Annals of Biomedical Engineering (© 2016)
DOI: 10.1007/s10439-016-1669-4

CareToy: Stimulation and Assessment of Preterm Infant's Activity Using a Novel Sensorized System

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(*Received 12 February 2016; accepted 1 June 2016*)

Associate Editor Amit Gefen oversaw the review of this article.

Abstract—Early intervention programs aim at improving cognitive and motor outcomes of preterm infants. Intensive custom-tailored training activities are usually accompanied by assessment procedures, which have shortcomings, such as subjectivity, complex setups, and need for structured environments. A novel sensorized system, called CareToy, was designed to provide stimulation in the form of goal-directed activity training scenarios and motor pattern assessment of main developmental milestones, such as rolling activity, grasping, and postural stability. A group of 28 differently skilled preterm infants were enrolled. Acquired measurement data were analysed with dedicated sensor data processing algorithms, along with clinical evaluation of motor ability. High correlation among technically determined parameters and Alberta Infant Motor Scale values was determined by Pearson correlation coefficients. Due to good accuracy and possibility of single motor skill subfield analysis, results confirm system suitability for motor ability assessment. Statistical analysis of inter-motor ability group and inter-training goal data comparisons demonstrate system's appropriateness for goal-directed activity stimulation. The proposed system has evident potential of being an important contribution to the field of infant motor development assessment, expanding accessibility of early intervention programs and affecting rehabilitation effectiveness of preterm infants.

Keywords—Early intervention, Motor development, Goal-directed activity, Sensor data-based motor ability evaluation, Clinical assessment scales.

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ABBREVIATIONS

AIMS	Alberta infant motor scale
AP	Anterior-posterior
ASD	Autism spectrum disorders
ASQ-3	Ages & stages questionnaire® Third Edition
CNS	Central nervous system
COP	Centre-of-pressure
EI	Early intervention
FA	Forearm
ICT	Information and communication technology
IMU	Wireless magneto-inertial measurement unit
IVH	Intra-ventricular haemorrhage
ML	Medial–lateral
NDD	Neurodevelopmental disorders
PVL	Periventricular leukomalacia
ROM	Range-of-motion
UKF	Unscented Kalman filter

INTRODUCTION

Every year an estimated 15 million infants worldwide are born preterm[47] (i.e., birth less than 37 weeks gestational age). They are at high risk for neurodevelopmental disorders (NDDs), including motor, cognitive or behavioural problems, mainly due to Central Nervous System (CNS) impairment.[6,16]

Early intervention (EI) programs have been developed and used with the aim of improving cognitive and motor outcome.[26] Several existing types of EI pro-

Published online: 10 June 2016

grams are focusing also on family factors and the home environment. However, there is still high heterogeneity in the content, focus, duration, intensity of the intervention, and also in the measurement data.[43] Generally, the main factors for effective EI are promptness, intensity, and repetitiveness. The possibility of providing a custom-tailored, incrementally challenging training with active involvement of infants and their families is also important.[4,10]

A crucial point to take into account in the EI programs is that the child is an active learner and not a passive recipient of therapy.[11,31] Therefore the stimulation to rehabilitate is not intended as a passive condition in which stimuli (e.g., toys, lights, and sounds) are used to passively stimulate infants. Conversely, stimulation should have the ability of providing a specific situation, being able to catch infants' motivation to repetitively perform goal-directed activities. Repetition is not intended as execution of the same movement using the same trajectory, but as training of achieving the same goal by improvement of performance through practice. An important aspect to achieve the target of active stimulation and of repetition is the ability to maintain attention and motivation. This could be performed by changing something in the environment, while maintaining the same goal and practice. Moreover, another aspect that can provide variability along with maintaining the same goal are the different rewards for the infants (e.g., the reward is the sound in general, but the sound is different and not always the same).

The challenge for the child therapist is the possibility of creating different conditions for active stimulation of infants in relation to their abilities and potentialities. The selection of goal-directed activities to be practiced by the infant in fact depends on their specific abilities and needs. One of the main obstacles for the child therapist on the course to successful rehabilitation of infants is the limitation to the clinical setting, as infants are less accustomed to clinical centres than to their home environment. The rehabilitation training should be daily, intensive, and adaptive. However, time and duration of training are usually affected by the already tight schedules of clinical staff. Scheduling rehabilitation routines only once or few times per week also decreases the effect of training adaptation, according to infant motor abilities and performance improvement. Moreover, the active and passive involvement of families in the EI promotes infants' learning.[28]

For these reasons another important aspect is the accurate assessment of infants' abilities. By measuring their performances, the rehabilitation staff can thus detect potential abilities that need to be promoted. Moreover, the assessment is essential to monitor the treatment and to measure the changes, and should thus be accurate, reliable, and most of all frequent. EI that satisfies all these factors in terms of stimulation and assessment would impose high costs on the Health Care System, as the therapies should be daily and of longer duration. However, information and communication technology (ICT), including tele-Health system models might allow a reduction of costs, enabling use of EI on a large scale.

Currently, the studies on infants' motor behaviour are mainly clinical, based on functional scales or on direct observation of infants while playing; quantitative variables coming from the clinical scales, even if validated in large samples, are however dependent on evaluator's experience. An example of such clinical measure is the arm range of motion,[29] which is important for diagnosis, evaluation of treatment, and quantification of possible changes. It can be roughly assessed by goniometric measurements in static condition[19] or by upper limb observations with the Upper Limb Physician's Rating Scale.[33] Such clinical measures are however strongly limited by subjectivity and mostly not applicable to the assessment of very young infants. The need for EI in infants is also predicted mostly through careful clinical evaluation (i.e. developmental tests, neurological examination, observation of spontaneous movement patterns), occasionally combined with neuroimaging (cranial ultrasounds, brain magnetic resonance imaging), neurophysiological tests (electroencephalography, evoked potentials), and genetic tests (karyotype, comparative genomic hybridization-microarray).[10]

On the other hand, it is important to mention some of the sophisticated technologies, already available and widely used in research laboratories for quantitative and objective studies of human development and motor coordination. These advanced technologies include sensor-supported systems for movement analysis, such as optoelectronic measurement systems,[25,27] electromagnetic systems,[23] accelerometers,[20,32] pressure mattresses,[17,18] and force platforms.[24] Sophisticated computer-based video analysis of infants' movements is for example already appropriate for detecting early signs of cerebral palsy.[1] Furthermore, kinematic quantification of specific lower limb movement features, such as joint angles, was performed on kicking movements.[21] The mentioned technologies provide accurate, objective, and repeatable measurements, but are due to certain drawbacks usually inappropriate for longer, intensive, daily tele-rehabilitation routines. An important limitation is that for the acquired data to make sense, the assessments should mostly be performed in well-controlled and highly structured environments, including accurately known and repeatable conditions. This is especially problematic in case of infant assessment, as infants cannot follow a pre-determined protocol. Level of use is also limited in poorly structured environments, such as clinical centres and houses.[7]

The successful application of these technologies on infants has an enormous potential, as quantitative, accurate, and objective assessment would enable monitoring of infant's development and treatment outcomes. However, as infants are non-collaborative subjects, the assessment should be focused on measuring their natural movements, performed in an ecological setting with realistic tasks, such as toy play.[14,42] Kinematic description of upper limb infant motility in natural environment and during play was however despite large importance scarcely studied.[22] A natural setting in combination with adequate sensor systems could be suitable for studying infants' interaction with objects, which could lead to establishment of standard approach development characteristics. Consequently, comparison of these standards against results of infants at risk for neurodevelopmental disorders, particularly Autism spectrum disorders (ASD), could provide the possibility for detection of early signs of disturbed development.[7,46] Other works[8,14,39,45] presented similar approaches (i.e., sensorized toys with embedded low-cost technology) for assessing psychomotor development of infants. The main aim of these studies is to extend screening of infants for diagnostic and rehabilitation purposes to a larger scale, whereas feasibility is normally limited by high costs and equipment availability. A recent review of main methods for motor function assessment in early infancy has lately been presented by Allievi *et al.,*[3] providing also important benefit-of-use indications, when applying technology-assisted methods with non-intrusive technological solutions. These are lately available due to remarkable technological advancements.

This paper and the present study have several aims. The first goal is to evaluate suitability of a novel sensorized system, called CareToy for providing response-specific stimulation in view of motor skill training of pre-term infants. Second aim is to verify suitability of integrated sensor setup for assessment of infant's activity, especially focusing on motor skill subfields, such as rolling activity, toy play ability, and postural stability. Third goal is to evaluate correlation of the technically determined parameters, calculated by sensor data processing, and well-established clinical assessment scores of infants' motor skill levels.

MATERIALS AND METHODS

This section first presents characteristics of the CareToy platform, followed by description of the proposed outcome measures, including the corresponding posture, movement, grasping, and stability assessment algorithms, as well as applied clinical assessment scales. Afterwards, details of enrolled infants are given. Finally, a description of methods for statistical analysis is provided.

CareToy System

The CareToy platform,[9] designed for the home environment, is composed of different modules (see Fig. 1), aiming to stimulate and measure infant's actions. The system is infant friendly and has during the process of prototype development also passed the tests about conformity to safety requirements for a medical device with a CE mark. The instrumented baby gym is equipped with interactive walls for audio-visual stimulation of infant attention, activity, and gaze movements. This is achieved with a monitor in the frontal wall for showing short videos, along with coloured lights, speakers, and switches in the lateral walls. Floor is covered with two Tekscan pressure mattresses (CONFORMat System, model: 5330) for pressure distribution and infant posture assessment.[38] Each pressure mattress has 1024 force-resistive sensors, whereas pressure data are sampled with 30 Hz.

Wearable wireless magneto-inertial measurement units (IMU) on trunk and forearms are intended for postural control measurement, as is in full detail also described in Rihar *et al.*[38] Battery powered IMUs that comprise three-dimensional gyroscopes (L3GD20), accelerometers and magnetometers (LSM303DLHC) were developed by STMicroelectronics and are integrated in specially designed bracelets and chest strap. These bracelets have additional dedicated artificial silicone soft covers of neutral beige colour. Along with the light weight and minimum size of IMUs this en-

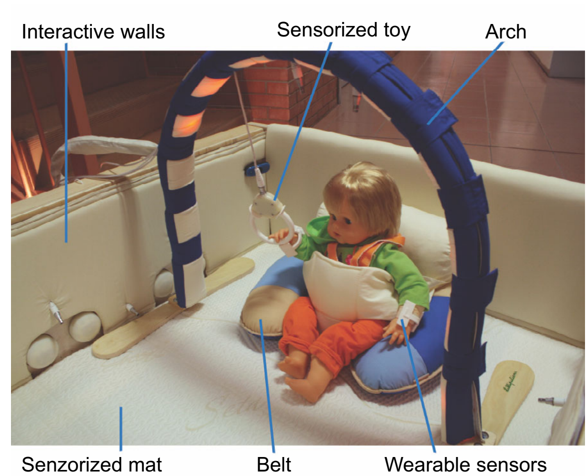

FIGURE 1. CareToy platform and its main modules, which are indicated with text and blue lines.

sures negligible effect on characteristics of infants' behaviour. Moreover, IMUs were already placed on infant's wrists and trunk some minutes before the beginning of training, which helped the infants to become familiar with IMUs, also reducing the behavioural effects, related to having something new on the body. Sampling frequency of IMUs is 100 Hz.

A central arch with 12 lights and connectors for mechatronic toys[34] serves for gaze movement stimulation and manipulation capability assessment. The purposively developed toys[9,34] were inspired by commercial toys for infants and were designed on the basis of affordance[30] to encourage different manipulation approaches and to be compliant with infants' hand dimensions.[2] Different basic shapes and sizes, including toroidal and cylindrical shape ensure grasping variability. Toys include multicolour LEDs for stimulation and light feedback, along with integrated pressure sensors, force sensors, and IMUs for toy interaction assessment.[9] Sampling frequency of sensors in toys is 100 Hz. The tele-rehabilitation module allows the system to remotely communicate with the clinical staff for monitoring and assessing the rehabilitation techniques. Data is stored on a server for post-processing.

CareToy Clinical[36] represents another part of the larger CareToy environment, but is not directly relevant for the present study. It was designed to be located in the clinical centres and comprises five video screens and an eye tracker for stimulation and analysis of infant gaze characteristics. Full details of CareToy Clinical are given in Pratesi *et al.*[36]

The reader is most kindly invited to review other details of the CareToy platform hardware in Cecchi *et al.*[9] Passetti *et al.*[34] and Rihar *et al.*[38]

Outcome Measures

This subsection provides a description of the selected outcome measures and the corresponding applied algorithms for sensor data extraction, processing, and analysis, consecutively presenting the various addressed fields of infant activity.

Rolling Range-of-Motion (ROM)

IMU sensor data, namely vectors of angular velocity, acceleration, and magnetic field are for each performed scenario collected throughout the entire training session with a sampling frequency of 100 Hz. Data are first processed by applying the unscented Kalman filter (UKF),[15] which was implemented similar as in Beravs *et al.*[5] No calibration step is needed to orient the IMUs, as consistent placement is achieved by proper labelling of IMU sensor covers. The evaluated trunk IMU orientation is then expressed relative to the gym IMU coordinate system. To minimalize the possible effects of potential trunk IMU displacement, trunk IMU orientation data are corrected by taking into account the trunk orientation, estimated from the pressure imprint data. The full sensory data fusion procedure is in detail given in Rihar *et al.*[38] The range of rolling angle from supine to prone and back to supine is 360°. By using the improved trunk orientation information, the rolling range-of-motion (ROM) parameter is calculated for each measurement session as the angular distance between the values of 90th and 10th percentile of the angular rolling data.

Forearm Orientation Intensity and Area

Forearm (FA) IMU sensor data are also processed with the UKF and expressed in the trunk coordinate system to determine the FA orientation relative to the trunk posture. Afterwards, orientation data are recalculated into two orientation angles, namely elevation and azimuth. Elevation is calculated as the angle between the FA orientation vector and the coronal plane, while the azimuth is determined as the angle between the sagittal plane and the FA orientation vector projection onto the coronal plane. Both angles describe FA orientation in a sphere, whereas range of azimuth is 360° and range of elevation angle is 180° (see Fig. 2).

Following this, spherical orientation data is transformed into planar presentation, whereas orientation angle data (azimuth and elevation) are first grouped

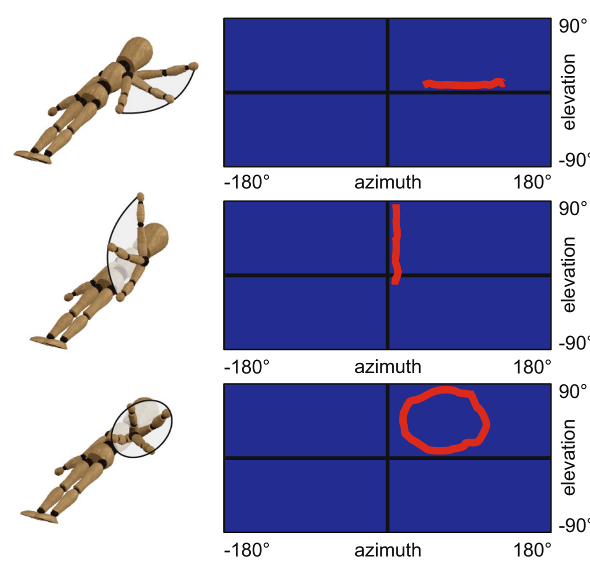

FIGURE 2. Representation of the FA orientation map determination for arm movements with changes of azimuth angle (top subplot), elevation angle (middle subplot), and both angles simultaneously (bottom subplot).

into small areas of 3 by 3° to reduce data amount, and further organized with azimuth and elevation data on horizontal and vertical axis, respectively. This produces a FA orientation map for each arm (see Fig. 2). Following this, FA orientation intensity parameter is calculated as the percentage of session duration with the FA oriented in lateral-medial direction. Lateral-medial FA orientation area parameter is determined as the percentage of frontal lateral-medial orientation map subpart area, covered with the FA orientation data. Finally, parameter values are averaged for both arms.

Toy Grasping and Toy-Hand Interaction Percentage

Toy grasping and toy-hand interaction actions are analysed by processing data of force, pressure, and IMU sensors, integrated in the mechatronic toys[34] (see "CareToy System" section). Grasping activity in this context covers all toy grasping activities with sufficient grasp strength. First low-pass filtering and signal trend removal methods are applied on the pressure sensor signal to remove high-frequency noise and signal drifting character, which can be a consequence of the pressure chamber air temperature changes. Afterwards, threshold comparison and data connectivity method are used on the pressure signal to extract and determine the pressure-based grasping activity intervals with adequate grasp strength. Potential artefacts, such as extremely short grasping intervals are removed from further analysis. Maximum and mean values of the pressure signal are calculated.

Since force sensor signal is less subject to drift, only low-pass filtering method is applied along with threshold comparison and signal data grouping to extract the force sensor-based grasping activity intervals. Unity of both signals (pressure and force) is used to assess the general grasping activity. Toy grasping percentage is determined as the ratio between grasping time and session duration for each measurement session.

Toy-hand interaction activity in this context covers all activities, when infant was in contact with the toy, herewith included grasping the toy, touching the toy without grasping, and hitting the toy. With this in mind, interaction starts as soon as infant touches the toy and ends when infant loses contact with the toy. To evaluate interaction activity, toy IMU gyroscope data are first transformed to the gym coordinate system. Low-pass filtering and wavelet transform are applied on the angular velocity data to determine the toy oscillation intervals, which ensure toy movement without interaction. Following this, signal energy of angular velocity data is calculated and compared to an empirically pre-determined threshold to determine the toy movement intervals. This threshold represents the maximum signal energy of angular velocity data of mechatronic toys in standstill. Removal of toy oscillation intervals from the toy movement intervals determines the interaction intervals. Interaction percentage is determined as the ratio between the acquired interaction time and session duration.

COP Movement Parameters

The characteristics of centre-of-pressure (COP) movement of infants in sitting position are used to evaluate the level of infant's postural stability.[13,20] COP movement is assessed based on the pressure imprint data, which are sampled with 30 Hz. First, pressure imprint data are pre-processed with bias and superposed noise removal methods. Following this, the buttocks pressure imprint is extracted by taking into account the pre-determined position settings and thus removing potential imprints of the dedicated belt pillow. Centre-of-pressure coordinates of the buttocks pressure imprint are calculated for the entire measurement session. The obtained COP movement vector is then for each training trial analysed by calculation of some well-established parameters, such as root-mean-square displacement, circle area, along with anterior-posterior (AP) and medial–lateral (ML) range-of-motion.[12,37]

Alberta Infant Motor Scale

The infants were assessed with a battery of clinical tests[41] before and after training with the CareToy system. For the current work, the main clinical test was the Alberta Infant Motor Scale (AIMS).[12,35] This standardized scale, used in infants from term until 18 months of age, assesses infant's motor abilities, quality of posture and movement outcomes in four positions: prone, supine, sitting, and standing. It is a reliable measurement in detecting delayed and abnormal motor development.

Subjects

According to the clinical study protocol,[41] eligible infants were preterm infants born between 28 + 0 and 32 + 6 (weeks + days) of gestational age, aged 3–9 months (12–38 weeks) of corrected age (CA), who had achieved a predefined cut-off score in gross motor ability, derived from Ages & Stages Questionnaire® Third Edition (ASQ-3).[44]

Exclusion Criteria were: (i) birth weight below the 10th percentile (infants small for gestational age); (ii) brain damage i.e. intra-ventricular haemorrhage (IVH) more than grade 1, any degree of periventricular leukomalacia (PVL), or brain malformation; (iii) epilepsy or other form of seizure; (iv) severe sensory deficits (blindness, deafness) and v) other severe non-neurological malformations. These were determined at the onset of the CareToy project during definition of the clinical study protocol by the clinical staff (child neurologists and neonatologists). At the beginning of the enrolment phase, they were evaluated by screening the clinical history of infants, admitted at the Neonatal Intensive Care Unit (NICU) of Santa Chiara Hospital in Pisa, Italy.

28 preterm infants with CA between 13 and 27 weeks and with AIMS score between 8 and 23 at the beginning of the training were enrolled. The infants were equally distributed into three groups, based on their AIMS scores: 9 were included in the lower group (AIMS ≤ 10), 12 in the middle group (10 < AIMS ≤ 16), and 7 in the higher group (16 < AIMS). Such cut-off criteria were chosen to enable similar differences among group motor skill levels.

The study has been approved by the Ethics Committee of Pisa University Hospital (Italy) and Tuscan Region Paediatric Ethics Committee (Italy), and it has involved the clinical centre IRCCS Fondazione Stella Maris, Department of Developmental Neuroscience, in Pisa (Italy), in collaboration with Neonatal Intensive Care Unit, Pisa University Hospital "Santa Chiara". The trial is registered at ClinicalTrials.gov (NCT01990183) and adheres to the Declaration of Helsinki. All the parents of the enrolled infants provided their written informed consent to enter the study.

Training Scenarios and Goals

The rehabilitation staff, including child therapists and child neurologists, selected a set of response-specific goals, most important for the development course of pre-term infants during their first year of life. These among other cover promotion of rolling activity, arm movement, toy play (touching and various grasping abilities), and postural stability. Each of these goals can be promoted in various different ways, therefore clinicians have designed a library of goal-directed activities, namely scenarios to be promoted inside the CareToy system. These are posture-specific and can be presented to the infant, while in supine, prone or sitting position.

From a technical point of view, the scenarios comprise an activation sequence of specific CareToy modules, such as LED lights, speakers, and video screen. Toys can be used in infants with higher motor abilities for promotion of reaching and grasping behaviours, but also in younger infants for promotion of attention and pre-reaching movements. Duration of each scenario is determined by the rehabilitation staff before training and is normally set between 2 min and 10 min, according to the level of complexity, training goals, as well as infant's age and general motor skill capabilities. The same training goal can be addressed by different scenarios of different lengths, whereas achieved effects can be enlarged according to their duration. Stimuli activation can be automatic or reward-based, according to specific prefixed thresholds, such as strength of grasp or successfully accomplished rolling activities. The form of scenarios can thus be changed on the basis of infant's activities, capabilities, and success rate. High success rate and quick responses can result in quick reward-based stimuli activation and consequential shortening of training scenario's duration. This adaptation is needed and implemented to ensure that the training sequences are challenging and motivating enough, regardless of the motor skill capabilities. In case of very high success rate, rehabilitation staff can take the response-related results into account and adjust the scenario complexity before the beginning of next training. The library of scenarios is organized by each infant and position, while the scenarios are grouped by CareToy modules involved, main rehabilitation goals, and sub-goals.

Although the final aim of the CareToy system is common to all infants and is focused on general progress in cognitive and motor skill development, different infants' behaviours and activities are expected in relation to their motor abilities. In this work we focused on evaluating the capability of CareToy to stimulate and assess infants' activity in supine and sitting positions.

For supine position, the designed scenarios can be grouped into training goals, as follows. *Reaching and grasping toys on midline (Toy on midline)*. Scenarios with this goal aim to address one of the main activities to be promoted for infant's development, namely capability of developing reach-to-grasp manoeuvres. With this in mind, toys are hung in the central position of the arch for promotion of reaching and grasping activities on midline.

Reaching and grasping toys on sides of the arch, while rolling for small ranges (Toy on arch). Infants are stimulated to slightly turn their body in order to reach and grasp with ipsilateral and contralateral upper limbs the toys that are placed either on the right or left side of the arch.

Reaching and grasping toys on feedback walls, while rolling for high ranges (Toy on sidewalls). Infants are stimulated to roll in order to reach the side position (either on right or left side of the CareToy system) and maintain this side position during toy play (reaching and grasping) with toys on lateral walls.

Head rotation (Without toys) and rolling (Rolling stimulation). The activities for this goal are mainly aimed to stimulate infants to follow with their gaze and/or with rolling of their bodies the visual stimuli, which is provided by lights on the arch and/or on lateral walls.

Infant activity for the supine position related goals with toys is assessed with arm posture-based (forearm orientation intensity and area), rolling activity-based (rolling ROM), as well as toy play-based (grasping and interaction time) outcome measures. For the goals in supine position without toys, activity is analysed by calculation of rolling ROM, as well as forearm orientation intensity and area parameters.

For sitting position, scenarios can be grouped into two main goals, as follows.

Head rotation and trunk control (Without toys). Infants are stimulated by catching their visual attention (on the screen wall and/or on the feedback walls) and controlling movement of trunk and the head (maintaining head on midline, rotating head to follow visual stimuli and/or sounds).

Head rotation and trunk control while reaching and grasping toys (With toys). Infants are stimulated to reach and grasp the toys, which are placed on the arch, while maintaining head and trunk control in the sitting position.

Selected outcome measures for the sitting position related goals are focused on postural stability assessment and are obtained by COP movement analysis in view of calculating parameters, such as RMSd, circle area, and AP and ML ranges.

Infants were presented with numerous scenarios of all these goals during the course of 1 month training, which altogether consisted of 100–150 performed training sessions for each infant. Each infant performed up to ten mostly different scenarios per day, summing up to one and a half hours of training per day. For the purposes of this study, however only data of first five sessions for each goal were taken into account. These were evenly distributed over a few days in the first week of training. We hypothesized that the approach of analysing data from the first week of training guarantees a reliable quantification of the variability of infants' behaviour and ensures sufficient strength (sufficiently high number of training scenarios) for performing statistical analyses, while reducing the effects of training-related behavioural changes and progress, expected throughout the course of 1 month training with the CareToy system.

As duration of training scenarios is dependent on infants' success rate and motor ability, meaning that different infants probably performed different duration of training, the mean and standard deviation values of first five performed scenarios of all infants for each goal were calculated. In particular, for the supine position, Head Rotation and Rolling was assessed for 317 ± 87 s, Reaching and Grasping toys on midline (Toy on midline) for 327 ± 75 s, Reaching and Grasping toys on arch side while rolling for small ranges (Toy on arch) for 342 ± 59 s, and Reaching and Grasping toys on feedback walls, while rolling for high ranges (Toy on sidewalls) for 325 ± 62 s. For the sitting position, Head rotation and Trunk control was assessed for 225 ± 57 s and Head rotation and Trunk control, while reaching and grasping toys for 307 ± 100 s.

Statistical Analysis

Statistical analysis was applied on the large amount of data not only to provide the possibility of inter-group, inter-goal, and other comparisons, but also to ensure an intuitive interpretation. With this in mind only data of first five training sessions for each infant were used for statistical analysis of rolling, forearm orientation, interaction, and grasping based parameters. Data reduction was performed to reduce the effects of 1 month long training on the statistical measures, but still ensure a large enough amount of data to retain statistical reliability. Only COP movement data were statistically analysed in full, because infants have performed less scenarios in sitting, thus affecting statistical measures negligibly.

Kruskal–Wallis test was selected for inter-goal, as well as inter-group data comparison, providing statistical assessment of data similarity. The calculated statistically significant ($p < 0.05$) and very significant ($p < 0.01$) values were additionally marked with * and **, respectively. Inter-parameter correlation (for example rolling ROM and grasping percentage) and correlation among technically evaluated parameters and clinical motor assessment scales (for example rolling ROM and AIMS scores) were estimated by calculation of Pearson correlation coefficients R. Median values of first five training sessions' data were used for the correlation calculation. Inter-parameter correlation describes the similarity of different technically determined data trends, while the second correlation coefficient denotes the similarity among technically and clinically evaluated motor skill assessment. Correlation coefficients were only determined for data pairs that were presumed relevant and clinically meaningful.

RESULTS

In the following section the results of infant activity and behaviour assessment are presented. First the rolling activity analysis is presented, which is followed by the results of forearm orientation intensity and area assessment. Afterwards, results on toy interaction and grasping activity are given. Finally, results of COP movement assessment parameters of infants in sitting position are provided. All results are displayed in the form of boxplots, where black horizontal lines denote the median values, the edges of the coloured boxes present the 25th and 75th percentile of data, while the whiskers extend to the most extreme data points not considered outliers. Infants are grouped in three groups according to their motor abilities by taking into account the AIMS values. Different training scenario based goals are marked with different colours.

Rolling Range-of-Motion

Rolling activity analysis results are presented with rolling ROM parameter values for four different goals (see Fig. 3), namely goals with toys on midline, arch, sidewalls, and for rolling stimulation. Statistically significant differences can be identified in case of inter-goal comparison among rolling stimulation and toys on midline goals for the middle and higher groups. Inter-group comparison demonstrates statistically significant differences especially among the middle and higher groups, as well as towards the group with lower abilities (see Fig. 3). Correlation was tested on rolling ROM data for the rolling stimulation goal and the corresponding AIMS values and is statistically very significant ($p < 0.01$**) with Pearson correlation coefficient of 0.71.

Forearm Orientation Intensity and Area

Activity and behaviour of infant arm movement in terms of FA orientation intensity and area are first presented for goals with toys on midline and without toys (see Fig. 4), followed by results for goals with toys on midline, arch, and sidewalls (see Fig. 5). Results demonstrate statistically significant inter-goal differences, related to presence of toys (see Fig. 4), as well as statistically significant inter-goal differences, related to position of toys (see Fig. 5), especially in the lower and medium groups. Additionally, inter-group comparison reveals statistically significant differences especially when comparing outcomes towards the lower group (see Fig. 5). Correlation was tested on FA orientation intensity data for the goal with toys on arch and corresponding AIMS values, and is statistically significant ($p < 0.05$*) with Pearson correlation coefficient of 0.44. Pearson coefficients R for rolling ROM and FA orientation intensity for goals with toys on sidewalls and arch are 0.68 ($p < 0.01$**) and 0.54 ($p < 0.01$**), respectively. Correlation values for rolling ROM and FA orientation lateral-medial area for the same goals are 0.64 ($p < 0.01$**) and 0.65 ($p < 0.01$**).

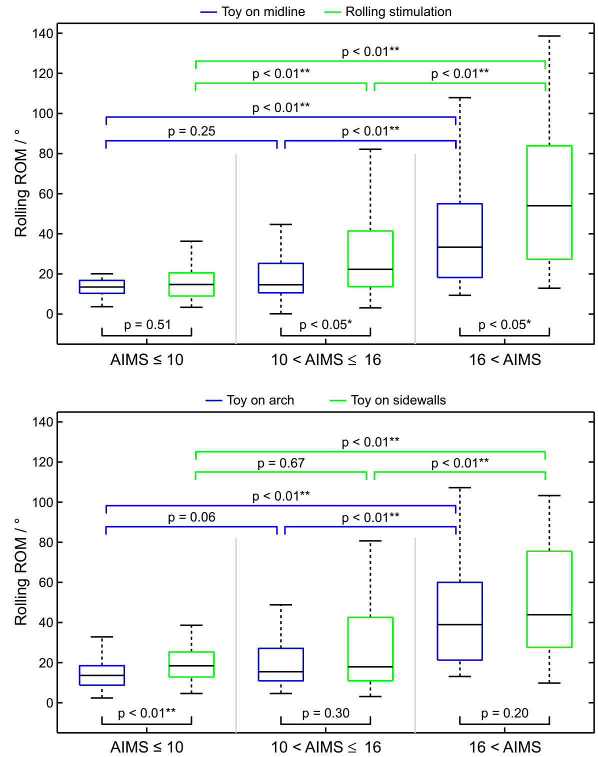

FIGURE 3. Rolling range-of-motion (ROM) parameter values for comparison of toys on midline and rolling promotion goals (upper subplot) and goals with toys on arch and sidewalls (lower subplot). Kruskal–Wallis test based *p* values are given above the coloured and black horizontal lines and describe the inter-group and inter-goal data comparison statistics, respectively.

Toy Grasping and Toy-Hand Interaction Time

Results for hand-toy interaction and grasping activity are given for three goals with toys in different positions, namely midline, arch, and sidewalls (see Fig. 6). Kruskal–Wallis test results are presented for inter-goal and inter-group comparison. Results reveal statistically significant differences for inter-goal comparison and especially for inter-group comparison, when comparing the middle and higher groups (see Fig. 6). Correlation coefficient R of interaction percentage data for midline and sidewalls, and corresponding AIMS values are 0.52 ($p < 0.01$**) and 0.54 ($p < 0.01$**), respectively. R values for the max grasp pressure data and AIMS values were for goals with toys on midline 0.60 ($p < 0.01$**), arch 0.52 ($p < 0.01$**), and sidewalls 0.62 ($p < 0.01$**).

Rolling ROM and interaction percentage data for goals with toys on midline and sidewalls correlate with factors of 0.45 ($p < 0.05$*) and 0.57 ($p < 0.01$**), respectively. Grasping percentage and rolling ROM data for the goal with toys on sidewalls correlate with a Pearson coefficient R of 0.42 ($p < 0.05$*). Correlation

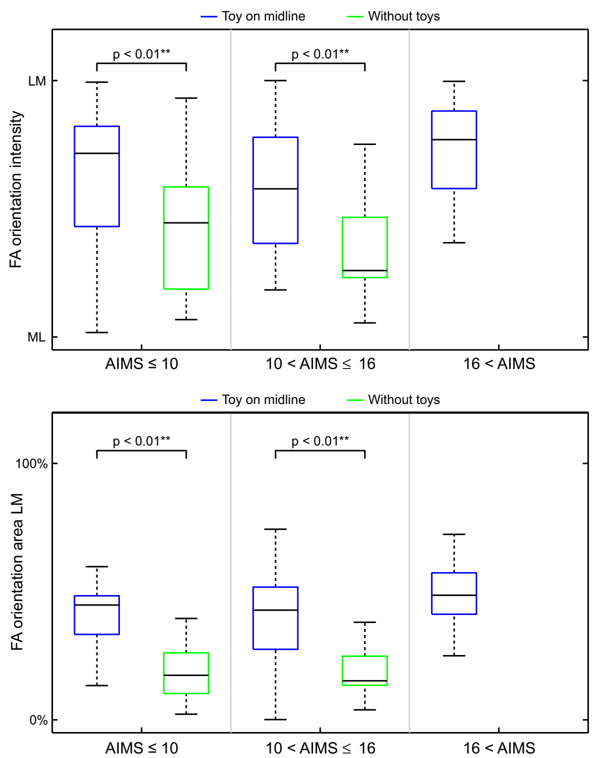

FIGURE 4. Forearm (FA) orientation intensity (upper subplot) and lateral-medial orientation area (lower subplot) values for goals with toys on midline (blue boxes) and without toys (green boxes). *p* values are given for the inter-goal data comparison. LM and ML denote lateral-medial and medial–lateral orientation.

of FA orientation intensity and interaction percentage data was additionally tested, resulting in *R* values of 0.61 ($p < 0.01$**) and 0.60 ($p < 0.01$**) for goals with toys on midline and arch, respectively. R values were determined also for the pair of FA orientation intensity and grasping percentage data and are 0.49 ($p < 0.01$**) for midline and 0.60 ($p < 0.01$**) for toys on the arch. Correlation of rolling ROM and max grasp pressure data is 0.67 ($p < 0.01$**) for the sidewalls.

COP Movement in Sitting Position

Posture stability evaluation values for the sitting position trials are shown in Fig. 7. Data are given for scenarios with and without toys along with statistical data comparison values. Statistically significant differences were identified for inter-goal comparison for the middle and higher groups, as well as consistently for the inter-group comparison. Correlation was estimated by taking into account the jointly included technically assessed stability parameter data of goals with and without toys and AIMS values. Coefficient *R* values are for the root-mean-square displacement parameter 0.58 ($p < 0.01$**) and for the circle area parameter 0.56 ($p < 0.01$**).

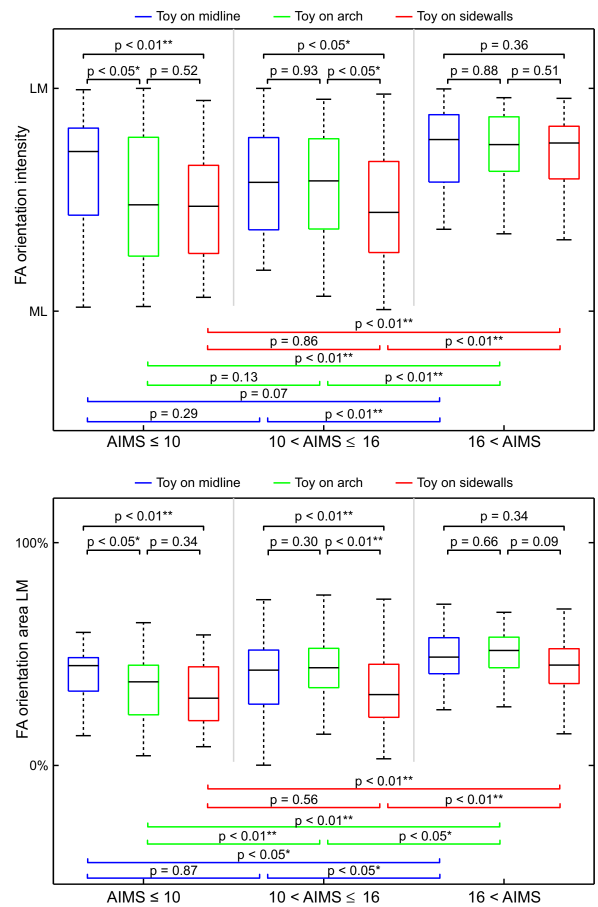

FIGURE 5. Forearm (FA) orientation intensity (upper subplot) and lateral-medial orientation area (lower subplot) values for goals with toys on midline (blue), arch (green), and sidewalls (red). The *p* values located above the coloured and black horizontal lines describe the inter-group and inter-goal data similarity comparison.

DISCUSSION

The present work aimed to demonstrate that CareToy replies to the main requirements in the field of EI, allowing rehabilitation staff to remotely assess and stimulate preterm infants in the first year of life.

The high and significant correlation values between the quantitative data of CareToy system and the AIMS scores, and the possibility of detecting different values between the three groups with different motor abilities (AIMS ≤ 10; 10 < AIMS ≤ 16; 16 < AIMS) demonstrate reliability of CareToy measurement data for discrimination of different infant's motor abilities. Moreover, the quantitative data determine specific assessments of different body segments (e.g. forearm

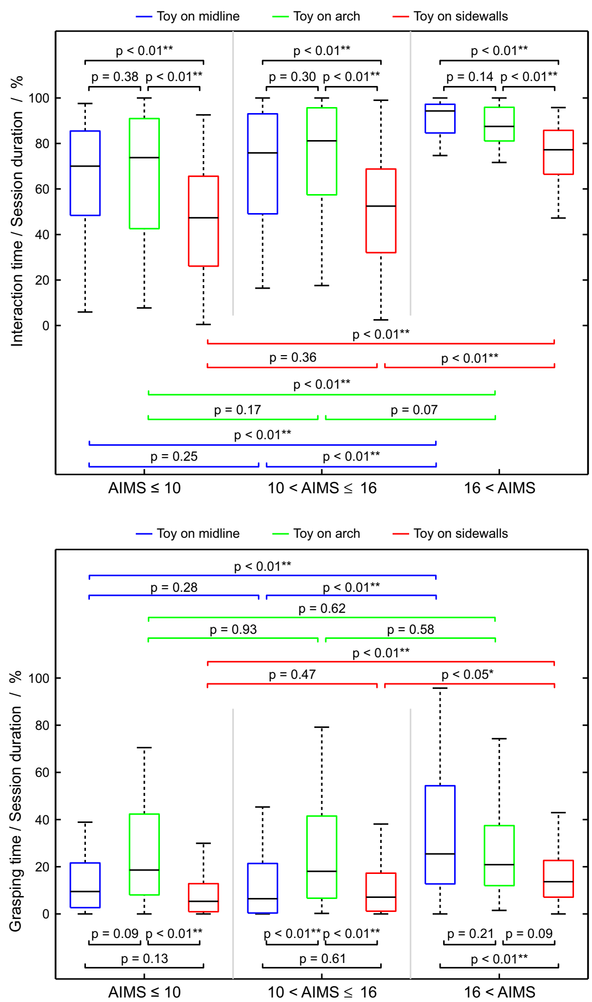

FIGURE 6. Toy interaction (upper subplot) and grasping (lower subplot) percentage values for goals with toys on midline (blue), arch (green), and sidewalls (red). The *p* values above the coloured horizontal lines describe the inter-group differences, while the ones above the black horizontal lines describe the inter-goal differences.

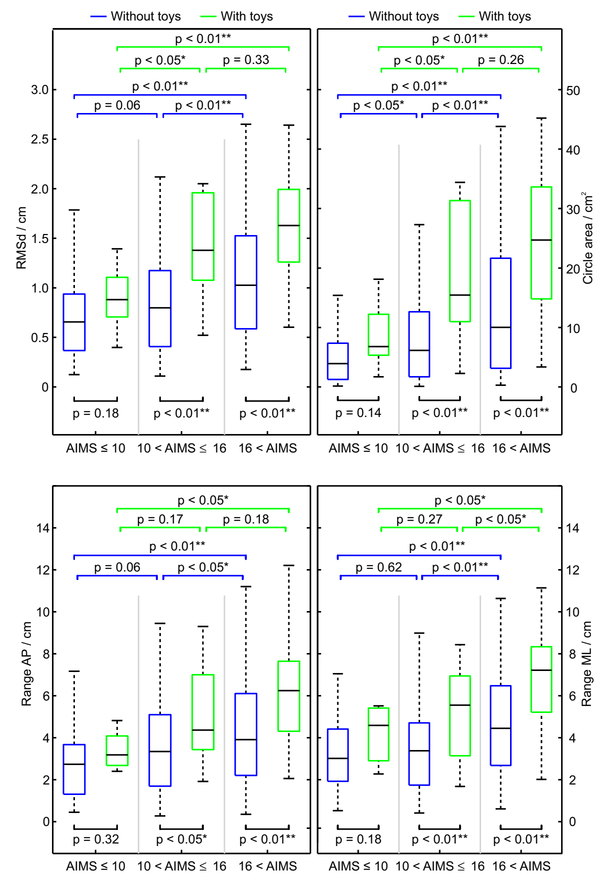

FIGURE 7. Sitting posture stability assessment results for goals with (green) and without toys (blue) in sitting position. Root-mean-square distance, circle area (both upper subplot), anterior-posterior and medial-lateral range (both lower subplot) of centre-of-pressure (COP) movement are given for infant groups, according to their AIMS values. The *p* values near the coloured horizontal lines describe the inter-group differences, while the ones next to the black horizontal lines describe the inter-goal differences.

orientation, body's rolling range of motion, grasp strength of the hands, etc.) and of different activities (e.g. toy interaction, postural stability) that cannot be detected by clinicians using only clinical scales.

Regarding the motor abilities in supine position, CareToy data have shown that the group with higher abilities is significantly different from the other two groups. Comparison of these two groups has shown similar results, when reaching and grasping activities are required (toy on midline, toy on arch, and toy on sidewalls). As can be roughly detected by the items of AIMS, only infants with higher scores in supine position are able to roll for reaching and grasping activities, but in this case we quantitatively measured the differences in the body rolling ROM.

In relation to the stimulation purpose of the CareToy system, results have indicated that all the infants, regardless of the AIMS-related group, orient their forearms significantly different, if they have the toy on midline or not (see Fig. 4). In fact, the presence of the toy on midline induces reaching behaviour with the forearms towards the medial position, while whenever the toy is not present the forearms are oriented laterally.

Reaching and grasping toys on midline (Toy on midline) is a fundamental goal to be promoted in the group of infants with lower and medium competencies, while it is already consolidated in infants with higher competencies. Rolling stimulation is intended for the lower group as head rolling, related also to the gaze movements, while it is for the other two groups more related to head and body movement. These two different clinical aims are confirmed by CareToy data, when comparing ROM values for the both goals and reviewing statistical analysis values. These reveal no significant differences in the group with lower abilities (only head rotation in sense of gaze following was expected), and statistically significant differences for the other two groups (see Fig. 3). Comparing the other two assessed goals (Toy on arch and Toy on sidewalls), a difference in variability of the rolling ROM was expected and detected mainly in the first two groups of infants, because the toys, placed on the lateral walls, induced a higher displacement of the body. For the higher group, which is able in rolling, no differences were discovered, which was expected (see Fig. 3). Moreover, this was additionally confirmed by the forearm orientation intensity data that were more lateral in the lower group: this group does not roll a lot in view of reaching laterally positioned toys (arch and sidewalls), thus covering larger lateral area with the forearms (see Fig. 5). These goal-directed activities are mainly of reaching than grasping as confirmed by the data of interaction and grasping time that were significantly higher (mainly for reaching, detected by the interaction time) for toy on midline and on the arch (Fig. 6).

Regarding the middle group an interesting finding, in accordance with the clinical aims, is that there were no significant differences in all parameters between the toy on midline and toy on the arch. These infants have acquired a good ability of reaching and grasping toys on midline, as well as crossing the midline for lateral grasping, showing same competencies in both goals (see Fig. 5). Another important finding are also the differences for the stimulation of reaching and grasping for small and high ranges that have in the last condition induced a significantly higher laterality of the forearm orientation intensity and area, which was however not followed by an increase of interaction and grasping time (see Fig. 6).

The higher group showed a different strategy. In relation to their rolling ability, their forearm orientation remained medial in all the different aims of grasping, despite their ability of interaction and grasping of toys being lower in the extreme positions (toys on sidewalls) (see Fig. 6).

The resulting statistically significant differences for the sitting position assessment, when comparing tasks that require only head and trunk control (without toys) and tasks that require reaching and grasping behaviour (with toys) (see Fig. 7) are also very interesting. Middle and higher groups showed significant differences in all the computed parameters for higher trunk movements, when toys were present, stimulating infants in moving their trunk and upper limbs towards the toys. The lack of differences in the group with lower competencies could be related to their very initial trunk control abilities, in which sense they perform very few attempts on moving their body towards the toys. This hypothesis is confirmed by the differences in the variability of trunk movements among the group with lower competencies and the other two groups, when the toys are present.

Study Limitations

The presented work had some specific study limitations. Training duration was absolutely limited to under 2 hours of training per day to avoid overburdening the infants' parents and loss of interest in the CareToy environment. Longer training duration would naturally result in more acquired sensor data that could perhaps enable more complex and reliable statistical analyses. On the other hand, the sole complexity of acquired data was the main reason for the need of such robust, complex, advanced data processing algorithms. Involvement of families in the rehabilitation process had several advantages, but also minor shortcomings. As the large part of rehabilitation process can take place at infants' home environment, parents can be present throughout training trials, and can by interaction additionally stimulate infants' activity and interest for training. This can however affect data processing, as parents occasionally stimulate infants by moving and shaking the CareToy sensorized toys, which can result in outliers and result inaccuracy. In the context of the presented study, this was however avoided by reviewing videos of all training trials and omitting the affected ones.

CONCLUSIONS AND FUTURE WORK

The presented results verify that the CareToy system can be suitably used for highly relevant assessment and stimulation purposes. The selected outcome measures demonstrate good correlation to clinical assessment scores, while the proposed training scenarios and goals are adequately designed to stimulate task-specific infant activity responses. A clinical pilot study[40] has recently additionally demonstrated that the CareToy system seems to be a feasible device for providing EI, but future work is needed to show if the CareToy system is able to provide a tele-rehabilitation program and detect changes through the training. It is expected that the proposed home environment-based stimulation and assessment system could, besides the ability of realistic toy play and natural environment, due to high accuracy, reliability, and objectivity of integrated sensor systems provide the opportunity i) to practice activities, more enjoyable than traditional therapy tasks, thereby encouraging training intensity through high trial repetitions and ii) to perform a family and child-centred approach, supporting them at implementation of the rehabilitation training.

Additionally, training trials on other populations, such as preterm and term infants at high risk of developing cerebral palsy due to congenital brain lesions or infants with developmental delay due to genetic abnormalities (e.g. Down syndrome) are already planned for additional identification of system suitability for providing assessment, stimulation, monitoring, and training of infants in the first year of life. The comparison of results will most definitely be interesting also for clinicians and could provide the possibility of further data analyses. Moreover, a comprehensive analysis of clinical and instrumental results could provide predictive indicators of responses to intervention, as well as correlation between the developmental changes and the amount of training with the CareToy system.

ACKNOWLEDGMENTS

This work was funded by the European Union Collaborative Project CareToy grant ICT-2011.5.1-287932 and additionally supported by the Slovenian Research Agency. The authors gratefully acknowledge help of all members of CareToy project Consortium, as well as all the parents and infants participants.

CONFLICT OF INTEREST

No benefits in any form have been or will be received from a commercial party related directly or indirectly to the subject of the manuscript.

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