A pilot study on early home-based intervention through an intelligent baby gym (CareToy) in preterm infants

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ABSTRACT

Background: CareToy is an intelligent system, inspired by baby gyms, aimed to provide an intensive, individualized, home-based and family-centred early intervention (EI) program.
Aims: A pilot study was carried out to explore the feasibility of CareToy intervention in preterm infants, aged 3–9 months of corrected age.
Methods: Twenty low-risk preterm infants, without brain lesion or other clinical complications (14 allocated to CareToy intervention and 6 to Standard Care) were recruited. The Infant Motor Profile (IMP) was predefined as the primary outcome measure and Alberta Infant Motor Scale and Teller Acuity Cards as secondary measures. Moreover, 202 pre-programmed training scenarios were developed and instructions for the management of CareToy intervention were defined as general guidelines.
Outcomes and results: All infants received 4 weeks of their allocated intervention and were evaluated with the selected tests before and immediately after the 4 weeks. The mean difference changes in IMP total score and Teller Acuity Cards over the intervention period were higher in the CareToy group than in the Standard Care group.
Conclusions and implications: CareToy seems a feasible device for providing EI. An adequately powered randomized clinical trial is warranted.

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What this paper adds

CareToy is a collaborative research project that lasted 3 years (2011–2014), funded by the European Commission under the Seventh EU framework programme, theme ICT-2011.5.1 "PHS Personal Health Systems". The project aimed to design and develop a new Information and Communication Technology (ICT) smart modular system for the tele-rehabilitation of infants in the first year of life. In this pilot study a controlled clinical trial using ICT in low-risk preterm infants was performed for the first time. We demonstrated that, even if in a preliminary prototypal phase, the CareToy system is a feasible devise to provide an intensive, individualized, home-based and family-centred early intervention. ICT of CareToy system allowed rehabilitation staff to individualize, tailor and customize the training. We were able to monitor and change sets of interactive games made of goal directed activities, to be managed by the parents at home, modified according to results achieved by the infants, sent daily by the system to the clinical centres. Moreover, we preliminary tested the feasibility of the study design and the possibility to promote infant's motor and visual development. This paper shows for the first time that ICT have the potential to become suitable tools for EI, with positive effects on functional development, as indicated by the preliminary results on the outcome measures obtained in CareToy infants compared to those in Standard Care.

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1. Introduction/background

There has been a growing interest in recent years for designing and providing early intervention (EI) programmes in preterm infants, with the aim of improving the outcome for infants at increased risk of neurodevelopmental disorders (Lundqvist-Persson, Lau, Nordin, Bona, & Sabel, 2012). EI has been defined as "the multidisciplinary services provided to children from birth to 5 years of age to promote child health and well-being, enhance emerging competencies, minimize developmental delays, remediate existing or emerging disabilities, prevent functional deterioration and promote adaptive parenting and overall family functioning" (Blauw-Hospers & Hadders-Algra, 2005). EI falls within the theoretical framework of the enriched environment (EE) concept. EE can be defined as a set of environmental modifications aimed to enrich motor, cognitive, sensory, or social aspects of the infant's environment. EE should be organized to encourage the infant to perform specific tasks, tailored on her/his developmental needs, while the parents are actively engaged with the infant, with the purpose of promoting learning (Morgan, Novak, & Badawi, 2013). Recently, a Cochrane Systematic Review (Spittle, Orton, Anderson, Boyd, & Doyle, 2012) has summarized the publications in the field, with the conclusion that EI programs seem to have positive effects on infants' development. However, the high heterogeneity among the interventions (e.g. varied background and theoretical constructs, timing, duration, focus, setting, etc.) and the lack of high quality Randomized Controlled Trials (RCT) limit the conclusions that can be drawn. Therefore, further RCTs that specifically target the needs of the infant and family are required.

The development of EI programs suitable for infants is challenging. As reported by Basu, Pearse, Kelly, Wisher, and Kisler (2015), the evaluation of the effects of therapy is hard in a group of subjects with ongoing developmental changes, in which the outcome without intervention can vary. Infants have short attention spans and little or no understanding of the need for therapy or its aims, and it is therefore difficult to develop approaches that will be tolerated (Basu et al., 2015). This becomes particularly laborious if we want to satisfy the main factors for effective EI: promptness, intensity, custom-tailoring, active involvement of infants and their families (Benzies, Magill-Evans, Hayden, & Ballantyne, 2013; Cioni, Inguaggiato, & Sgandurra, 2015).

EI programs that fully satisfy these essential criteria are necessarily very expensive. However, Information and Communication Technology (ICT) and tele-Health system models might allow a reduction of costs, enabling use of EI on a large scale. Use of ICT could permit the development of an enriched environment at home, operated by parents and remotely managed by rehabilitation staff and able to quantitatively measure the infant's activities and progresses.

In this framework and in the context of the CareToy European research project (www.caretoy.eu), we have collaborated to design and develop a new system, called CareToy. It is an intelligent system inspired by gyms composed by different modules (i.e. sensorized toys and mat, interactive walls, arch, screen, wearable sensors, etc.) that can be variably combined and activated (for more details see Sections 2.2 and 2.3). It is aimed to provide a tool for an intensive, individualized, home-based and family-centred EI remotely managed. A study protocol (Sgandurra et al., 2014) has been designed to evaluate the efficacy of CareToy training in a first sample of low-risk preterm infants with gestational age from 28 to 32 + 6 weeks.

We decided to adopt quite selective criteria for the subjects to enrol in this study, in order to have a more homogeneous group of infants. Moreover, the choice to use initially the Caretoy in low-risk preterm infants was also due to ethical reasons (a new medical devise should be carefully tested, before being used with the most fragile subjects). Lastly, CareToy, when validated, could potentially be useful also for the chosen population of low-risk preterm infants that represents, however, a large number of babies born preterm. Infants born between 28 and 32 weeks of gestational age, that are more than 10% of all preterm births (Blencowe et al., 2013; Shapiro-Mendoza & Lackritz, 2012), even when negative for brain damage are at increased risk of mild but significant neurodevelopmental disorders (Xiong, Gonzalez, & Mu, 2012) and early intervention programmes can positively change their outcomes (Larroque et al., 2008).