Protocol PAL-643783-2

Descriptive Title: PAL – Personal Assistant for healthy Lifestyle, INITIAL PHASE – FIRST DEVELOPMENT AND VALIDATION.

Sponsor code: Grant Agreement n° 643783

Protocol Date and Version: **04/02/2016, 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: 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".

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 - eg .: 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

[1] www.aldebaran.com

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)

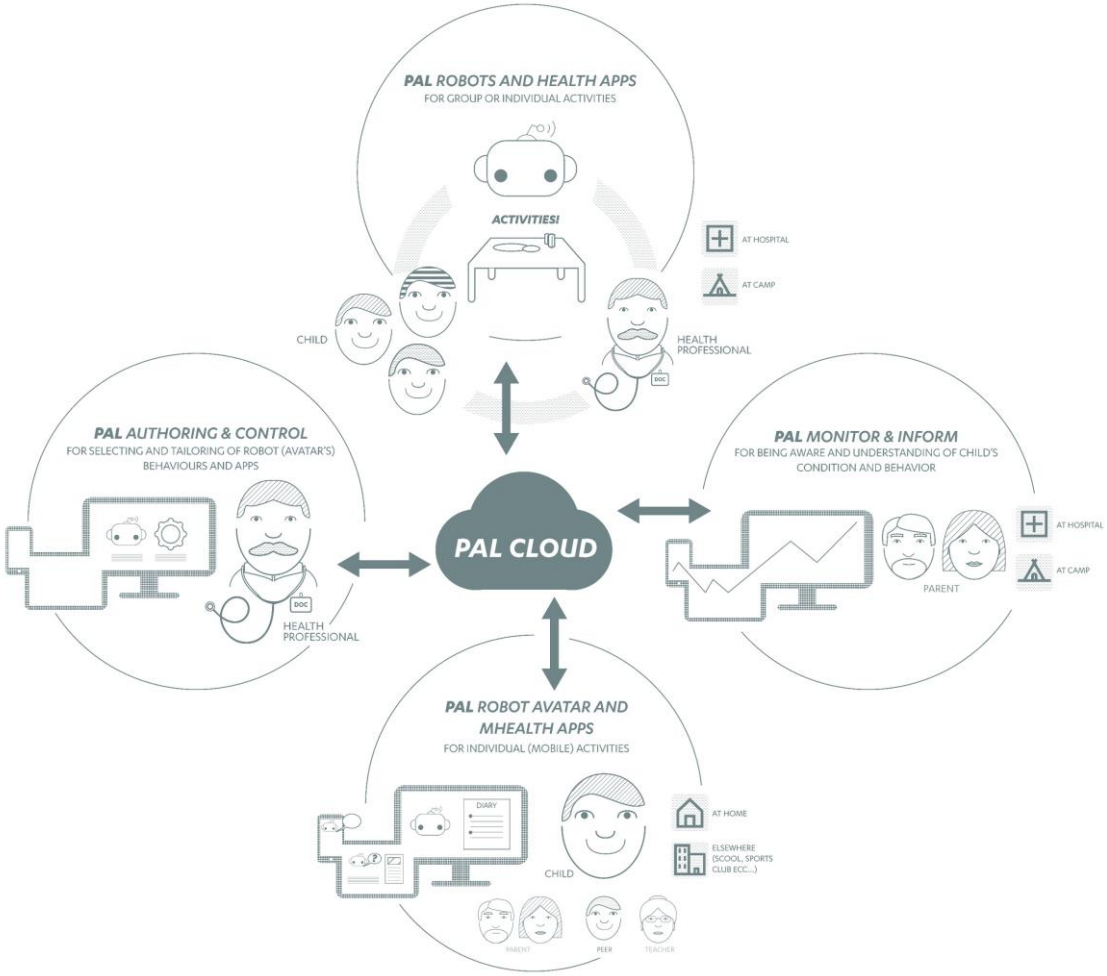


Figure 1: PAL system architecture

Specifically, the entire project presents the following objectives, which can be summarized in five 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. For example:

   a. The determining factors for a child/ teenager (eg: knowledge, habits, attitudes, needs, etc ...) that may impact on disease management (eg: adherence) and then be reflected on his state of health (eg: metabolic and glycemic control)
   b. The determining factors for parents (eg: 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.
2. 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.
3. 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 ...)
4. Develop a user-model to tune the educational support and motivational hints given to children/ young people depending of their behavioral and evolutionary change, their preferences, knowledge, skills and experience.
5. Develop a series of applications for mobile technology focused on the promotion of healthy lifestyles and strengthening of knowledge (eg. 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
  - 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
  - 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 Protocol, to be assessed by the Ethical Committee, is intended to describe the objectives and research activities that will be brought forward during the FIRST DEVELOPMENT AND VALIDATION of the INITIAL PHASE.

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 question and aims of the study

Overall research question: How can the first release of the PAL system, made up by a personal electronic buddy (both embodied and virtual) and of a set of mHealth apps (timeline and quiz game), 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)?

Specific research aims:

The primary aim of this experimental campaign is to have a first explorative evaluation of: (i) the effects of the 1st PAL system prototype on the User Experience (see below) of the participants (both children, their parents and the physicians following them) and (ii) of the Determinants (see Table 1) characterizing the end-users involved.

(i) 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, behaviors and accomplishments that occur before, during and after use.

- Children's PAL user experience:
  - Accessibility, understandability, visual appealingness
  - Attitude towards PAL system: whole system and aspects of system
  - Pleasure and engagement
  - Relatedness (development and maintenance of close personal relationships) to PAL actor
  - Actual usage of PAL system
  - Motivation to (continuing to) use PAL
  - Feedback on current PAL system
  - Requirements for improving PAL system
- Parents' PAL user experience:
  - User experience and attitude (considered through the two Determinants of trust and knowledge) with regards to PAL system. Parents, in fact, would have the possibility to support their children in using the system if needed and discuss directly with them its features and its applicability in the real everyday life
- Healthcare Professionals' (HCP) PAL user experience:
  - User experience and attitude (considered through the two Determinants of trust and acceptance)

Detailed research questions about User Experience:

- Is the 1st PAL system prototype easily accessible for the end-users? (Children, Parents, HCPs)
- Is the 1st PAL system prototype clearly understandable for the end-users? (Children, Parents, HCPs)
- Is the 1st PAL system prototype appealing for the end-users? (Children)

- Is the 1st PAL system prototype sufficiently engaging for the end-users to foster motivation in its usage both in the intervention period and in a long term perspective? (Children)
- Is the 1st PAL system prototype sufficiently engaging for the end-users to foster motivation towards the achievement of the personalized diabetes management goals? (Children)
- Is the 1st PAL system prototype perceived as a useful and trusted tool by the end-users? (Child, Parents, HCPs)
- Is the 1st PAL system prototype able to vehiculate to the end-users and reinforce key contents about T1DM? (Child, Parents, HCPs)

(ii) The overall PAL's Determinants, over the three different phases previously described, are displayed in the following Table 1 according to the various end-users categories. The second main focus for the current protocol is to get insights in the children's knowledge, awareness, attitude, self-efficacy and skills, their parent's attitude and knowledge and the health care professionals' trust and acceptance of the PAL system. This analysis is particularly interesting in order to qualitatively identify possible future patterns of change over time, such as knowledge and skills (learning), awareness, attitude and self-efficacy (but also mood and self-disclosure).

	Initial Phase	**Intermediate Phase**	**Final Phase**
Determinants	**Knowledge & Awareness**	Diabetes Regimen Adherence	Shared Child-Caregiver Responsibility
Children - age dependent claims	7-10 yr: + knowledge + awareness + attitude + self-efficacy + skills	7-12 yr: + regime adherence + glucose monitoring	7-14 yr: + 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	diary, quizzes, sorting game, miniApps	diary, quizzes, sorting game, miniApps

Table 1: project roadmap - three specification & evaluation cycles with an increasing scope.

A secondary aim is to get a first qualitative indication of the possible effect on diabetes/health/lifestyles-related behaviours of the children involved. This will lay the basis for the investigation field of the PAL's future studies.

- Children's indicators for self-management
  - Goals reached (if any), as set with healthcare professionals and parents
  - Any possible change in knowledge about disease and self-management behaviors (based on the document "*diabetes know&do-goals. pdf*")

Thirdly, it is intended to analyse the participants' descriptors (e.g. gender, age, socioeconomic status, ethnic background - Netherlands & Italy -, etc.) in order to see if they trigger any influence on User Experience. These results will be 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.

4. Description of the Experimental Design

4.1 Study's participants: description, sample size and its justification

This protocol is going to enrol the following categories of end-users:

1. *Children with T1DM in the age of 8-10 years old*, belonging to the three different hospitals 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 of 15 subjects per hospital. In this way a total pool of 30 to 45 subjects will be ensured, which generally constitutes a sufficient amount of people for a pilot study. An inclusion criteria is that all children participating must have been diagnosed with Type 1 Diabetes for at least six months, to avoid potential strong effects of a recent diagnosis on the intervention's results;
2. *Parents of the participating children* are going to 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* are going both to take actively part to the execution of the current protocol alongside the project researchers and to provide useful feedbacks and insights about their experience with the 1st PAL prototype. 2 healthcare professionals per hospital are going to be involved among the three paediatric diabetological teams: one with a medical profile (e.g.: paediatrician/diabetologist, a nurse or a nutritionist) and another with a psychological one (i.e.: psychologist specialized in developmental age).

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 10, with an onset not less than six months;
- at least one parent per child participating (from 10/15 to 20/30 parents);
- 2 healthcare professionals 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 10, with an onset not less than six months;
- at least one parent per child participating (from 10/15 to 20/30 parents);
- 1 or 2 healthcare professionals belonging to the MMC and GV paediatric diabetological team.

Being this current an exploratory and preliminary research, the sample size involved in the "INITIAL PHASE - FIRST DEVELOPMENT AND VALIDATION" protocol cannot be defined with certainty in advance, but the minimum thresholds chosen guarantee a numerosity 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.

The number of participants to be included in the studies with a 'user-centered' approach is a matter of discussion amongst all the experts in the sector since a long time [5]. Although in statistical studies the sample size is crucial, in User Experience contexts of analysis it is generally more contained. For example, Beyer and Holtzblatt [6] have deduced that, depending on the purposes of the research, from 6 to 20 participants might be included. In [7][8] it is suggested that, even in the presence of a number of participants between 5 and 10, an adequate consistency can be achieved in the research.

According to these studies, the minimum threshold for the children with T1DM participating, who are the main focus of the present research, has been set to 10. The maximum threshold of 15 has been chosen so to be able to handle a greater afflux of volunteers for the activities and to eventually be able to face possible drops out (so to guarantee in any way the minimum required threshold of 10 children).

4.2 Settings

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 two visits to the hospitals (at the beginning 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. Moreover, in between, children and their families will interact with the 1st PAL system at home.

4.3 Timeline

From April 2016 to May 2016 (included): each participant will use the first release of the currently available components of PAL system for approximately one month.

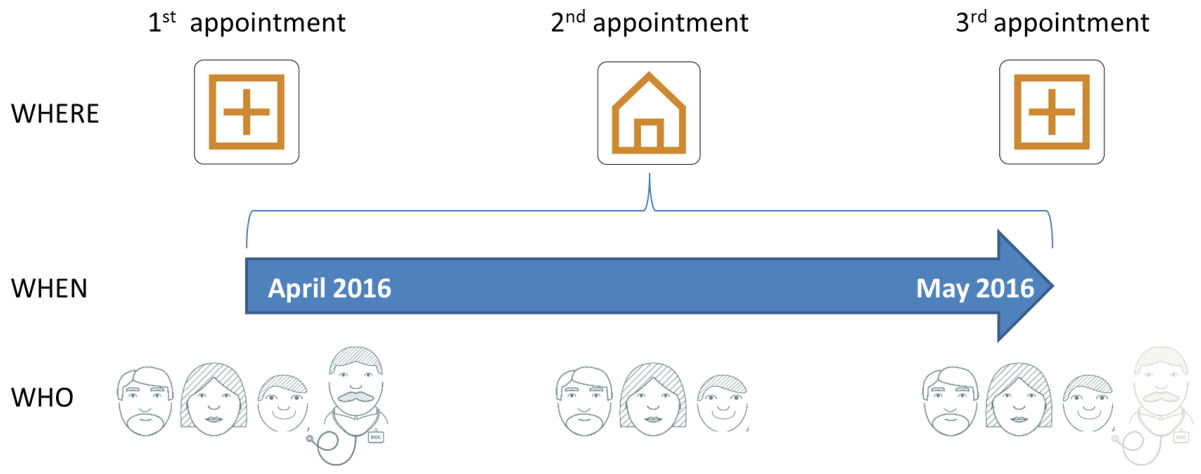


Figure 2: Protocol timeline and settings schema, "Where" defines the settings of the activities (at home or at the hospital), "When" exemplifies the time-gap of the intervention, and "Who" summarizes the figures involved in the process (the parents, their child and the healthcare professional).

4.4 Materials

Technological components of the 1st PAL system:

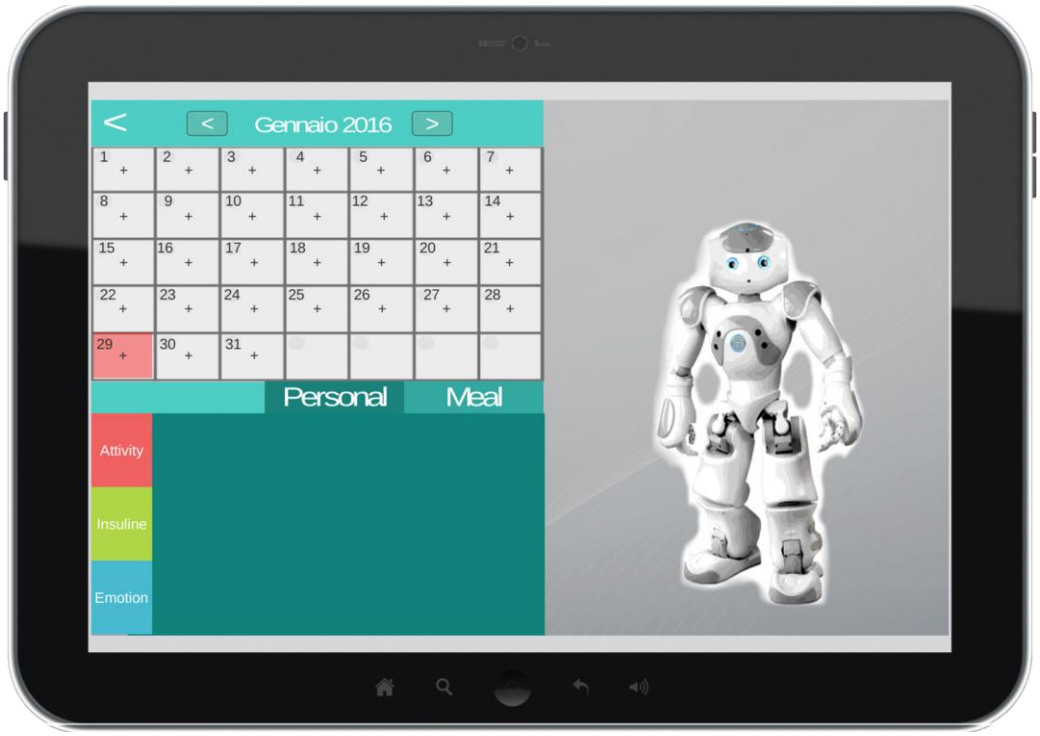
- *NAO robot* - the Nao robot is manufactured by a French company (Aldebaran Robotics) as a safe and tested product (see the document "Declaration of conformity NAO robot.pdf"). It is important to underline the NAO robot is not a medical device.
- *Tablets (one per child)* - the Timeline and Quiz functionalities, 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 1st PAL system

The 1st release of the PAL system is composed by the following parts:

- Quiz game with the NAO robot (physically present at the hospital premises) - children and the NAO 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.
- the mHealth PAL app (named *MyPAL*) for tablets, comprehensive of the Timeline 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 3. 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").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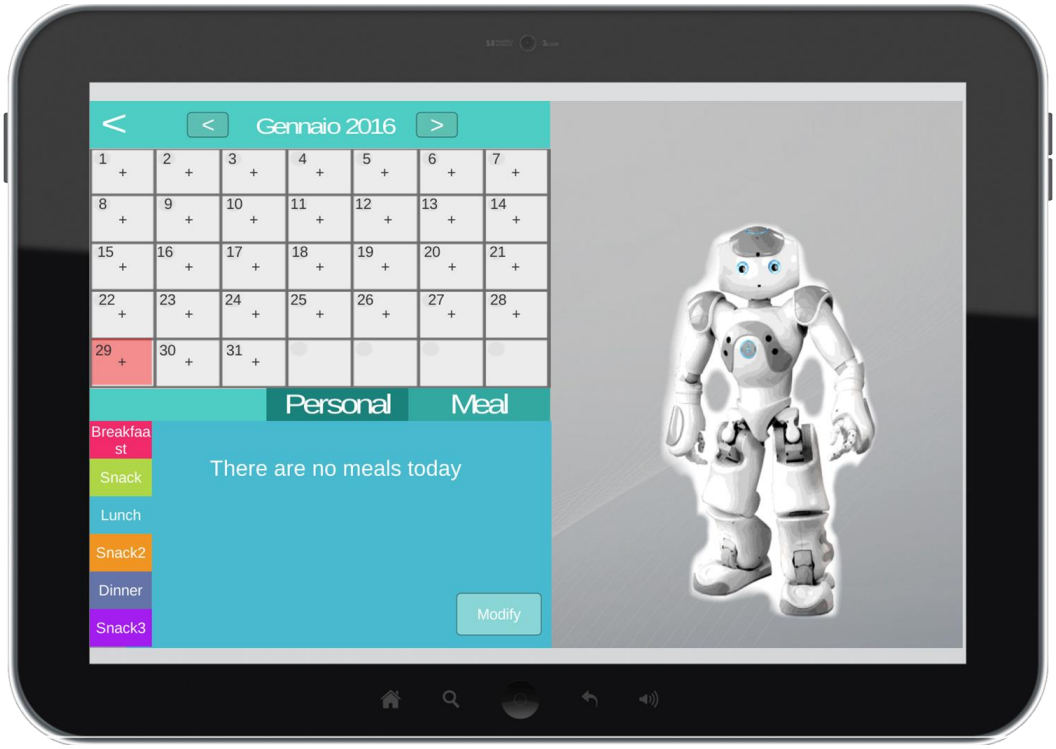
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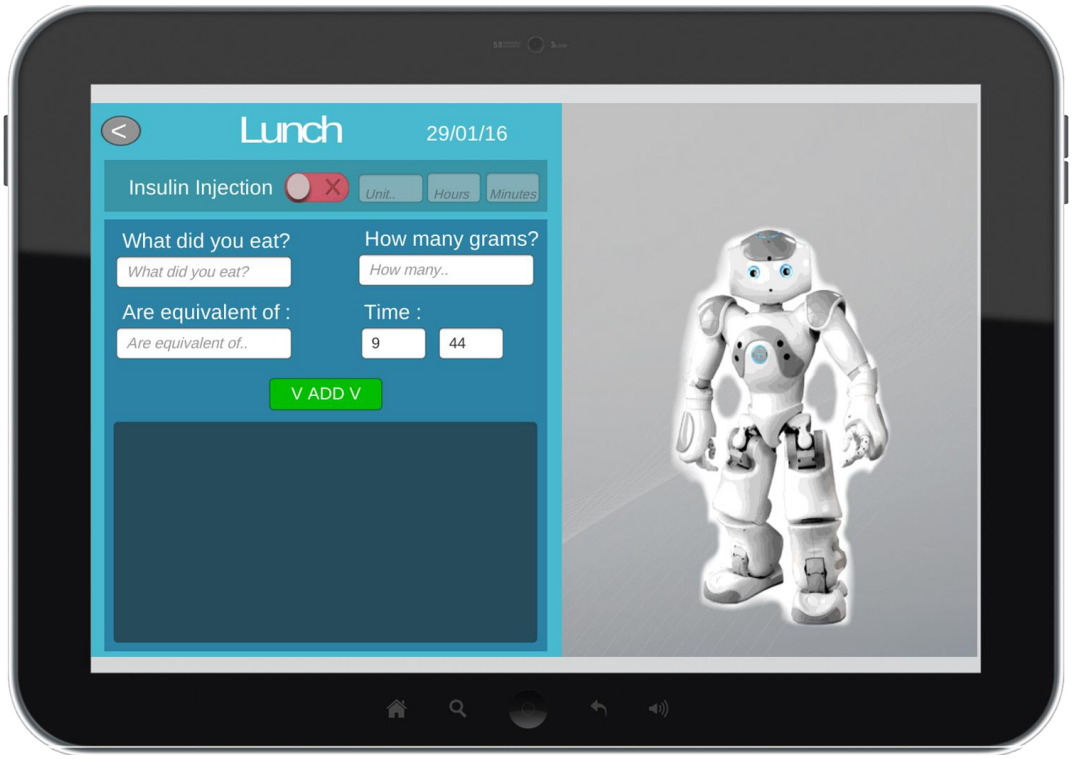

Figure 3 - views of the Timeline functionality of the *MyPAL* mHealth app

The *MyPAL-Quiz game* is an interactive game for tablets in which the child and the robot compete in a contest with multiple questions both about general knowledge and diabetes-related. The database of the *Quiz game* questions, is the same used for the Child-Robot Interaction with the physical NAO at the hospital.

➢ The *PAL Control* panel for the healthcare professionals, is a web-based portal dedicated to the caregivers involved in the activities and it is directly connected to the *MyPAL* app. By creating their own account, each caregiver can fill in the data of the young patients involved in the activities (e.g.: name, surnames, onset, type of T1DM therapy, sport activity if any, hobbies, information about the family, etc…) and set the objective to be pursued for each child in the intervention period (based on the document "*diabetes know&do-goals. pdf*").

4.5 Procedure

In the following are reported the details of the experimental design. Please make reference to Figure 2 for a schematic visualization of the actors involved, the timeline of the experiment and the different locations of the experiment.

Previously 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, three appointments are scheduled during the intervention period, so once every 2 weeks: two in person at the hospital and one remotely managed (i.e.: telephonic/Skype appointment and on-line questionnaire).

First appointment at the hospital premises:

The participating children and 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 - the psychologist and the caregiver, a medical professional profile among the paediatric diabetological tem (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:

- *Children*: quality of life questionnaires (*Pedsql™* – generic and diabetes modules for 8-12 y.o., see document "*Pedsql™_8 12*.pdf" and "*Pedsql™_8 12_T1DM*.pdf") [14];
- *Parents*:
    - Family demographics questionnaire - see document *"Family demographic questionnaire.pdf"*;
    - Parents' perception of child's quality of life questionnaires (*Pedsql™* – generic and diabetes module, see document "*Pedsql™_parents*.pdf" and "*Pedsql™_parents_T1DM*.pdf"), one per family [14];

As soon as children finish to complete the Pedsql questionnaires, while their parents are completing the other ones, they are interviewed by a member of the research team following the schema of the semi-structured interview reported in document "*Initial Interview_children.pdf*".

As long as both parents and children finish to complete the given questionnaires and reply to the interview (children only), they meet with the healthcare professionals and start to complete together the children's profile on the *PAL Control* account 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, 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 from an educational point of view (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. Then they start to play the quiz game together. The Child-Robot Interactions are going to last about 20 minutes each and are video and audio recorded.

The appointment lasts approximately one hour in total; all the questionnaires are given to the participants in their native language (Italian or Dutch).

First two weeks of usage of the 1st release of the PAL system at home:

Children and their parents go home and set up the *MyPAL* app on the tablet; then children start to interact with it depending on their assigned goals and/or the engagement in the PAL system. If they need any assistance or have some doubts they can call the technical researcher(s).

Second appointment (remotely managed, via Skype or telephonic call):

Children receive the notification by MyPAL that today they are going go have a call with the PAL researchers, in order to have a mid-time evaluation of the experience with the system. At the agreed time the call starts and the researchers discuss with children (a/the parent/s can be present, especially for the younger children) on the following points (please refer to document *"Intermediate Interview_children.pdf"* to see the mid-term interview track):

- ➢ grade of achievement of the assigned goals and discussion on this basis
- ➢ grade of engagement with the PAL system and feedbacks on it

All the Skype and/or telephonic appointments are going to be audio recorded.

After the call, on the basis of the healthcare professional feedbacks on the results achieved child per child, new diabetes-related goals are inserted in the PAL Control panel and sent directly to the MyPAL app (to be visualized by children) or the old ones are re-confirmed, for the last two weeks of intervention.

The parents, instead, are going to receive an online questionnaire to be compiled (see document *"Intermediate questionnaire_parents.pdf"*), in order to explore the following points:

- ➢ grade of achievement of the assigned goals of their children and discussion on this basis
- ➢ grade of trust and acceptance of the PAL system and feedbacks on it

Third appointment at the hospital premises:

Children receive the 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 health care 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.

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"*) and, on its basis, a brief semi-structured interview. Please refer to document *"Final_interview_parents.pdf"* to see the structure of the interview. The interviews are going to be audio-recorded.

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)

The discussion will take cue, as a basis, from the reply of children to some questions given to them in a form of a brief questionnaire (see document "*Final_interview_children.pdf"* for more details).

The children's User Experience investigation, instead, will be handled through the Interactive Journey Map methodology (please refer to document *"journey_map_guidelines_MyPAL user experience.pdf"*).

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

At the end of the intervention period:

Short semi-structured interviews are going to be held with the involved HCP in order to derive their feedbacks and suggestions on the experience. Also in this case, the interviews are going to be are going to be audio-recorded. Please refer to document *"Final_interview_HCPs.pdf"* for more details.

4.6 Methods - Instruments used to collect the data and information on their validation

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

- *Semi-structured interview* - this particular type of interview is typically used in social sciences and in all the occasions in which the interviewer has a framework of themes to be explored. While a structured interview has a rigorous set of questions which does not allow the interviewer to divert, a semi-structured interview is open, allowing new ideas to be brought up during the conversation as a result of what the interviewee says [10]. In qualitative research and explorative studies, like the one described in the present document, semi-structured interviews represent a flexible and effective method to derive the desired insights [11]. It is conducted by two researchers and, with the consent of the interviewed, recorded on a digital media.

In this context two different types of semi-structured interviews are going to be exerted, different for structure and aims:

- the initial interview is aimed at children with T1DM and is intended to explore the attitude of the child towards robots before the experiments starts, their expectations and their current use of technology and the internet. The details of its structure can be found in *"Initial Interview_children.pdf"*;
- the mid-term interview is aimed at children with T1DM and is intended to derive the first impressions of the interviewed end-users on the usage in a real life setting of the PAL technology and its usefulness to support children in achieving their own personalized diabetes-management goals. The details of its structure can be found in *"Intermediate Interview_children.pdf"*;
- the final interview is aimed at the participating end-users (children with T1DM, parents and the healthcare professionals) and is intended to derive the final impressions of the interviewed on the PAL system and discuss in detail their User Experience. The main theme explored in these occasions are related to the perceived trust and acceptance of this kind of technological innovation, its possible potentialities and expected impacts, its usability. For what concerns the last point, usability, the issues covered by the parents' and HCPs' interviewers are directly referring to the System Usability Scale, a simple - ten-item scale giving a global view of subjective assessments of usability [13]. In this way all the three factors influencing an usability evaluation (i.e.: efficiency, effectiveness, satisfaction) are going to be covered [12]. Please refer to "*Final_interview_children.pdf", "Final_interview_parents.pdf"* and *"Final_interview_HCPs.pdf"* for the interview's details.

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

- the Family demographic questionnaire 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™* – generic and diabetes modules for 8-12 y.o., see documents "*Pedsql™_8 12*.pdf" and "*Pedsql™_8 12_T1DM*.pdf"). The PedsQL™ Measurement Model is a modular approach to measuring health-related quality of life (HRQOL) in healthy children and adolescents and those with acute and chronic health conditions (like T1DM in this case). The PedsQL Measurement Model integrates seamlessly both generic core scales and disease-specific modules into one measurement system [14]. Among all the available QoL questionnaires, in the current context is used the PedsQL™ 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™* – generic and diabetes modules, see documents "*Pedsql™_parents*.pdf." and "*Pedsql™_parents_T1DM*.pdf"). It is the same questionnaire but aimed at the parents of children participating [14].
- Parent's mid-term questionnaire (please refer to the document "*Intermediate questionnaire_parents.pdf"*), is a questionnaire aimed at evaluating the first impressions of the parents' regarding the MyPAL app, their preliminary perception of its usabilty and usefulness and their personal impressions on their children experience in this activity.
- 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*")

➢ *The Interactive Journey Map* tool provides a graphic and structured visualization about all the factors that influence the user experience, constructed from the user's perspective. In this occasion, the journey map is used with the purpose to extrapolate qualitative and quantitative data, involving directly the users (children with T1DM) by mapping their experience and telling their feedbacks and expectations about the PAL system in a playful and stimulating environment. Please refer to "*journey_map_guidelines_MyPAL user experience.pdf*" for more information.

5. Data analysis

The before and after information of the structured interviews with the children are compared with explorative methods. The user experiences of the children, parents and HCP's are collected and explored, and user requirements are derived from the data for the further development of the PAL system. Furthermore the usage of outcome measures, such as a diabetes-related quality of life questionnaire, and the effect of background variables on user experience and usage of system (logged time) will be explored, for future effect evaluation and future development of the PAL system.

More specifically, the data collected will be analyzed using the most appropriate analytical methodologies, in the following can be found the details of the most common techniques of qualitative and quantitative analysis that are going to be 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 centering on particular phrases, incidents, or types of behavior. We can distinguish between general analysis techniques and specific ones (i.e.: related to the methods described in section 4.6).

- **General analysis - Constant comparison analysis.** Also known as the method of constant comparison, can be used to analyze many types of data (e.g.: brainstorming data-interview-focus group data). Three major stages characterize the constant comparison analysis. During the first stage (i.e., open coding), the data are chunked into small units. The researcher attaches a descriptor, or code, to each of the units. Then, during the second stage, these codes are grouped into categories. Finally, in the third and final stage (i.e., selective coding), the researcher develops one or more themes that express the content of each of the groups.

- **General analysis - Classical content analysis**. Similar to previous one, the classical content analysis includes creating smaller chunks of data and then placing a code with each chunk. However, instead of creating a theme from the codes (as with constant comparison analysis), with classical content analysis these codes are placed into similar groupings and counted. The researcher will not only provide information regarding the frequency of each code (i.e., quantitative information) but also supplement these data with a rich description of each code (i.e., qualitative information), which would create a mixed methods content analysis.
- **General analysis - Keywords-in-context.** The purpose of this analysis is to determine how some words (keywords) are used in context with other words. The main hypothesis is that people use the same words in a different way, which requires an examination of the context in which they are used. These contexts are particularly important, for example, in focus groups or multiple interviews because of the interactive nature of the same: every word must not only be interpreted in light of all the other words spoken by a specific person, but it should also be interpreted with respect to the words spoken from all the other members of the study group.
- **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.
- **Specific analysis - Interviews.** Qualitative research and, in particular, interviews generate large amounts of data, which tend to be overwhelming. Following this concept, there's the need to manage the data, make sense of what is going on, get rid of extra and irrelevant information and travel safely through the maze of large and complicated paths of information. There are a number of approaches to the analysis of qualitative data we obtain, however, for the current protocol the choice falls on the Krueger's [16] "framework analysis", composed by five key stages: familiarization; identifying a thematic framework; indexing; charting; mapping and interpretation. The other distinctive aspect of framework analysis is that although it uses a thematic approach, it allows themes to develop both from the research questions and from the narratives of research participants. The process of data analysis begins during the data collection, by skillfully facilitating the discussion and generating rich data from the interview, complementing them with the observational notes and typing the recorded information. This stage is followed by familiarisation with the data, which can be achieved by listening to tapes, reading the transcripts in their entirety several times and reading the observational notes taken during interview and summary notes written immediately after the interview.

The aim is to immerse in the details and get a sense of the interview as a whole before breaking it into parts. During this process the major themes begin to emerge. The next stage involves identifying a thematic framework, by writing memos in the margin of the text in the form of short phrases, ideas or concepts arising from the texts and beginning to develop categories. At this stage descriptive statements are formed and an analysis is carried out on the data under the questioning route. The third stage, indexing, comprises sifting the data, highlighting and sorting out quotes and making comparisons both within and between cases. The fourth stage, charting, involves lifting the quotes from their original context and re-arranging them under the newly-developed appropriate thematic content. Indexing and charting could also be viewed as managing the data. One of the most important aspects of this task is data reduction, which is achieved by comparing and contrasting data and cutting and pasting similar quotes together. The data are now ready for the final stage of analysis, i.e. mapping and interpreting.

- **Specific analysis - Video/audio recording and content analysis**. It consists of a bundle of techniques for the analysis of the text systematic. 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 [15] and pre-defined templates. These steps to be followed for this content analysis are:
  - Decide the level of analysis.
  - Decide how many concepts to code for.
  - Decide whether to code a concept for existence or frequency.
  - Decide on how to distinguish among concepts.
  - Develop rules for coding the texts.
  - Decide what to do with "irrelevant" information.
  - Code the texts.
  - Analyze the results.

Once the coding is done, the data and attempt are analyzed to draw whatever conclusions and generalizations are possible.

➢ *Quantitative analysis:* the use of only qualitative results can not 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 (ie 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 "INITIAL PHASE - FIRST DEVELOPMENT AND VALIDATION", 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 glycemic values and insulin doses);
- ➢ Feedbacks and insights from the methodologies described in "4.6 Methods - Instruments used to collect the data, with information on their validation";
- ➢ Video and audio recordings of the Child-Robot Interactions and of the interviews with all the end -users (i.e.: children, parents and healthcare professionals).

The collection of such data will be carried out after signing an appropriate informed consent (see corresponding documents "*infconsChildren/infconsParents/infconsHCPs. pdf*").

Data collected in this Protocol will be managed and stored, either in paper or electronic formats, depending on their different nature. They will be exclusively used for research purposes related to the PAL project, in accordance with the principles of necessity and not excess.

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

7. Possible obstacles to testing and countermeasures

- Children will not be present at all three appointments because of:
  - o External factors, e.g.: child needs to be hospitalized or unforeseen family affairs
  - o Internal factors, e.g.: child does not want to use the PAL system
- Children and their families miss one of the three appointments:
  - o due to External factors, e.g.: the child is sick
  - o 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:
  - o due to External factors, e.g.: they are sick; they have emergencies in the ward
  - o due to Internal factors, e.g.: the PAL control panel is not functioning
- Technological problems:
  - o the MyPAL app is unstable
  - o the MyPAL app is not properly working
  - o the MyPAL app is not easy to understand and usable
  - o the PAL robot is not properly functioning
  - o 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 is 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 were to happen, the defecting end-users will be specifically 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 have been taken to alleviate obstacles?

- A detailed description of what is going to happen, during the study lifetime, will be provided to all the participants before the beginning of the activities;
- The participants, in particular, will be warned that the present is a preliminary study, with a first release of the PAL system and, because of that, the system performances will be limited. Nevertheless, it will be pointed out that for the researchers it is of key importance to have this preliminary 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 will try 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 audiovisual 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.

11.Responsible investigators

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Signatures

……., ……/……/…….

Promoter Signature:

……., ……/……/…….

Principal Investigator signature:

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Annexes

Consent form child and parents:

- *infconsChildren.pdf*
- *infconsParents.pdf*
- *infconsHCPs.pdf*

Diabetes Know&do goals document - "*diabetes know&do-goals. pdf*"

Questionnaires (in Italian and in Dutch, depending on the case):

- *Family demographic questionnaire.pdf*
- *Intermediate questionnaire_parents.pdf*
- *Parents_final_questionnaire.pdf*
- *PedsqlTM_8 12.pdf*
- *PedsqlTM_8 12_T1DM.pdf*
- *PedsqlTM_parents.pdf*
- *PedsqlTM_parents_T1DM.pdf*

Interviews:

- *Initial Interview_children.pdf*
- *Intermediate Interview_children.pdf*
- *Final_interview_children.pdf*
- *Final_interview_parents.pdf*
- *Final_interview_HCPs.pdf"*

Journey map guideline - *journey_map_guidelines_MyPAL user experience.pdf*