M. (2020). Emotional and behavioural distraction by a social robot for children anxiety reduction during vaccination. International Journal of Social Robotics, 12(3), 765-777. DOI https://doi.org/10.1007/s12369-019--00616-w

Schüssler, S., Zuschnegg, J., Paletta, L., Fellner, M., Lodron, G., Steiner, J., … & Russegger, S. (2020). The effects of a humanoid socially assistive robot versus tablet training on psychosocial and physical outcomes of persons with dementia: Protocol for a mixed methods study. JMIR research protocols, 9(2), e14927. https://doi.org/10.2196/14927

Sinha, M., Christopher, N. C., Fenn, R., & Reeves, L. (2006). Evaluation of nonpharmacologic methods of pain and anxiety management for laceration repair in the pediatric emergency department. Pediatrics, 117(4), 1162-1168. https://doi.org/10.1542/peds.2005-1100

Stanko, D., Bergesio, R., Davies, K., Hegarty, M., & von Ungern-Sternberg, B. S. (2013). Postoperative pain, nausea and vomiting following adeno-tonsillectomy–a long-term follow-up. Pediatric Anesthesia, 23(8), 690-696. https://doi.org/10.1111/pan.12170

Stewart, D. W., Ragg, P. G., Sheppard, S., & Chalkiadis, G. A. (2012). The severity and duration of postoperative pain and analgesia requirements in children after tonsillectomy, orchidopexy, or inguinal hernia repair. Pediatric Anesthesia, 22(2), 136-143. https://doi.org/10.1111/j.1460-9592.2011.03713.x

Strauss, A., & Corbin, J. (1998). Basics of qualitative research techniques.

Sutters, K. A., & Miaskowski, C. (1997). Inadequate pain management and associated morbidity in children at home after tonsillectomy. Journal of pediatric nursing, 12(3), 178-185. https://doi.org/10.1016/S0882-5963(97)80075-9

Taylor et al., (2021, August). Exploring the applicability of the socially assistive robot Stevie in a day center for people with dementia. In 2021 30th IEEE International Conference on Robot & Human Interactive Communication (RO-MAN) (pp. 957-962). IEEE. https://doi.org/10.1109/RO-MAN50785.2021.9515423

Trost, M. J., Ford, A. R., Kysh, L., Gold, J. I., & Matarić, M. (2019). Socially assistive robots for helping pediatric distress and pain: a review of current evidence and recommendations for future research and practice. The Clinical journal of pain, 35(5), 451. https://doi.org/10.1097%2FAJP.0000000000000688

Van Der Drift, E. J., Beun, R. J., Looije, R., Henkemans, O. A. B., & Neerincx, M. A. (2014, March). A remote social robot to motivate and support diabetic children in keeping a diary. In 2014 9th ACM/IEEE International Conference on Human-Robot Interaction (HRI) (pp. 463-470). IEEE. https://doi.org/10.1145/2559636.2559664

Venham, Larry L., and Elise Gaulin-Kremer. "A self-report measure of situational anxiety for young children." Pediatr Dent 1, no. 2 (1979): 91-6.

Wang, Z. X., Sun, L. H., & Chen, A. P. (2008). The efficacy of non-pharmacological methods of pain management in school-age children receiving venepuncture in a paediatric department: a randomized controlled trial of audiovisual distraction and routine psychological intervention. Swiss Medical Weekly, 138(39-40), 579-584. DOI: https://doi.org/10.4414/SMW.2008.12224

Wismeijer, A. A., & Vingerhoets, A. J. (2005). The Use of Virtual Reality and Audiovisual Eyeglass Systems as Adjunct Analgesic Techniques: A Review of the Literature. Annals of behavioral medicine: a publication of the Society of Behavioral Medicine, 30(3), 268-278. DOI: https://doi.org/10.1207/s15324796abm3003_11

Wren, A. A., Neiman, N., Caruso, T. J., Rodriguez, S., Taylor, K., Madill, M., … & Nguyen, L. (2021). Mindfulness-Based Virtual Reality Intervention for Children and Young Adults with Inflammatory Bowel Disease: A Pilot Feasibility and Acceptability Study. Children, 8(5), 368. https://doi.org/10.3390/children8050368

Appendices

Appendix A-I. Informed consent pre-implementation period

Informatie over het onderzoek naar de inzet van sociale robots bij medische (nazorg)behandelingen

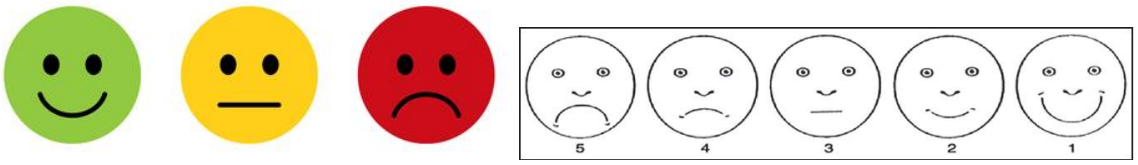
Waar gaat het over?

We willen je vragen om mee te doen aan een onderzoek. We willen graag weten of we behandelingen voor kinderen prettiger kunnen maken. Daarom willen we graag meekijken met jouw behandeling. We willen graag meekijken wat er gebeurd tijdens de behandeling en hoe goed jij de behandeling uitvoert.

Je mag samen met je ouders beslissen of je meedoet.

Wat gaat er gebeuren?

Als je samen met je ouders besloten hebt om mee te doen, dan gaat er één extra collega meekijken met jouw behandeling. Tijdens de behandeling schrijven we belangrijke informatie op zoals bijvoorbeeld het aantal keer dat de verpleegkundige je komt helpen. Daarna stellen we jou en je ouders een aantal vragen over jouw ervaring van de behandeling. Je mag antwoorden geven door de juiste smiley aan te wijzen.



Wanneer en hoe lang?

We willen graag met je meekijken op jouw kamer op de afdeling wanneer je een behandeling uitvoert. De behandeling wordt op de normale manier uitgevoerd, dit duurt niet langer dan normaal. Het beantwoorden van de vragen duurt ongeveer 5 minuten, dit is extra tijd die we van jou vragen.

Wat zijn de voordelen van meedoen aan het onderzoek?

- Het voordeel van dat je mee doet aan dit onderzoek is dat je ons helpt met het prettiger maken van behandelingen voor kinderen.

Belangrijk om te weten:

- Meedoen is **niet verplicht**
- Je mag altijd **stoppen zonder dat je hoeft te vertellen waarom**
- Je mag altijd **vragen stellen**.

Als je vragen hebt

Vragen kun je met je ouders bespreken. Of je kunt ze samen aan de onderzoeker Veere stellen.

Je kunt de onderzoeker mailen op: vlamberts@rijnstate.nl of bpapenberg@rijnstate.nl

Schrijf jouw vragen hier op:

Toestemmingsformulier verzorgers

Ik ben gevraagd om toestemming te geven voor deelname van mijn kind aan dit onderzoek

Extra informatie voor u als verzorger:

Dit onderzoek wordt uitgevoerd vanuit Rijnstate Robotics in samenwerking met Universiteit Twente. Er worden geen medische gegevens van uw kind verzameld, enkel de op dit toestemmingsformulier ingevulde persoonsgegevens. Uw persoonlijke gegevens worden anoniem in het onderzoeksrapport verwerkt en uitsluitend gebruikt voor doeleinden gerelateerd aan dit onderzoek. Dit formulier wordt veilig opgeslagen op een beveiligde schijf van Rijnstate en wordt binnen twee jaar vernietigd. Dit onderzoek is beoordeeld en goedgekeurd door de interne wetenschappelijke commissie van Rijnstate.

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn goed genoeg beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe. Ik had genoeg tijd om te beslissen of ik wil dat mijn kind mee doet.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen dat mijn kind en ik toch niet mee willen doen met het onderzoek. Ik hoef hiervoor de reden niet aan te geven.
- Ik heb begrepen dat deelname aan het onderzoek gepaard gaat met een audio opname en schriftelijke aantekeningen.
- Ik heb begrepen dat de door mij verstrekte informatie gebruikt zal worden voor een onderzoek gericht op de effectiviteit van een robot tijdens het vernevelen van kinderen, onder toezicht van Rijnstate Robotics en de faculteit BMS van Universiteit Twente.
- Ik begrijp dat mijn persoonlijke informatie of dat van mijn kind, zoals bijvoorbeeld naam en leeftijd, niet buiten het behandelteam gedeeld zal worden.
- Ik begrijp dat er geen medische gegevens, zoals bijvoorbeeld ziekte of medicatie, nodig zijn.
- Ik doe mee aan dit onderzoek.
- Ik ga ermee akkoord dat mijn kind meedoet aan dit onderzoek.

Klachten?
Indien u klachten heeft over het onderzoek, kunt u dit bespreken met de onderzoeker of uw behandelend arts. Wilt u dit liever niet, dan kunt u zich wenden tot de klachtenfunctionaris van Rijnstate ziekenhuis: telefoon: 088-0057539; Postbus 955, 6700 TA Arnhem.

Appendix A-II. Informed consent implementation period

Informatie over het onderzoek naar de inzet van sociale robots bij medische (nazorg)behandelingen

Waar gaat het over?

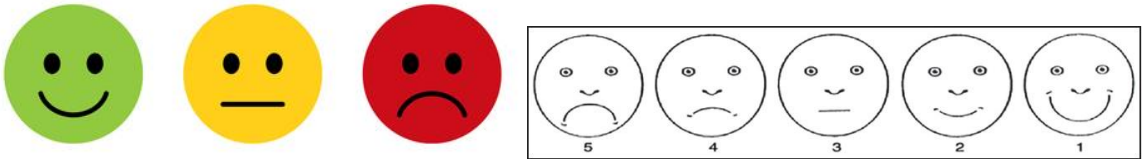
We willen je vragen om mee te doen aan een onderzoek. We willen graag weten of we behandelingen voor kinderen prettiger kunnen maken met een robot. De robot die we hiervoor gebruiken is robot James. James kan uitleg geven over een behandeling en hij heeft filmpjes die je tijdens de behandeling met hem kunt bekijken.

Om erachter te komen of James jou kan helpen tijdens de behandeling, willen we graag meekijken hoe James samen met jou de behandeling uitvoert.

Je mag samen met je ouders beslissen of je meedoet.

Wat gaat er gebeuren?

Als je samen met je ouders besloten hebt om mee te doen, dan gaat er één extra collega meekijken met jouw behandeling. Tijdens de behandeling schrijven we belangrijke informatie op zoals bijvoorbeeld het aantal keer dat de verpleegkundige je komt helpen. Daarna stellen we jou en je ouders een aantal vragen over jouw ervaringen van de behandeling. Je mag antwoorden geven door de juiste smiley aan te wijzen.



Wanneer en hoe lang?

We willen graag met je meekijken op jouw kamer op de afdeling wanneer je een behandeling uitvoert. De behandeling wordt op de normale manier uitgevoerd, dit duurt niet langer dan normaal. Het beantwoorden van de vragen duurt ongeveer 5 minuten, dit is extra tijd die we van jou vragen.

Wat zijn de voordelen van meedoen aan het onderzoek?

- Het voordeel van dat je mee doet aan dit onderzoek is dat je ons helpt met het prettiger maken van behandelingen voor kinderen.

Belangrijk om te weten:

- Meedoen is **niet verplicht**
- Je mag altijd **stoppen zonder dat je hoeft te vertellen waarom**
- Je mag altijd **vragen stellen**.

Als je vragen hebt

Vragen kun je met je ouders bespreken. Of je kunt ze samen aan de onderzoeker Veere stellen.

Je kunt de onderzoeker mailen op: vlamberts@rijnstate.nl of bpapenberg@rijnstate.nl

Schrijf jouw vragen hier op:

Toestemmingsformulier verzorgers

Ik ben gevraagd om toestemming te geven voor deelname van mijn kind aan dit onderzoek

Extra informatie voor u als verzorger:

Dit onderzoek wordt uitgevoerd vanuit Rijnstate Robotics in samenwerking met Universiteit Twente. Er worden geen medische gegevens van uw kind verzameld, enkel de op dit toestemmingsformulier ingevulde persoonsgegevens. Uw persoonlijke gegevens worden anoniem in het onderzoeksrapport verwerkt en uitsluitend gebruikt voor doeleinden gerelateerd aan dit onderzoek. Dit formulier wordt veilig opgeslagen op een beveiligde schijf van Rijnstate en wordt binnen twee jaar vernietigd. Dit onderzoek is beoordeeld en goedgekeurd door de interne wetenschappelijke commissie van Rijnstate.

- Ik heb de informatiebrief gelezen. Ook kon ik vragen stellen. Mijn vragen zijn goed genoeg beantwoord. Ik had genoeg tijd om te beslissen of ik meedoe. Ik had genoeg tijd om te beslissen of ik wil dat mijn kind mee doet.
- Ik weet dat meedoen vrijwillig is. Ook weet ik dat ik op ieder moment kan beslissen dat mijn kind en ik toch niet mee willen doen met het onderzoek. Ik hoef hiervoor de reden niet aan te geven.
- Ik heb begrepen dat deelname aan het onderzoek gepaard gaat met een audio opname en schriftelijke aantekeningen.
- Ik heb begrepen dat de door mij verstrekte informatie gebruikt zal worden voor een onderzoek gericht op de effectiviteit van een robot tijdens het vernevelen van kinderen, onder toezicht van Rijnstate Robotics en de faculteit BMS van Universiteit Twente.
- Ik begrijp dat mijn persoonlijke informatie of dat van mijn kind, zoals bijvoorbeeld naam en leeftijd, niet buiten het behandelteam gedeeld zal worden.
- Ik begrijp dat er geen medische gegevens, zoals bijvoorbeeld ziekte of medicatie, nodig zijn.
- Ik doe mee aan dit onderzoek.
- Ik ga ermee akkoord dat mijn kind meedoet aan dit onderzoek.

Klachten?
Indien u klachten heeft over het onderzoek, kunt u dit bespreken met de onderzoeker of uw behandelend arts. Wilt u dit liever niet, dan kunt u zich wenden tot de klachtenfunctionaris van Rijnstate ziekenhuis: telefoon: 088-0057539; Postbus 955, 6700 TA Arnhem.

Appendix B. Example composition

- Hallo, mijn naam is James.
- Ik ben een nieuwe collega hier op de afdeling.
- Ik heb gehoord dat jij iets heel stoers hebt gedaan.
- Echt super knap!
- Weet je nog wat er vanmorgen is afgesproken?
- Het drinken van slokjes water is belangrijk, het zorgt ervoor dat je sneller beter wordt.
- Ik ben er vandaag om je nog even te helpen met drinken.
- Ondertussen kunnen we samen filmpjes kijken.
- Ga je nu eerst even drie slokjes drinken? Dan start ik ondertussen de App YouTube.
- Over een kwartiertje kom ik terug, om je te helpen herinneren aan het nemen van slokjes drinken.
- Veel kijk plezier!
- “wacht 15 min”
- Daar ben ik weer, neem je weer even een paar slokjes drinken?
- Dan mag je ondertussen weer verder met het kijken van filmpjes.
- “wacht 15 min”
- Hé topper, drink je weer even een paar slokjes?
- “wacht 10 seconden”
- Je doet het tot nu toe super goed!
- Mijn taak zit er helaas op voor vandaag, ik ga nog even langs bij andere kinderen.
- Ondertussen ga jij nog door met het nemen van slokjes drinken.
- Ik weet zeker dat je dat kan zonder mij!
- Mag ik een virtuele High-Five?!
- “toont virtuele high-Five”
- Yes, dankjewel!
- Tot ziens

Appendix C. Observation scheme 1 – safety

Participant-studie nummer:…….

1. Kruis het type bijwerking(en) aan dat zich tijdens en ten gevolge van het gebruik van James heeft voorgedaan tijdens de nazorgbehandeling van een tonsillectomie:

Pijn of ongemak Eventuele toelichting:…
Lichamelijk (mechanisch) letsel Eventuele toelichting:…
Overige bijwerkingen, namelijk: …
Geen bijwerkingen

Appendix D. Observation scheme 2 – feasibility

Participant-studie nummer:……

1. Aantal keren dat er een interventie vanuit de verpleegkundige plaats vond (bijvoorbeeld het op de kamer komen om sturing te bieden in het nemen van 3 slokken water):

……. keer

#	Type interventie
1	
2	
3	
4	
5	

**alleen invullen tijdens interventie sessies*

2. Is het gelukt om James zijn compositie te starten tijdens de nazorgbehandeling?

   A. Ja, zonder problemen
   B. Ja, met enkele problemen
   C. Ja, met veel problemen
   D. Nee, het is niet gelukt.

3. Hoe lang duurde het om James te installeren (vanaf het moment dat James naar de kamer gereden wordt tot aan de start van de compositie)?

…….. minuten

4. Hoe lang duurde het om James te verwijderen bij de patiënt, schoon te maken en terug te plaatsen op zijn startpunt?

…… minuten

5. Hoeveel professionals waren er **noodzakelijk** om de patiënt te laten vernevelen met James?

…….. medewerkers

6. Noteer het type en het aantal (technische) problemen en omcirkel de categorie waar het probleem volgens jou onder valt.

#	Type (technische) probleem	**Categorie**
1		Technisch / Patiënt / Overig
2		Technisch / Patiënt / Overig
3		Technisch / Patiënt / Overig
4		Technisch / Patiënt / Overig
5		Technisch / Patiënt / Overig

Appendix E-I. Dual-interview schemes pre-implementation period

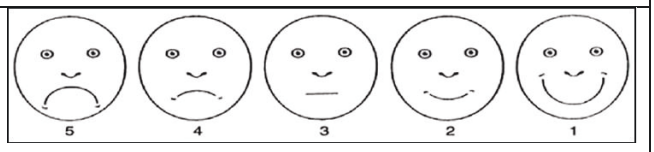
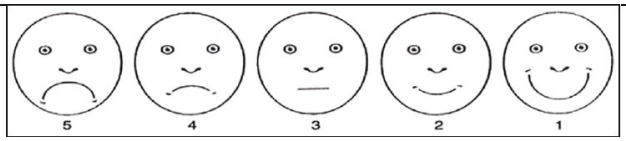
Participant-studie nummer: ……

1. Kun je aan mij vertellen hoe oud je bent?..... jaar

2. Geslacht:
   Jongen
   Meisje
   Anders, namelijk:……..

3. Aanwezige ouder/verzorger:
   Moeder
   Vader
   Beide
   Anders, namelijk:……

**Onderstreepte interviewvragen dienen gesteld te worden aan ouders/verzorgers*

Pre-interventie interview schema	
4. Wat vond je van het slokjes drinken? Het linker gezichtje geeft aan dat je het heel spannend vond en het rechter gezichtje geeft aan dat je het helemaal niet spannend vond.	 5. Wat vond je spannend/niet spannend? 6. <u>Waarin uitte zich dit bij uw kind volgens u?</u>
7. Wat vond je ervan om hier op de afdeling te zijn? De gezichtjes betekenen weer hetzelfde: Het linker gezichtje geeft aan dat je het heel spannend vond en het rechter gezichtje geeft aan dat je het helemaal niet spannend vond.	 8. Wat vond je het spannend/niet spannend? 9. <u>Waarin uitte zich dit bij uw kind volgens u?</u>
10. <u>Hoe vond u de nazorgbehandeling verlopen?</u>	<u>Wat ging er goed?</u> <u>Wat ging er niet goed?</u>
11. <u>Op een schaal van 1 tot 10, waarbij 1 heel slecht meewerken is en 10</u>	

heel goed meewerken is, hoe werkte uw kind mee met de behandeling? 1 2 3 4 5 6 7 8 9 10 12. Kunt u dit toelichten?	
13. Heb je tips voor ons wat er een volgende keer beter kan?	14. Wat kan er volgens u een volgende keer tijdens een nazorgbehandeling beter?

Appendix E-II. Dual-interview schemes implementation period

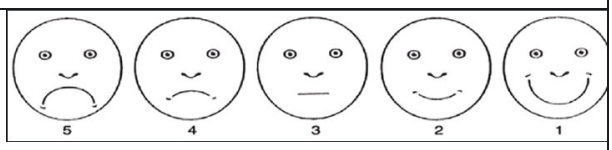
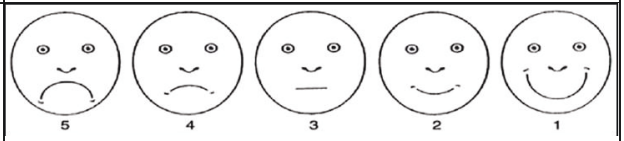
Participant-studie nummer:……..

1. Kun je aan mij vertellen hoe oud je bent?..... jaar

2. Geslacht:
   Jongen
   Meisje
   Anders, namelijk:……

3. Aanwezige ouder/verzorger:
   Moeder
   Vader
   Beide
   Anders, namelijk:……

**onderstreepte interviewvragen dienen gesteld te worden aan ouders/verzorgers*

interventie interview schema	
4. Wat vond je van het slokjes drinken? Het linker gezichtje geeft aan dat je het heel spannend vond en het rechter gezichtje geeft aan dat je het helemaal niet spannend vond.	 5. Wat vond je spannend/niet spannend? 6. <u>Waarin uitte zich dit bij uw kind volgens u?</u>
7. Wat vond je ervan om hier op de afdeling te zijn? De gezichtjes betekenen weer hetzelfde: Het linker gezichtje geeft aan dat je het heel spannend vond en het rechter gezichtje geeft aan dat je het helemaal niet spannend vond.	 8. Wat vond je het spannend/niet spannend? 9. <u>Waarin uitte zich dit bij uw kind volgens u?</u>
10. <u>Hoe vond u de nazorgbehandeling verlopen?</u>	<u>Wat ging er goed?</u> <u>Wat ging er niet goed?</u>

11. <u>Op een schaal van 1 tot 10, waarbij 1 heel slecht meewerken is en 10 heel goed meewerken is, hoe werkte uw kind mee met de behandeling:</u>

1 2 3 4 5 6 7 8 9 10

12. <u>Kunt u dit toelichten?</u>

13. Wat vind je van James?

Leuk leuk | Beetje leuk | Niet

14. Vond je de filmpjes leuk?

Leuk | Beetje leuk | Niet leuk

15. Helpt James jou goed tijdens het de nazorgbehandeling?

JA | Een beetje | NEE

16. Zou je tijdens een volgende medische behandeling James nog een keer willen gebruiken?

JA | Misschien | NEE

17. Wat kan James een volgende keer beter doen?

18. <u>Wat vindt u van James?</u>

	19. Wat zijn volgens u verbeterpunten voor de inzet van James bij een volgende nazorgbehandeling? 20. Heeft u nog andere tips/ideeën over de toekomstige inzet van James?

Appendix F-I. Questionnaire nursing staff pre-implementation period

Participant-studie nummer:……

Naam Verpleegkundige:……

Datum:……

1. Hoe vond u de behandeling (slokjes drinken) verlopen?	Heel goed Overwegend goed Overwegend slecht Heel slecht
2. Op een schaal van 1 tot 10, waarbij 1 heel slecht meewerken is en 10 heel goed meewerken is, hoe werkte de patient mee met de behandeling: 1 2 3 4 5 6 7 8 9 10	
3. Wat vond de patiënt van het drinken van de slokken water volgens u?	Fijn Niet fijn maar ook niet vervelend Vervelend
4. In hoeverre was de patiënt gespannen/ angstig volgens u?	Gespannen Beetje gespannen Ontspannen
Ruimte voor eventuele aantekeningen: …	

5. Wat kan er een volgende keer beter volgens u?
   ….

Appendix F-II. Questionnaire nursing staff implementation period

Participant-studie nummer:……

Naam Verpleegkundige:……

Datum:……

1. Hoe vond u de behandeling (slokjes drinken) verlopen?	Heel goed Overwegend goed Overwegend slecht Heel slecht
2. Op een schaal van 1 tot 10, waarbij 1 heel slecht meewerken is en 10 heel goed meewerken is, hoe werkte de patient mee met de behandeling: 1 2 3 4 5 6 7 8 9 10	
3. Wat vond de patiënt van het drinken van slokken water volgens u?	Fijn Niet fijn maar ook niet vervelend vervelend
4. In hoeverre was de patiënt gespannen/ angstig volgens u?	Gespannen Beetje gespannen Ontspannen
5. Ruimte voor eventuele aantekeningen/opmerkingen …	

6. Ik ga James tijdens een volgende vernevelbehandeling nogmaals inzetten	Mee eens Niet mee eens, niet mee oneens Niet mee eens
7. Wat kan James een volgende keer tijdens een nazorgbehandeling beter doen? …	

Appendix G . Observation scheme 4 – protentional effectiveness

Participant-studie nummer: ……..

1. Op een schaal van 1 tot 10, waarbij 1 heel slecht meewerken is en 10 heel goed meewerken is, hoe werkte de patiënt mee met de behandeling:

1 2 3 4 5 6 7 8 9 10

2. Noteer het (aantal keren dat) gedrag/emotie zich voordoet doormiddel van te turven. Er is een mogelijkheid om omschrijvingen van gedragingen/emoties toe te voegen wanneer er gekozen wordt voor ‘overige’.

(poging tot) het weigeren van het drinken van 3 slokken water	
Andere vorm van tegenwerken, namelijk:	…
Huilen	
Overige negatieve emoties, namelijk:	…
Overige positieve emoties, namelijk:	…

Appendix H. Evaluation interview scheme

Welkom allemaal,

ten eerste, wat fijn dat jullie vandaag allen tijd hebben voor mij. Jullie mening over de inzet van James de robot is namelijk van groot belang voor mijn onderzoek. Ik ben dan ook erg nieuwsgiering naar jullie kijk op de inzet van James op jullie afdeling.

Ik ga jullie tijdens deze groepssessie vragen stellen over James. Mijn vragen zijn gericht op zowel de implementatie van James op jullie afdeling als James zijn gebruiksvriendelijkheid, zijn uiterlijk/voorkomen, zijn functionaliteiten en over de effecten van de inzet van James. Het is belangrijk om te weten dat er geen goede of foute antwoorden mogelijk zijn. Wees vooral eerlijk en geef ook aan wanneer een vraag niet duidelijk is. Verder is het belangrijk om te weten dat iedere mening telt en is het van belang dat er telkens één persoon aan het woord is.

Ik zal deze groepssessie opnemen doormiddel van een audiorecorder zodat ik het nog een keer terug kan beluisteren. Vervolgens zal het audiobestand worden getranscribeerd waarna deze verwijderd zal worden. Mochten er namen genoemd worden, dan zal ik deze verwijderen om anonimiteit te waarborgen.

Zijn er nog vragen?

Dan start nu de sessie.

1. Wat vinden jullie van James?	• Vinden jullie James passend binnen jullie afdeling? • Wat vinden jullie van James tegenover andere bestaande innovaties die worden ingezet bij jullie op de afdeling (denk bijvoorbeeld aan IPads, Cliniclowns etc) • Kunnen jullie zowel positieve punten benoemen als punten voor verbeteringen?
2. Wat vinden jullie van de manier waarop James is geïntroduceerd/geïmplementeerd op jullie afdeling?	• Hebben jullie voldoende informatie ontvangen voortijdig aan/tijdens de implementatie van James? • Was voor jullie de planning/het implementatie plan duidelijk? • Was er voldoende ruimte voor eventuele vragen/verbeteringen?
3. Wat vinden jullie van James zijn uiterlijk/voorkomen?	• Wat vinden jullie van zijn lengte/breedte? • Wat vinden jullie van zijn gezicht/beeldscherm? • Wat vinden jullie van zijn spraak/stem?

	• Wat vinden jullie van zijn mobiliteit/bewegelijkheid? • Kunnen jullie ook hierin weer denken aan zowel positieve punten als punten voor verbeteringen benoemen?
4. In hoeverre vinden jullie James gebruiksvriendelijk?	• In hoeverre vinden jullie James gemakkelijk in gebruik? • Wat vinden jullie van James zijn besturingssysteem? • In hoeverre vinden jullie James zijn kiosk logisch ingedeeld?
5. Wat vinden jullie van de verschillende afleidingsstrategieën?	• Wat vinden jullie van de verschillende video's? • Wat vinden jullie van de verschillende spelletjes? • Wat vinden jullie van de verschillende muzikale applicaties?
6. Welk effect (positief en/of negatief) heeft de inzet van James bij een tonsillectomie..	• Op kinderen (denk aan angst, positieve herinnering aan de opname). • Op ouders/verzorgers (denk aan verbeterde participatie). • Op jullie werkzaamheden als verpleegkundige.
7. In hoeverre kan James volgens jullie voldoende ondersteuning bieden aan de patiënt tijdens een nazorgbehandeling van een tonsillectomie?	• Wat vinden jullie van de uitleg en instructies over de nazorgbehandeling die James verstrekt? • Wat vinden jullie van de motiverende en complimenterende quotes die James verstrekt? • Wat zouden we nog kunnen toevoegen of veranderen aan James (of de manier waarop hij wordt ingezet) om nóg beter te kunnen ondersteunen bij (voorbereiden op of het herstel van) tonsillectomie?
8. Hebben jullie tips of ideeën voor verder gebruik/inzet van James in de toekomst?	• Wat moet er gebeuren om verdere implementatie van James te bevorderen? • Moeten er meerdere robots aangeschaft worden?

Appendix I. Content analysis dual interview

Coding schemes Dual interview parental outcomes control group

Own facilated distracition devices - soft (cuddly toys) - IPad/tablet/smartphone	**Anxiety** - Anxiety when taking the first sip - loss of control - suspense/tense regarding the overall hospital environment - deviant behaviour	**Relaxation** - calm behaviour	**Good cooperation** - drinking went well - drinking provides relief - did not refuse to participate - asking to drink themselves
Low cooperation level - increased resistance - making up reasons to not drink - panic/crying	**Points of improvement** - more entertainment - More attractive appearance of patients rooms - WiFi improvement		

Coding scheme Dual interview parental outcomes Study group

Own facilated distracition devices - soft and/or (cuddly) toys - IPad/tablet/smartphone	**Anxiety** - Anxiety when taking the first sip - loss of control - consequence of significant pain - suspense/tense regarding the overall hospital environment	**Good cooperation** - drinking went well - SAHR improved the treatment performance - drinking went natural - asking to drink themselves	**Low cooperation level** - distracted from the treatment - increased resistance
High SAHR satisfaction - helpful/supportive robot - user friendly - human like - tailor-made - friendly appearance	**Low SAHR satisfaction** - Harsh voice - Bad driving skills	**Points of improvement** - More interaction - WiFi improvement - User friendly voice	**Future use** - Information provision in other treatments - A guide function - Support in patient mobilisation

Appendix J. Final coding scheme focus group interviews

Coding scheme focus-group evaluation interviews

Intervention	**Outer Setting**	**Inner Setting**	**Individual**
- User-friendly - Proper appearance - Good mobility - SAHR has limited interaction skills - SAHR's voice is too low - Good access to Knowledge & information - Lack of Evidence, Strength & Quality	- Known importance of good patient drinking skills - Lack of available resources (training)	- Reduced capacity in nursing staff - COVID-19 - Non-use of the SAHR	- Low self-efficacy - positive about having a SAHR in the department
Process	**Future use**		
- helped in thinking of an appropriate treatment - helped write the compositions in focus language - high engagement	- patient mobilisation - guide function - (general) information provider - Interactive playmate		