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Recalling shared memories in an embodied conversational agent

Personalized robot support for children with diabetes in the PAL project

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Master's Thesis at KTH Information and Communication Technology

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Abstract

The PAL project aims to help children with type 1 diabetes to improve their self-management skills using a social robot and its virtual avatar. It has been challenging to gain a long-term relationship with a robot or virtual character. After the novelty effect wears off, the interest of the user decreases over time. The aim of this project was to explore and develop personalized interactions with the children, using episodic memory to improve the engagement and diabetes self-management. A module was built that could capture and refer to shared experiences between the PAL actor and the child. During an experiment with children, the usage decreased over time after the novelty effect wore off. No increases in affection, motivation and diabetes self-management were found after the implementation of the episodic memory module. The full potential of episodic memory was however untested, as the novelty effect already wore off before the implementation. Further research is recommended in order to assess the benefits of an improved version of the episodic memory update during an A/B test.

Sammanfattning

Att framkalla delade minnen i en förkroppsligad samtalsagent

Pal-projektet syftar till att hjälpa barn med diabetes typ 1 att förbättra färdigheter för att klara av diabetes-relaterade rutiner med hjälp av en social robot och dess virtuella avatar. Det har visat sig vara svårt att behålla relationen till en robot eller virtuell karaktär under längre tid. Efter att nyhetseffekten försvinner så sjunker användarens intresse relativt snabbt. Syfte med mitt examensarbete har varit att utforska och ta fram personanpassade interaktioner med barn genom att använda episodiskt minne för att öka engagemanget och på så sätt förbättra diabetes-relaterade rutiner. Första steget var att utveckla en modul som fångar och hänvisa till gemensamma erfarenheter mellan roboten och användaren. Detta testades därefter med hjälp av ett experiment som ingick i en större försök där denna modul användes. Resultat visar att barnen minskade användningen över tid även i detta fall, och vi har inte kunnat visa någon ökning i känslomässig spänning, motivation och förbättrade diabetes-relaterade rutiner. Det episodiska minnets fulla potential har dock inte kunnat testmts i detta experiment, eftersom nyhetseffekten delvis redan avtagit i det aktuella försöket. Framtida forskning rekommenderas att utvärdera fördelarna av en förbättrad version av det episodiska minnets uppdatering under en kontrollerad a/b-test.

This thesis is dedicated to the memory of my grandmother, Helene Tollenaar-Groen (1932 - 2017).

Acknowledgements

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I would first like to thank my supervisors Rosemarijn Looije and Mark Neerincx from TNO. They gave me the opportunity and the freedom to explore my own interests within the context of the PAL project. They supported me with continuous and in-depth feedback, which greatly improved the work in this thesis.

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Bart Schreuder Goedheijt

Contents

List of Acronyms and Abbreviations

PAL	Personal Assistant for a healthy Lifestyle
T1DM	Type 1 Diabetes Mellitus
OWL	Web Ontology Language
RDF	Resource Description Framework
AEO	Affection-based Episode Ontology
SDT	Self-Determination Theory
CET	Cognitive Evaluation Theory
sCE	Situated Cognitive Engineering
5W1H	Who, What, Where, When, Why, How
EMA	Ecological Momentary Assessment

Chapter 1

Introduction

"Hey! It's nice to see you again! Did you enjoy the party yesterday?" It's such a small gesture, but the role of remembering is highly important in daily life. The feeling that someone cares and thinks about you is one of the cornerstones of a friendship. This is probably even more meaningful for children with a chronic disease.

1.1 Background

1.1.1 Type 1 Diabetes Mellitus

Type 1 Diabetes Mellitus (T1DM) is a disease that prevents the pancreas from creating insulin. The body breaks down food into glucose and sends it into the blood. The insulin is needed for moving the glucose from the blood into the cells. This is either directly used as fuel for energy or stored for later use. People with T1DM have to keep their blood glucose level at a normal level to prevent hypoglycemia (blood glucose level too low) or hyperglycemia (blood glucose level too high). This is done by checking blood glucose levels, planning meals (choosing what, how much and when to eat), taking insulin and by performing physical activity. This is required in order to feel well during the day and to prevent or delay long-term health problems. The disease therefore requires a high level of self-management. T1DM is usually diagnosed in children and young adults. [1]

1.1.2 PAL Project

The PAL (Personal Assistant for a healthy Lifestyle) project aims to help children (between the age of 7 and 14) with type 1 diabetes to improve their self-management skills using a social robot and its virtual avatar combined with a set of mobile health apps (figure 1.1). The robot and avatar act as a pal for these children and help them to achieve diabetes-oriented goals. Alongside the robot and the virtual avatar, the PAL system includes a module for use by health professionals to instruct and supervise the system, as well as a module to monitor progress and inform the parents. All of these modules are connected to the PAL cloud environment. The project is funded by the European Union in the Horizon2020 program (ref. H2020-PHC-643783). The project builds on work that has been done in earlier projects, including the ALIZ-e project [2]. The PAL project is coordinated by TNO (Netherlands Organisation for Applied Scientific Research) and includes partners from The Netherlands, Italy, the United Kingdom and Germany [3].

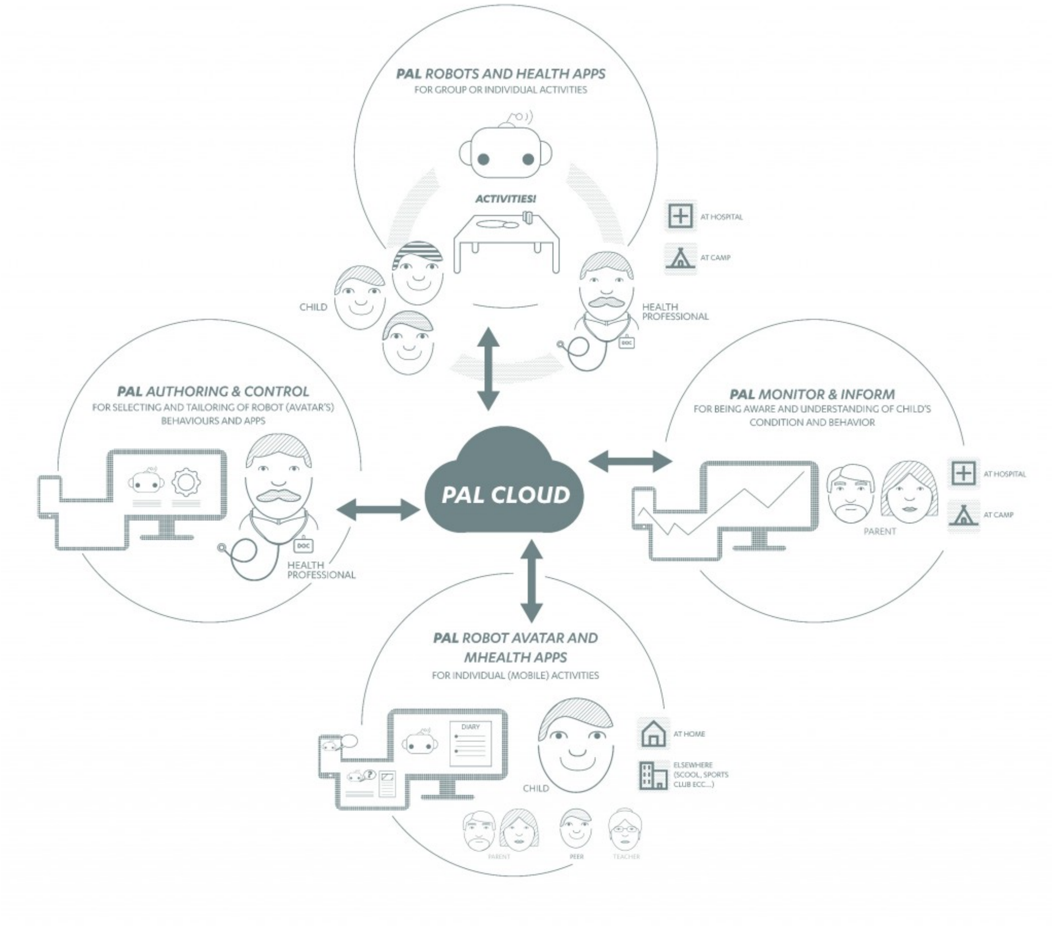

Figure 1.1. Overview of the PAL system [4]

Diabetes self-management

The self-management skills are measured using learning objectives. These learning objectives are set to acquire knowledge and skills or to do certain tasks. These objectives are based on the Know&Do goals from the Expertise group Paediatric Diabetes Nurses (EPDN) (see Appendix B). The healthcare professionals from the hospitals in the PAL project validated these goals and categorized them in to age groups based on their difficulty. The learning objectives are integrated in the mobile health apps. The current system has the following mobile health apps:

- **Timeline:** a diary for the children which also contains blood-sugar measurements.
- **Quiz:** a quiz that helps the children to achieve knowledge goals related to their diabetes.
- **Break and sort game:** a game that helps children to identify and categorize different types of food.

These apps can be used with the physical robot in the hospital or at diabetes camps, but also with the virtual avatar on a tablet at home.

Long-term relationships with virtual and robotic characters

It has been challenging to gain a long-term relationship with a robot or virtual character. After the novelty effect wears off, the interest of the user decreases over time. In previous work of the PAL project, a way was found to decrease this novelty effect wear-off using self-disclosure (see § 3.9). Besides self-disclosure, it has been demonstrated that a long-term memory in (virtual) robots further decreases this novelty effect. This includes having and recalling shared experiences. Kasap et al. developed a system with the sole purpose of keeping the attention of users after the first interaction [5]. They found that the users' interest in the system did not decrease with time by remembering and referring to the engagement level of users.

1.2 Problem statement

As mentioned before, T1DM requires essential self-management by the young patients. One of the objectives within the PAL project is to develop an agent-based reasoning mechanism to set personalized learning and behavioural goals, and engagement strategies for children. This objective would support and increase the self-management of the children [4]. During several meetings in the hospital, the children will perform different activities with the social robot. In the Netherlands and in Italy, the robot also makes its appearance during diabetes related summer camps. These camps provide valuable input for the PAL project, as they provide greater insight into the practical usage of the PAL system using observations and by conducting interviews. Besides these hospital and camp sessions, the children will also use a tablet at home with the virtual avatar of the robot to perform these activities. In order to support and increase the children's diabetes self-management, the child has to gain a long-term relationship with the (virtual) robot. After the novelty effect wears off, the children still have to use the PAL system in order for it to be effective. To prevent the decrease in usage over time, it could be useful to memorize and refer to earlier meetings. For example, the robot should be able to keep track of goals and give feedback on the actual progress compared with earlier meetings. It should give feedback on the stored measurements of their blood sugar level (e.g. in case that the child forgot to fill it in). Also, if the child tells the robot that (s)he will go to a birthday party, the robot could ask if they enjoyed it in the next meeting. The robot is currently unable to memorize and refer to earlier meetings. In addition, the improvement of diabetes self-management due to making reference to earlier meetings still has to be proven empirically.

1.3 Purpose and goal

The purpose is to research, explore and develop personalized interactions with the children using episodic memory to increase the overall engagement and usage of the health apps, which would ultimately lead to increased diabetes self-management. The goal of the project is to develop a memorization module that could be integrated with the current robot and the virtual avatar. This module should be able to capture two types of memory: the augmented memory of the child (activity reports and observed behaviour) and the episodic knowledge of the PAL actor (see § 3.4). It should therefore be able to reason over the intersection of these captured memories: the shared experiences between the PAL actor and the child. Finally, it should fit within the current system and architecture. The PAL system uses Ontologies for defining its knowledge and data storage (see § 3.3). Therefore, it should support and build upon the current PAL Ontology (see § 3.3.1).
The module is built in different iterations. The goal for the first iteration is to implement the ability to memorize goals and progress in order that they can be used to give summarized feedback. This would increase the effectiveness as mentioned in the Goal-Setting Theory (see § 3.2). Besides the Goal-Setting Theory, the Nudge Theory could be used in order to push the behaviour change in the right direction (see § 3.8). The second iteration would include the memorization and reasoning over blood sugar measurements in order to improve the intrinsic motivation (see § 3.1). The third iteration would contain the ability to memorize and reason over the activities that the children entered in the diary, which could be solved by using an Affection-based Episode Ontology (see § 3.6). The final experiment with real users should at least contain the first iteration.

1.4 Research question

The main research question in this project is:

> **How should the PAL actor capture and refer to past experiences that were shared with the child?**

The PAL actor is the social robot or the virtual avatar. The past experience in this case is a memory that has been shared between the PAL actor and the child. The

PAL actor should therefore be able to capture these shared memories and refer to them at a later moment.
To answer this research question, five subquestions have been defined. The breakdown of the main research question into these subquestions is shown in figure 1.2

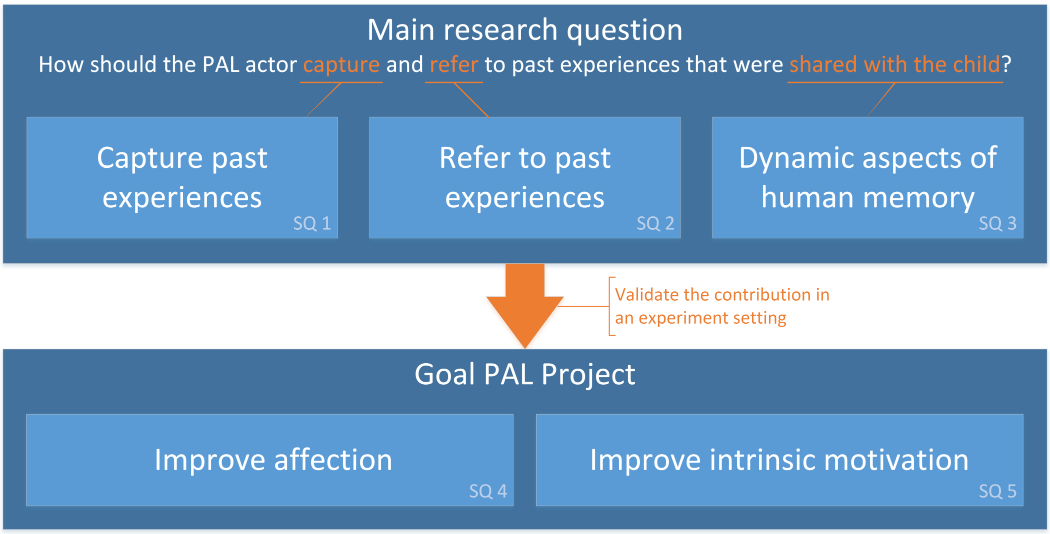

Figure 1.2. Research question breakdown

The first subquestion regarding the capturing of past experiences is:

SQ1: Which ontological model can capture the main concepts with their relations of the child-PAL shared episodic memory?

This question is intended to research the memory capture process. We need to define a memory and how to store it. This should be the shared experience between the PAL actor and the child. The second question is:

SQ2: Which reasoning mechanism can the PAL actor apply for constructive memory reference expressions?

A reasoning mechanism is essential in order to refer to these memories at a later moment. It should be able to reason about the memories stored in the ontological model from the previous subquestion.

SQ3: How could dynamic aspects from the human memory (e.g. forgetfulness, context association, memory combining and generalization) be translated to the PAL actor episodic memory?

The third subquestion is defined to investigate the possibilities of translating dynamic aspects of the human memory to the PAL actor. This question is added to make the reasoning mechanism stay closer to the actual shared experience with the child.

SQ4: Does the addition of episodic memory alter the affection with the embodied conversational agent?

SQ5: Does the addition of episodic memory improve the intrinsic motivation for achieving goals?

The last two subquestions are defined to evaluate how the system affects and contributes to the PAL project goals. This will be done in an experiment using a system that will be developed using the answers from subquestion 1, 2 and 3. Subquestions 4 and 5 are defined to answer the hypothesis.

1.5 Hypothesis

The hypothesis is that referring to past memories will delay the novelty effect wearing off. This will prevent the usage decrease of the PAL system. In other words, children will still like to use the system after the experiment ends. This effect will result in the improvement of the intrinsic motivation of the children and the affection with the PAL actor.

Chapter 2

Situated Cognitive Engineering

This research is using the Situated Cognitive Engineering method (sCE) [6]. This method was designed by the TU Delft and TNO for complex, intelligent and interactive technology. The sCE method allows quick, incremental and iterative cycles, which requires researchers to continuously specify, refine and integrate different parts of the system. It supports the collaborative process of multi-disciplinary teams as it addresses human factors, technical and operational issues. An active involvement of stakeholders is also included to understand users' support needs and to enhance user acceptance. As the overall PAL project also uses sCE, this research involves the usage of sCE for the creation of a module in several iterations.

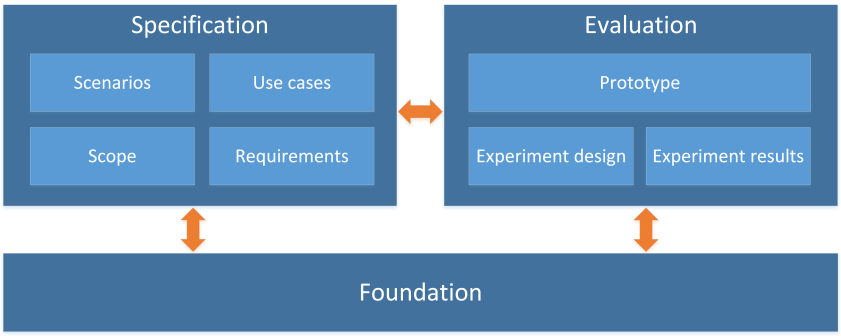

Figure 2.1. Situated Cognitive Engineering method

The upcoming chapters are formed according to the segments from the sCE method. As seen in figure 2.1, sCE distinguishes three main segments: Foundation (chapter 3), Specification (chapter 4) and Evaluation (chapter 5).

2.1 Foundation

The theoretical framework or background is called foundation in the sCE method. The foundation segment describes the relevant existing knowledge on ways to solve the problem. It also contains envisioned technologies or available options to develop the new solution. These can use existing technologies or involve the creation of new technologies.

2.2 Specification

The specification describes the system design of the solution. It is based on the identified relevant human factors knowledge and the envisioned technology from the foundation layer. The specification consists of the design scenarios, the use cases, the artifact scope and the requirements.

2.3 Evaluation

The evaluation segment aims to test and validate the system's design, or to compare multiple design options in order to improve the current design in an iterative way. The three relevant parts of the system evaluation are: the artifact (an implementation or prototype), the evaluation method (experiment design) and the evaluation results in which the claims are tested. The experiment was designed and conducted by the PAL consortium and therefore out of the scope of this thesis. The creation of the prototype that was tested in this experiment as well as the analysis of the results are part of this thesis work. The experiment design is, however, still described in § 5.2 for completeness.

Chapter 3

Foundation

The following theories are part of the foundation:

Chapter	Theory	Relevant SQ
§ 3.1	Self-Determination Theory and Intrinsic Motivation	SQ2, SQ5
§ 3.2	Goal-Setting Theory	SQ2, SQ5
§ 3.3	Ontology	SQ1 - SQ5
§ 3.3.1	PAL Ontology and handling time	SQ1 - SQ5
§ 3.4	Episodic memory	SQ1 - SQ5
§ 3.5	Retroactive learning	SQ1
§ 3.6	Affection-based Episode Ontology	SQ1
§ 3.6.1	5W1H Extraction	SQ1
§ 3.7	Motivational interviewing	SQ2, SQ4, SQ5
§ 3.8	Nudge	SQ2, SQ5
§ 3.9	Self-disclosure and long term interaction	SQ2, SQ5

Table 3.1. Foundation overview

3.1 Self-Determination Theory and Intrinsic Motivation

The Self-Determination Theory (SDT) is a fusion of two different theories about psychological growth and personality development. The first view assumes that the will to learn new capabilities is congenital. In other words, the motivation to facilitate psychological growth is natural behaviour. In the second view it was argued that external factors are necessary for the learning process. The social context of a human influences the self-development and thus facilitates psychological growth. Ryan and Deci combined these two views into the SDT. They assume that people have the natural tendency for self-development, but the environment can either facilitate or undermine this. In order to facilitate this growth, three main needs are required from the environment: competence, relatedness and autonomy [7].

Deci and Ryan also presented the Cognitive Evaluation Theory (CET) as a subtheory within SDT. This theory involves the specification of factors that influence intrinsic motivation. Intrinsic motivation is the inherent tendency to seek, learn and explore new capabilities. CET focuses on the effects of social-contextual events (e.g. feedback or rewards) on intrinsic motivation. CET also specifies that only the combination of competence and autonomy will enhance intrinsic motivation. Some studies also show that the factor relatedness can influence intrinsic motivation, however, Deci and Ryan suggest that there is a stronger link between the intrinsic motivation and the combination of competence and autonomy [7]. Intrinsic motivation is essential when it comes to achieving goals.

3.2 Goal-Setting Theory

Alongside intrinsic motivation, the goal setting theory is helpful in achieving goals. It concerns the relation between conscious goals, intentions and task performance. Based on different studies, Locke concluded that specific and challenging goals lead to higher performance than easy goals, 'do your best' goals, or no goals at all. Goal setting is most likely to improve the task performance when specific and sufficiently challenging goals are used [8]. Giving summary feedback during the achievement of a goal results in an even higher performance. Becker describes this as one of the best-established findings in psychology [9].

3.3 Ontology

Hoekstra describes the term Ontology as a method of knowledge representation. This is a field of Artificial Intelligence that deals with problems regarding the design and use of formal languages that are suitable for capturing human knowledge. It is a way to translate human knowledge to a computer model. The ultimate goal is to perform intelligent automated reasoning on these models. This knowledge-based reasoning can be used to perform tasks that are normally carried out by humans, but can, for example, involve large amounts of data which is difficult for humans to process. [10] Ontologies are often designed in the Web Ontology Language (OWL); a Semantic Web language designed to represent rich and complex knowledge about things, groups of things and relations between things [11]. It builds on top of the Resource Description Framework (RDF) which is a specification of how to write triples (e.g. Mary - eats - a pancake). Using OWL, the aspect of semantics is included to write a valid ontology.

3.3.1 PAL Ontology and handling time

Krieger et al. described the ongoing work carried out in the PAL project which described the unified ontology that was constructed [12]. It consists of seven independently developed sub-ontologies which were combined in an eighth sub-ontology

using a set of hand-written interface axioms. They extended the triple model of RDF by adding two extra arguments in order to represent time-varying data. The information within the PAL system was categorized as TBox (terminological knowledge), RBox (general information about properties), and ABox (assertional knowledge). The TBox and RBox of the PAL domain stay constant and will not change over time. The relation instances in the ABox might change over time (e.g. the weight of a child can change, but the birthdate will not). The PAL project used HFC as a semantic repository and bottom-up forward chainer in order to store the TBox and RBox information, but also to query the ABox time-varying data. A use case for this would be the processing of dialogs, which uses if-then-like rules in order to match those against dialog situations. Both the matching information as well as the derived new information is grounded in time, thus the time sequence should be recorded. Another use case is the progression of goals to inform the child, its parents and the healthcare professionals on the current status of self-management. The progression is also important for the PAL system to provide suitable content and activities. The children can achieve goals over time by answering quiz questions or by doing other activities. As soon as the child masters all the related knowledge or skills, the goal is achieved.
The next step for the PAL Ontology will be the creation of a sub-ontology that is able to capture episodic memory.

3.4 Episodic memory

Endel Tulving was the first to describe episodic memory 45 years ago [13]. The concept of episodic memory has changed a lot since then. Nowadays, episodic memory is seen as one of the major neurocognitive memory systems that allows humans to re-experience their own previous experiences. Turing describes it as “a possibility for mental time travel through subjective time, from the present to the past” [14]. The application of episodic memories in intelligent agents, as described by Nuxoll, makes task-independent episodic memories possible that support a wide range of cognitive capabilities within a cognitive architecture [15]. They made an artificially intelligent agent that was able to demonstrate five cognitive capabilities: virtual sensing, action modeling, decision-making based on past experiences, retroactive learning and boosting other learning mechanisms.

3.5 Retroactive learning

Nuxoll also described retroactive learning in the same paper. This is the theory of understanding an experience or review of learning experiences when resources become available [15]. It is, for example, useful to schedule the intense use of resources later, when the system is not in use. As a memory is, by definition, in the past, it does not matter if it is captured after the conversation with a child. This concept can therefore be used for the resource intensive algorithms that the capture process of an episodic memory can bring.

3.6 Affection-based Episode Ontology

Lim et al. describe an affection-based episode ontology [16]. In this model, they combined Ontology-based unified robot knowledge (OUR-K) [17] with temporal episode ontology in order to model event episode knowledge. They state that knowledge about an event episode can be closely related to an emotion. Therefore, they added emotion ontology to episode ontology. As a result, the following affection-based episode ontology was defined:

- Definition 1: Affection-based Episode Ontology (AEO)
  AEO = [TES, Emotion]
  TES is Temporal Episodic Structure,
  Emotion is Emotion ontology,

- Definition 2: Temporal Episodic Structure (TES)
  TES = [When, Where, Who, Why, What, How, Inst]
  When is Time ontology,
  Where is Space ontology of OUR-K,
  What is Object ontology of OUR-K,
  Who is Human ontology of OUR-K,
  How is Action ontology of OUR-K,
  Inst is additionally recognized knowledge instance of OUR-K

3.6.1 5W1H Extraction

The temporal episode ontology from the previous section is built around the 5W1H (When, Where, Who, Why, What and How) principle. In the paper of Han et al., a method to extract the 5W1H from natural language is described [18]. They designed a Natural Language Understanding module that used a conditional random field (CRF) model [19], combined with lexical word features (lexical trigrams) to train their model. This was used to create a counseling dialog system. The system was able to interact with users by recognizing what the users said, by predicting the context, and by following the users' feelings. The counselling was done using three basic counselling techniques in order to attend and show empathy with clients: open questions, paraphrasing and reflection of feelings. This could become interesting as a method to capture the shared experiences between the child and PAL actor.

3.7 Motivational interviewing

In addition to the capturing of episodic memory, an episode also needs to be referred to in a proper way. Motivational Interviewing (MI) [20] is a method of interacting with patients in order to enhance behaviour change. It tends to improve the patients own motivation and commitment to change. The method is well-tested and established with over 160 randomized clinical trials. It defines three ways of interaction with the patient: directing, following and guiding. In the directing style, the practitioner provides information, instruction and advice. The following style is doing the opposite by listening and understanding to the patient but respectfully refraining from inserting his/her own material. Motivational Interviewing is mostly built around the guiding style. Guiding lies between and incorporates elements of the directing and following styles. The overall goal is to guide the patient through the proper thought processes that will inevitably result in the salient reason for behaviour change. MI is built around the principles of partnership, acceptance, compassion and evocation. The partnership implies that it has to be done 'for' or 'with' the patient and not 'on' or 'to' them. Related to this partnership is acceptance of what the client brings. Compassion is a deliberate commitment to pursue the welfare and best interests of the other. Lastly, evocation is to detect deficits to be corrected and to install those. The implicit message is "I have what you need, and I'm going to give it to you". MI uses five different communication styles that are shared with many forms of counseling: asking open questions, affirming, reflective listening, summarizing, and providing information and advice. In order to improve the intrinsic motivation and with that the diabetes self-management of the children, the PAL actor could use the communication styles from MI.

3.8 Nudge

Alongside the techniques from motivational interviewing, a nudge can be useful to motivate the users to achieve certain goals. Thaler and Sunstein developed the nudge theory [21]. A nudge can be described as a push in the right direction. It is used to design policies that push individuals toward better choices without limitations on their liberty, also known as 'libertarian paternalism'. It is allowed to influencea the behaviour of others to improve their quality of life (paternalism), but it should be unobtrusive and not an obligation (libertarian). The famous example is to have fruits on the counter and place the unhealthy food a bit further away at high schools. This nudge is used in order to make children eat more healthy food. A nudge in the context of the PAL project could be that by achieving a goal, children will also receive a reward. It is still a choice to achieve goals, but the children will become extra motivated in order to earn the reward. For example, during the diabetes camps where the PAL robot also appears, the reward could be to do a fun activity with the robot, like dancing. In the home situation, children could be allowed access time to use games or apps out of the PAL context. This is, however, out of the scope for this research.

3.9 Self-disclosure and long term interaction

It is considered difficult to keep children interested in a companion agent after the novelty effects wear off. Burgers presented a way to include self-disclosure in long-term child-avatar interaction as a way to cope with this problem using different theories. [22] The Self-Determination Theory argues that motivation is sustained if the human feels related to the agent. According to the Social Penetration Theory, this relatedness can be forged through the reciprocal disclosure of information about the self. As a result, a disclosure dialog module was developed to study the self-disclosing behaviour of children in response to that of a virtual agent. The module was implemented in the PAL system. Tests showed that the relative number of disclosures was an indicator for the relatedness children felt towards the agent at the end of the study. Also, girls disclosed significantly more than boys and children preferred to respond to avatar disclosure of lower intimacy.

Chapter 4

Specification

This chapter contains all the specifications that have been used in order to build a prototype for the PAL actor. It contains the scenarios, the use cases, the scope of the artifact and the requirements.

4.1 Scenarios

4.1.1 Scenario 1: Feedback on goals

Esther had her first encounter with robot Charlie in the hospital a little over a week ago. During the meeting, the nurse discussed the first set of goals with Esther and her parents. In the days after the meeting, Esther played with the PAL app once or twice per day. The PAL avatar gave summarized feedback on her goals on a daily basis. It was quite clear that she had mastered one of the goals. After a phone conversation with the nurse, the goals were adjusted in order to challenge Esther a bit more. The previous time, the PAL robot was part of the meeting in the hospital, but could of course not attend the phone conversation. Esther wanted to see if the new goal was updated in the app. The avatar knew that the goals were changed, but it did not attend a meeting together with the nurse and the child. The avatar asked: “Hey! Did you have a conversation with the nurse over the phone today?”. Esther confirmed this and explained the new goals. The avatar replied: “Oh, great to see that you understand the goals! Shall we start?”. Afterwards, Esther and the avatar played the quiz with newly added questions.

4.1.2 Scenario 2: Measurements of blood sugar

Fred loves playing soccer with his friends. He does not like to worry about his diabetes all day and relies quite a bit on his mother. She makes sure that the blood sugar levels are measured and that the carbs are counted well. He does like to interact with the PAL app, but he often skips it in order to play soccer after school. When he launched the app one day, the avatar greeted him: “Hey, I did not see you in a while! How are you doing?”. Fred wrote to the avatar: “Hey! I was playing soccer with my friends again yesterday and today!". The avatar replied: "Oh, that's really nice! I can imagine that you did not have time to fill in your blood sugar levels yesterday. Do you still have them for me? I'm curious about how you did.". He asked his mother what his values were yesterday and added them to the diary.

4.1.3 Scenario 3: Activity

Maaike returned home from school. She had a hypo during gym class and therefore she had to quit. Maaike was quite angry at herself because she knew that she in fact did not eat enough before she started. As soon as she arrived, she took the tablet out and started the PAL app. She wrote about what happened in the diary. The avatar replied: "That is very unfortunate! I really do appreciate the fact that you shared this with me.". One week later, Maaike returned home from the gym again. Luckily, she was well prepared this time. She was very happy and excited. After she told her mother about the day at school, she grabbed the tablet and greeted the avatar. The avatar asked Maaike if she had gym lessons again and if it went better than previous week. She told the robot enthusiastically that she indeed had gym class which went very well as she paid special attention this time. The avatar gave her a compliment in return: "Well done Maaike!".

4.2 Use cases

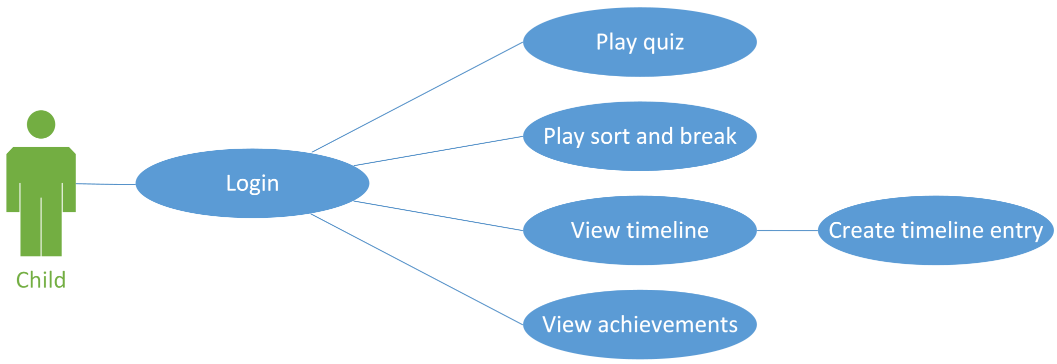

Figure 4.1. Use case diagram

In figure 4.1, the identified use cases from the MyPAL app are shown. In this research project, only alternative flows will be added to the existing main flows. As an example, the login use case including the added alternative flow is shown in Table 4.1 and Table 4.2.

Name	**Login**
ID	1.0
Summary	A child can login to the PAL system
Primary actors	Child
Secondary actors	
Preconditions	An account has been made for the child
Main Flows	1. Actor launches the app 2. Actor enters name and password 3. Actor selects ‘Login’ 4. System checks the combination of name and password [1] 5. System opens the main menu with the virtual avatar [2] 6. Virtual avatar welcomes the user with a question 7. Actor enters answer and selects ‘OK’ [3]
Postconditions	Main menu is visible. Actor may proceed with an activity.
Alternative	[1] No internet connection [2] Username / password wrong [3] Stored episode available with OnLogin trigger

Table 4.1. Login use case description: Main flow

Name	**Stored episode available with OnLogin trigger**
ID	1.3
Summary	If an episode is available with the OnLogin trigger, mention the episode.
Primary actors	Child
Secondary actors	
Preconditions	Unmentioned episode with OnLogin trigger is captured in an earlier session
Main Flows	1. System refers to episode
Postconditions	Continue with 1.0 postconditions
Alternative	

Table 4.2. Login use case description: Alternative flow

4.3 Scope

The following scope is defined for the artifact:

Iteration	**Subject**
Iteration 1	Goals and progress *Example: Shall we practice goal X again? Previous time it was quite challenging, remember?*
Iteration 2	Blood sugar measurements *Example: Oh, you forgot to fill in your measurements yesterday. Do you still have them for me?*
Iteration 3	Activities *Example: How was the birthday party? Did the organizer take your diabetes into account?*

Table 4.3. Artifact scope

4.4 Requirements

The functional requirements in this section are defined per iteration. Each iteration has a claim that corresponds with the hypothesis in § 1.4.

Iteration 1: Goals

ID	Requirement	Prio*
G01	**The PAL actor shall motivate the child to play the quiz again**	**S**
G01A	in case that the child is almost done with achieving a specific goal.	S
G01B	in case that a specific goal was too difficult for the child during the previous session	S
G02	**The PAL actor shall mention the overall goal progress of the child**	**S**
G02A	when the child launches the app (e.g. previous time we achieved goal X, let's go for goal Y today!)	S
G02B	when the child finishes a quiz game (e.g. we are almost done with goal X, let's finish it next time!)	C
G03	**The PAL actor shall notice changed goals that were set by the nurse**	**S**
G03A	at home: the virtual avatar shall ask the child if (s)he had a phone call with the nurse (not a shared experience)	S
G03B	in the hospital: the physical robot shall show awareness of the new goals (as it is a shared experience)	C
G04	**The PAL actor shall be aware of situational differences (hospital, camp, app)**	**C**
G04A	in this way, the PAL actor is able to mention the location it was previously at (e.g. we finished goal X in the hospital together)	C

Table 4.4. Requirements iteration 1

Claim: Children will stay motivated to play the quiz.

Iteration 2: Measurements

ID	Requirement	Prio*
M01	**The PAL actor shall remind the child to enter a measurement from the past**	**S**
M01A	in order to get a complete overview of the measurements (e.g. hey, you forgot to enter a measurement for yesterday's dinner. Do you still have that one perhaps?)	S
M02	**The PAL actor shall give summarized feedback over measurements**	**C**
M02A	for example to tell the child that the values were all in range for the past week	C
M02B	for example to ask the child if (s)he knows why the values were mostly out of range during the day	C

Table 4.5. Requirements iteration 2

Claim: Children will stay motivated to add diary entries.

Iteration 3: Activities

ID	Requirement	Prio*
A01	**The PAL actor shall extract an event from the child's input**	**S**
A01A	using the 5W1H model (Who, what, where, when, why, how)	S
A02	**The PAL actor shall store a trigger for referring to an event in the future**	**S**
A02A	in this way, when the event is over, the ECA can refer to this (e.g. did you enjoy event X?)	S
A03	**The PAL actor shall ask the child specific questions based on knowledge databases**	**C**
A03A	when the child, for example, mentions a place, the PAL actor could ask if (s)he saw highlight X of that place)	C

Table 4.6. Requirements iteration 3

Claim: Children have a higher affection with the PAL actor.

** MoSCow prioritization (M=must have, S=should have, C=could have, W=won't have)*

Chapter 5

Evaluation

This chapter starts with the development of the prototype. Afterwards, the experiment in which the prototype was tested will be discussed.

5.1 Prototype

5.1.1 Context viewpoint

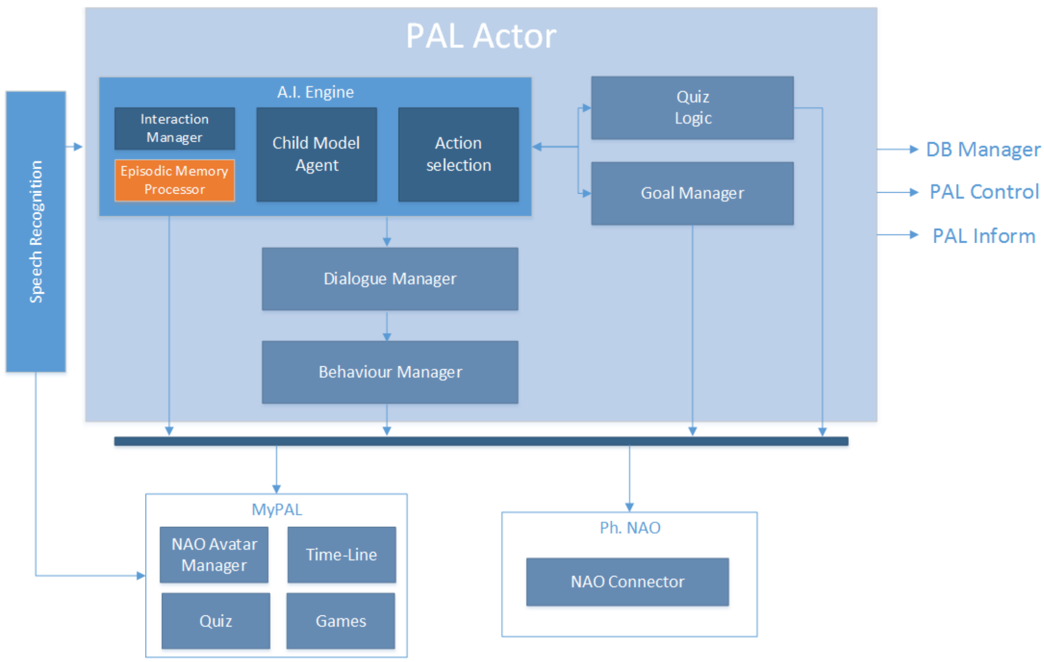

Figure 5.1. PAL overview

In figure 5.1, the architecture of the PAL system is shown. The Episodic Memory Module is added to this and marked orange. It is part of the A.I. Engine.

5.1.2 Functional viewpoint

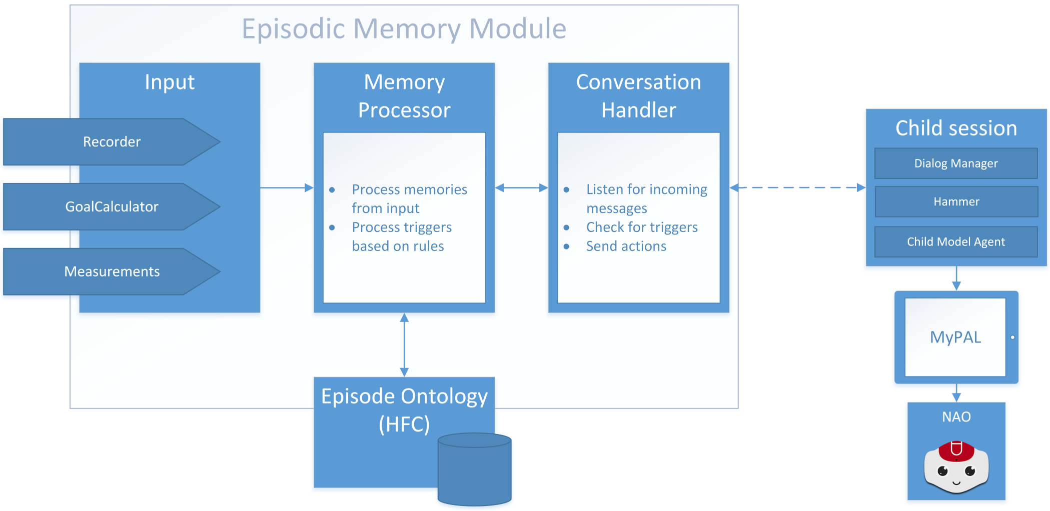

Figure 5.2. Overview of the Episodic Memory Module

The Episodic Memory Module consists of four parts: the input connectors, the memory processor, the episode ontology and the conversation handler. The input connectors provide the source for the memories. The memory processor gathers memories from these inputs and saves these into episodes (Episode ontology in the HFC database). Based on rules, each episode is tagged with possible triggers. As soon as a child session is live, the conversation handler listens to the session. It checks in the memory processor if there are memories available for specific triggers. When this is the case, the conversation handler forms an action and passes this on to the child session.

5.1.3 Ontology design

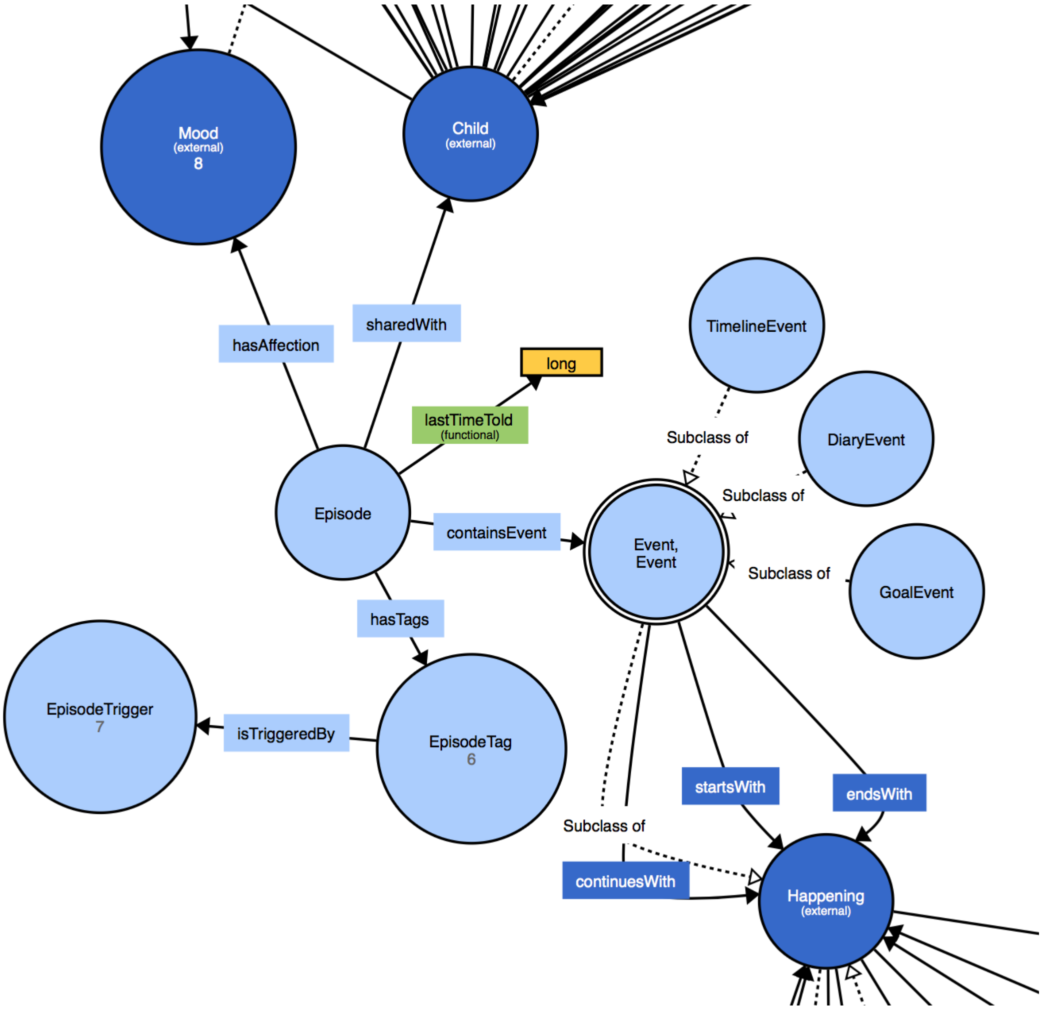

Figure 5.3. Visualization of episodic memory ontology, generated by WebVOWL

In figure 5.3, the relations in the episodic memory ontology are visualized. The Episode class is the main element that defines the memory. The concept of 5W1H (When, Where, Who, Why, What and How) is achieved using the relations. 'Who' is the child that has been mapped to the episode. 'When' is mapped in an Event, which is a subclass of the already existing ontology of a Happening. The 'What' is an Entity, that is also stored in the superclass Happening. The 'How' is mapped to the Happening in the form of an already existing class Activity, which involves a certain action like cooking, playing, or performing the quiz. The 'Why' was the most difficult part to map into an ontology. For now, it's part of the EpisodeTag. The EpisodeTag has several instances which defines the 'What' and implies the

'Why'. For example, the EpisodeTag contains an instance 'GoalWasTooDifficult'. The 'What' in the tag is a goal, but the specific instance of this goal is stored in the Event. In addition to the GoalWasTooDifficult, there are other instances like 'GoalAchieved' and 'GoalAlmostAchieved'. These EpisodeTags are important, as they are used to define what triggers them. This is done using the relation to EpisodeTrigger. A trigger is, for example, 'OnChildLogin' or 'QuizCompleted'. The relation between the Trigger and Tag is made to define when to mention a specific episode.
The current PAL ontology contains three different mappings of an emotion. They all have their pros and cons. To cope with this problem, they will soon be replaced by a new ontology of an emotional state, which would become the only mapping of an emotion in the PAL domain. The emotion is currently mapped as the already existing class 'Mood', but it is in fact a placeholder.

5.1.4 Reasoning mechanism

Dialog generation

The dialogs of the robot are being generated in the dialog manager project within the PAL project. This subproject is managed by the PAL project partner DFKI (Deutsche Forschungszentrum für Künstliche Intelligenz GmbH). In order to refer to episodic memories, a dialog for the robot should be written. DFKI developed a language for defining these dialogs, called Content Planner (CPlan) [23]. It uses a set of rules which all have a match part and an action part. The rule applies if the first part matches the input (also called SpeechAct). The action part is then executed which forms the actual dialog.

Rule

```
//SuggestPlayQuiz
:dvp ^ <SpeechAct>suggestion ^ <Content><About>Activity ^ <what>quiz
->
# ^ :canned ^ <stringOutput>concatenate("Shall we ", random("play", "do", "check out", "start")," the
quiz ", random("today", "soon", "now", ""), random(" in order to practice a bit extra ", " ", " so we
can continue our work on the goals "))
        ^ <SpeechModus>interrogative.
```

Action

Figure 5.4. CPlan example

As seen in the example dialog in figure 5.4, the first part defines the rule and the second part the action. The SpeechAct is a suggestion, and the content is about an activity. The activity in question is a quiz. This implies that the robot wants to suggest that the user does the activity 'quiz'. The action part forms a string which will become the spoken dialog from the robot. The syntax makes it possible to generate a variety of dialogs from one action. Two possible dialogs in the example are: 'Shall we play the quiz soon?' or 'Shall we check out the quiz today so we can continue our work on the goals?'.
The rule part can also contain variables which are usable in the action part. This is,

for example, used in the mentioning of specific goals. It could, for example, create a sentence: 'We finished the goal counting carbs yesterday.' in which 'counting carbs' is a variable associated with a specific goal.
These variables could also help to implement the dynamic aspects of the human memory. Forgetfulness could be simulated by creating very specific dialogs and gradually less specific dialogs. It would be possible to have a dialog as specific as 'The goal correct a hypo was a bit difficult yesterday in the quiz.', but also as general as 'Previous time, the quiz was quite difficult.'. Also, memory combining could be possible by having multiple subjects in the SpeechAct. It could, for example, generate a dialog that mentions that the goal was difficult but, after lots of practice, it is almost achieved. All possible sentences that are implemented from the scope of iteration 1 are defined in figure 5.1.4.

What	**Variations**	**Example sentence**
Goals updated	5	It looks like you have three new goals that we can work on! I see that you got some new goals!
Goal almost achieved	3	The previous time, we almost achieved the goal counting carbs! The goal counting carbs is almost done! Just a tiny bit of work left and we are able to finish the goal counting carbs!
Goal completed	2	We finished the goal counting carbs the previous time. Previous time you achieved the goal counting carbs!
Goal was too difficult	2	The goal counting carbs was a bit difficult the previous time. Previous time that we practiced the goal counting carbs, it was a bit challenging.
Suggest play quiz	48	Shall we start with the quiz? Shall we do the quiz soon in order to practice a bit extra? Shall we check out the quiz now so we can continue our work on the goals?

Table 5.1. Sentences currently possible in CPlan

Reasoning flow

Two different flows for reasoning about episodes have been identified:

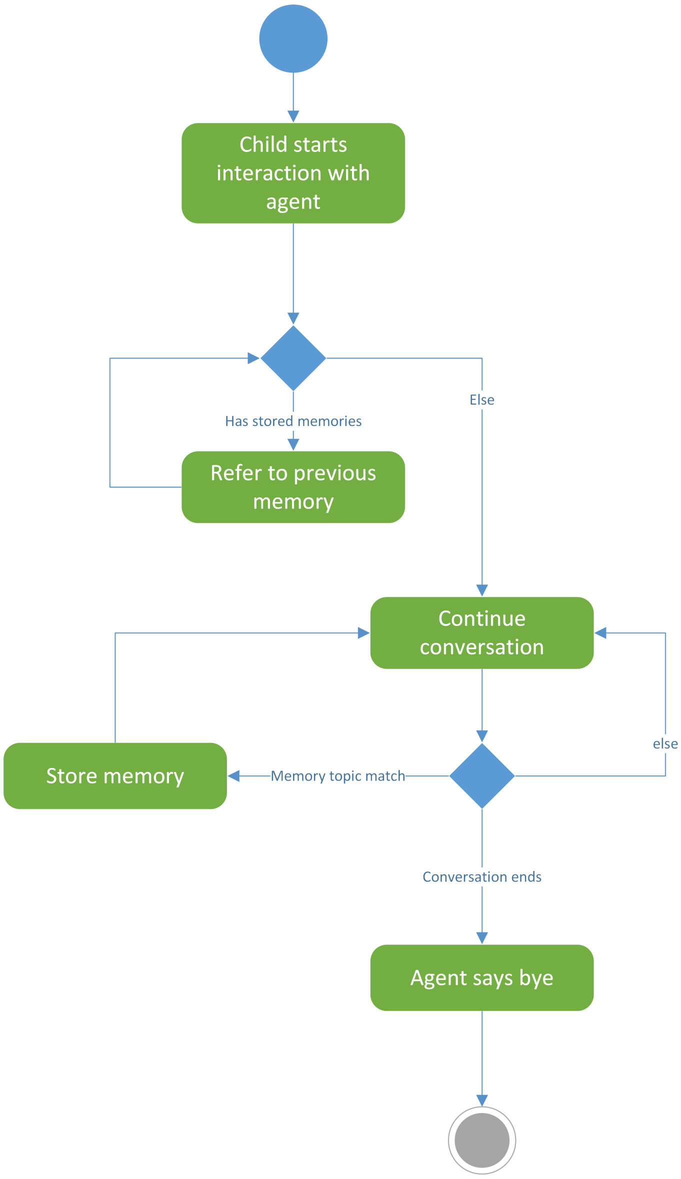

Figure 5.5. Reasoning flow 1: refer at the beginning

The first flow involves one fixed moment at the beginning of a conversation to refer to a previous memory. The second one is more dynamic and also involves the retrieval of episodic memory during the conversation.

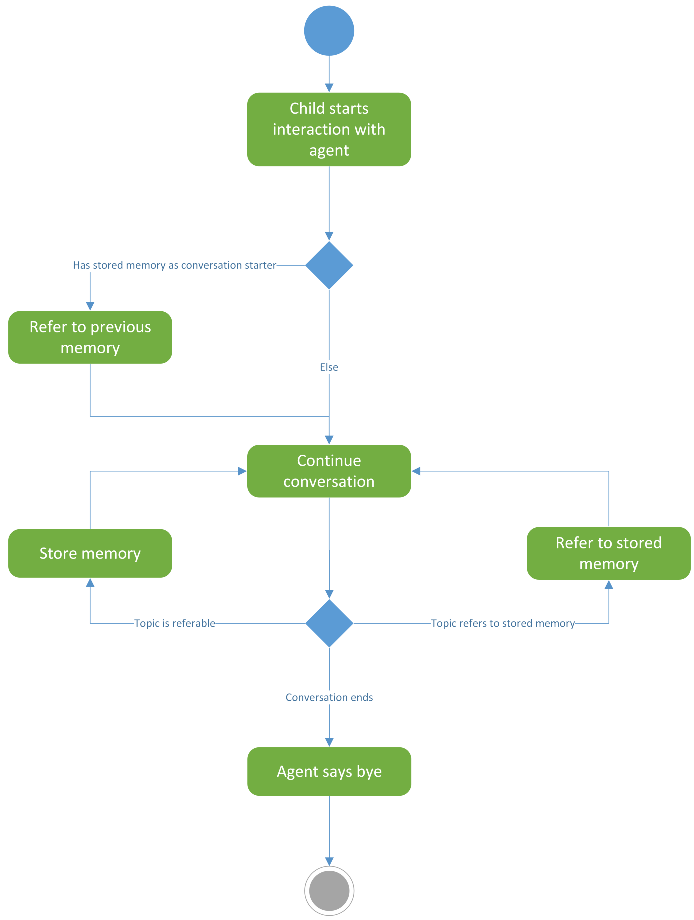

Figure 5.6. Reasoning flow 2: refer at the beginning and during conversation

The second flow would be preferable for iteration 2 and 3 as these contain feedback that is given during a conversation as seen in the scenarios (§ 4.1). The first flow would be sufficient for iteration 1, as referring to a goal or achievement is only done at the beginning of a session. Therefore, the first flow will be implemented in iteration 1 and can be extended to the second flow in iteration 2.

The moment to mention the episode is defined in the ontology using the EpisodeTrigger. In iteration 1, only the trigger 'OnChildLogin' is used which complies to reasoning flow 1. Each trigger has to be implemented in the right part of the dialog flow within the dialog manager. The part that handles the child login should therefore check for possible episodes to refer to which can be triggered using the 'OnChildLogin' trigger. This will generate a dialog which mentions the episode. Each mention of an episode updates the lastTimeTold value in the ontology. This prevents the robot from mentioning the same episode twice.

5.1.5 Artifact

The final artifact that was created for the experiment contained the scope of iteration 1. It was able to capture memories and refer to them according to reasoning flow 1. All requirements from iteration 1, except for requirement G02B and G04 (both with lower priority), were successfully implemented (see Table 4.4). In figure 5.7 below, the robot refers to an almost achieved goal and gives the suggestion to play the quiz afterwards.

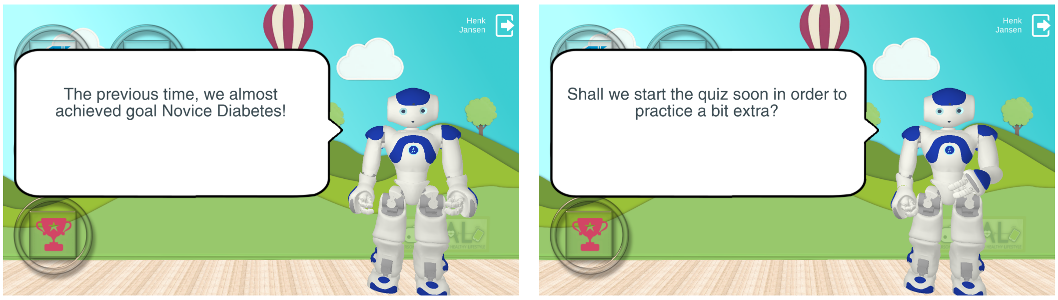

Figure 5.7. Charlie refers to an almost achieved goal

5.2 Experiment design

As this research is a small part of the bigger PAL project, the execution of the experiment will be out of the scope of this thesis. This is organized by other project members. The processing of the results that are relevant for this thesis will of course be within the scope. For completeness, the experiment is described briefly in this section. The full experiment protocol is added as an appendix (see Appendix C).

5.2.1 Participants

The participants will be children with T1DM (age 8 - 12), recruited from the hospitals or associations of the PAL consortium (Meander MC and Stichting ziekenhuis Gelderse Vallei -NL- and Ospedale San Raffaele -IT-) with a minimum number of 10 to a maximum number of 15 subjects per hospital. Thus, a total pool of 30 to 45 subjects will be ensured. The parents are also involved in the research.

5.2.2 Ethics

As this experiment involves the use of a humanoid robot in a medical context with children, the ethical considerations are important. This section will only highlight some aspects of the considerations as the full protocol is added in Appendix C. The PAL actor is made to be strictly educational and it will not manage the diabetes in any way. Therefore, it will not give suggestions on, for example, the insulin dosages or the estimated carbohydrates. The consent form has to be signed by both parents or a legal guardian in the case of parental separation. Data will be in a totally anonymous form within publications or scientific conferences. The data from the Dutch participants is stored at TNO in the Netherlands in a secure environment. Data can be deleted any time at the request of the parents of the participating child. The protocol was approved by the ethical committee of the European Commission.

5.2.3 Materials

Every child will receive a tablet with the MyPAL app, containing the virtual robot. Every hospital will have a physical NAO robot. As well as the NAO robot, every hospital will have access to a tablet on a rotating stand for the quiz and a touchscreen table for the games.

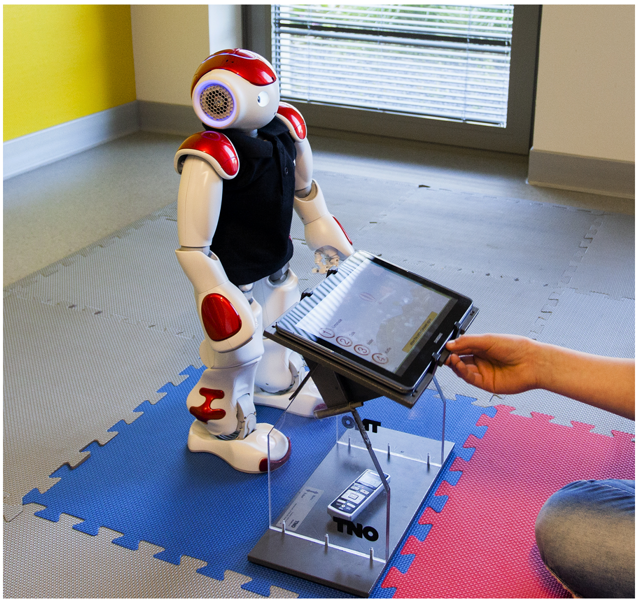

Figure 5.8. PAL robot and rotating tablet in Meander MC. Photographed by Rifca Peters in 2016

5.2.4 Procedure

The experiment will take place in three hospitals. The two hospitals in the Netherlands will organize the experiment from the end of May 2017 untill the end of August 2017. The experiment at the hospital in Italy will take place from the end of June untill the end of September.

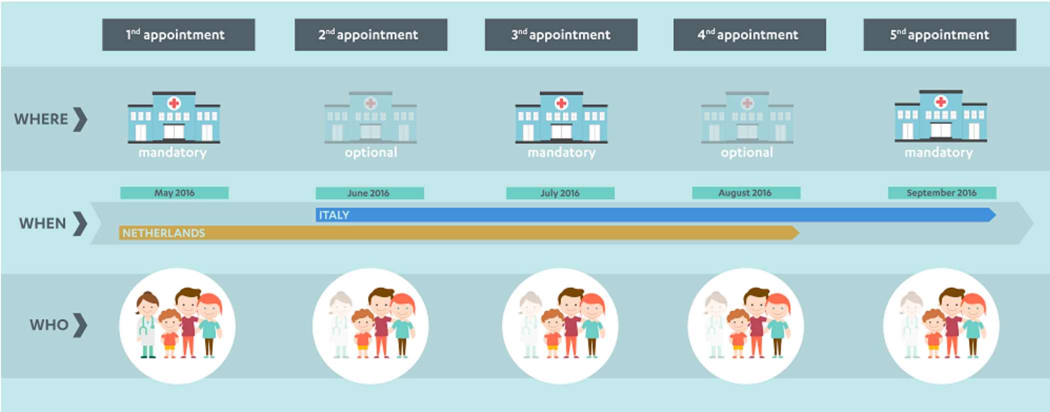

Figure 5.9. Experiment timeline (see Appendix C)

Every child will use the PAL system for approximately four months. In these four months, four appointments at the hospital are scheduled. During these appointments, the children can play with the physical NAO robot. Only the first and third appointment have a mandatory attendance in the hospital. The second and third appointment contain changes to the PAL system.

Appointment	PAL improvements
T1	Initial version
T2	Major update for diary in the MyPAL app
T3	Episodic memory update
T4	No changes

Table 5.2. PAL improvements during appointments

The episodic memory update will contain at least the first iteration of the episodic memory module. That includes memorizing as well as referring to achieved goals and related progress. The second and third are considered optional and can be implemented after this experiment.

The children as well as the parents are asked to fill in an EMA (Ecological Momentary Assessment) survey on a weekly basis. All questions have an answer option with a continuous Likert scale, which is stored as a score between 1 and 9. The survey questions for the children are shown in Table 5.3.

Claim	EMA question
Well-being	1. How do you feel right now?
Affection	2. Do you see the robot as a good friend?
Similarity	3. Is the robot in the app the same as the robot you have met in the hospital?
Motivation	4. Are you looking forward to play with the robot right now?
Diabetes Self-Management behaviour	5. Does the robot help you well in diabetes activities?
Diabetes knowledge	6. Does the robot teach you a lot about diabetes?

Table 5.3. Survey questions for children

The questions for the parents are stated in Table 5.4. The survey for parents also has an additional comment field in contrast to the survey for children.

Claim	EMA question
Stress	1. Do you often worry about your child?
Disclosure	2. How often does your child talk about diabetes?
Diabetes Knowledge	3. How much does your child know about diabetes?
Diabetes Self-Management Behaviour	4. How many diabetes activities can your child do him/her-self right now? (for example count carbs or prick him/her-self)
Motivation	5. Is your child motivated to play with the robot app?

Table 5.4. Survey questions for parents

Not all survey questions are relevant for the research in this thesis, but are meant for other researchers within the PAL consortium. In order to answer the research questions and confirm the claims, the questions regarding affection, motivation and diabetes self-management behaviour are included in the evaluation.

5.2.5 Data collection

The data will be collected from three sources. Usage data will be extracted from the HFC database in the PAL system. A method to retroactively capture episodes was developed by checking the episode conditions on each database insert from the past. Therefore it was possible to measure the number of episodes that could have been made before its implementation. In addition to the PAL system, a weekly survey from both the parents and the children will be used. In Table 5.5, the relevant topics and sources are defined.

Topics	**Source**
Usage (sessions per child)	HFC database
Goals (progress and achievements per child)	HFC database
Episodes (stored and that have been referred to)	HFC database
Motivation and affection over time	Survey (parents and children)
Self-management behaviour	Survey (parents and children)

Table 5.5. Data collection

The topics and sources were used to form two different data files. The first one was ordered per participant per week. The second one was ordered per participant per session. In this way, it was possible to extract more detailed information regarding the usage of the system, but maintain one dataset with all sources combined. The variables are defined in Table 5.6.

Data	**When**	**Description**	**Value**
ParticipantId	T1	General identifier used to combine data from different sources	Text
Gender	T1	Gender of participant	Text
Age	T1	Age of participant	Number
Hospital	T1	The hospital that provides diabetes care for the participant	Text
Active	On change	1 = Active, 0 = Participant stopped	Number (0/1)
Child_q1	Weekly	Question regarding well-being	Number (1-9)
Child_q2	Weekly	Question regarding affection	Number (1-9)
Child_q3	Weekly	Question regarding similarity	Number (1-9)
Child_q4	Weekly	Question regarding motivation	Number (1-9)
Child_q5	Weekly	Question regarding diabetes self-management behaviour	Number (1-9)
Child_q6	Weekly	Question regarding diabetes knowledge	Number (1-9)
Parent_q1	Weekly	Question regarding stress	Number (1-9)
Parent_q2	Weekly	Question regarding disclosure	Number (1-9)
Parent_q3	Weekly	Question regarding diabetes knowledge	Number (1-9)
Parent_q4	Weekly	Question regarding diabetes self-management behaviour	Number (1-9)
Parent_q5	Weekly	Question regarding motivation	Number (1-9)
Parent comment	Weekly	Additional comments from parents	Text
TotalGoals	Weekly	Total number of goals set for the participant	Number
TotalAchieved	Weekly	Total number of goals that the participant achieved	Number
Sessions	Weekly	Number of sessions that a participant had	Number
QuizPlayed	Weekly	Number of sessions with at least one played quiz	Number
EpisodeMentioned	Weekly	Number of sessions with a mentioned episode	Number
EpisodeTag	Per session	Episode subject that was mentioned	Text
StartTime	Per session	Login time of a session	Timestamp
EndTime	Per session	Logout time of a session	Timestamp

Table 5.6. Variables

5.3 Experiment results

The gathered results in this chapter are only based on the data from the Dutch hospitals. Unfortunately, the Italian hospital data was delayed and therefore could not be included in this thesis research.

5.3.1 Participants

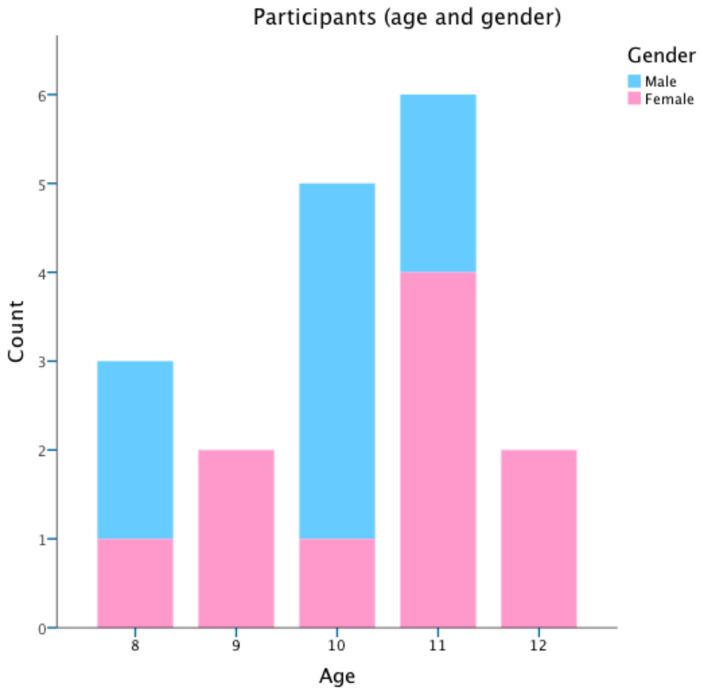

Figure 5.10. Participants: age and gender

As seen in figure 5.10, there were 18 participants in total in the Netherlands. Eight of them were boys and ten were girls.

5.3.2 Usage

The usage of the system over time is shown in figure 5.11. The usage was calculated using the cumulative child sessions that were sorted by date. Every successful child login attempt was considered to be a session. The first blue reference line marks the timeline update (T2) and the second reference line marks the implementation of the episodic memory (T3).

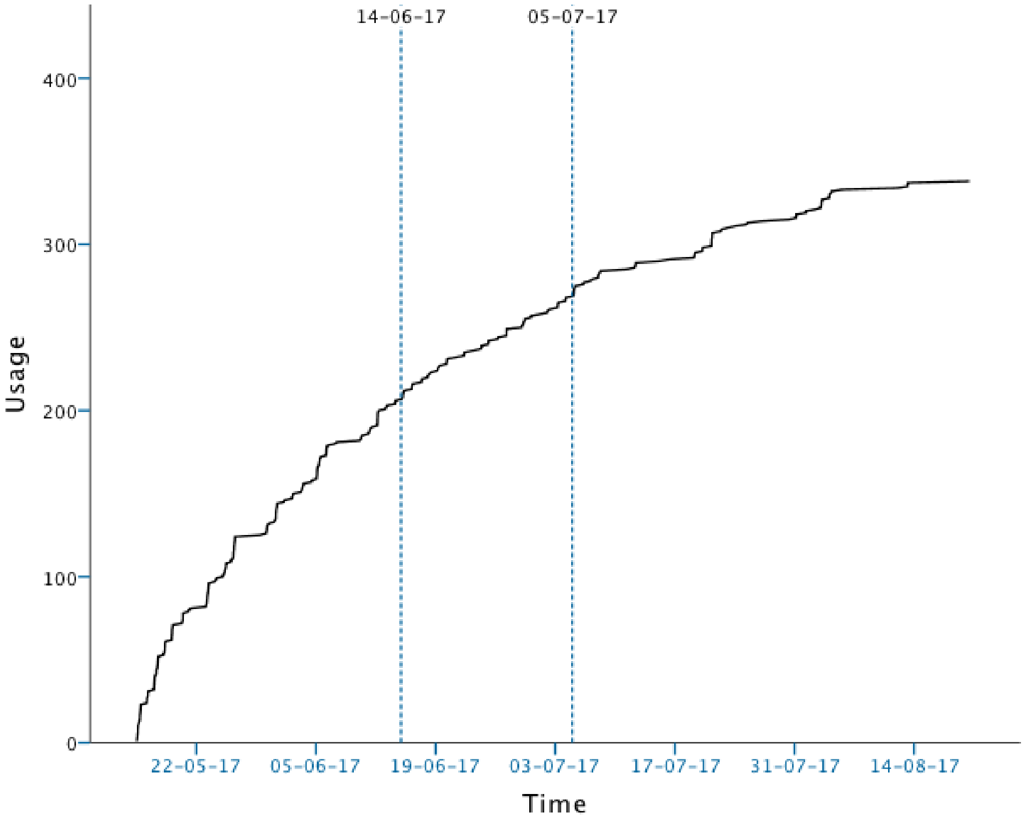

Figure 5.11. Cumulative sessions over time

In total, the children had 338 sessions with the PAL robot. The children played the quiz during 42.9% of the sessions before T3. After T3, 34.9% played a quiz during a session. The PAL actor referred to an episode in 23.8% of the cases after T3. All of these episodes contained the suggestion to play the quiz. The suggestion to play the quiz was accepted in 66.7% of the cases. This corresponds to 10 out of 15 cases.

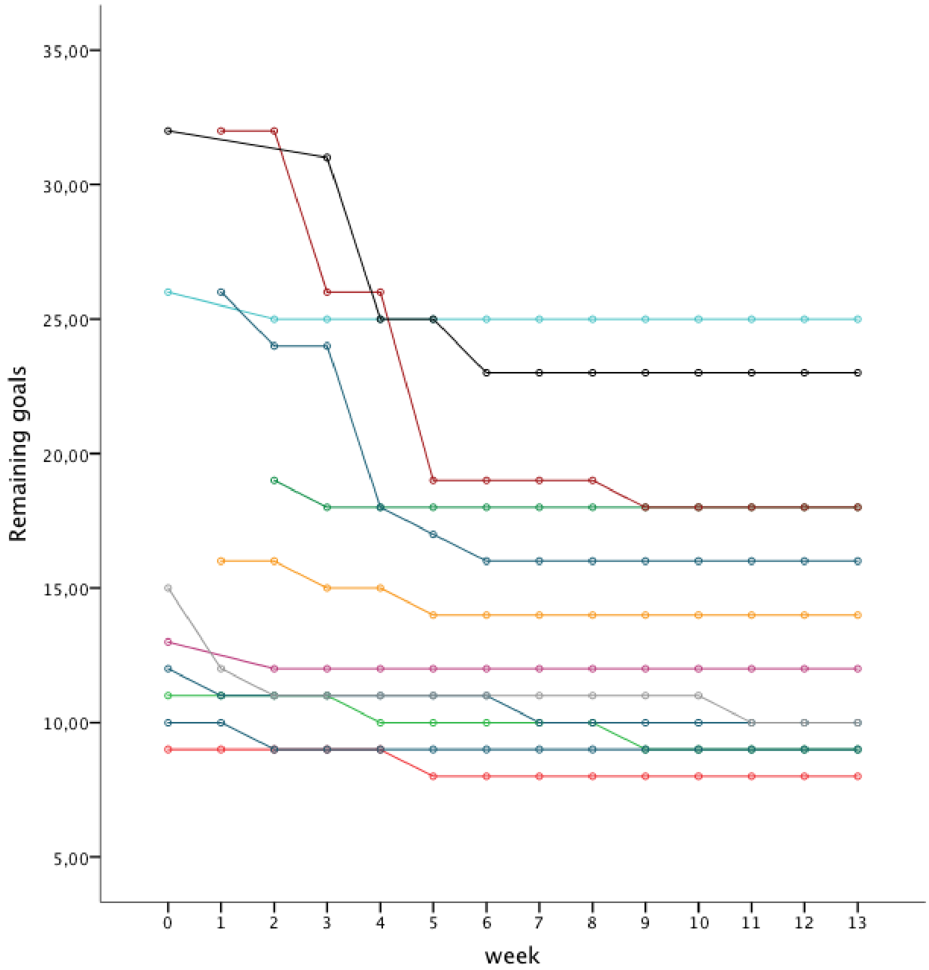

Figure 5.12. Remaining goals per participant

At the beginning of the experiment, the nurse in the hospital determined specific goals per child. The child was able to achieve these goals by performing certain tasks in the MyPal app (e.g. playing the quiz). In figure 5.12, the number of goals per child over time are shown. 6 of the 18 participants were filtered out of this chart, as they did not achieve any goal.

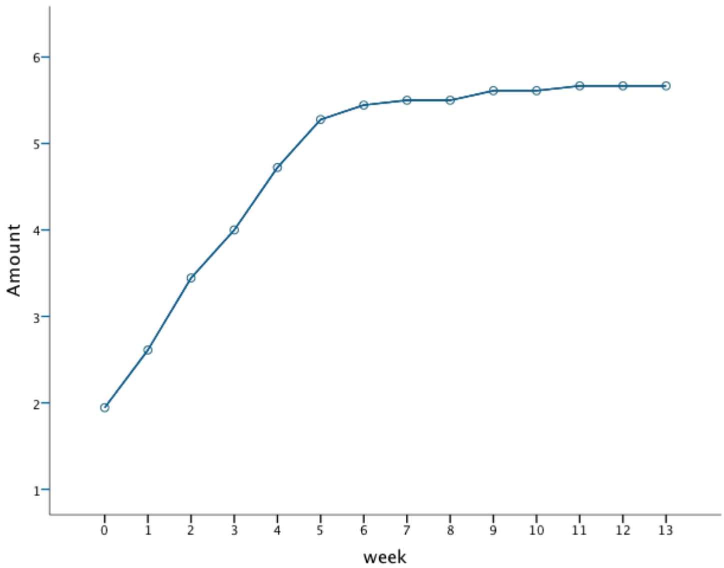

Figure 5.13. Mean achieved goals per participant

The mean achieved goals per child in figure 5.13 gives a better view of the decrease over time. A major decrease in the achieved goals per week was seen after the fifth week.

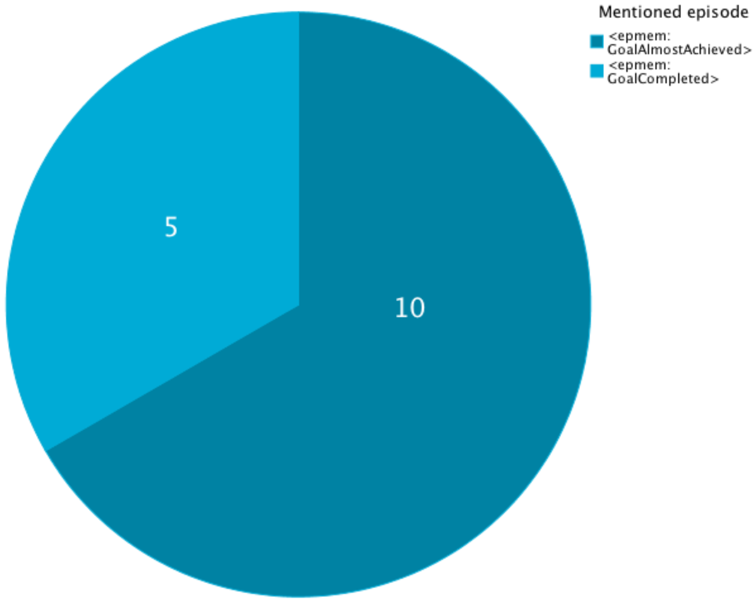

Figure 5.14. Mentioned episode types

Interestingly, as seen in figure 5.14, in the 15 cases of a mentioned episode, only two of the implemented types were captured. The goals were not updated in the meantime which explains the fact that the corresponding episode type was never captured. Also, the quiz was too difficult type was never captured.

Correlations

		usage_episodeMentioned	usage_quizPlayed
usage_episodeMentioned	Pearson Correlation	1	,245**
	Sig. (2-tailed)		,000
	N	252	252
usage_quizPlayed	Pearson Correlation	,245**	1
	Sig. (2-tailed)	,000	
	N	252	252

**. Correlation is significant at the 0.01 level (2-tailed).

Table 5.7. Pearson correlation between mentioned episodes and quiz played

The mentioning of an episode and therefore the suggestion to play the quiz did seem to have a positive impact on the motivation to play the quiz according to Table 5.7. The Pearson correlation was, however, not very strong.

5.3.3 Affection

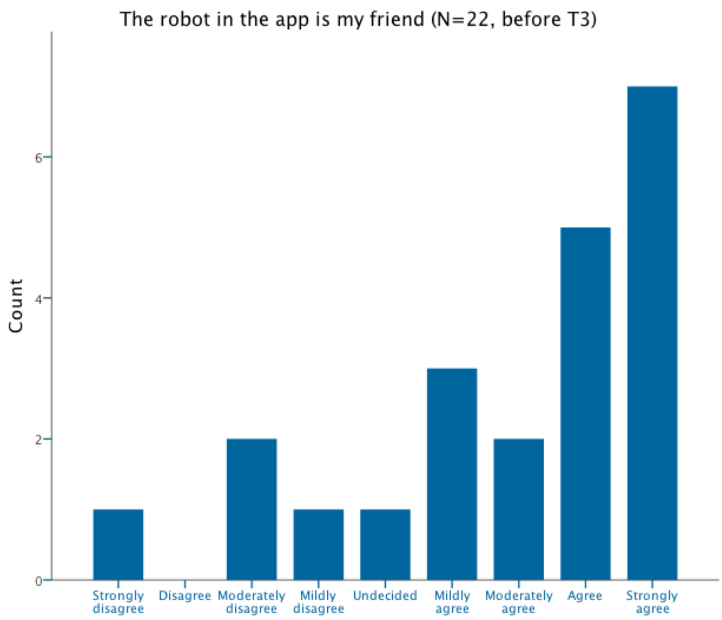

Figure 5.15. Self-assessed affection with robot before T3

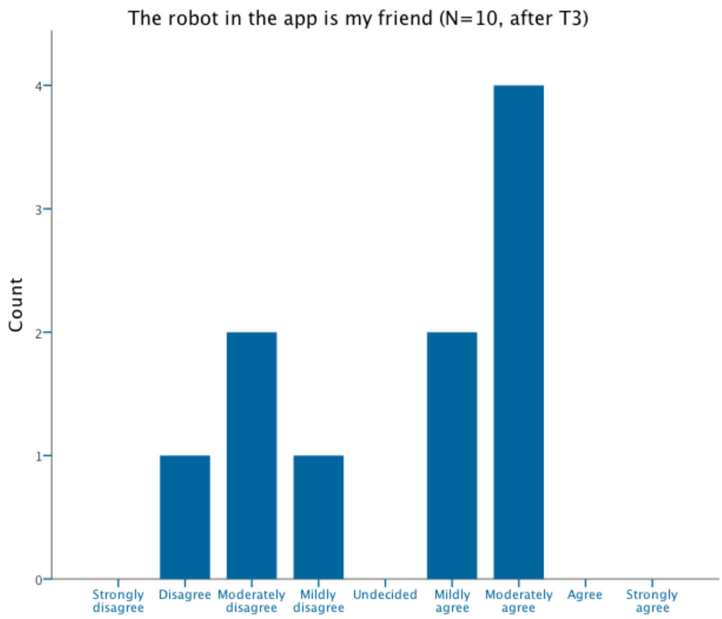

Figure 5.16. Self-assessed affection with robot after T3

The children filled in the survey 32 times. The affection level assessed by children is shown in figure 5.15 and figure 5.16. The median affection level of the children dropped from agree before T3 to mildly agree after T3. Unfortunately, the survey was only filled in once by a boy, which makes it impossible to explore the correlation between survey results and gender.

Correlations

		usage_episodeMentioned	The robot in the app is my friend
usage_episodeMentioned	Pearson Correlation	1	,275
	Sig. (2-tailed)		,270
	N	252	18
The robot in the app is my friend	Pearson Correlation	,275	1
	Sig. (2-tailed)	,270	
	N	18	18

Table 5.8. Pearson correlation between mentioned episodes and affection (children)

The survey of the parents did not contain a question regarding the affection with the PAL actor. Therefore, the affection was only measured by asking the children themselves. The Pearson correlation test (Table 5.8) did not show significance between the mentioning of episodes and the affection with the avatar.

5.3.4 Motivation

Not only the self-assessed affection, but also the self-assessed motivation dropped. The motivation level according to the children is visible in figure 5.17 and figure 5.18.

The median motivation level of the children dropped from moderately agree before T3 to mildly agree after T3.

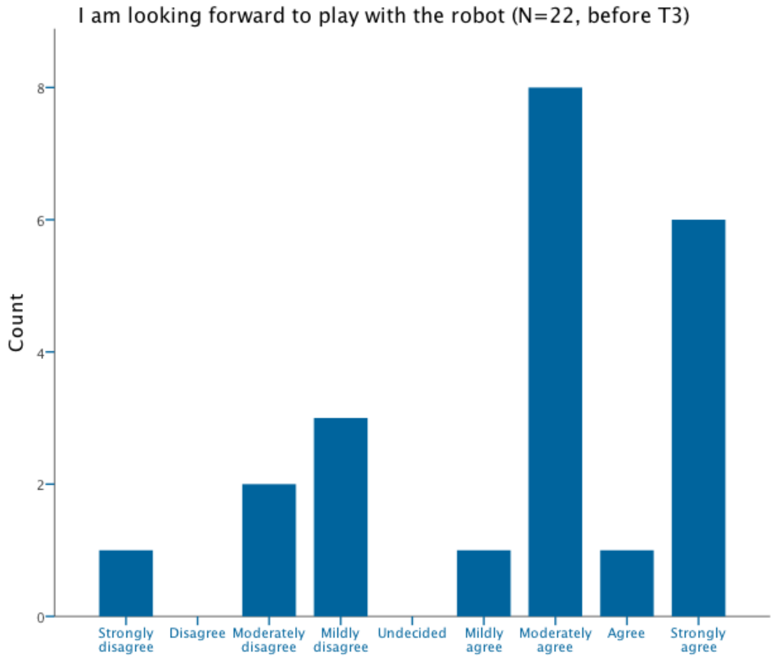

Figure 5.17. Self-assessed motivation of children before T3

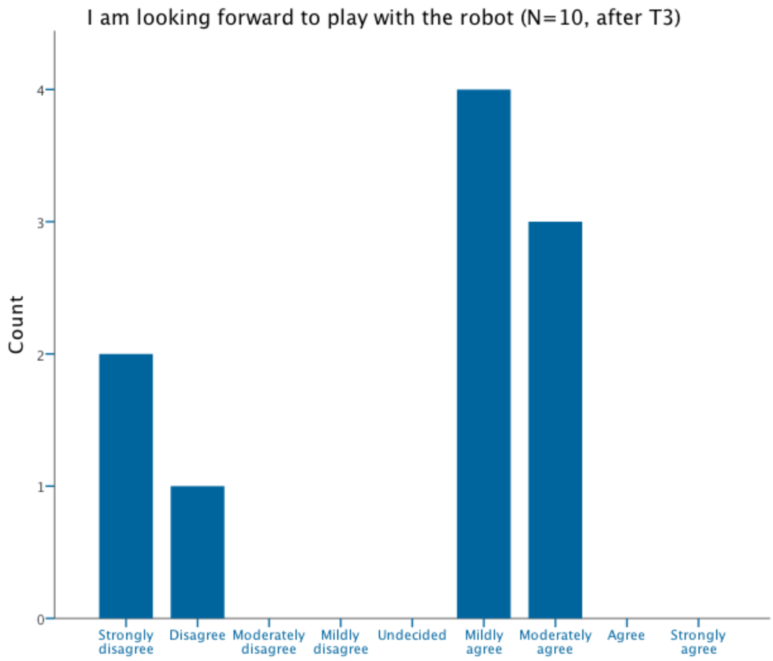

Figure 5.18. Self-assessed motivation of children after T3

The parents filled in the survey 69 times. The survey question regarding motivation for the parents is shown in figure 5.19 and figure 5.20. The median motivation level that was assessed by the parents dropped from undecided before T3 to moderately disagree after T3.

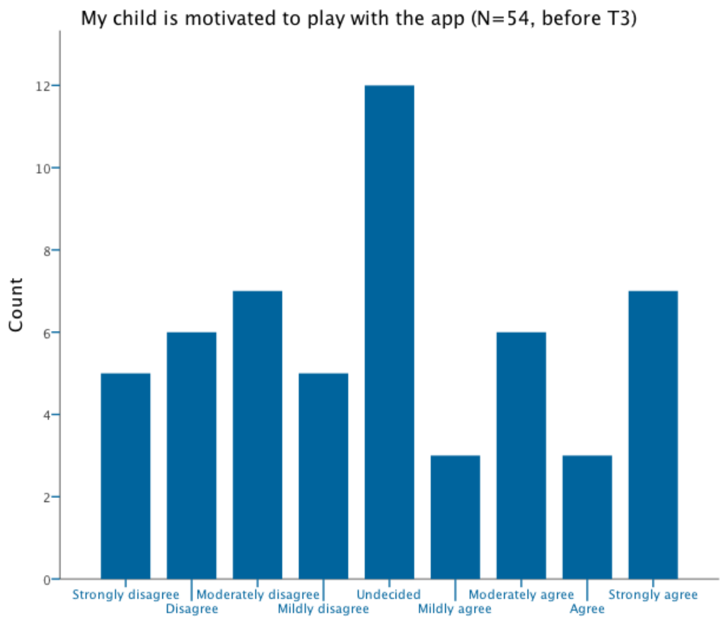

Figure 5.19. Motivation assessed by parents before T3

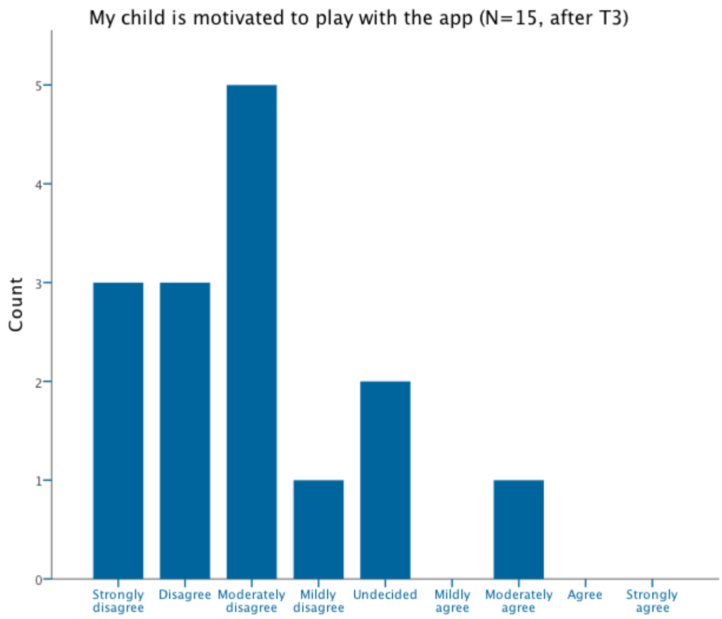

Figure 5.20. Motivation assessed by parents after T3

Correlations

		usage_episodeMentioned	I'm looking forward to play with the robot
usage_episodeMentioned	Pearson Correlation	1	,250
	Sig. (2-tailed)		,316
	N	252	18
I'm looking forward to play with the robot	Pearson Correlation	,250	1
	Sig. (2-tailed)	,316	
	N	18	18

Correlations

		usage_episodeMentioned	My child is motivated to play with the app
usage_episodeMentioned	Pearson Correlation	1	-,026
	Sig. (2-tailed)		,857
	N	252	51
My child is motivated to play with the app	Pearson Correlation	-,026	1
	Sig. (2-tailed)	,857	
	N	51	51

Table 5.9. Pearson correlation between mentioned episodes and motivation (left: children, right: parents)

The Pearson correlation test (Table 5.9) also did not show significant results. The mentioning of episodes did not lead to a significant change in motivation.

5.3.5 Diabetes self-management behaviour

The median diabetes self-management behaviour that was measured by the children (figure 5.21 and figure 5.22) stayed unchanged. The median before and after T3 was moderately agree.

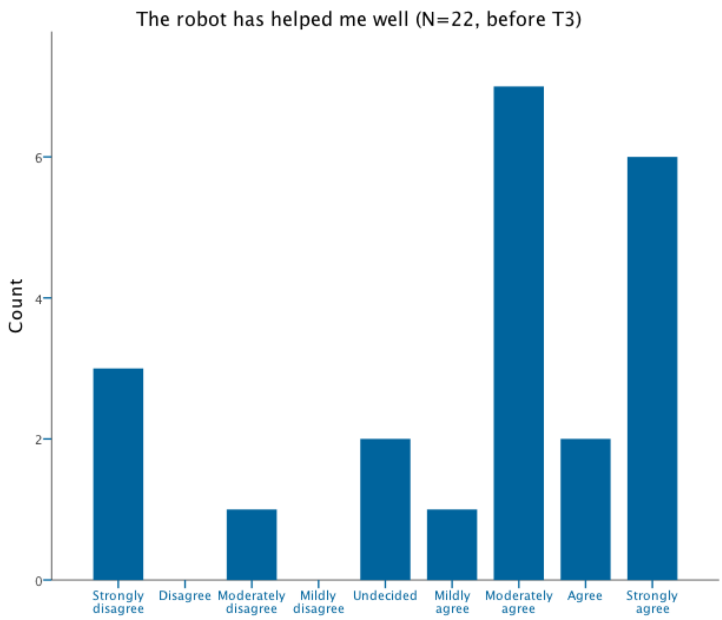

Figure 5.21. Self-assessed diabetes self-management behaviour of children before T3

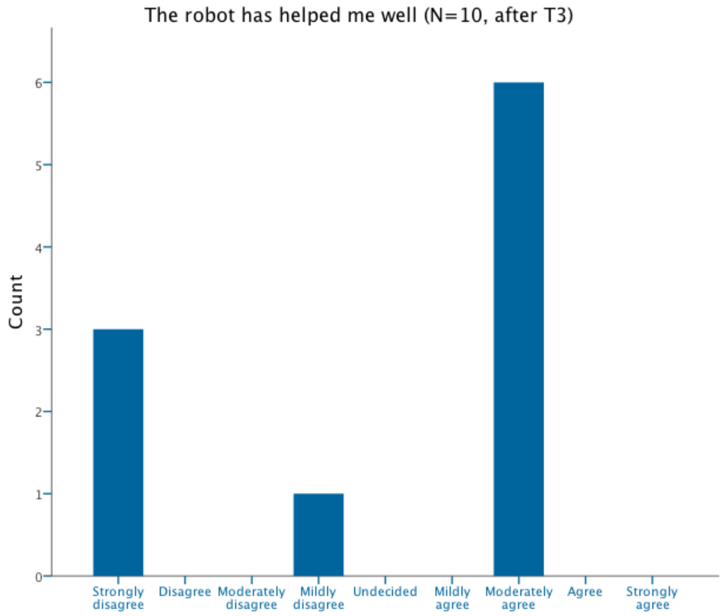

Figure 5.22. Self-assessed diabetes self-management behaviour of children after T3

The parents were also asked about the self-management behaviour of their children (figure 5.23 and figure 5.24). The median diabetes self-management behaviour level that was assessed by the parents dropped from undecided before T3 to mildly disagree after T3.

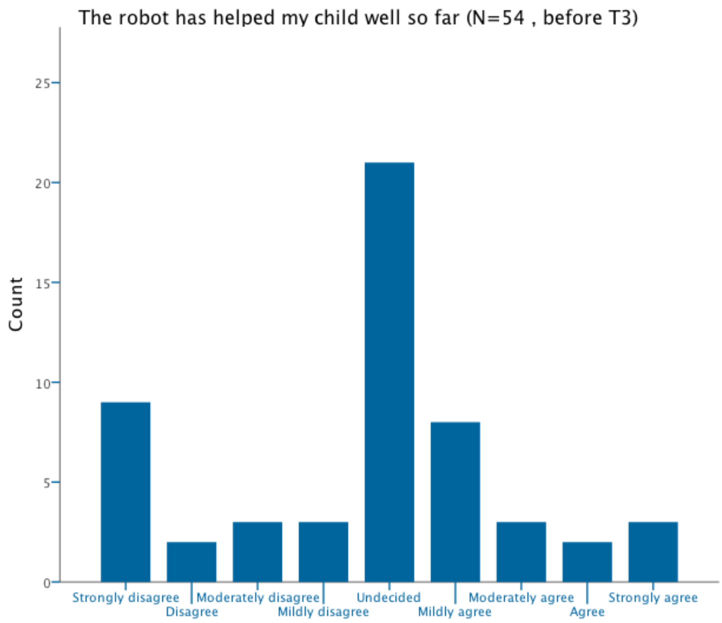

Figure 5.23. Diabetes self-management behaviour assessed by parents before T3

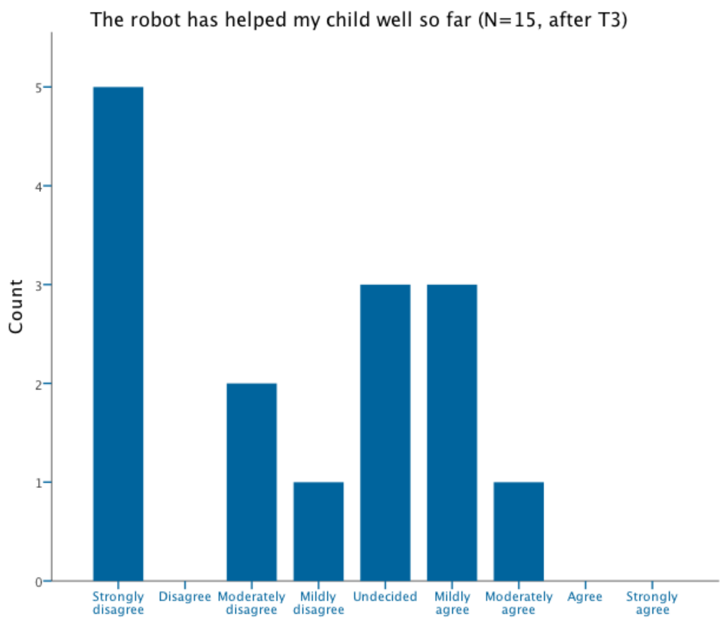

Figure 5.24. Diabetes self-management behaviour assessed by parents after T3

Correlations

		usage_episodeMentioned	The robot has helped me well
usage_episodeMentioned	Pearson Correlation	1	,268
	Sig. (2-tailed)		,282
	N	252	18
The robot has helped me well	Pearson Correlation	,268	1
	Sig. (2-tailed)	,282	
	N	18	18

Correlations

		usage_episodeMentioned	The robot has helped my child well so far
usage_episodeMentioned	Pearson Correlation	1	-,112
	Sig. (2-tailed)		,434
	N	252	51
The robot has helped my child well so far	Pearson Correlation	-,112	1
	Sig. (2-tailed)	,434	
	N	51	51

Table 5.10. Pearson correlation between mentioned episodes and self-management (left: children, right: parents)

According to the Pearson correlation test in Table 5.10, the mentioning of episodes did not result in any significant change in self-management behaviour, according to the children and parents.

Chapter 6

Discussion and conclusion

This chapter discusses the findings and contributions from this thesis, points out the limitations of the current work, and also provides directions for future research. It consists of the sections Discussion (§ 6.1), Limitations (§ 6.2), Future work (§ 6.3) and Conclusion (§ 6.4).

6.1 Discussion

In this section, each of the subquestions from § 1.4 will be revisited and discussed using the theoretical framework, the system design and the gathered results. Each subquestion adds up to the answer of the main research question as seen in figure 1.2.

SQ1: Which ontological model can capture the main concepts with their relations of the child-PAL shared episodic memory?
The ontology of an episodic memory as defined in this project (figure 5.3) was found suitable for storing memories about goals as defined in the first iteration. As both goals and measurements are part of the PAL ontology, the implementation of the second iteration using this ontology will not be a problem. The third iteration is, however, a bit tricky as it involves gathering episodes from an event that the child is talking about. Right now, the 'Why' in combination with a 'What' is stored in an EpisodeTag. It would be impossible to map all the possible cases that a child can talk about. The same applies to the 'How' which would require mapping all the actions in the ontology. This is however less of a problem than the EpisodeTag as an action is still defined atomically instead of as a combination of entities. The EpisodeTag should therefore be replaced by a separate 'What' and 'Why'. The reasoning using the EpisodeTrigger should check the precondition based on multiple relations instead of the single EpisodeTag. This would make it possible to have a goal that was too difficult, but also, for example, a test at school that was too difficult. In both cases the 'Why' is the same, as they were both too difficult. The moment to mention each episode could still be different, so just the 'What' or 'Why' would not be sufficient.

The current mapped Emotion is just a placeholder as a new ontology of the emotional state of a child is being created. As soon as this improved ontology is done, it should replace the mood in the episode ontology.

SQ2: Which reasoning mechanism can the PAL actor apply for constructive memory reference expressions?
The solution using the current dialog manager using CPlan was found suitable to reason about episodic memories. Two reason flows were identified from which the simple version (figure 5.5) was implemented. In order to proceed to the third iteration, the extended flow (figure 5.6) should be implemented which would require the implementation of other EpisodeTriggers in the dialog manager.
The recording of episodes is still a work in progress. The assumption that the stored episode is actually a shared experience with the child should be validated. Also, the rules when a goal is seen as almost finished or too difficult for the child would require evaluation.

SQ3: How could dynamic aspects from the human memory (e.g. forgetfulness, context association, memory combining and generalization) be translated to the PAL actor episodic memory?
The dialog manager is able to generate specific to gradually more general dialogs. This could simulate forgetfulness over time. The dialog manager is also able to combine memories using multiple episodes as inputs. The rules to perform these dynamic aspects are yet to be created. Context association was scheduled for iteration three, which would connect the episode to large knowledge databases. In this way, the robot could actually reply to memories that the child shared. The robot could, for example, connect and ask about the highlights of a certain city when the child mentions a day trip to that place.
Generalization was not taken into account as it is mostly used in a negative context. Generalization could also be dangerous when it is applied to diabetes factors like measurement values.

SQ4: Does the addition of episodic memory alter the affection with the embodied conversational agent?
The children rated their affection with the PAL actor considerably lower after the implementation of the episodic memory (figure 5.15 and figure 5.16). The usage of the system also gradually decreased over time (figure 5.11, figure 5.12 and figure 5.13). However, a significant correlation between mentioned episodes and affection was not found (Table 5.8). One explanation could be the fact that the experiment took place during the summer holidays. Some parents mentioned in the survey that they did not bring the tablet with them. Another explanation is the fact that only iteration 1 was implemented. The claim for iteration 3 is the increased affection with the avatar. The claim could still be proven after the implementation of this iteration.

SQ5: Does the addition of episodic memory improve the intrinsic motivation for achieving goals?
Unfortunately, the addition of episodic memory did not result in a decrease of the novelty effect according to the results. The parents as well as the children themselves rated their motivation lower (figure 5.15, figure 5.16, figure 5.19 and figure 5.20). The diabetes self-management behaviour stayed unchanged according to the children, but the parents rated it slightly lower (figure 5.21, figure 5.22, figure 5.23 and figure 5.24). However, a significant correlation between the mentioned episodes and motivation was not found (Table 5.9). This was also the case for the correlation between mentioned episodes and self-management behaviour (Table 5.10). The possible explanation here is the same as in SQ4. The usage gradually decreased over time, which could be the effect of the summer holidays.
The suggestion to play the quiz after a mentioned episode did seem to work. 66.7% of the children decided to play the quiz after the robot suggested to do so. However, the number of mentioned episodes was too low to prove this. Further research is needed in order to confirm this. Due to the limited number of cases, not all episodic memory types were covered and therefore the episodic memory update did not reach its full potential. It would be interesting to schedule a new experiment which is not in a holiday period. Also, the test results would be easier to validate using an A/B test in which one group of participants use the version with episodic memory and the other group uses the system without episodic memory. In this case, the novelty effect that was caused by the version without episodic memory in the weeks before T3 is prevented.

6.2 Limitations

The full potential of the episodic memory was not tested in this research due to different factors. First of all, the prototype was limited to feedback on goals and achievements. The claim regarding the increased affection with the PAL avatar would have been tested in iteration three.
The experiment design was mainly flawed due to the later introduction of the prototype while the experiment was ongoing. The experiment was designed this way by the PAL consortium with other researches in mind. The episodic memory was also not finished at the start of the experiment. It was not feasible to set up a completely separate experiment at a later stage for solely the episodic memory part as the medical focus of the project, combined with the fact that it involved children, requires approval from the ethical committee, which would take months.
The participants that stopped taking part before the introduction of episodic memory were not filtered out of my analysis. As the number of usages after the introduction of episodic memory were already limited, the complete analysis would be based a very small number of participants. Unfortunately, the results from the hospital in Italy were delayed, which would have been helpful in this case.

6.3 Future work

The new ontology that was built for capturing an episodic memory requires two changes in order to have it ready for the third iteration. The first important change is splitting up the EpisodeTag in a separate 'What' and 'Why'. The second change is the replacement of the mood ontology by the new emotional state ontology. This new sub-ontology is expected to be finished after the end of this thesis project.
The capturing rules that have been introduced in this prototype were not validated. The mentioned episodes by the PAL avatar could therefore not have been actual shared experiences between the PAL actor and the child. These rules should be validated before they can capture true shared experiences.
A new experiment should be designed as an A/B test. The prototype should also have the second and third iteration ready to be tested in this context. This would hopefully show the true potential of episodic memory.

6.4 Conclusion

The purpose of the current study was to design and evaluate personalized interactions with the children using episodic memory. The main aim of the developed episodic memory module for the PAL robot and its virtual avatar was to increase the overall engagement and usage of the health apps, which would ultimately lead to increased diabetes self-management.
This study has identified a suitable method for storing shared experiences between the child and the PAL actor, using the designed episodic memory ontology. Secondly, a reasoning mechanism was found suitable for referring to past episodes. Additionally, dynamic aspects from the human memory were identified and suggestions to translate those to the PAL actor were given. The results of the study did not prove that an increase in motivation, affection or diabetes self-management was due to the addition of episodic memory. The most important limitation lies in the delayed introduction of episodic memory while the novelty effect wear-off was already in progress. The study was also limited by the absence of the feedback about measurements and activities (iteration 2 and 3) in the prototype for the experiment. The delay of the results of the Italian hospital was unfortunate, which resulted in a small sample size.
Further studies need to be carried out in order to validate the capturing rules of episodic memory. This would make the capture of true shared experiences between the child and the PAL actor possible. It would be interesting to assess the effects of the second and third iteration in a working prototype. For this, some small changes are mandatory for the episodic memory ontology. Finally, a key policy priority should be that the experiment is carried out as an A/B test in order to mitigate the effects of the novelty effect wear-off before the introduction of the episodic memory module.

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Appendix A

Minor Thesis EIT: Commercializing E-Health apps

KTH Information and
Communication Technology

Commercializing eHealth apps without ethical consequences

Development of a business case without compromising the users data

BART SCHREUDER GOEDHEIJT

Minor Thesis for the EIT Innovation and Entrepreneurship module at KTH
Supervisors: Drs. R. Looije (TNO) & S. Temiz (KTH)

Abstract

Preventive apps in the eHealth domain are often struggeling with the switch from temporary finances to permanent finances. This research was intended to help eHealth apps to be launched commercially without ethical consequences for the users. The PAL project was used as a case to investigate possible ways to enter the Dutch healthcare sector. As a result, two different strategies were formed after a stakeholder analysis.

Contents

List of Acronyms and Abbreviations

PAL	Personal Assistant for a healthy Lifestyle
T1DM	Type 1 Diabetes Mellitus
UDID	Unique Device Identifier

Chapter 1

Introduction

1.1 Background

The PAL (Personal Assistant for a healthy Lifestyle) project aims to help children with diabetes type 1 (between the age of 7 and 14) to improve their self-management skills using a social robot and a virtual avatar combined with a set of mobile health apps. The robot and avatar act as a pal for these children and help them to achieve diabetes-oriented goals. Next to the robot and the virtual avatar, the PAL system consists out of a module for the health professionals used to instruct and supervise the system, as well as a module to monitor progress and inform the parents. The project is funded by the European Union in the Horizon2020 program (ref. H2020-PHC-643783). It continues work that has been done in earlier projects including the ALIZ-e project [Wölfl, 2012]. The PAL project is coordinated by TNO and includes partners from The Netherlands, Italy, the United Kingdom and Germany [Looije, 2015].

Figure 1.1. PAL robot and mobile health apps [PAL4U, 2015]

1.2 Problem statement

Preventive apps in the eHealth domain are often struggeling with the switch from temporary finances (e.g. subsidy) to permanent finances [Politiek and Hoogendijk, 2014, p. 285].

The permanent finances are often offered by the healthcare industry (pharmaceutical companies, insurance companies, etc.). One of the business developers at TNO mentioned that in order to get funding, it is nowadays quite normal to hand over the data of the users to these companies. He even mentioned that there is no proper business case for eHealth apps without doing so. This also applies to the PAL project.

1.3 Purpose & Goal

The PAL project contains an app for children with diabetes. This app can be seen as a diary which will contain their emotional state, the activities that they did during the day and the measurements of their blood sugar level. In order to make the app accessible, the end customer should be able to download the app for free. The purpose of this project is to find a fitting business model in order to launch the platform commercially that won't compromise the data of the users.

1.4 Research questions and hypotheses

The main research question is:

Can eHealth apps be launched commercially 'for free' without ethical consequences?

In order to answer the main research question, the following subquestions have been defined:

ID	Question
SQ1	Which business models are nowadays often used in eHealth apps?
SQ2	Which data gathered in eHealth apps is valuable without privacy issues?
SQ3	What would be a valid way of funding the solution that won't include selling data of the users?

Table 1.1. Research subquestions

Chapter 2

Literature analysis

2.1 Market analysis

According to Research2Guidance, nearly 100.000 eHealth apps have been added since the beginning of last year. That makes the total number of eHealth apps currently available in major apps stores 259.000 [Research2Guidance, 2015].
As seen in figure 2.1, most eHealth publishers don't use traditional app store revenue sources, such as paid apps, in-app advertisements or in-app purchases. Just 24% of the eHealth apps use these sources. Licensing, app development fees and service sales are the top three most common revenue sources.

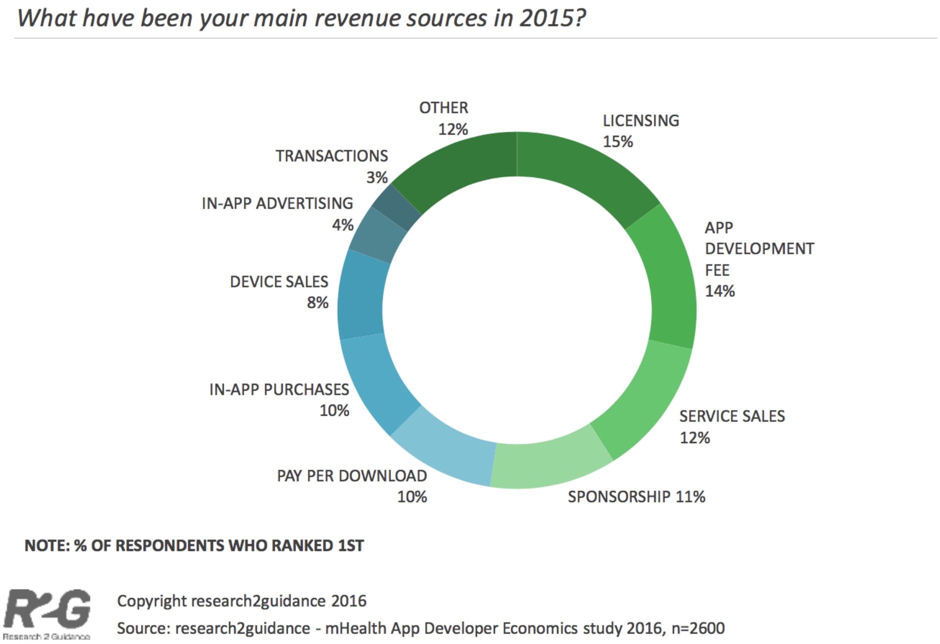

Figure 2.1. Common revenue streams for eHealth apps [Research2Guidance, 2015]

According to 82% of the eHealth practitioners, there could be a key role to play for Health Insurance companies in eHealth app publishing. The industry even expects that health insurance members would be willing to use the apps provided to them by Insurance companies, as well as share their data. "In return, members expect cheaper insurance plans (53%), receive health recommendations (18%) or support research (14%). Only 15% of eHealth market players do not foresee that members would share their data with Health Insurance companies via apps at all."

Research2Guidance further expects that in 5 years from now, eHealth can play a very imporant role in reducing hospital length of stay and reducing readmission costs. They also expect that diabetes will remain the number one chronic disease that offers the best business potential for eHealth app publishers.

2.2 Privacy and laws

Privacy is very important in the eHealth industry and it is a well-discussed topic in ethics. An insurance company could for example use certain information in someone's disadvantage. If the eHealth data shows that the person has an unhealthy lifestyle, it could increase the monthly fee. Big data can help pharmaceutic companies to develop new types of medication, but they can also use it to create a monopoly position using the knowledge that was gained from the data. This could lead to higher medication costs. These examples stress that privacy should have a high priority for eHealth products. In this case, the health related data is from children, which makes it even more crucial to preserve their privacy.
According to a study from Privacy Rights Clearinghouse, many health and fitness applications collect a great deal of personal information [Privacy Rights Clearinghouse, 2014]. Also, mobile applications, especially the free apps, depend on advertising to make money. "They may share personally identifiable information with advertisers, or allow ad networks to track you. Almost all applications send non-personal data about how you use an application to data analytics services. If an application collects your universal device ID (UDID) or embeds a unique ID in the application you download, analytics data can be tracked back to you personally." They found that 55% of paid and 60% of free apps that were investigated use third-party analytics services.

Chapter 3

Case analysis

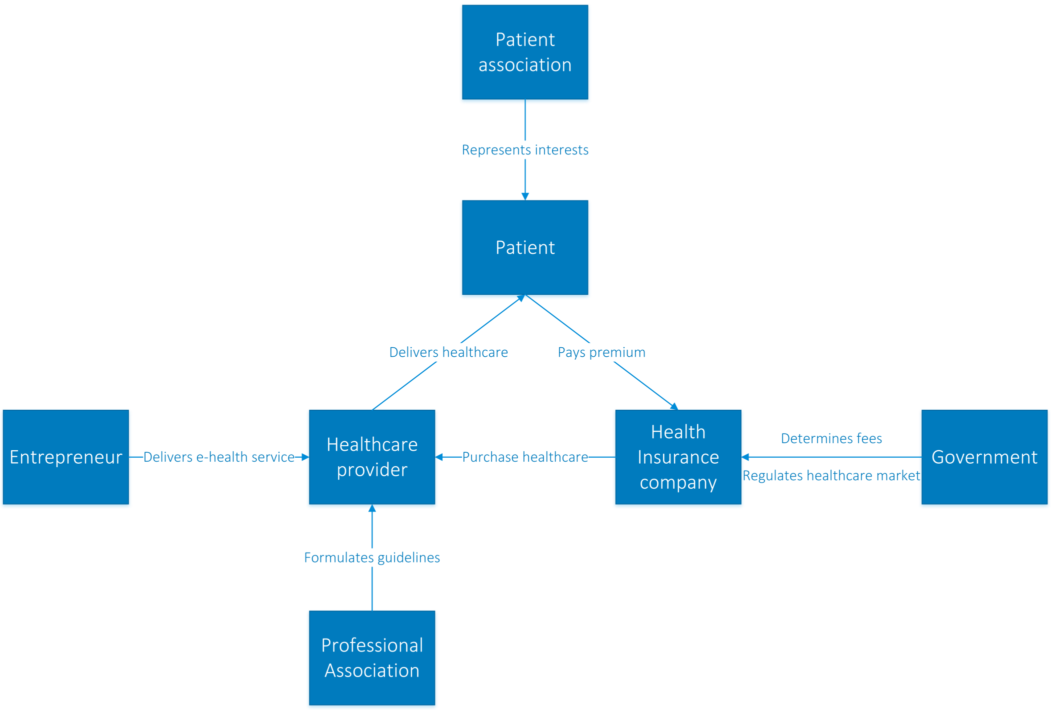

Figure 3.1. Innovation routes in the Dutch healthcare system [Hettinga, 2013]

The case will be analyzed using the innovation routes method from Windesheim [Hettinga, 2013]. This method is applied to the Dutch healthcare system.

3.1 Stakeholders

3.1.1 Patient

The patient is playing the central role in this case. The patients are children with diabetes type 1 (between the age of 7 and 14). Important in this case is that the parents or caregivers are involved as they can influence the usage and effectiveness of the solution. The patients main benefit for using the solution is the stimulation of their self-management skills in diabetes. The child is not able to choose the solution by themselves due to their age. The parents or caregivers need to be convinced in order to gain an user base.

3.1.2 Insurance company

The insurance company is responsible for covering the costs of the care that is given to patients. This party therefore has a big influence, as they want to provide good care for a low price. Insurance companies have different departments with interests in the eHealth market. The innovation department selects and ranks eHealth innovations, while the investment fund supports these innovations. The purchasing department negotiates with companies providing healthcare and purchashes this in big quantities in a preferably efficient way. The role of eHealth services in these negotiations is therefore limited. The commercial department on the other hand assembles the insurance packages for customers and organizations and sees the eHealth as a distinctive feature. The departments therefore don't share the same enthusiasm in eHealth.

3.1.3 Healthcare provider

The healthcare provider is the company that is using the eHealth solution to provide care to patients or customers. This party represents the medical professionals and nurses. Within the PAL project, several hospitals including their stakeholders like medical professionals are helping to co-create the solution. This would benefit the acceptance and integration of the solution in a later stage.

3.1.4 Patient association

The patient association (in our case the Dutch diabetes fund) serves the interests of the patients by influencing the insurance companies, professional associations, healthcare providers and the government. They are well up-to-date in the specifics and ongoing research of the disease and the needs of their target group. A patient association can become a strong partner to support and promote a solution in an early stage when they see a clear added value of an innovation. They can support the development with funds or evaluation with real users and promote the solution for patients, healthcare providers, professional associations, insurance companies, as well as the government.

3.1.5 Professional association

The professional association is the scientific association of professionals in a certain expertise. They tend to improve the education and accreditation of the professionals in order to improve the quality of the provided care. They define the standards and guidelines for doing so. They could be an interesting partner if the solution has a clear improvement in the safety or quality of the provided care.

3.1.6 Government

The Dutch Healthcare Authority is supervising for the healthcare market. They do this by defining performance of the healthcare and by determining the rates. The eHealth solution first has to become a performance before it can be provided and charged for. The National Health Care Institute is the governing body responsible for determining the primary healthcare package that is mandatory for all Dutch citizens. They follow the principles of 'evidence based medicine' for rating which care has to be allowed in the primary package and which not. Next to that, it is responible for stimulating the quality of the healthcare and to advice the government in new healthcare innovations.

3.2 Innovation routes

Innovation routes are different ways to publish an eHealth innovation, each involving different stakeholders. In this section, four different innovation routes are described.

3.2.1 Consumer route

In this route, the eHealth innovation is directly offered to the public (patients and customers). The solution can still be advertised by an insurance company, but the patient/consumer has to pay for it. The main focus point of this route is that the solution has to be fairly priced and that it solves a recognizable problem. It works the best for solutions focusing on wellness and comfort. The user could get the app for free by selling ads or by sharing their data with 3rd parties. This could lead to specific ads about medication according to their preferences, but this conflicts with the privacy of the user. As this solution has a different focus and the fact that TNO doesn't want to charge the end user, this route is not suitable for the solution.

3.2.2 Healthcare provider route

The healthcare provider route seems more relevant. This route is typically used for solutions that give direct benefits to the healthcare provider. These benefits are for example a more efficient healthcare, a competitive advantage, or an image improvement. Healthcare providers generally have own funds available for these kind of investments. Co-creation helps to improve the recognition and acceptation of the solution for this target audience. The current PAL solution is made in close collaboration with two hospitals in the Netherlands and one hospital in Italy.

3.2.3 Insurance company route

In this route, the insurance company adds the eHealth solution to their insurance packages. Therefore, the patient is compensated for the costs. The contents of the healthcare stays unchanged, but it does change the way it is offered. It for example makes the healthcare more accessible or more efficient. The key to be successful in this route is that healthcare providers, patients and the patient association need to be excited about the solution and support it. They can influence the professional association which plays an important role in the creation of guidelines for provided care. Insurance companies have to follow these guidelines.
If the solution leads to cost or labor reductions without changing the quality of the healthcare, it is recommended to stay on the healthcare provider route without involving the insurance companies. If the solution on the other hand leads to a more sustainable healthcare which is significantly better, the insurance company route would be a good option. It is also recommended to leave the negotiations to an enthusiast healthcare provider instead of doing this directly.
It is furthermore crucial for an insurance company that the solution leads to replacement of the current healthcare, for example due to substitution or self management which in the end leads to less claims and thus reduced costs. As the main focus of this project is to increase the self-management of children with diabetes, this could definitely be interesting for insurance companies.

3.2.4 Government route

The government route is only possible when a medial-technological solution leads to new ways of healthcare, which are not offered or which are not compensated for. The route is used when the solution fundamentally changes the healthcare, the way it works or simply because it was not possible to deliver the healthcare before. The government route is therefore not applicable for most eHealth solutions. The PAL system tends to improve the self-management of the children with diabetes, but the healthcare itself stays unchanged. The children still need to measure and control their blood sugar levels. The government route is therefore not the optimal route for this project.

3.3 Route comparison

The previous section already highlighted certain pros and cons of the different routes. In this section, we defined the criteria and weights in order to properly rank them. The criteria and priorities were defined in collaboration with project members of the PAL project. The scores are based upon interviews with partners from the project.

Criteria	Weight	Consumer	Healthcare provider	Insurance company	Government
The service can be offered without costs to the end-user	10	○	●	●	●
The privacy of the end-user is maintained	10	●	●	◕	●
Valuable data of the end-user won't be sold to 3rd parties	10	●	●	◕	●
Easy to expand service to other countries	7	◕	◑	◑	◕
PAL project goals are important and will be maintained	8	◔	●	◕	◕
Time to market is relatively short	6	◕	◕	◑	○
Own funds that are mandatory for market launch are relatively low	6	◔	◑	◑	○
	57	**58%**	**86%**	**71%**	**72%**

Figure 3.2. Criteria and scores per innovation route

As seen in the scores, the consumer route is generally not preferred. The healthcare provider route seems to have the best support. The government route had support from the partners, but due to the extended requirements of this route given in § 3.2.4, this route is unsuitable for this project. To conclude, in the following subsections, the two most preferable outcomes are matched with an appropriate strategy.

3.3.1 Healthcare provider strategy

In this situation, the solution will be sold to hospitals providing diabetes care. As the solution is co-created with hospitals, it would be relatively easy to integrate the solution with their workflow. The nurses and specialists are already familiar with the PAL ecosystem, so there is no learning curve for the employees of the hospital. The PAL project brings a more efficient healthcare and an image improvement for the hospitals, thus there is added value for them. This could lead to competitive advantages. The disadvantage is a possible lock-in as specific hospitals can choose to integrate it. The solution is not widely available, but just for patients of the specific hospital(s). An advantage for the PAL team is that this solution is very suitable for retaining the privacy of the users. Hospitals need access to the personal data in order to provide healthcare. The data stays with the professionals and is therefore not available for 3rd parties.
To overcome the hospital lock-in, a freemium business model could be proposed. Hospitals can provide the full extended version to their patients which helps them to achieve personalized goals in self-management. The professionals and nurses can closely monitor their progress and provide an efficient healthcare. In the hospital, the PAL robot can be used, while the patients use the virtual avatar on a tablet at home. The general audience still has access to a simplified version of the virtual avatar in the tablet app. However, to maintain the competitive advantage, the hospital(s) can choose to leave out the personalization of self-management goals, but just make the basic games and diary function available. A premium version could still be made available using in-app purchases. Parents can choose to activate the full functionality including the monitoring functions. Children with diabetes from other hospitals are then able to fully use the app without consequences for the privacy.

3.3.2 Insurance company strategy

In this strategy, the insurance company covers the costs of the PAL system. They can be convinced by underlining the cost reduction due to a more efficient healthcare by improving the self-management skills of the children. This leads to replacement of existing care, and thus less claims. A convinced insurance company is a great first step in nation wide coverage, as insurance companies determine together with professional associations which care is covered by all the insurances. The writers from the innovation route method further recommend to have at least one enthusiast healthcare provider to convince the insurance company instead of trying to do this alone. In this case, the hospitals from the PAL consortium could initiate this process.

In exchange, the insurance company might want to have proof that the solution indeed improves the self-management of the children and thus results in a cost reduction. This could be resolved by making anonymous usage statistics available to them, which they could compare to the overall number of hospital visits from their patients. This number should decrease over time to proof the cost reduction. The insurance company that helps with the funding could have the exclusive right to use the system for their patients at the start. After this period, the system should be generally available to patients from other insurance companies too. This could be arranged in cooperation with the professional associations.

3.4 Conclusion and discussion

We saw that the most-used business models for eHealth apps didn't use traditional app store revenue sources, but rather licensing, app development fees and service sales. To protect the privacy of the end-users, the app should not give information to third parties that could expose the identity of the user in any way. Due to this, advertisements are not an option. For the PAL case in particular, two possible strategies were discussed.

One of the major shortcomings of this research is the fact that it's applied to the specific case of the PAL project, which is not comparable to simple eHealth apps from small publishers or start-ups. The PAL project is a research project with different partners all over Europe.

This leads to the second shortcoming of the research. We discussed the entry of the Dutch healthcare system, which is one of its kind. It would require a more specific research for each country, as they all have their own healthcare system, politics and laws. Currently, only the Dutch and Italian hospitals are involved in testing, so it would be a logical step to launch the solution at one of these countries. In order to continue, it would be helpful to investigate the Italian health care system. Besides partners, there are also potential users in both countries.

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Appendix B

Diabetes Know&Do goals

Know&Do self management goals for Children with Diabetes		AGE					
#	**DIABETES IN GENERAL**	**6-7 yrs**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Can explain in own words that he/she has diabetes						
2	Can explain in own words that his/her body needs insulin						
3	Can explain in own words that insuline is being given with a insulin pen/pump						
4	Can explain in own words that if he/she uses insulin and eats regular, he/she can feel good and grow up as other children						
5	Knows that diabetes is a chronic disease and will not go away						
6	Knows that diabetes is not contagious						
7	Knows that nobody knows why some get diabetes and others do not						
8	Knows that not he/she, nor anybody else, is to blame that he/she has diabetes						
9	Can explain in own words that the insuline reaches his/her body through a insuline pen or pump in his/her belly or butt						
10	Knows why blood glucose needs to be pricked						
11	Can explain in own words that diabetes is a chronic disease and will not go away						
12	Can explain in own words that diabetes is not contagious						
13	Can explain in own words that nobody knows why some get diabetes and others not						
14	Can explain in own words that not he/she, nor anybody else, is to blame that he/she has diabetes						
15	Can explain in own words why blood glucose needs to be pricked						
16	Knows which organs are involved in digestion and the function of the pancreas						
17	Can explain in own words what diabetes is and it's impact on daily life						
18	Knows the fuction of the pancreas and the effect of insuline on the body						
19	Knows how the most important bodily organs and systems work and what diabetes means						
	BLOOD GLUCOSE	**6-7 engl**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Can assist parents with measuring glucose by getting the meter ready or even prick under supervision						
2	Can explain what the number on the glucose meter means						
3	Can prick glucose by him/herself, but glucose value is being interpreted by parent						
4	Can prick and interpret glucose value by him/herself and how to act accordingly						
5	Knows at which times glucose needs to be measured						
6	Know when to measure glucose in between						
7	Can explain the influence of insulin, carbohydrates and exercise on their blood glucose						
8	Know the causes and symptoms or high or low blood glucose						
9	Know what to do when they have a high or low blood glucose						
10	Know how to prevent a high or low blood glucose						
11	Is responsible for measuring and interpreting own blood glucose						
12	Can interpret the consequences of values that fall out of normal range						
13	Can explain the causes of high or low blood glucose						
14	Can recognize the symptoms and knows how to prevent and treat high or low blood glucose						
15	Know it is important to talk to others about diabetes						
16	Will tell others what to do during a serious hypo						
17	Know it is important to explain about Glucagon when they stay somewhere else with others						
18	Know that long-term high blood glucose values are a risk for ketoacidosis						
	LOW BLOOD & HIGH GLUCOSE	**6-7 yrs.**	**8-9 yrs.**	**10-11 yrs.**	**12-13 yrs.**	**14-15 yrs.**	**16-17 yrs.**
1	Children who already experienced a low blood sugar can describe the symptoms of a hypo and know that they should alert an adult immediately. Children who haven't experience a low blood sugar yet, know they should a alert an adult when they do not feel well.						
2	Knows to take glucose pills or lemonade when he/she has low blood sugar						
3	Knows the symptoms of low blood sugar						
4	Knows how many glucose pills of lemonade they need to get their blood sugar at a normal level						
5	Knows at which value a blood sugar is too low						
6	Can explain what the possible causes of a low blood sugar can be						
7	Can correct for a low blood sugar by taking dextrose pills or lemonade						
8	Knows that he/she can't always depend on the symptoms of a hypo and therefore should always, if possible, measure his/her blood sugar.						

	INSULIN INJECTIONS & INSULIN PUMP	6-7 yrs	8-9 yrs	10-11 yrs	12-13 yrs	14-15 yrs	16-17 yrs
1	It is the responsibility of parents to prepare and inject the insulin pen. The child can assist by counting the number of units, by pointing the right place of injection and counting aloud after injection.						
2	Children with a insulin pump can take a bolus under supervision if the child has knowledge of numbers.						
3	Knows that parents will indicate and control the amount of bolus.						
4	Knows that the dosage of insulin is the responsibility of the parent.						
5	Can self-administer a insulin injection						
6	Knows the difference between different kinds of insulin.						
7	Knows when they need which kind of insulin.						
8	Knows how to preserve insulin.						
9	Can self-administer a bolus.						
10	Can help prepare and insert the new system in stages to learn this their selves.						
11	Learn how to adapt the insulin dosage to the blood glucose values and amount of carbohydrates.						
12	Can independently operate the insulin pump.						
13	Can compute the size of the bolus with the blood glucose values and amount of carbohydrates.						
14	Can independently replace a reservoir and system.						
15	Are learning how they independently can adapt the insulin to special occasions through a custom bolus or temporary basal.						
16	Can independently adapt the insulin to special occasions through a custom bolus or temporary basal.						
17	Knows how to set up the basal and bolus and can independently replace an ampule and system.						

	NUTRITION	6-7 yrs	8-9 yrs	10-11 yrs	12-13 yrs	14-15 yrs	16-17 yrs
1	Knows how much to eat at school or somewhere else.						
2	Knows when and what to eat, possible with a reminder of an adult.						
3	Knows to mention their diabetes if someone offers candy.						
4	Knows to consult an adult if candy is offered, to discuss whether to eat it immediately or take it home.						
5	Knows what products contain a lot or a little carbohydrates.						
6	Knows when and how much candy they can have.						
7	Knows how to vary with different foods and carbohydrates.						
8	Knows what food products are best to use.						
9	Understand information on nutrition labels.						
10	Knows different kinds of artificial sweeteners.						
11	Have general knowledge about nutrition.						
12	Knows of most food how much carbohydrates it contains or knows how to find out.						
13	Knows what food contains good an bad lipids.						
14	Knows how the human body uses food.						
15	Knows how to apply their knowledge to daily situations, sports, school, party's and eating fast-food.						

	PHYSICAL ACTIVITY	6-7 yrs	8-9 yrs	10-11 yrs	12-13 yrs	14-15 yrs	16-17 yrs
1	Can give a simple explanation of the relationship between nutrition, insulin and physical activity.						
2	Knows the relationship between insulin, nutrition and physical activity, take precautions with adults when exercising.						
3	Learn how to independently adapt nutrition and insulin to the amount of physical activity.						
4	Knows what problems can occur while and after physical activity and how to solve this.						
5	Knows trough experience and testing blood glucose how exercising and physical activity can influence blood glucose values.						
6	Knows what precautions should be taken if they participate in sports						

	SOCIAL ENVIRONMENT	6-7 yrs	8-9 yrs	10-11 yrs	12-13 yrs	14-15 yrs	16-17 yrs
1	As preparation for child and parent, parents are encouraged to let the child play with others. Child can be involved in explanation of own parents to other adults.						
2	Is involved in the transfer of care of the parents to other adults when he/she has a sleepover.						
3	Can independently have a sleepover with others, whereas an adult is responsible for care taking.						
4	Can manage their diabetes mostly themselves, but need parental/adult support.						

5	Can be more independent than others, but sometimes care should be taken over by adults again without a reason.						
6	Can have a normal life between friends and peers.						
7	Knows how to independently cope with diabetes, but it is important that parents support child.						
8	Should always inform an adult in their environment (school/sports)						
9	Knows there are compensation rules for diabetics.						
10	Knows where to get diabetic materials.						
11	Knows there are several occupations that may not be carried out						
12	Knows there are custom rules for driving license and a medical declaration is required.						
	SMOKING & DRUGS & ALCOHOL	**6-7 yrs**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Knows smoking and diabetes is a bad combination.						
2	Knows smoking influences the insulin functioning, through the contraction of the blood vessels because of nicotine there is a decrease of insulin functioning.						
3	Knows long term smoking leads to a decreased insulin sensitivity						
4	Knows smoking can cause eye problems.						
5	Knows drugs influence the brain, which makes it difficult to control diabetes.						
6	Knows drugs are addictive.						
7	Knows alcohol use influences blood glucose.						
8	Knows there is no contra-regulation because the liver is breaking down alcohol.						
9	Knows that he/she should measure blood glucose before going to bed after drinking alcohol.						
10	Knows their blood glucose should be higher with than without alcohol and therefore they should eat long-working carbohydrates like bread, potato chips or French fries.						
11	Knows that when you have alcohol hypo symptoms are harder to notice						
12	Knows that he/she should inform his/her friends that hypo symptoms look like inebriation.						
13	Knows the advice to avoid drinking until 24.						
	ILLNESS	**6-7 yrs**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Is being told the influence of being ill on blood glucose						
2	Knows the influence of being ill on blood glucose, they should determine with parents what is the best to do.						
3	Knows to regularly check blood glucose, potential ketones and body temperature if they have a fever.						
4	Knows which precautions should be taken if being ill.						
5	Knows how to adjust their insulin dosage when having a fever.						
6	Knows how to handle nausea and vomiting.						
7	Knows the possibility to call for the help of the child diabetes team						
	LONG TERM COMPLICATIONS	**6-7 yrs**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Is being told the connection between blood glucose and the influences on the long term.						
2	Knows the importance of good regulation of the blood glucose because of the long term complications.						
3	Knows the regular checks to detect long term complications in an early stage. HbA1c determination, blood pressure, examination of urine microalbuminuria, eye- and foot control.						
4	Knows why every examination is done, how the results are assessed and what should be done if the results are aberrant.						
	TRAVELING	**6-7 yrs**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Can travel independently.						
2	Knows blood glucose should be well regulated before travels.						
3	Knows how to transport and preserve insulin.						
	SEXUALITY AND PREGNANCY	**6-7 yrs**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Knows the effect of sex on blood glucose.						
2	Knows the risks of diabetes and pregnancy.						
3	Knows the importance of contraception/birth control.						
4	(girls) Knows blood glucose should be well regulated before and while pregnancy.						
	EDUCATION	**6-7 yrs**	**8-9 yrs**	**10-11 yrs**	**12-13 yrs**	**14-15 yrs**	**16-17 yrs**
1	Has acces to education materials for their age what can be studied with parents.						

Appendix C

Experiment protocol

Protocol PAL – 643783-4

“Personal Assistant for healthy Lifestyle”

Funded by the Horizon 2020 Framework Program of the European Union under grant agreement no **643783**

European Commission

PROTOCOL PAL - 643783-4

Descriptive Title: PAL – Personal Assistant for healthy Lifestyle, INTERMEDIATE PHASE – REFINEMENT OF USER REQUIREMENTS ANALYSIS.

Sponsor code: Grant Agreement nº 643783-4

Protocol Date and Version: XX/XX/2017, V. 01

Promoter: Dr. Rosemarijn Looije, TNO Netherlands Organization for Applied Scientific Research, coordinator of a Consortium of 11 European partners, financed by the European Commission (EC) under the research programme HORIZON 2020, call PHC-26-2014 "Self-management of health and disease: citizen engagement and mHealth (ii) mHealth applications for disease management".

Coordinator Center of the entire Project: TNO - Netherlands Organization for Applied Scientific Research

Financing Sponsor: European Commission (EC) under the research programme HORIZON 2020, call PHC-26-2014 "Self-management of health and disease: citizen engagement and mHealth (ii) mHealth applications for disease management".

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1. General introduction on the PAL project

Type I Diabetes Mellitus (T1DM) is a complex disease, with a worsening prevalence and a therapeutic regimen that has to be adapted to the living conditions and activities of the patient. If not correctly handled it can lead to serious complications up to a reduction in life expectancy. All these factors represent a major challenge for younger patients, who need to familiarize with their condition and acquire knowledge and autonomy in managing their own therapy.

The PAL project "Personal Assistant for healthy Lifestyles", is a four-year (March 2015- February 2019) project funded by the European Commission, whose purpose is the development of a multi-system technology that can support young patients with T1DM (aged between 7 and 14 years), their families and the medical staff, in order to accompany them in a shared educational path towards a proper management of the disease. PAL will also provide these young patients with an educational tool able to strongly motivate children/ teens, eventually helping them in adopting healthy lifestyles. PAL refers to an interactive platform consisting of: (*i*) web applications – e.g.: a virtual timeline composed by therapeutic, nutritional, activity, emotional diaries and quizzes - , (*ii*) applications for the mobile technology - mHealth app and games - (*iii*) a humanoid robot (NAO[1]) which is able to interact playfully with children (Figure 1). All these components use a common knowledge-base and reasoning mechanism. PAL is a multicentric project, shared by a Consortium of 11 partners that ensures the right balance of the skills required for this kind of research:

1. Nederlandse organisatie voor toegepast natuurwetenschappelijk Onderzoek - TNO (the Netherlands), the coordinating Center
2. Fondazione Centro San Raffaele (Italy), in collaboration with Ospedale San Raffaele
3. Imperial College of science, technology and medicine (United Kingdom)
4. Mixel Scarl (Italy)
5. Deutsches Forschungszentrum fur Kunstliche Intelligenz GmbH - DFKI (Germany)
6. Technische universiteit Delft (the Netherlands)
7. Bierman egbertus petrus bartholomeus – PRODUXI (the Netherlands)
8. Stichting ziekenhuis gelderse vallei – (the Netherlands)
9. Meander MC – (the Netherlands)
10. Diabetesvereniging Nederland (the Netherlands)
11. SOStegno70 insieme ai ragazzi diabetici ONLUS (Italy)

[1] www.aldebaran.com

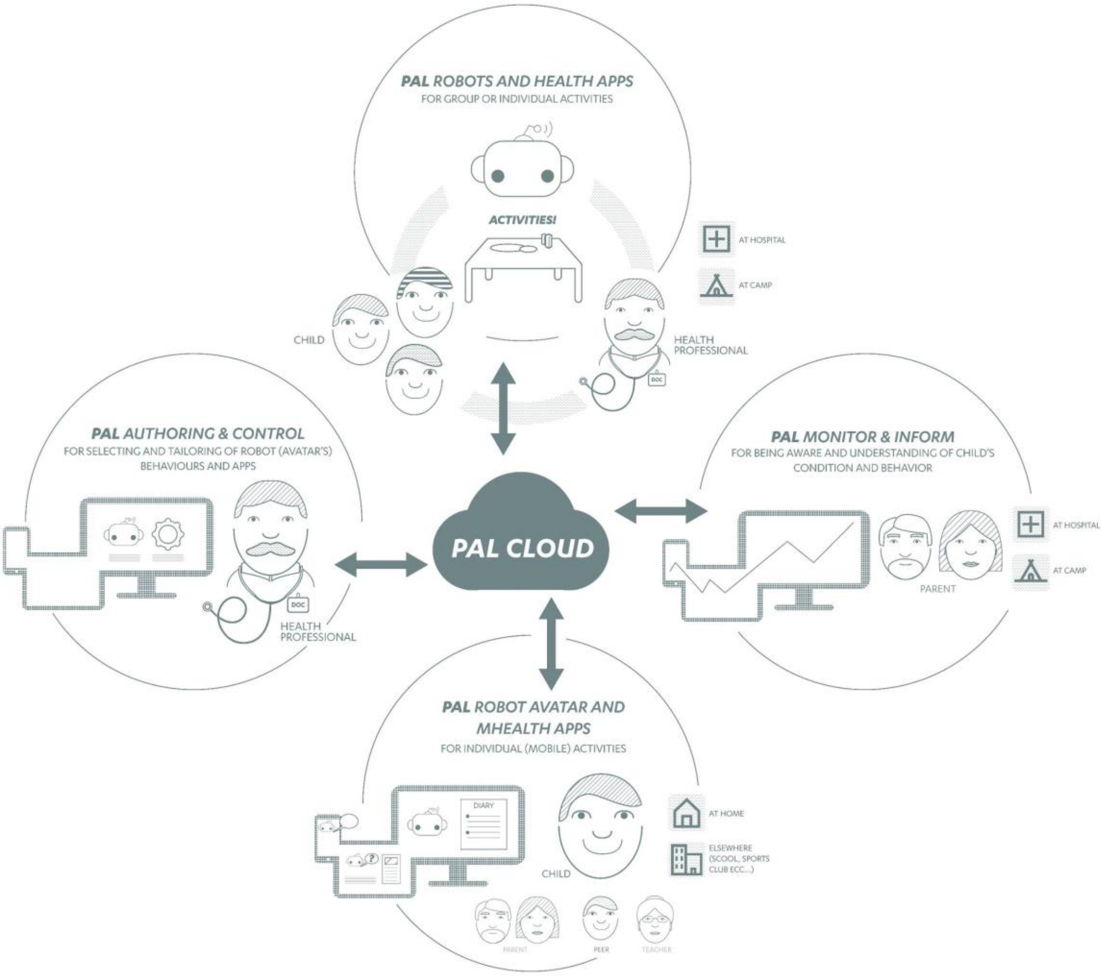

Figura 1PAL system architecture

Specifically, the entire project presents the following objectives, which can be summarized in the following five sub-points:

1. Determine the needs of the users of the system (children /teenagers, their families and the (in) formal caregivers) to support a conscious and sustained management of their own condition during the transition from childhood to preadolescence. This means, for example, individuating:
    a. the determining factors for a child/teenager (e.g.: knowledge, habits, attitudes, needs, etc ...) that may impact on disease management (e.g.: adherence) and then be reflected on his state of health (e.g.: metabolic and glycaemic control):
    b. the determining factors for parents (e.g.: knowledge, understanding, trust) in order to offer their children a support and a shared responsibility in achieving autonomous management of the disease;

c. the benefits and possible obstacles of using the PAL system for the healthcare professionals in order to offer a personalized support in the process of education and care of young patients.

The PAL system, through the interaction of single activities (quizzes, online diaries, mHealth apps for mobile technology, ...) aims to leverage on the determinants identified, to promote a correct approach to the management of the disease.

1. Develop an ontology towards a multi-user support, based on correct medical and health knowledge, able to evolve with different engagement strategies and customize them according to the learning objectives of each child.
2. Develop a support system for caregivers that articles in:
    a. A control module for the medical staff that allows you to customize the educational development of each child and to monitor
    b. A form of information for parents that allows to monitor the location of their children, in different ways depending on the needs (age, etc ...)
3. Develop a user-model to tune the educational support and motivational hints given to children/ young people depending of their behavioural and evolutionary change, their preferences, knowledge, skills and experience.
4. Develop a series of applications for mobile technology focused on the promotion of healthy lifestyles and strengthening of knowledge (e.g. Health rules, food composition, ...), design customized multimodal interaction with the robot NAO in order to promote the involvement and commitment over the long term with the PAL system by all stakeholders.

The project activities will be articulated in the following phases:

- ➢ INITIAL PHASE (executed in 2015-2016)
    - ○ USER REQUIREMENTS ANALYSIS: This first phase of the study is primarily exploratory and aims to define the technical and functional requirements of the system, based on expectations and real needs of both end users (*patients and families*) that experienced users (*medical staff and healthcare professionals*);
    - ○ FIRST DEVELOPMENT AND VALIDATION: a first group of the results obtained by the User Requirements Analysis will be implemented within the first prototype of the PAL technology. It will be validated through a test campaign dedicated to end-users of the system.
- ➢ INTERMEDIATE PHASE (planned for 2017 as described in this protocol)
    - ○ **REFINEMENT THE USER REQUIREMENTS ANALYSIS: following the validation of the initial phase, the technology components and the contents of the PAL system will be revised and improved according to the feedback and suggestions obtained from the users involved (iterative approach of co-creation methodology [1]);**

  - DEVELOPMENT AND VALIDATION: the results of the first revision of the User Requirements Analysis will be implemented within the integrated prototype of the PAL system. Such a system upgrade will be validated as a result of successive test campaigns dedicated to end-users of the system.
- FINAL PHASE
  - RELEASE: the focus will be on the implementation and release of the final PAL integrated system, as a result of the findings obtained in the intermediate steps of validation;
  - VALIDATION: users will benefit in the long term the system developed, final impressions on the solution developed and tested will be collected to verify the achievement of the project objectives.

This specific protocol (PAL-643783-4), to be assessed by the Ethical Committee, is intended to describe the objectives and research activities that are planned for the REFINEMENT THE USER REQUIREMENT ANALYSIS of the INTERMEDIATE PHASE (2017). It is a continuation of the work as described in the previous protocols (PAL-643783-1_2).

2. RATIONALE

Type 1 Diabetes Mellitus (T1DM) is the most pervasive endocrine-metabolic condition in childhood. Diabetes self-management plays a crucial role, in order for young patients to maintain health-related quality of life and to avoid long-term complications (e.g.: heart and blood vessel diseases, nerve/ kidneys/ eyes damages, etc.). A proper management of the disease, and a healthy lifestyle, can help to prevent these complications [2]. One of the key objectives for the care of young patients is the acquisition of sufficient autonomy in the therapy management. This goal is not easy to achieve, as it requires long-term motivation and perseverance to eventually become a 'lifestyle'. The autonomous management of therapy in children and adolescents is strongly influenced by a variety of personal and environmental factors, such as the development of the child and the support/ care provided by the reference adults [3] [4].
A number of interventions exist to promote the acquisition of self-management skills, but it remains unclear which particular types of intervention are most beneficial and for which type of patient. It is in this context that technological innovations can help to improve care, especially for paediatric populations. This, for example, has been illustrated in the European project ALIZ-E (grant agreement n° 248116), that examined how a social robot can provide support, diabetes knowledge and skills gain, to children with T1DM (10-14 years old), through personalized, adaptive and long-term interaction.
With a vision to work further and advance the knowledge-base and support models of ALIZ-E, the PAL project, Personal Assistant for Healthy Lifestyle (PAL) is currently being developed[2]. Thanks to its multivariate nature, the PAL system offers the possibility for children to make use of it in various settings: in the hospital and diabetes camps children can interact with the social robot, at home and/or at school the interaction can be continued, through the virtual avatar of the robot, helping them in reinforcing key diabetes-related notions and procedures.

[2] http://www.pal4u.eu/

3. Research questions and aim of the study

Overall research question: Which are the opinion/feedback of the end-users (children with Type 1 Diabetes Mellitus and their parents) about the MyPAL app on the basis of the implementations developed as consequences of the preliminary results gained during the Cycle 2 Experiments (See protocol PAL643783-2, and PAL643783-3)?

How can a second release of the System provide social, educational and pleasurable support to children with T1DM, at the hospital and home, to achieve personalized diabetes management goals (decided together with the Healthcare Professionals involved)?.

The primary aim of the experiments in the *Intermediate Phase* is to refine, further develop and evaluate the the second release of the PAL System in iterative steps during a longer period of use (e.g. 4 months). This is done by evaluating:

(1) User experience, which affects the use of the PAL System, in children, parents and health care professionals;

(2) Effect of the use of the PAL Systems related to diabetes self-management of children. These effects are measured at three levels (divided over the three phases/cycles of the project, respectively): a) determinants of behavior (e.g. knowledge and skills), b) the actual self-management behavior (i.e., adhering to diabetes management regime), and c) the treatment outcomes (e.g., glycemic control).

In regard to User experience, the international standard on ergonomics of human system interaction, ISO 9241-210 [9], defines User Experience as "a person's perceptions and responses that result from the use or anticipated use of a product, system or service". According to the ISO definition, User Experience includes all the users' emotions, beliefs, preferences, perceptions, physical and psychological responses, behaviours and accomplishments that occur before, during and after use. The user experience data will be used to formulate user requirements. These user requirement provide input for the developers to refine and further develop the PAL System. Then we identify the user experience for three kinds of end-user with their attributes, which are quality components that assess how easy user interfaces are to use (Nielsen, 1994). These are the user experience with the PAL System of **children** (understanding, visual appealingness, pleasure and engagement, bonding, motivation and actual usage), **parents** (user experience and attitude with regards to PAL System), and **healthcare professionals** (HCP) (user experience and attitude).

In regard to diabetes self-management, in last year's study (**Cycle 1**), we studied the impact of the PAL System on determinants of diabetes self-management, including knowledge, skills, attitude and self-efficacy. The main focus for the current protocol of the intermediate phase (**Cycle 2**) is to get further insights in the children's treatment adherence and glucose monitoring, their parent's trust and skills and the health care professionals' awareness of the PAL System. Determinants from the initial phase will also be partly taken into account, considering that the forthcoming experiments will last a more long period and it will be possible to compare them with the previous version of the System. In addition parental stress is observed to be a possible determinant that might be influenced by usage of the PAL System by the child. Determinants such as gender, age, socioeconomic status, etc. will also be explored in order to see if they have an influence on User Experience. These results will be useful inputs to understand which factors are most important for a proper personalization of the System, to be implemented in the next phases of the project

Tabella 1PROJECT ROADMAP - THREE SPECIFICATION & EVALUATION CYCLES WITH AN INCREASING SCOPE.

	Initial Phase (Y1)	**Intermediate Phase (Y2)**	**Final Phase (Y3)**
Determinants	**Knowledge & Awareness**	**Diabetes Regimen Adherence**	**Shared Child-Caregiver Responsibility**
Children - age dependent claims	<u>7-10 yr:</u> + knowledge + awareness + attitude + self-efficacy + skills	<u>7-12 yr:</u> + treatment adherence + glucose monitoring	<u>7-14 yr:</u> + shared responsibility + coping with anomalies - hypos/ hypers + glycemic control
Usage of the system	1 month	4 months	9 months
Caregivers - Claims	*Professionals:* + trust + acceptance *Parents:* + attitude + knowledge	*Professionals:* + awareness *Parents:* + trust + skills	*Professionals:* + tailoring *Parents:* + shared responsibility
Settings	hospital, home	hospital, home, camp	hospital, home, camp, elsewhere
mHealth apps	Timeline, Quiz game	Timeline, Quiz game, Sort&Break	Timeline, Quiz game, Sort&Break, other miniApps

In Cycle 2, we will deploy a PAL System, which is enhanced in comparison to Cycle 1. See for more detail section 4.4. In short, the PAL System at Cycle 1 covered a robot buddy for children with diabetes at the hospital. Children can have a short conversation with the robot and they can play a diabetes quiz together. At home, children can use the MyPAL app, which contains an avatar (i.e., digital version) of the robot. The avatar looks, speaks and behaves the same as the robot. Moreover, children can play the diabetes Quiz with the avatar and keep track of diabetes related information (including self-management activities, measures, emotions) on a ‘timeline’, somewhat similar to a diary. Finally, children can achieve self-management goals (i.e., objectives), which are set with the HCP at the beginning of the study with PAL Control. Children can achieve these goals through the use of MyPAL. For example they can have a goal to improve their knowledge about counting carbs and they can get knowledge points by playing the diabetes Quiz with the avatar.

The enchantments for Cycle 2 consist of the following **additional features**. We added a new educative game to the System, called ‘Sort&Break. Also, we have improved the visualization of MyPAL, including more user-friendly timeline and more natural dynamic behaviour of the avatar. Finally, we have improved the interaction, that is to say, the robot and avatar’s dialogue is enriched and more natural, and the they provide more feedback on the entries in the timeline and the on the objectives (self-management learning goals).

The **research questions** we aim to answer in Cycle 2 of our study, over a course of four months, are the following:

1. Do the enhancements of the PAL System contribute to increased user experience of children, parents and HCP and to the usage of the PAL System by children?
2. Does increased user experience in children contribute to a stronger bond with the PAL robot and avatar?
3. Does the improved user experience in children, parents and HCP and a stronger bond between children and PAL robot and avatar contribute the increased use of the PAL System?
4. Does the use of the PAL System contribute to improved self-management determinants in children, including knowledge, motivation and awareness of their self-management objectives?
5. Does the use of the PAL System contribute treatment adherence and glucose monitoring in the participating children?

As we aim to study the effect of each feature, we will introduce them step by step during the study. We will start with a PAL System with improved visualization (T1, onset of study), then we will introduced feedback on entries in the timeline (T2, after 3-4 week), then we will introduce feedback on the self-management learning objectives (T4, after another 6-8 weeks). We also measure the impact of the System at T3 (3-4 week after T2) and T5 (end of study, 3-4 weeks after T4). For details see section 4.3.

Based on Table 1 and the discussed enhancements, we come to the following **hypotheses**. Where T1 and T4 point to the introduction times in the experiment.

T1. Children will use the PAL System (input timeline, number of times using PAL System, time spent with PAL System) more and find it more usable (SUS questionnaire), in comparison with previous year, due to the redesign of the timeline and quiz. This is indicative for the adherence, glucose monitoring and motivation (usage and number of times measuring).

T2. Children will be more aware (awareness questions in EMA) of what their objectives are when the visualization of the objective section is changed. This is indicative for the adherence, glucose monitoring and motivation (usage and number of times measuring).

T3. Children will feel a stronger bond with the avatar (bonding questions) when the avatar provides feedback on “glucose” “meal” and “activities” in the timeline. This is indicative for adherence and motivation (usage).

T4. Children will feel a stronger bond with the avatar (bonding questions), are more aware of their objectives (awareness questions in EMA) and know better how to reach their objectives (question, knowledge gain). This is indicative for the adherence, glucose monitoring and motivation (usage and number of times measuring).

Other hypotheses are:

- Children will see the avatar and robot as more similar (questions on similarity and relatedness) than in previous experiment in 2016, due to the improved appearance (T1) and the improved interactivity (T3 and T4);
- Children enjoy the choice in activities they have (questions on the different activities)
- Professional Awareness: Professionals will have awareness of what it means for the children if they set objectives, due to PAL control and knowledge of quiz questions (interview)
- Parent trust: Parents have more trust in the self-management of their children when the child uses the PAL System (before/after measurement in trust) - CVS, child initiated diabetes tasks
- Parent skills: Parents provide more self-control to the child when the child uses the PAL System. (before/during/after measurement in task support by parent -- child and parent perspective.) EMA, CVS, and question in MyPAL

4. METHODS

4.1 PARTICIPANTS

Study participants enrolled in this study belonged to following categories:

1. **Children with T1DM (age range 8 to and including 12)** recruited from the hospitals or the associations of the PAL Consortium (Meander MC and Stichting ziekenhuis gelderse vallei -NL- and Ospedale San Raffaele -IT-) with <u>minimum number of 10 to a maximum of 15 subjects per hospital,</u> in this way a total pool of 30 to 45 subjects will be ensured.

Inclusion criteria will be:

(i) Informed consent signed by both parents or legal guardian in case of parental separation;
(ii) T1DM onset with at least of 6 months before the enrolment;
(iii) Children treated by Healthcare Professionals of the hospitals of the PAL Consortium;
(iv) Children native speaking

Exclusion criteria will be:

(i) Neurodevelopmental disorders (e.g. intellectual disability, autism spectrum disorders, cerebral palsy, genetic disorders)
(ii) Informedconsent not signed by both parentsor legal guardian in case of parental separation;
(iii) T1DM onset less than 6 months
(v) Children not treated by Healthcare Professionals of the hospitals of the PAL Consortium;
(iv) No children native speaking

Among the participants, children who already took part of the previous experimental campaign will be allowed to participate to the forthcoming experiments. In the analysis, we will explicitly look at moderating effect of having previous experiences with the PAL System. Amongst others on usability and use of PAL, and self-management behavior.

2. **Parents of the participating children** will be active and integral part of the protocol. At least one parent per child will always be involved in the investigations (minimum of 30/45 parents to a maximum of 60/90).

3. **Healthcare Professionals** will be involved in the implementation of the PAL System. They will support the recruitment of participants, introduction of PAL with children and their parents, and set and review elf-management objectives (see section on the mHealth PAL app). Also, they will provide a short evaluation of their trust and acceptance of the PAL System and awareness of the children’s self-management (objectives).

According to what is previously described, in Ospedale San Raffaele are going to be involved:

- from 10 to 15 children with T1DM aged 8 to 12, with an onset not less than 6 months;
- at least one parent per child participating (from 10/15 to 20/30 parents);
- at least 1 Healthcare Professional belonging to the OSR paediatric diabetological team.

According to what is previously described, in the 2 hospitals in the Netherlands (Meander MC and Gelderse Vallei) are going to be involved, per hospital:

- ➢ from 10 to 15 children with T1DM aged 8 to 12, with an onset not less than 6 months;
- ➢ at least one parent per child participating (from 10/15 to 20/30 parents);
- ➢ 3 healthcare professional working for the MMC and 2 Healthcare Professional working for the GV paediatric diabetological team.

Being this current an exploratory phase, the sample size involved in the “INTERMEDIATE PHASE - REFINEMENT THE USER REQUIREMENT ANALYSIS” protocol cannot be defined with certainty in advance, but the minimum thresholds chosen guarantee a numericity sufficient to conduct an effective analysis of the issues. Obviously the greater the participation is, the greater the evidences, the lessons learned and features which can be improved or developed in the future releases of the PAL system.

4.2 MATERIALS

Technological components of the MyPAL app

➢ NAO robot - the NAO robot is manufactured by a French company (Aldebaran Robotics) as a safe and tested product (see the document “Declaration of conformity NAO robot.pdf"). It is important to underline the NAO robot is not a medical device.

➢ Tablets (one per child) - the Timeline and Quiz functionalities, that are going to be described in the next paragraph, are implemented as a PAL app (called MyPAL) running on commercial tablets (owned by the participants or supplied by the researchers if needed). The tablets are bought in common electronics stores for commercial purposes and therefore automatically CE certified.
In addition to that, all the Child-Robot interactions and the interviews with the end-users are going to be audio and video recorded. The tools used for the collection of audiovisual data will consist of digital video cameras and microphones, also in this case found in electronics stores for commercial purposes and therefore CE certified.

Functionalities implemented in the 2nd PAL system

The 2nd release of the PAL system is composed by the following parts:

- ➢ Quiz game with the robot (physically present at the hospital premises and also a game on the table) - children and the robot ask each other multi-choice questions from various domains, both general knowledge and diabetes-related. The database of the Quiz questions, especially for those regarding to diabetes, has been validated by the diabetological pediatric units cooperating to the project and are modulated (in terms of language and difficulty) depending on the age of the children. For the second release of the MyPAL System, it have been added new questions related to the management of the T1DM, which are tailored to different range of age of the children.

Figura 2 Quiz with the physical NAO robot and with the robot avatar on the tablet

➢ Sort and break game with the robot (physically present at the hospital premises and also a game on the table) - during the Summer Camp held in Italy in 2016, children were allowed to free use this game, during the lessons held by the nutritionist of the camp. Feedbacks from them were very good and the Consortium decided to implement that game in the MyPAL System. The insertion of another game specific to nutrition and T1DM was a requirement evaluated during the Cycle 1 of the Experiments conducted in May 2016, both in Netherland and in Italy. Both children and their parents requested the possibility to have other games to make them learn more about nutrition related to T1DM in a play manner. In the game the robot plays with the children for which they need to break open boxes and then sort the items inside in order of number of carbohydrates etc.

Figura 3 Sort and break game with the robot avatar on the tablet and with the physical

NAO robot:

➢ the mHealth PAL app (named MyPAL) for tablets, comprehensive of the Timeline, Sort & Break and Quiz game functionalities with the virtual NAO robot avatar. The MyPAL-Timeline is intended to be a diary feature, in which children have the possibility to fill in a personalized report of their daily activities, as shown in Figure 4-8. Through the timeline children, according both to their specific diabetes management objectives and engagement in the system, can compile day by day: (i) the therapy diary - with details of glycaemia checks and insulin doses; (ii) a nutritional diary - with the details of the meals; (iii) an activity and emotion diary - in which they can freely describe what they've done during the day, also by uploading pictures, (e.g.: sports, party with friends, excursions, etc.) and which feelings they have experienced in this occasions. The virtual avatar of the NAO is going to interact with the children during the MyPAL-Timeline use, for example with greetings and personalized/ motivational feedbacks tuned on the activities done (e.g.: "Hi Sam, it's nice to see you today", or "Good work, you're accomplishing your objective very well today").

➢ Diabetes self-management learning objectives (i.e., goals). To manage diabetes children need to acquire certain knowledge, skills and attitudes. These are formulated as learning goals. Each learning goal should be a small step towards self-management that can be learned in a reasonable time. Not all goals are relevant to all children. Therefore, goals are selected by a professional in collaboration with the child and their parent(s). At the onset of the study HCP set self-management learning goals for the children to pursuit during the study. The HCP have an interface to the PAL System, called PAL Control. It enables them to add users (children), enter details (demographics) and set diabetes self-management goals. PAL Control also has been used in the previous year's experiments. Goals are intended to motivate the child to learn about diabetes. After setting goals, for the children, MyPAL displays the (active) goals relevant to the child, and provide progress feedback (i.e., display attained goals and progress of active goals). Moreover, they have tasks to attain a goal. MyPAL offers activities that are related to goals for this purpose (e.g., a child can play the sorting game to learn about carbohydrates in food products).

Figura 4 View of a functionality of the MyPAL app – Begin screen (Design 2017)

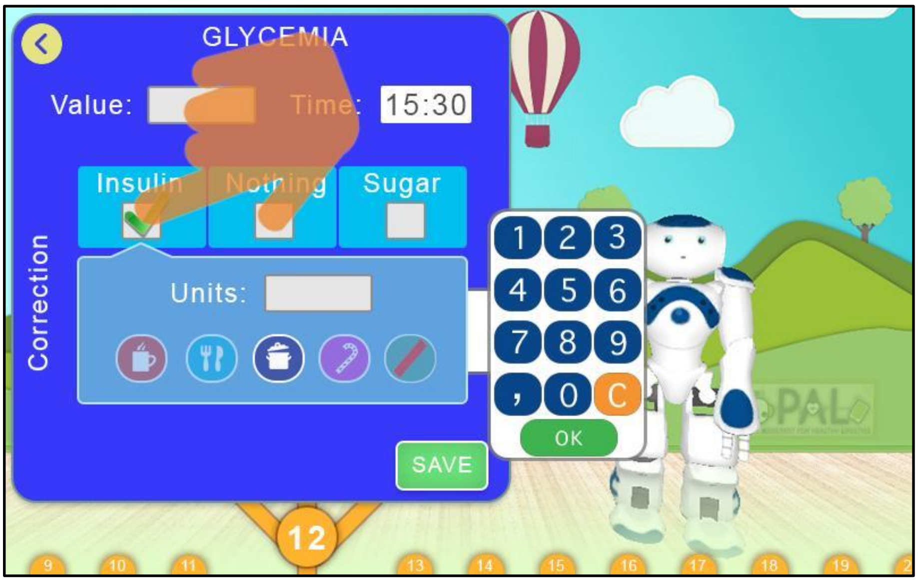

Figura 5 View of a functionality of the MyPAL app – Glycaemia section (Design 2017)

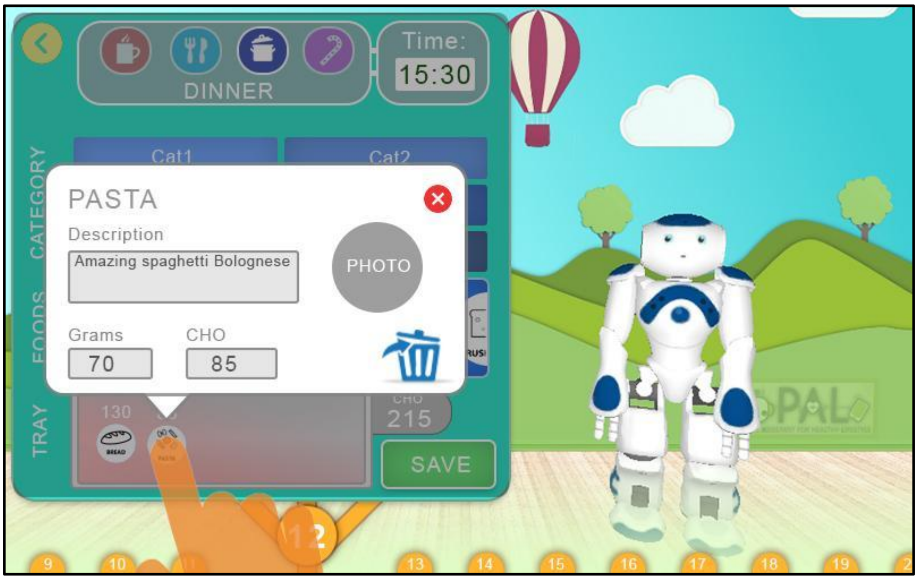

Figura 6 View of a functionality of the MyPAL app – Meals section (Design 2017)

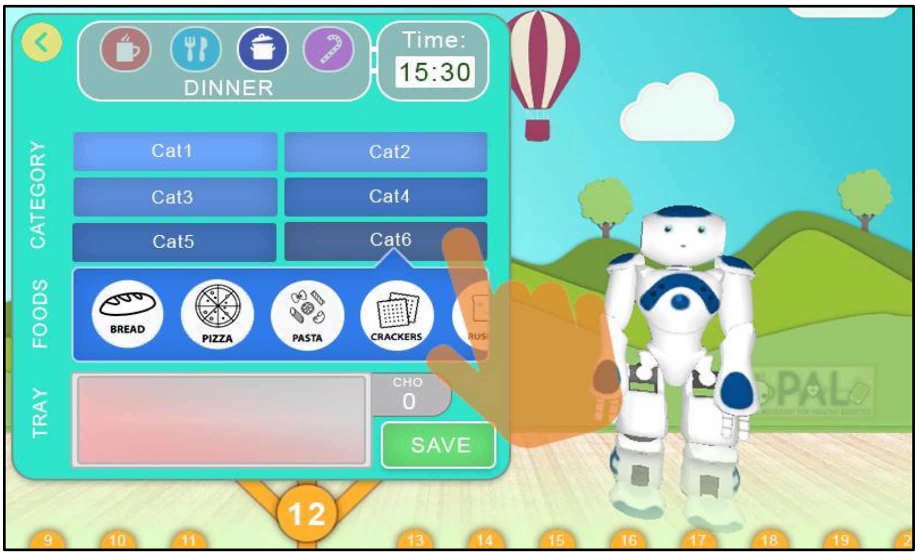

Figura 7 View of a functionality of the MyPAL app – Categories within meal section (Design 2017)

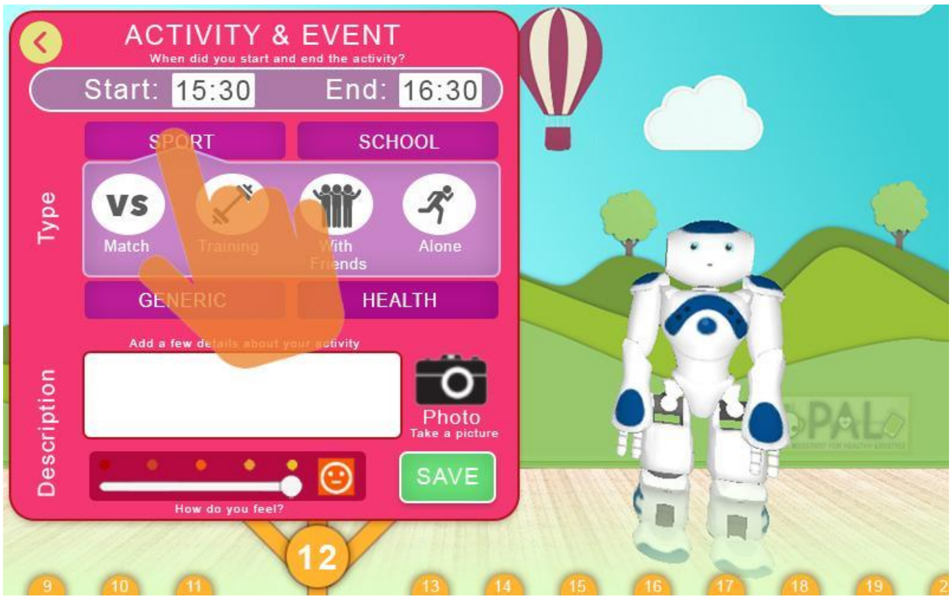

Figura 8 View of a functionality of the MyPAL app –Activity section (Design 2017)

4.3 PROCEDURE

Timeline of the experiments will be slightly different in Netherland and in Italy to match local requests, such as organizing visits around holidays. In Netherland the experimental campaign will be held from May 2017 to August 2017 (included), while in Italy it will be held from June 2017 to September 2017 (included). Each participant will use the second release of the currently available features of PAL System for approximately four months.

The activities related to the present Protocol will take place both in the premises of the hospitals involved and in the houses of the participating families. Children and their families are going to be scheduled three mandatory visits to the hospitals (at the beginning, halfway and at the end of the study period), where each child will have the possibility to interact with the NAO robot and the families will meet the research team and the healthcare professionals in order to be instructed about the activities proposed. In between visits 1 and 3, and visit 3 and 5, children and their families will interact with the PAL System at home. In addition, two optional events are organized at the hospitals, between visit 1 and 3 and between visit 3 and 5.

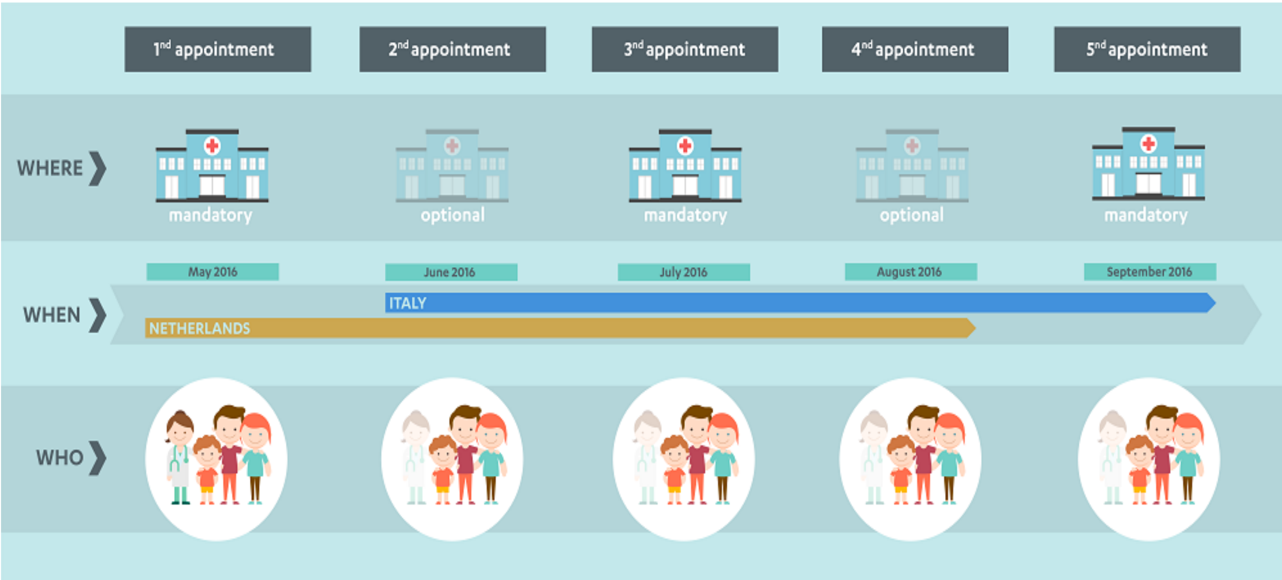

Figura 9 Timeline of the experiments

In the following section we report the details of the experiments' conduction of the Cycle 2 Experiments.

Before to the intervention period:

Children responding to the proper inclusion criteria, and their parents, are going to be contacted and briefly informed about the current study details and aims, and then invited to participate by the health care professionals (HCPs) involved and/or by the technical research team members. If they show interest in participating, will receive an information letter to take home. After approximately 1 week the parents and their children are asked whether they are willing to participate (or not). If so, further information will be given and there will be for them the opportunity to ask for any question or doubt. Then, five appointments are scheduled during the intervention period.

First appointment at the hospital (T1):

The participating children and their parents arrive at the hospital on the basis of their appointment schedule and are received by the multidisciplinary PAL team, composed by: the technical researcher(s) and the healthcare professional figures among the researcher team - the psychologist and the caregiver, a medical professional profile among the paediatric diabetological team (e.g.: paediatrician/diabetologist, a nurse or a nutritionist - depending on their availability). Before starting the encounter, they have the opportunity to ask further questions and sign the informed consent forms - specifically designed for this protocol - before the activities take place (see documents "*infconsChildren/infconsParents/infconsHCPs.pdf*").

Firstly, both children and parents have to fill in some questionnaires, that are aimed to collect data to characterize the involved population. All the questionnaires to be used during this appointments and the others, are specified in section 4.4 Materials and measurements.

As long as both parents and children finish to complete the given questionnaires, they meet with the Healthcare Professionals and start to complete together the children's profile on the *PAL Control* panel of the Caregiver. After this introductory moment, the whole family is introduced to the *MyPAL* app by the team, who explains its functionalities and how to interact with it on a tablet. Then the Caregiver and the family collectively decide the diabetes self-management goals that each child has to accomplish in the study period. These goals are set in the *PAL Control* panel and directly transmitted to the *MyPAL* app. The personalized goals are strictly depending on children's age and doctor's judgement, T1DM-related knowledge, skills and degree of autonomy and combine objectives strictly related to system that have an impact on the self-management of the disease <u>from an educational point of view</u> (e.g.: fill in the MyPAL therapy diary for at least three times a week in autonomy, try to insert in the therapy diary regularly the glycaemic checks, remember that's important to check glycemic level before and after doing sport, etc).

It has to be underlined that the activities performed through the MyPAL app have not a direct impact on the therapeutic management of type I diabetes (e.g.: they does not affect the insulin dosages of the children or provide an estimation of the carbohydrates counting), but are focused on the educational importance of fostering a correct management of the disease following the proper medical guidelines (e.g.: fill in the glycaemic and nutritional diaries, follow the correct sanitary norms before checking the glycaemia, etc…).

To conclude, before going away, children are brought by the technical researcher(s) to the robot-interaction room. Here they are introduced to the NAO robot and start chatting, exchanging a few questions to break the ice and get familiar to each other, starting to create a bond. Then they start to play the quiz together. The Child-Robot Interactions are going to last about 20 minutes each and are video and audio recorded.

The appointment lasts a maximum of two hours in total; all the questionnaires are given to the participants in their native language (Italian or Dutch).

Event at the hospital and measurements (T2, 3 and 4):

In between visit 1 and the final appointment there are three events. During the events, children and parents receive a short presentation about the PAL project and relevant updates of the System (i.e., new features added, new feedback when using the timeline). Also, they can ask questions about the PAL System (e.g., working of MyPAL or technical issues they experienced). They complete a number of surveys, as listed in section 4.4. Then children can interact with the PAL System (e.g., Quiz and Sort&Break with Robot) in groups and join social and creative sessions to share their experiences with the PAL System in an informal and pleasurable way (e.g., image theater, user Journey Map and photo collage) (Blanson Henkemans et al., 2016 HRI2016). We specify that the event at T3 is mandatory for both children and parents, while the events at T2 and T4 are optional.

Final appointment at the hospital (T5):

The children receive a notification by MyPAL that today they, together with their parents, are going go visit at the hospital the PAL research team and will interact again with the NAO robot. As soon as they arrive they are received by the technical researcher(s) (also the Healthcare Professionals might be present, depending on their availability). Children are brought to the robot-interaction room and have the chance to play with it another time. The Child-Robot Interactions are going to be video and audio recorded according to the consent of the parents.

In the meanwhile, the parents are invited to discuss together with the researchers their experience, focusing on their acceptance of the tool, the perceived usefulness, its usability and the performance of their sons in reaching the assigned goals. This discussion will be handled through a first questionnaire ("*Parents_final_questionnaire.pdf"*).

As soon as children finish to play with the robot, they undergo a last brief discussion with the researchers, focusing on:

➢ Their own diabetes self-management goals

➢ Self-efficacy

➢ Their perception of the robotic character (both embodied and virtual)

Before going away, children receive a little gift for participating in the current protocol (e.g.: a photo with the robot).

Observations at home

At home the children and parents will receive weekly a pop-up request by an installed EMA-app to complete a short questionnaire with some short questions.

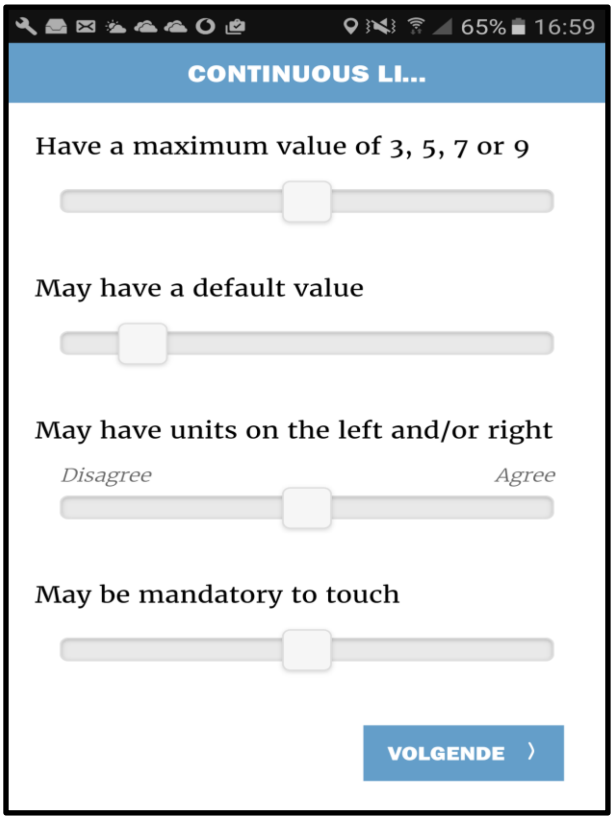

Figura 10 The EMA-app for short questions, eg. once a week

Tabella 2 Questions in EMA app (weekly pop-ups of short questions):

Child/ Parent	Claim	EMA question	Answer
Child	Well-being	1. How do you feel right now?	Very bad :-(<> Very good :-)
Child	Bonding	2. Do you see the robot as a good friend?	A very good friend <> not a very good friend
Child	Similarity	3. Is the robot in the app the same as the robot you have met in the hospital?	Very much the same <> Totally different
Child	Fun	4. Do you have a lot of fun with the	Lots of fun <> Not much fun

		robot right now?	
Child	Motivation	5. Do you look forward to playing with the robot right now? (Why yes/no?)	I do not look forward to playing with the robot <> I do look forward to playing with the robot.
Child	Diabetes knowledge	6. How much do you know about diabetes right now?	Not much <> A lot
Child	Diabetes Self-Management Behavior	7. How much diabetes activities can you do yourself right now? (for example count carbs or prick yourself)	Not much <> A lot
Parent	Stress	1. Do you often worry about your child?	Not very often <> Very often
Parent	Disclosure	2. How often does your child talk about diabetes?	Not very often <> Very often
Parent	Diabetes Knowledge	3. How much does your child know about diabetes?	Not much <> A lot
Parent	Diabetes Self-Management Behavior	4. How much diabetes activities can your child do him/her-self right now? (for example count carbs or prick him/her-self)	Not much <> A lot
Parent	Motivation	5. Is your child motivated to play with the robot app?	Very motivated <> Not very motivated

4.4 MEASURES AND INSTRUMENTS

Tabella 3 Overview of the measurements to be used during the Experiments

Measure	Instrument (participant)	Time	Country
Family Demographic questionnaire (used in PAL year 1 experiment)	Parents	T1	NL+IT
Health-Related Quality of Life (used in PAL year 1 experiment)	Parent: PedsQoL-Diabetes Module, 25 items Child: PedsQoL-Diabetes Module, 28 items - subset PedsQoL treatment 1 & 2: 11 items	T1 - T3, T5	NL+IT
SUS questionnaire	Children - 10 items based on methodology plus other 5 questions from researchers	T2, T3, T4, T5	
Bonding	Child: BOND robot+avatar-child 20 items as used in NL camp (also compare Avatar vs Robot again?) (also in EMA*)	T1, T3, T5	NL+IT
Attitude child robot and avatar	Child: part of SUS & BOND	T1-T5	NL+IT
Expectations of PAL	Child & parent: Open question	T1	NL+IT
Trust child and parent of PAL	Child & parent: BOND	T1, T3, T5	NL+IT
Acceptance child and parent of PAL	To what extent do children and parents feel that PAL could/would be a part of their daily life in the future (additional questions)	T1, T3, T5	NL+IT
Similarity PAL Robot and Avatar	Child: 3 items as used in PAL year 1 experiment/camp (also in EMA*)	T1, T3, T5	NL+IT

Usability child parent and HCP	Child: SUS 10 items Parent: SUS 10 items HCP: SUS 10 items + interview	T3, T5	NL+IT
Motivation to use PAL	3 items as used in PAL year 1 experiment/camp (also in EMA*)	T1, T3, T5	NL+IT
T1DM Self-management	Child & Parent: 3 items as used in PAL year 1 experiment/camp (also in EMA*)	T1, T5	NL +IT
T1DM Knowledge	Child & Parent: derive from quiz performance (objective calculator)	T1, T5	NL +IT
Child initiated diabetes talk	Parent: 3 items how often child initiates talk about Diabetes? (also in EMA*)	T1, T5	NL+IT
Perceived child vulnerability by parents	Parents: child vulnerability scale	T1, T5	NL
Parent's stress	Parents: time investment for child self-management, free time, influence on work, parental stress (also in EMA*)	T1, T3, T5	NL+IT
Log files system use	System usage, self-disclosures and information inserted in timeline, knowledge during quiz, goal attainment, Sort&Break performance.	T1->T5	
*=EMA (Ecological Momentary Assessment)	EMA app: randomized pop-ups of short questions: parents & children (see table of questions at EMA description)	T1->T5	weekly in NL+ monthly in IT
T1DM values	Glucometer values	T1, T3, T5	NL + IT
Wishlist PAL Y3	Creative co-design session	T2 and T4	NL+IT

*T1=first visit; T2=event 1 (optional); T3=event (mandatory) ;T4=event (optional); T5= final visit

The activities concerning the data collection phase for the present protocol will be conducted through the use of the following methodological tools:

➢ *Questionnaires* - the following questionnaires are going to be exerted:

  ○ <u>the Family demographic questionnaire</u> is aimed to the participating parents. It's objective is to derive a preliminary database of descriptors for the participating pool, to see if there can found any differences among them (e.g.: age related, cultural related, etc…). It is composed by two sections, the first one aiming at collecting general data about the family (age of the parents, level of instruction, age of the child, gender, when s/he was diagnosed with T1DM, etc.) and the second one more focused on exploring the diabetes management dynamics in the family (perceived level of knowledge, communication, relation with the school, etc.). Please refer to *"Family demographic questionnaire.pdf"* for more details.

○ Children's quality of life questionnaires (*Pedsql^{TM}* – diabetes modules for 8-12 y.o., see documents "*PedsqlTM_8 12_T1DM*.pdf"). The PedsQL^{TM} Measurement Model is a modular approach to measuring health-related quality of life (HRQOL) in children and adolescents with T1DM). Among all the available QoL questionnaires, in the current context is used the PedsQL^{TM} as it is available both in Dutch and in Italian. This feature ensures the comparability of the results obtained.

○ Parents' perception of child's quality of life (*Pedsql^{TM}* – diabetes modules, see documents and "*PedsqlTM_parents_T1DM*.pdf"). It is the same questionnaire but aimed at the parents of children participating [14].

○ Parents' final questionnaire, is aimed at the participating parents and is focused on deriving their opinion on the usability of the PAL system and their impressions on the experience (see "*Parents_final_questionnaire.pdf*").

5. Data analysis

The before and after information of the usability test activities with the children were compared with explorative methods. The user experiences of the children, were collected and explored, and user requirements were derived from the data for the further development of the PAL system.

More specifically, the data collected were analysed using the most appropriate analytical methodologies. In the following points they can be found the details of the most common techniques of qualitative and quantitative analysis that were used in the present protocol.

- *Qualitative Analysis* uses analytical categories to describe and explain specific phenomena and reads the data to identify and index themes and categories centring on particular phrases, incidents, or types of behaviour. We can distinguish between general analysis techniques and specific ones (i.e.: related to the methods described in section 4.6).
  - **Specific analysis - Questionnaires.** In this phase of the study a frequency analysis will be used. Regardless of whether manual or automated methods are used to prepare a frequency distribution, it is usually necessary to encode the data numerically to facilitate their subsequent analysis. The frequency distributions summarize and compress data by

grouping it into classes and record how many data points fall within each class, by converting these raw numbers into percentages. The frequency distribution is the foundation of descriptive statistics. It is a prerequisite both for the various graphics used to display data for both basic statistics used to describe a set of data - the mean, median, mode, variance, standard deviation, and so on. The frequency analysis allows to condense and summarize large amounts of data in a useful format and describe all sorts of variables in terms of user needs.

● **General analysis - Video/audio recording and content analysis**. It consists of a simple visualization of the registration of the activity held by the children participating, in order to check all the steps done by them. The qualitative content analysis is defined, in this context, as an approach to a controlled empirical analysis of texts in their context of communication, following the rules of content analysis [12] and pre-defined templates.

● **General analysis – collection of anonimous data –** data collected about the impressions and the suggestions on MyPAL app during an activity such as the brainstorming with the caregivers, will be analyzed in form of a report, in order to collect a list of information.

- *Quantitative analysis:* the use of only qualitative results cannot determine how effectively a system is usable or if there are significant differences in the participating pools; hence the need to apply quantitative studies to test the research hypotheses formulated. The present study will apply, wherever it is possible, different analyses that can range from simple descriptive analysis of data reduction to more elaborate techniques of multivariate associations. Below some examples of possibly used techniques:
    - **Descriptive statistics** shows the central tendency (i.e. the mean, median, mode) and will be used to describe the basic features of the study data. It provides a summary about the sample of the study and its measures of interest, such as the average value of a given parameter, its variability and dispersion and the relative frequencies. Together with the analysis simple graphical forms the basis of almost all quantitative data analysis of study.

6. Data management

During the "INTERMEDIATE PHASE - REFINEMENT THE USER REQUIREMENTS ANALYSIS", through the activities described in Paragraph 4, are going to be collected the following categories of data:

- Common data (personal data, information on lifestyle, hobbies, sporting activities carried out, etc ...) of the population involved in the present protocol;
- Children data that the privacy legislation defines as "sensitive" (information on the health status

and management of the diabetes therapy, such as glycaemic values and insulin doses);

- Feedbacks and insights from the methodologies (described in paragraph 5) used to collect the data, with information on their validation";
- Video and audio recordings of the children interacting with the MyPAL app.

The collection of such data has been carried out after the sign of an appropriate informed consent (see corresponding documents "*5_modulo CI_partecipante_SC_2016*").

Data collected in this Protocol has been managed and stored, either in paper or electronic formats, depending on their different nature. In Italy, they were and will be exclusively used for research purposes related to the PAL project, in accordance with the principles of necessity and not excess. In Netherlands, the modalities and possibilities to sharing data and video will depend on the written informed consent given by caretakers and children and by the ethical committees of the partners involved.

The personal and sensitive data, audio-video recordings of each participant, together with the other data collected during the activities has been identified by a code. With exception of the name, these data has been recorded, processed and stored through such code. Data collected were and will necessarily be shared, in their coded form, to the other partners of the PAL Consortium for the required research.

As we use online servers to store the data needed for the experiment, we have taken security precautions so only partners within the project can access the servers.

7. Potential threats and countermeasures

- Children will not be present at all three appointments because of:
  - External factors, e.g.: child needs to be hospitalized or unforeseen family affairs
  - Internal factors, e.g.: child does not want to use the PAL System
- Children and their families miss one of the three appointments:
  - due to External factors, e.g.: the child is sick
  - due to Internal factors, e.g.: the child/parents is/are bored of using the System and does not want to proceed in the activities proposed
- The Healthcare professionals are not able to participate:
  - due to External factors, e.g.: they are sick; they have emergencies in the ward
  - due to Internal factors, e.g.: the PAL Control Panel is not functioning
- Technological problems:
  - the MyPAL app is unstable
  - the MyPAL app is not properly working
  - the MyPAL app is not easy to understand and usable
  - the PAL robot is not properly functioning
  - the PAL backend system is not stable

Why are these inevitable?

- External factors can happen anytime and the participating end users must be really interested in the activities proposed.
- Internal factors are more difficult to be handled, as the participating pool were free to quit the study anytime, and these unforeseen are due to embedded problems in the System probably difficult to repair in time of the study.

If drops out from the study happen, the defecting end-users will be voluntarily interviewed, in order to discover the reasons of their choice and their impressions on the experience in general. All the information gathered in this way will constitute a valuable soil on which grounding the improvements to the system to be implemented in the next PAL System release

What measures will be taken to alleviate obstacles?

- A detailed description of what was the path of the activities will provided to all the participants before their beginning;
- The researchers, in particular, will explain to the participants that the present was an explorative study, in order to implement the System and, because of that, the System performances were limited. Nevertheless, it was pointed out that for the researchers it was of key importance to have this version tested in order to be able to improve the PAL System in the next project steps;
- The researchers will be available anytime for questions and clarifications by the participants and tried to be as flexible as possible in order to face possible unforeseen (e.g.: need to reschedule one of the appointments)

8. ETHICAL ASPECTS INVOLVED

In addition to some more traditional issues regarding the potential risks and benefits of this research protocol with respect to study participants, some more innovative considerations related to the specificity of this study might be pointed out. We will present the latter, by dividing them in two main categories:

i) *Ethical issues related to roboethics* (in particular, ethical issues related to the implications of the introduction of humanoid robots);

ii) *Ethical issues related to the use of humanoid robots in the biomedical context.*

1) Ethical issues related to roboethics

The characterizing feature of this project (which appears interesting also from an ethical standpoint) is the interaction of a humanoid robot (the so-called NAO) with the research subjects involved in the experiment: children, parents and healthcare professionals. However, since the two latter kinds of subjects will have only indirect contacts with NAO, most ethical concerns that we will highlight below, regard only the relationship between NAO and the paediatric population. Most of these concerns belong to the interdisciplinary field known under the label of “roboethics”, defined as the discipline which analyses and define the complex set of relationships between humans and their intelligent artefacts [19]. Since these latter highly differentiate amongst themselves, the identification of the ethical issues depends upon the definition of the specific type of artefact we are interested in. Within the *Roboethics Roadmap* [18] – the tool aimed at providing a “systematic assessment of the ethical issues involved in the Robotics R&D; to increase the understanding of the problems at stake, and to promote further studying and transdisciplinary research” [18] – a specific section is devoted to presentation of the ethical pros and cons to the use of humanoid robots. In what follows we will present and discuss those issues of the Roadmap that seem to be applicable also in our context and, therefore, that might have some interest for us.

Three benefits have been identified.

First of all, humanoids robots are intelligent machines that can assist humans to perform very difficult tasks, and behave like true and reliable companions in many ways. Translating this first issue in our context, we might claim that NAO appears as a fundamental element in the process of helping the paediatric patient to become more and more as an independent and autonomous agent in his/her therapeutic path.

Secondly, humanoids are robots so adaptable and flexible that will be rapidly used in many situations and circumstances. This is true also in our case. Although humanoids have shown particularly promising in the field of biomedicine (not only in the case of patients affected by diabetes, but also in the one of patients affected by autism), they will be probably be used in several different domains.

Finally, thanks to their shape, they seem able to stimulate those emotional channels which might otherwise be unreachable [17]. Regarding this last aspect, we might observe that it is precisely the physical resemblance of NAO with a young child which seems able to allow a natural and symmetrical relationship between NAO and paediatric patients.

Amongst the disadvantages of the use of robots that might have some relevance also in our context, we might point out the followings: i) reliability of the internal evaluation systems of the robots; ii) unpredictability of robots’ behaviour. However, our study seems to be able to exceed both these criticalities. Indeed, on the one hand, this protocol configures as the further development of a preliminary study, presented and approved by the Ethics Committee of this Institution, which preliminary evaluated the protocol in which the first version of NAO was involved. This fact seems able to ensure, at least preliminary, the validity of NAO. On the other hand, we might say that NAO’s behaviour is highly predictable, since it has been specifically devised in order to fulfil some very simple tasks; moreover, some trained researchers will monitor the entire course of the experiment so as to be ready to intervene in case of system malfunctioning.

2) *Ethical issues related to the use of humanoids robots in the biomedical context.*

In conjunction to what already said, some additional considerations might be added regarding the specific use of humanoid robots within the biomedical field, in particular when they interact with a paediatric population. In this specific field of inquiry, one of the main ethical issues regards to what extent is it ethically legitimate to substitute the role of humans, in this case healthcare professionals, with the one of machines in a domain, like biomedicine, where the emotional involvement appears to play a central role in the restoration of patient’s health.

Moreover, when the patient enrolled appears to be the child, some additional considerations might be pointed out. On the one hand it might be suggested that, by interacting with the robot, the child might develop an emotional attachment with the robot, which, however, will not receive anything in exchange. In other words, there cannot be reciprocity between the emotional investment sustained by the child and the robot. On the other hand, it can be observed that the interaction with the robot might provoke, in the child, the reconfiguration of the relationship with his/her peers, making the same child ever more devoid of those social and human capacities he/she will need in the course of his/her life.

Against this background, it can be argued that precisely the brevity of the child-robot interaction seems to prevent the development of such a scenario.

9. Data privacy

During scientific conferences or through scientific publications, such data can be disseminated in a totally anonymous form, so without reference to the person either in the form of code. In such circumstances, in case there would be the need to projected the collected video recordings or to show images reproducing the children, the faces will be blanked out to prevent recognition.

For what concerns the data collected during the intervention, they’re going to be managed and stored by the staff of Fondazione Centro San Raffaele and TNO (respectively for the Italian and Dutch participants) adopting appropriate security measures to prevent unwanted communication to third parties, their purloining or destruction.

The Ethical Committee, the European Commission, the Italian/Dutch and foreign Health Authorities can ask to look at the audio-video data concerning children participating, in order to assess the correctness and accuracy of the data collected by adopting, in any case, all the precautions so as to ensure the necessary confidentiality.

10. Data holder

The owner of the data collected during the years of the project are Fondazione Centro San Raffaele and TNO research center. The data collected will be accessible to the partners of the PAL Consortium limited to their competence and research area within the project. At the express request of the parents of the children participating, the collected data must be deleted. All data will be saved for 15 years.

11. Responsible investigators

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