CareToy: An Intelligent Baby Gym

Home-based intervention for infants at risk for neurodevelopmental disorders

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This article describes the design of an innovative system for early intervention (EI) at home in infancy. The aim is to develop a smart device capable of promoting and measuring the actions of infants in the first months of life. The CareToy system, inspired by a commercially available gym for infants and equipped with a variety of sensors, can provide an intensive, individualized, home-based and family-centered EI program remotely telemonitored by clinicians. An array of sensors measures the activity of infants inside the gym. The sensor signals related to infant's movement, interaction with toys, and pressure distribution are acquired and processed in real time to classify the infant's activities and behavior. Rewards (feedback) are provided to the infants on the basis of their activity. Data are interpreted offline in terms of clinical meaning, and experimental tests are also reported.

Neurodevelopmental Disorders

Scientific Rationale

Neurodevelopmental disorders (NDDs) are conditions that impair an infant's ability to grow up along a typical trajectory. Infants born preterm (i.e., birth at fewer than 37 weeks gestational age) are at high risk for NDDs, including motor, cognitive, and behavioral problems due to central nervous system impairment. The incidence of preterm births is very high. The World Health Organization estimates that, every year, 15 million infants are born preterm, and the number is increasing due to improved survival rates [1]. Systematic and Cochrane Reviews indicate the evidence of the positive effects of EI, mainly based on the involvement of parents, on the development of motor and cognitive functions in preterm infants and, in general, in other groups of infants at risk for NDDs [2]. The aim of EI is to improve the overall functional outcome for these infants [3]. The activities to be proposed in the field of EI should include goal-directed exercises, where meaningful goals are provided to indirectly drive the required movements [4]. The therapeutic approach should also involve repetitive practice in a similar playing environment, which is engaging for the infants, and would be stronger if provided at home by means of an enriched environment (EE), i.e., a home organized to encourage the infant to perform specific tasks, carefully tailored to the developmental needs of the infant. The parent is actively and positively engaged with the child to facilitate and promote learning [5], [6]. The home environment should also include safe toys adequate for the infant's ability level to pose learning challenges along with family interactions.

Technology can provide a solution to these requirements. More specifically, the field of rehabilitation robotics has grown substantially during the past 15 years with promising results on school-aged children with neurologically based movement disorders arising from cerebral palsy and acquired brain injury or stroke [7].

As far as infants are concerned, different systems are already available and regularly used in clinical practice. Several studies reported systems for monitoring infants in neonatal

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intensive care units with approaches such as electroencephalogram, heart rate measurement, infrared thermography, and others [8]. In addition, the use of functional magnetic resonance imaging as a tool that can shed new light on the intracerebral processes underlying neurodevelopmental impairment [9]. All of these technologies require highly structured environments and are not suitable for home applications. A recent review paper presented methods for assessing motor functions in early infancy and shows the potential benefits of applying technology-assisted methods with nonintrusive technological solutions [9]. These include instrumented toys, equipped with lightweight sensors [10] that encourage play through goal-oriented activity with regular positive feedback as well as a game-like interface, similar to rehabilitation robots (though without the capability of moving the child's limbs). However, even if the main aim is to rehabilitate, these studies demonstrated only the feasibility of intelligent toys to derive quantitative movement measures in healthy infants.

To promote infants' skills, there is a need for tools that would provide not only quantitative measurement of infants' actions with the ecological approach but also rehabilitation intervention. The innovative aspect of this work is the development of a system that can be directly introduced at home to provide individualized training for each infant, combined with accurate, reliable, and repeatable measurements of relevant parameters related to infants' actions and movements during the training. Quantitative information is essential for the individualization of the training.

The CareToy Project

The framework for the development of the device presented in this article is the CareToy project (A Modular Smart System for Infants' Rehabilitation at Home Based on Mechatronic Toys). This project was a three-year (2011–2014) collaborative research project funded by the European Commission under the Seventh Framework Program, theme Information and Communications Technology (ICT)-2011.5.1 "Personal Health Systems (PHS)" aimed at developing ICT systems for the remote management of disease, treatment, and rehabilitation outside hospitals and care centers. It involved four European countries: Italy, Slovenia, Germany, and Denmark.

The partners had already developed platforms for measuring motor development in children (a mechatronic gym by Scuola Superiore Sant'Anna—Pisa [10], [11]). Preliminary clinical tests with typically developing infants showed that those devices are valid tools for continuous monitoring and quantitative measurements of infants' motor development without being stressful for the infants [12]. The aim of the CareToy project was to develop an innovative system to provide EI. The new platform, based on the concept of a baby gym equipped with a variety of sensors, can provide an intensive, individualized, home-based and family-centered EI program, remotely telemonitored by clinicians.

This article focuses on the design and development of the CareToy platform, i.e., hardware, software, and telerehabilitation architecture, along with preliminary tests and results with preterm infants. The purposes of these first tests were to check the capability of the CareToy platform to detect developmental differences among infants and to promote, monitor, and measure infant's development along the training.

Materials and Methods

The CareToy system was designed and developed from a clinical and technical point of view to fit the key factors of EI in NDDs. The technological solutions adopted are reported in the following sections.

Hardware Modules

The system is integrated in a wooden box structure with a footprint about 1 m^2 with a sensorized base and four walls (Figure 1). The base is covered with two Tekscan mats (ConforMat System, model: 5315, area: 47.14 cm × 47.14 cm) measuring pressure distribution by means of 1,024 force-resistive sensors each with a sampling rate of 30 Hz. The data from the two mats are combined to obtain information about the infant's weight distribution. The front wall is endowed with a large flat screen to show short animations and cartoons. The two lateral walls are divided into three points of interest for the infant (left, right, and center zones). Each wall is augmented with lights of different colors, lighting buttons, and speakers. The gym is enriched with an arch containing individually controlled lights and a belt to support the infant while sitting.

Based on the concept of affordance, a kit of four toys with different shapes, inspired by commercial toys for infants, was designed and developed. Shapes were carefully chosen to have a clear affordance and to encourage different manipulation approaches. The toys were designed on the basis of infants' hand dimensions, manipulation capabilities [13], and the experience from [10]. The hardware of the toys comprises pressure sensors (LPS331AP), a magnetoinertial sensor [inertial measurement unit (IMU)] board with a microcontroller (iNemo, ST Microelectronics), force sensors (Force Sensing Resistor, Interlink), and multicolor light-emitting diodes (LEDs) for light feedback. The microcontroller interfaces all sensors and lights embedded in the toy. The iNemo board is inserted into the housing of the toy; the other two sensors (force and pressure) are embedded into the silicone and compose its sensitive part. Purposive molds for silicone were developed for manufacturing the sensitive parts of different shapes. The sensing range is tuned on the basis of the force exerted by the infants in the first year of life (0–35 kPa and 0–20 N). Each toy is connected to the system via a universal serial bus (USB) interface. The aluminum connector (model DBPC 102 A053-13, Fischer Connectors SA) and cable were chosen to be compliant with safety requirements in terms of material and cable length (20 cm for avoiding strangulation).

Three shapes were chosen for the kit of four sensorized toys based on the type of grasp (palmar or digital) and hand action (unimanual or bimanual):

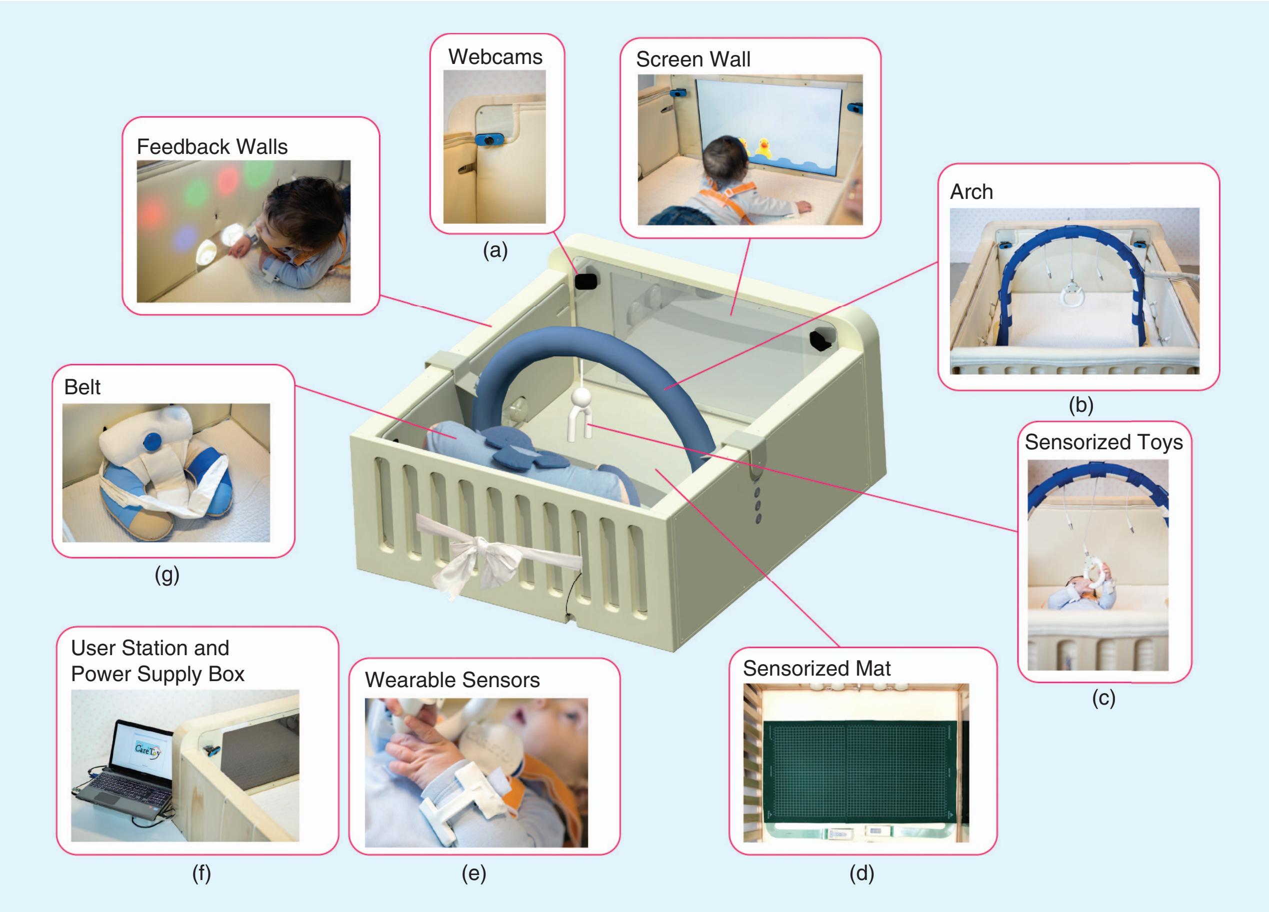

Figure 1. The CareToy platform and its components: (a) the box with interactive walls (lights, sounds, and four webcams), (b) an arched gym, (c) four sensorized toys, (d) a sensorized mat, (e) three wearable sensors (two bracelets and a chest strap), (f) a user station (laptop for the parents or operator) with a power supply box, and (g) a sensorized belt. (Photos courtesy of The BioRobotics Institute.)

- mouse-toy: a cylindrical pressure chamber equipped with a pressure sensor and LEDs inside and two small ears with an embedded force sensor and an LED
- U-toy: a horseshoe composed of two cylindrical pressure chambers with an embedded pressure sensor and LEDs
- large ring—a toroidal pressure chamber embedded with pressure sensors and LEDs inside

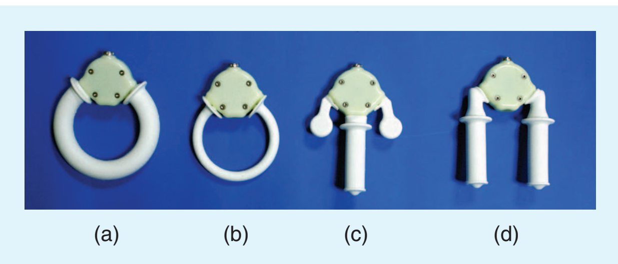

Figure 2. The CareToy kit of toys: (a) large ring, (b) small ring, (c) mouse-toy, and (d) U-Toy. The rings encourage a (unimanual or bimanual) palmar grasp, the (d) U-Toy induces a bimanual palmar grasp on each side of the toy, and the mouse-toy promotes a palmar grasp on the cylinder and a pincer grasp on the two small petals. (Photo courtesy of The BioRobotics Institute.)

- small ring—a toroidal pressure chamber with a smaller diameter and cross section (for younger babies) embedded with LEDs to attract infants' attention.

Two wireless bracelets and a wireless chest strap (sensor unit size 25 × 14 mm) with embedded wireless magnetoinertial measurement units (wIMUs) were designed to measure the infant's postural movements. The wIMU integrates a six-axis geomagnetic and accelerometer module and a three-axis gyroscope to provide a reliable drift-free three-dimensional (3-D) orientation estimation, a microcontroller (ARM Cortex M3 32 b) with embedded wireless transceiver (STM32W108), and a battery power management unit. The final platform and the kit of sensorized toys are shown in Figures 1 and 2, respectively.

Software Modules

The telerehabilitation concept comprises networked computer systems arranged in client-server architecture and three task-specific software modules: CareToy Administrator (CTA), CareToy Server (CTS), and CareToy Home (CTH). The modules have been developed using the cross-platform Qt (C/C++) software framework to ensure flexibility of deployment

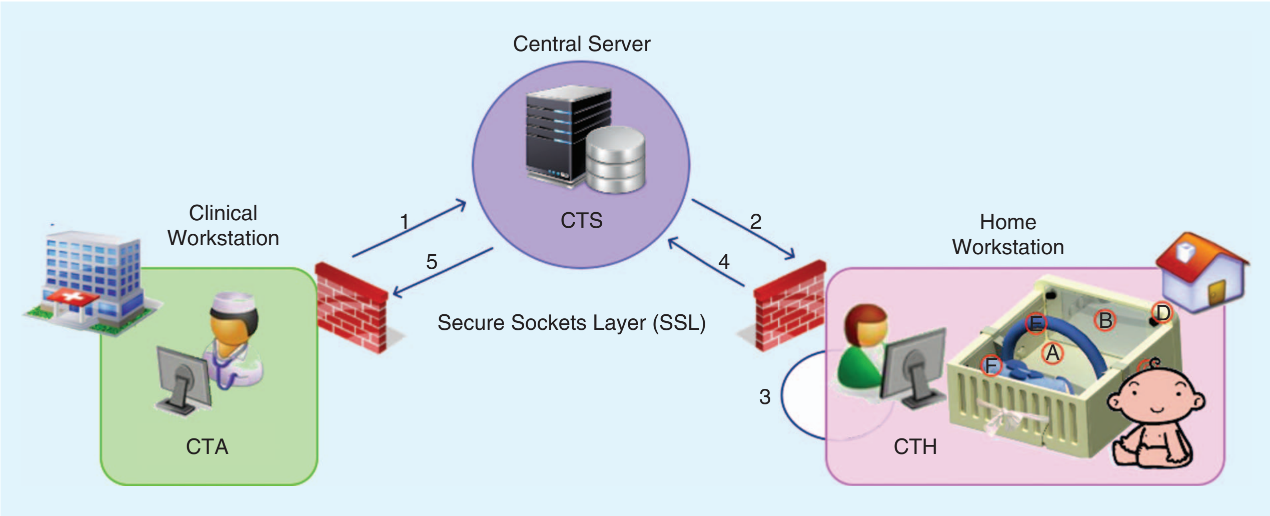

Figure 3. The telerehabilitation workflow: 1) programming and management of training scenarios, 2) download of training scenarios, 3) execution and data acquisition, 4) compression and upload of the data, and 5) evaluation of obtained training session results. (Images courtesy of The BioRobotics Institute.)

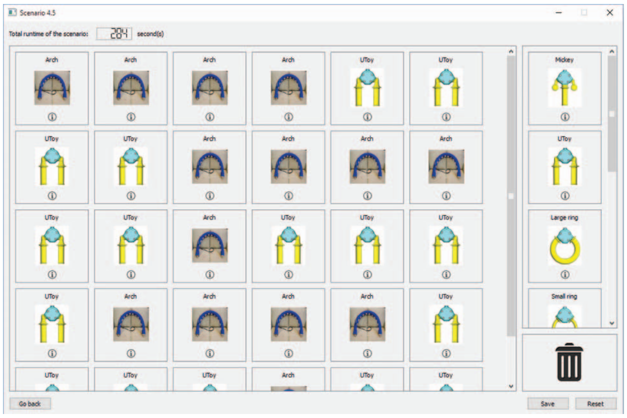

Figure 4. The purposive graphic user interface for scenario design. (Images courtesy of The BioRobotics Institute.)

and portability. The information exchange between the clinical site and the remote system is handled by these modules, as illustrated in Figure 3, and it follows a store-and-forward approach. Therefore, programming of the training scenarios is independent of the system's use, and raw sensor data acquired throughout training sessions can be transformed into meaningful information before visualization.

The CTA application is a standalone application exclusively used by the clinicians. It contains three main functionalities: 1) programming of the system's behavior in terms of training scenarios, 2) remote management of patient-related data residing in the central server, and 3) visualization of obtained data for a close inspection and evaluation of the progress of each infant. Part of the application is a dedicated visual programming tool [14] enabling the clinicians to author training scenarios in complete autonomy. Following the modular design of the CareToy system, training scenarios are defined as a sequence of blocks, each one corresponding to a programmable hardware component (i.e., walls, arch, screen, and available toys). Thanks to the purposive visual programming environment shown in Figure 4, the CareToy clinicians designed a library of training scenarios for promoting different activities for infants. Moreover, on the basis of specific clinical needs, the clinicians planned individualized training for each infant.

The CTS application has exclusive direct access control to the data-storage back-end. Communication channels between the CTS and the two client applications are encrypted using the secure socket layer protocol, and locked down on the basis of the role of the authenticated user. Furthermore, the incoming requests are processed only if their structure is conformed to a predefined data exchange protocol.

The CTH application is deployed and executed on workstations connected to the CareToy hardware system. Behind a simple user interface for interacting with the system, it runs background routines taking care of the system hardware status and the connection to the remote CTS application. Moreover, the CTH acquires visual data from the four cameras embedded in the system. Other sensor data recording procedures are handled by the CareToy Core (CTC) application with which CTH communicates through User Datagram Protocol (UDP) socket connections.

The CTC application enables the execution of training scenarios and real-time signal processing of CareToy gym data by integrating all processing algorithms into one framework. A block diagram of the CTC is shown in Figure 5. The CTC receives information about the training scenario from the CTH and executes the scenario on the basis of the provided instructions in XML and the infant's activity as measured by various sensors. The control of stimuli and rewards (feedback to the infant) is supervised by adaptive state diagrams that are customized by clinicians to individual needs of the particular infant. The system behaves as a closed loop, where infants are first stimulated to perform an action; their response is measured, analyzed, and classified; and then a reward is provided to the infants based on their activity.

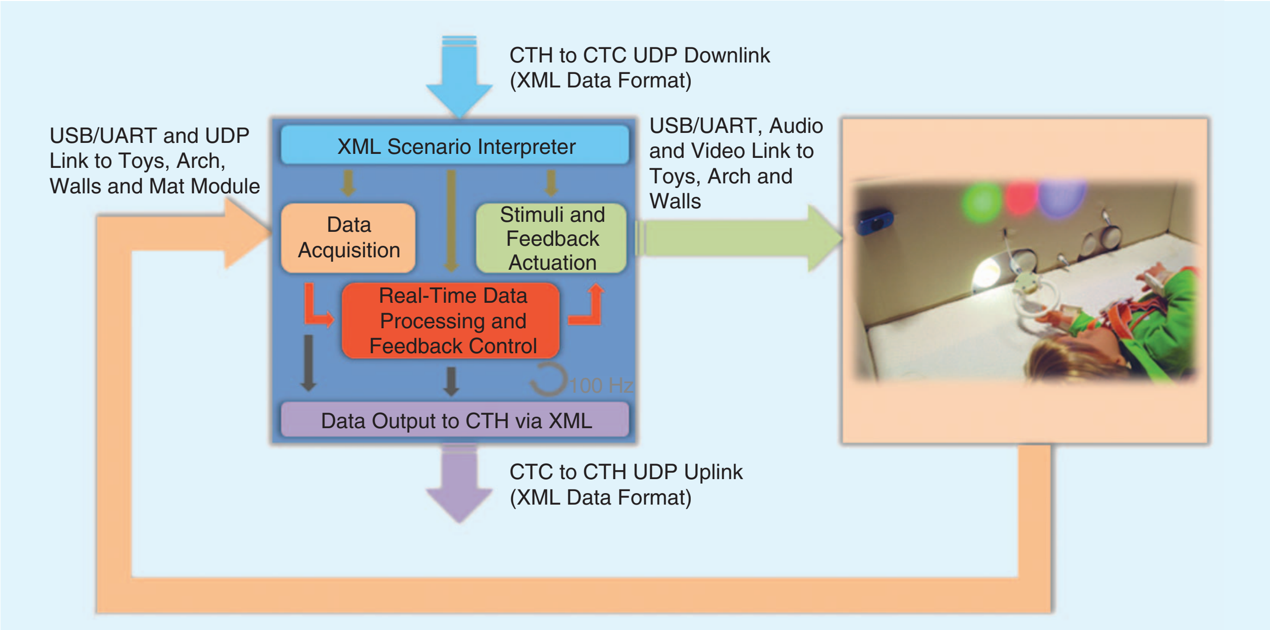

Figure 5. The CTC block diagram: CTC acquires data from toys, walls, wIMUs, and mat module via the USB/universal asynchronous receiver-transmitter (UART) ports (left side); the scenario file and commands to control the execution are received from the CTH (above); the data are processed in real time (central part); stimulation and reward to the infant are provided via lights and sounds (right); the data are sent to the server via CTH for offline processing (bottom). (Photo courtesy of the University of Ljubljana.)

Figure 6. An infant playing with the sensorized ring toy during a training session. Lights and sound feedback are activated from grasping actions on the sensorized toy and the activation threshold is purposively set for each infant. (Photo courtesy of The BioRobotics Institute.)

Signal Processing

An array of sensors measures the activity of an infant inside the gym. Sensor signals related to the infant's movement, interaction with toys, and pressure distribution are acquired and processed in real time to classify the infant's activities and behavior (e.g., rolling, pivoting, arm movement, head displacement, grasping or touching the toy, etc.). Data from the entire training program are then clinically analyzed and interpreted offline. To obtain meaningful results, training sessions with common goals are grouped together. The aggregate analysis of these training sessions provides insight into the motor development of a particular infant during the training period and enables comparison among infants of similar age.

Trunk and Head Activity Analysis

The head and trunk movements are relevant to the assessment of the infant's postural control. In the first month of life, head control is the first ability to develop followed by progressive development of trunk control, prerequisite for the sitting ability. These abilities are delayed and/or impaired in NDDs and represent the main goals to be promoted in the EI program.

Trunk and head activities are determined from mat and chest wIMU data. Pressure distribution matrix acquired by the mat modules is interpreted as an interpolated grayscale image of 165 pixels by 96 pixels (shades of gray indicate pressure) and can thus be processed with image-processing techniques. Individual body parts (trunk, shoulders, arms, and head) are determined through the segmentation of images. The infant's posture is determined by combining the trunk pressure image and the chest wIMU orientation obtained with an unscented Kalman filter. Coarse discretization is used to determine the infant's basic posture: supine, left/right side prone and sitting. The center-of-pressure (COP) provides an estimation of the infant's position within the gym. The COP trajectory is relevant for the analysis of infant's movement and stability, and is therefore characterized in terms of various statistical parameters (root mean square, kurtosis, and skewness). In the sitting position, COP displacement is an indication of buttocks asymmetry, which is important for characterization of stable sitting.

Head position is determined from the pressure matrix in relation to the trunk midline. Head movement is estimated by combining several algorithms, such as line-of-sight (algorithm searches for all image objects within the predetermined area in relation to the trunk), histogram analysis (in the case of connected imprints of the head and trunk), and head-tracking algorithm (based on the premise that head movements have limited dynamics). When the head imprint is not found in the pressure matrix, a head lift is assumed. Capability of lifting the head is also an indicator of motor development. Further details are reported in [15].

Arm and Hand Activity Analysis

Reaching and grasping activities are an important sign of infants' psychomotor development. They are skills that enable the infants to actively interact and learn from environments. Hand and arm activities can be estimated from wIMUs on the forearms, sensors embedded in the toys, and sidewall buttons. Forearm wIMU data are processed using an unscented Kalman filter to obtain the orientation of the limb. Considering the shoulder position determined from the pressure distribution matrix and the forearm orientation with known upper and forearm segment lengths, approximate hand position is calculated. Taking into account the entire hand trajectory during a training session, the path the hand travelled and the average speed can be calculated, and the infant's reachable arm workspace can be estimated (normalized to the maximum possible arm workspace represented by the front hemisphere). Hand acceleration and jerk (time derivative of acceleration) are determined from the forearm wIMU acceleration by subtracting the gravity vector. Instantaneous hand velocity is estimated as a cross product of the forearm wIMU angular velocity and the shoulder-to-hand vector (a better estimation than the one obtained with the integration of the hand dynamic acceleration). Movement smoothness is characterized by spectral arc length metrics that are computed from the hand velocity data. Further details are reported in [16].

Interactions with toys are an indicator of infant's manipulation capabilities. Two types of interactions are considered, simple contacts with the toy and grasping activity. The number of grasps, their strength, duration, and latency (in relation to the provided stimuli) are determined from the pressure and force sensors embedded into the toys. Contacts with the toy that do not include grasping are estimated by correlating the movement of the toy as determined from the IMU embedded into the toy with movement of infant's hand as determined from the wIMUs attached to the forearms. Dynamic acceleration and angular velocity as well as the energy content of these signals are used to determine hand activity in relation to the toy. Key events related to sidewalls are button presses and pressing latency in relation to the provided stimuli.

Experiments

Once the final prototype was ready, we planned the first experiments with infants and their parents. Although the general aim of the CareToy project was to assess the capacity of CareToy system to provide EI programs, the main aim of the first tests, performed in Italy, was to verify system acceptability and feasibility of the training of infants and parents. For this reason, we carried out single sessions with healthy and at-risk infants, which allowed us to verify the system capabilities to stimulate and measure infants' actions and to detect possible differences among infants. The following sections describe some results of a triplet of infants enrolled in the first tests. They are two girls and one boy born preterm at 30 weeks of gestational age. This triplet is interesting, since they were all clinically different. Infant 1 was a typically developing preterm infant, Infant 2 had a mild developmental delay, while Infant 3 was at risk to develop an NDD due to a perinatal stroke, in particular for an asymmetry mainly involving manual functions (right hand affected).

They were enrolled at 3.5 months of corrected age (i.e., adjusted age based on the due date of birth) and performed three weeks of training with the CareToy installed at their home, about 14 min per day. The total amount of training of each infant is reported in Table 1.

It is worth mentioning that a randomized controlled trial study is currently ongoing with 40 infants in Italy and Denmark. This clinical trial and the pilot preliminary study have been approved by the Tuscan Region Pediatric Ethics Committee (Italy), while the Italian Ministry of Health has approved the trials considering the configuration of the CareToy as a medical device without a Conformité Européenne (CE) mark. A similar approval procedure was obtained in Denmark. The parents of the enrolled infants provide their written informed consent to take part in the study. Further details of the clinical study are reported in [4].

We developed a short questionnaire, shown on the parents' interface, which was filled out by them at the end of each training session as early feedback about the acceptability and feasibility of the proposed goal-directed activities. All infants showed a good grade of acceptance of the system and enjoyed playing inside the CareToy. Figure 6 shows an infant during a training session.

The parents were highly involved and motivated in carrying on the study, and they become skilled in using the system during the course of the training.

Figure 7 shows an example of data analysis of Infant 1 lying in supine position with the large ring toy attached to the middle section of the arch. Figure 7(b) is the view from the four cameras attached to the corners of the CareToy gym. The infant is playing with the toy, and the behavior is automatically classified (information is superimposed on the video image for the left and the right hand). In general, five hand behaviors are classified: standstill, moving, interacting with the toy, hitting the toy, and grasping the toy. In this case, both hands are grasping the toy and moving at the same time.

Table 1. Minutes of training for the three infants.

User	Infant 1	Infant 2	Infant 3
Minutes of training	229	223	250

Figure 7. (a) The mat data are segmented and augmented with information from wIMUs. (b) An example of infant 1 interacting with the CareToy. Left- and right-hand activity is indicated with green boxes. (Photo courtesy of the University of Ljubljana.)

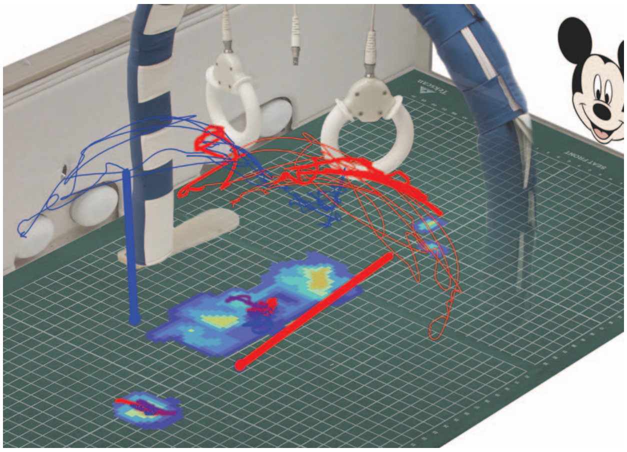

Figure 8. A composite representation of an infant's activity during a training session. The gym with the mat is in the background and pressure distribution and arm postures with shoulder positions (straight thick red and blue lines) are presented for a single moment. Hand trajectories are represented with thin red and blue lines and thicker parts of trajectory indicate postures where interaction with the toy occurred. The body and head COP are indicated with red and blue lines on the pressure distribution image. (Photo courtesy of the University of Ljubljana.)

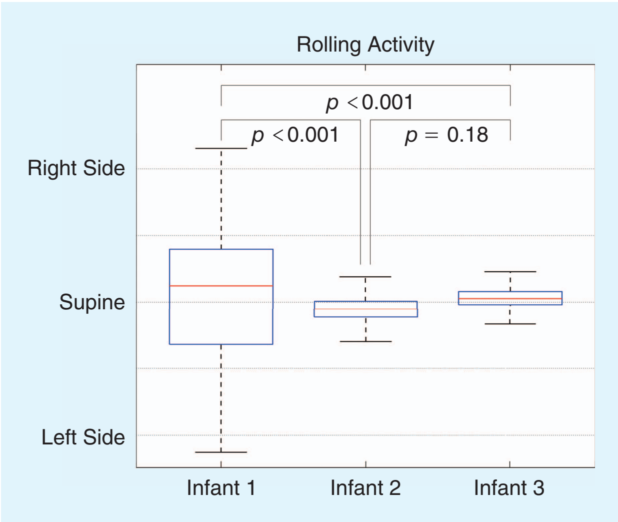

Figure 9. The range of rolling angles from supine position toward left and right side for the triplets during a period of three weeks. The red line indicates the median value, the bottom and top of the box are the first and third quartiles, the ends of the whiskers represent data within 1.5 interquartile ranges. The p-values indicate a nonsignificant difference between Infants 2 and 3 and significant differences between Infant 1 and the other two infants (balanced one-way ANOVA). (Photo courtesy of the University of Ljubljana.)

Figure 7(a) is the representation of the mat module data with the infant's silhouette and superimposed labels indicating the COP (white dot), trunk midline (red line), head, shoulders (pink dots), and arm segments (green lines).

Figure 8 is a composite representation of 10 s of the activity of Infant 1 with the gym and the mat module in the background. Movements of body COP, head trajectory, hand trajectories, and space coordinates where the infant was interacting with the toy are indicated. The pressure distribution map and arm postures are presented for a single time instant (still image).

Figure 9 indicates infants' rolling activity in terms of rolling angles from the supine position. Infant 1 was able of to roll from the supine position to the left or the right side, reaching

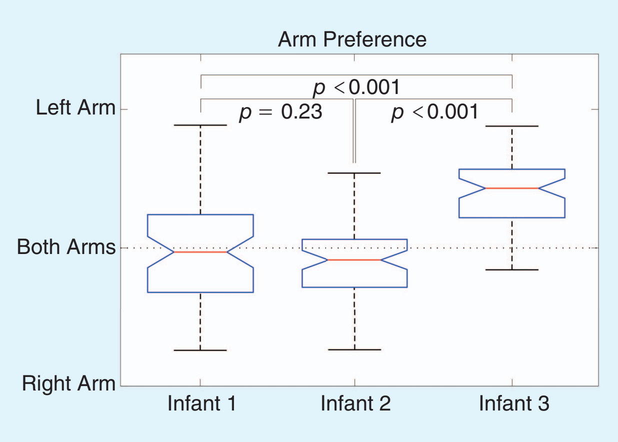

Figure 10. The arm use preference for triplets during a three-week period. Infant 1 and Infant 2 equally use both arms, while Infant 3 preferred to use his left arm because of a right hemiplegia. The red line indicates the median value, the bottom and top of the box are the first and third quartiles. The ends of the whiskers represent data within 1.5 interquartile ranges. The p-values indicate a nonsignificant difference between Infants 1 and 2 and significant differences between Infant 3 and the other two infants (balanced one-way ANOVA).

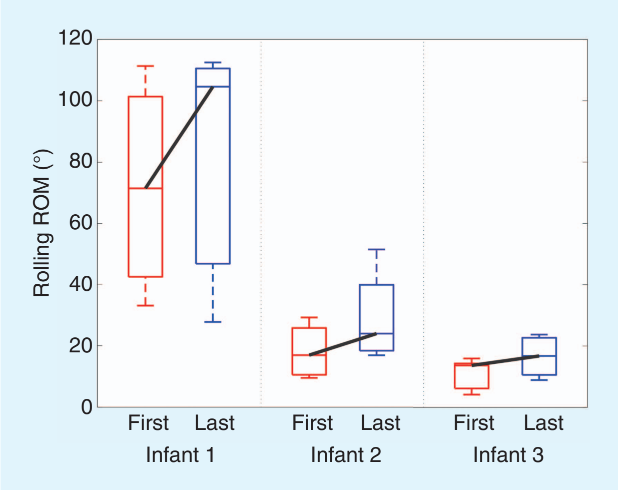

Figure 11. The rolling ROM for the first week of training (red) and the last week of training (blue) for the three infants. The middle line indicates the median value, the bottom and top of the box are the first and third quartiles, and the ends of the whiskers represent data within 1.5 interquartile ranges.

almost 90° rotations in either direction. Conversely, Infant 2 and Infant 3 show almost no rolling activity. In terms of motor activities, Infant 1 shows several attempts to roll significantly greater than the other twins. Balanced one-way analysis of variance (ANOVA) was used to test the differences between infants.

Figure 10 shows the preference of arm use, indicating which arm is mostly active during the interaction with the gym. In normal development, both arms should be approximately equally active. The preference is determined from the energy of the forearm dynamic acceleration signal $\ddot{x}$ (subtracted gravity acceleration from wIMU data). The energy is computed as $E = \int_{-\infty}^{\infty} |\ddot{x}|^2 dt$. The relative left arm preference is then determined as $ARM_{\text{Left}} = E_{\text{Left}}/(E_{\text{Left}} + E_{\text{Right}})$, where E_{Left} and E_{Right} are signal energies for the left and the right arm, respectively. From Figure 10, it is evident that Infant 1 and Infant 2 use both arms in equal proportions, while Infant 3 (who had perinatal stroke) used the left arm significantly more, confirming the clinical data. Balanced one-way ANOVA was used to test the differences between infants.

Figure 11 shows the rolling range of motion (ROM) for the three infants for the first and the last week of training. Infant 1 demonstrated better motor capabilities than the other two infants and rolled from a supine to a side position. At the same time, Infant 1's progress in terms of increased rolling ability is faster. The other two infants have lower motor abilities and do not reach the motor level required for moving from a supine to a side position. Nevertheless, Infants 2 and 3 showed a nonsignificant increase in their rolling ability in the last week of training compared with the first week of training.

The presented results are promising; however, as reported by [17], the evaluation of the effects of therapy is tricky in a group of subjects with ongoing developmental changes in which the outcome without intervention can vary.

Further studies with a larger sample should investigate the effect of the CareToy with respect to developmental changes. The presented platform is, to our knowledge, the first attempt to provide a telerehabilitation program in the field of EI for young infants. The potential of the platform relies on the proved effects reported in the literature about the use of technological solutions for stimulating and monitoring the sensory-motor functions of children. Recent studies have proved that robot-assisted therapies are useful for motor rehabilitation in children with cerebral palsy by providing treatment to upper [18], [19] and lower limbs [20].

Conclusions

An innovative platform for infants' telerehabilitation at home was successfully designed and developed. Integration of different technological solutions guarantees much greater training and assessment capabilities than the sum of the capabilities of individual components. The system allows quantitative and integrated (simultaneous observation of most relevant motor functions) measurement of the infants' actions with the ecological approach. Infants are measured while playing without perceiving the presence of the technology. The validity of measurement was demonstrated with reference systems [16].

From a clinical point of view, the developed platform allowed clinicians to plan the goal-directed activities during the three weeks of training while monitoring the infants' training daily. The telerehabilitation architecture, the modular organization of the system, and the possibility of activating its single parts according to the actions of the infant allow the rehabilitative staff to tailor the training to the individual needs of each infant remotely.

In summary, the innovative aspect of this work is the introduction of the intelligent system directly into the home and the possibility of providing individualized training for each infant, combined with accurate, reliable, and repeatable measurements of several parameters, describing infants' actions. Moreover, although this article reports the results of only three infants and relative findings cannot be extended to general conclusions, the platform seems reliable and consistent with the clinical evaluation, while sensitive enough to detect differences in development and training. All these aspects need to be confirmed by the ongoing clinical trial (with 40 preterm infants). A future aim is to apply the platform in further studies involving different populations of infants at risk of NDDs and to validate the CareToy approach as a new tool for an intensive, individualized, home-based and family-centered EI, managed remotely by clinicians.

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