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Supporting Parenting at Home-Empowering Rehabilitation through Engagement (SPHERE): study protocol for a randomised control trial

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ABSTRACT

Introduction Infants with neurodevelopmental disabilities (NDs) show emotional, cognitive and sociointeractive dysregulation dramatically impacting on caregiving behaviour. Early video-feedback interventions (VFIs) are effective in promoting sensitive parenting, which in turn supports infants' development, even in case of ND. In the light of limited resources of the healthcare systems, technological advances in telemedicine may facilitate the delivery of VFI to a greater number of families of infants with ND. To date, no study has implemented a telemedicine VFI (TVFI) for families of infants diagnosed with ND.

Methods and analysis The Supporting Parenting at Home-Empowering Rehabilitation through Engagement project is a randomised controlled trial aimed at assessing the effectiveness of an early family-centred TVFI parenting support on dyads with infants diagnosed with ND. It includes two arms (TVFI vs Booklet Psychoeducational Intervention) and three assessment phases: T0, baseline; T1, immediate postintervention; T2, 6-month follow-up.

Ethics and dissemination This study is funded by the Italian Ministry of Health and was approved by the Ethics Committee (Pavia). Results will be published in peer-reviewed journals and presented at national and international scientific conferences.

Trial registration number The study protocol has been also registered on NIH Clinical Trials (protocol code NCT04656483; Pre-results).

Strengths and limitations of this study

- This randomised control trial will develop, deliver and test a scalable video-feedback intervention to improve parental skills and developmental outcomes of infants with neurodevelopmental disabilities.
- The telemedicine approach of this intervention will allow to reduce the inequality of access to family-centred care in neurodevelopmental disability.
- Although neurodevelopmental disabilities include a wide range of clinical conditions, this intervention targets parenting challenges that are generally common and shared among parents of infants with diverse disability phenotypes.
- The telemedicine nature of the intervention is not free from potential technical issues related to poor quality of internet signal; nonetheless, no specific resources are needed on family side which will be able to connect with any device.

INTRODUCTION

Every year, about 53 million infants worldwide receive a diagnosis of neurodevelopmental disability (ND) and they represent the 13% of all health problems in infancy and childhood.[1] Although ND includes a wide range of diverse clinical conditions (eg, cerebral palsy, genetic or malformative syndromes, outcomes of severe prematurity, autism spectrum disorders), these infants may share common difficulties in emotional regulation, cognitive skills and sociointeractive abilities.[2 3] Such pattern of multisystemic dysregulation negatively impacts on parents' psychological and physical health as well as on caregiving behaviour.[4 5] Parents may report critical emotional burden with heightened risk for chronic levels of distress, depression and anxiety.[4–6] This constitutes a crucial point considering that parenting represents the front line of developmental resilience for infants' development, even in the presence of ND conditions. Indeed, infants with ND whose parents are rated high in parental sensitivity show better outcomes in emotional, cognitive and sociointeractive developmental trajectories.[7–9]

From this perspective, it is not surprising that early rehabilitation interventions have been found to be the most effective when they engage parents in a family-centred approach,[10] and they also are the most rewarding care strategies for healthcare systems in terms of economic return in the long term.[11] Specifically, the video-feedback intervention (VFI)[12] constitutes an early family-centred care strategy that proved to be effective in promoting sensitive parenting and infants' behavioural and socioemotional

adjustment.[13] The use of VFI intervention has been also documented to be beneficial in dyads of children with ND.[14–16] Previous research reported that these interventions may result in reduced child's disruptive and emotionally negative behaviours,[17] improved maternal sensitivity,[18 19] increased parental self-efficacy and less parenting stress.[20] As such, early supportive interventions directed at improving the quality of parental sensitivity and parent–infant interaction should be prioritised especially in a population of children diagnosed with ND.[10 21]

It should be highlighted that delivering VFI in hospital-based or home-based context are highly demanding for the healthcare systems due to high cost and disparities in access to services for families who live in remote areas. As such, delivering VFI through telemedicine (TVFI) approaches using videoconferencing is a valuable option that may reduce care access inequalities, promote early family-centred care culture, and contribute to a more effective and efficient healthcare approach to the rehabilitation programme of infants with ND.[22] Notably, videoconference approaches to parent training interventions (eg, cognitive educational training) showed to be as effective as traditional face-to-face approaches and were accepted with the same degree of satisfaction by parents.[23 24] Nonetheless, we still do not know how a TVFI support may end up in being effective in terms of promoting parental health and infants' development in families of little patients with ND.

METHODS AND ANALYSIS

Aims

Given the paucity of telemedicine interventions for parents of children with ND and limitations of the delivery of home-based or hospitalised VFIs, the Supporting Parenting at Home-Empowering Rehabilitation through Engagement (SPHERE) project was launched. The SPHERE project is a randomised control trial (RCT) that aims to develop, deliver and test the effectiveness of an early TVFI compared with an alternative educational intervention. The first specific aim is to assess the TVFI effectiveness in supporting maternal sensitive parenting in dyads of infants with ND. Previous studies suggested that a traditional VFI increased parental capacity to respond to child's communicative signals in parents of children with disabilities.[18 19] Consistently, we hypothesise that the TVFI will be effective in increasing maternal sensitivity (within-group difference) and will be more effective than the alternative not individualised intervention (between-group difference).

The second specific aim is to test the TVFI effectiveness in reducing infants' emotional stress reactivity. In line with a previous study highlighting a significant reduction of emotionally negative behaviours after VFI,[17] we hypothesise that the TVFI will be effective in reducing infants' emotional stress in the experimental group. Additional exploratory aims include the assessment of the SPHERE TVFI intervention on other maternal (ie, parenting stress, depressive symptoms, anxiety symptoms) outcomes and on infants' behavioural regulation (ie, temperament profile).

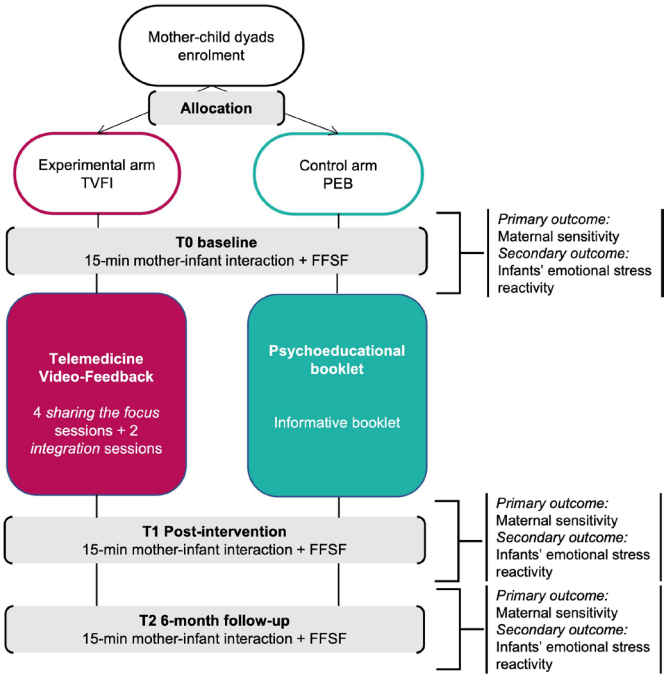

Figure 1 Schematic overview of the study design. FFSF, Face-to-Face Still-Face; PEB, psychoeducational booklet; TVFI, telemedicine video-feedback intervention.

Study design

The SPHERE project is an RCT with two arms and three assessment phases: T0, baseline; T1, immediate postintervention; T2, follow-up (6 months after the intervention). The experimental arm consists in the telemedicine intervention (TVFI arm), whereas the control arm consists in the delivery of a psychoeducational booklet (PEB arm). For both arms, each assessment session will include (1) an on-line questionnaire on maternal and infants' well-being (see below) and a 15 min mother–child dyadic interaction will be videotaped in remote. This interaction will include approximately 10 min face-to-face play interaction followed by a Face-to-Face Still-Face (FFSF) procedure.[25] The FFSF is a well-validated observational procedure to assess infants' socioemotional regulation and parenting sensitivity that has been previously used with infants with ND.[26] During the FFSF, the mother is asked to interact with her infant for 2 min (Play episode), then to interrupt any communication and to maintain a still poker face for 2 min (Still-Face episode), and finally to resume the interaction for two final minutes. An overview of the study protocol and procedures is reported in figure 1.

Population

The mother–infant dyads will be enrolled at the Child Neurology and Psychiatry Unit of the IRCCS Mondino Foundation, Pavia (Italy). They will be enrolled consecutively according to the following inclusion criteria: infants'

Table 1 Description of the TVFI sharing the focus sessions' themes

	Theme	Subthemes	Description
1	Stimulation	Type of stimulations	Type of stimulations (eg, auditory, tactile) preferred by the infant
		Intensity of stimulations	Infant's sensitivity to the intensity of stimulations
		Social touch	Maternal touch in promoting infant's body awareness and attentional orientation
		Sensory integration	Infant's sensory integration and body awareness
2	Responsiveness	Sense of agency	Supporting the infant's initiative to promote the development of his sense of agency
		Sensitivity	Perceiving and interpreting child's signals and responding in a prompt and appropriate way
		Exploration	Supporting the child's exploration and his use of the parent as a secure base
		Reparation	Repairing communicative ruptures
3	Teaching	Attention skills	Supporting the infant's attention orientation
		Modelling	Providing a model to the infant in order to foster the observational learning
		Scaffolding	Parental guidance to allow the infant to solve a task that he cannot yet carry out on his own
		Proximal development zone	Encouraging learning in the infant's proximal development zone
4	Parenting experience	Representations of the baby	Maternal representations of the infant and curiosity about his mind
		Self-regulation	Taking care of herself
		Self-efficacy	Mother's sense of efficacy and trust in her own experience

TVFI, telemedicine video-feedback intervention.

(corrected) age between 1 and 18 months; presence of developmental risk for or diagnosis of ND as defined by standardised clinical criteria; parental age greater than 18 years; parental mastery of Italian language; both parents living together with the infant. Exclusion criteria include presence of twins, infant's life-threatening conditions and maternal psychiatric disorders. The dyad's randomised allocation to each arm will be done through a computerised 0/1 sequence generator.

Intervention, TVFI arm

The TVFI will be standardised according to previously published RCTs.[27 28] The TVFI is inspired to concepts from the Collaborative Consultation approach from Zack Boukydis.[29] Specifically, 6 weekly TVFI sessions will be delivered in two subsequent phases, as in previous VFI research with families of children with ND.[30] Four sharing the focus 1-hour sessions will be dedicated to the discussion between the psychologist and the mother of specific themes related to parenting and parent–child interaction: physical stimulation, responsiveness, teaching and parenting experience (see table 1). During these sessions, the psychologist will conduct a dialogic interactive session connecting with the mother in videoconference. The videotaped interaction obtained at T0 will be discussed by the principal investigator (SG) and a senior author (LP) who is experienced in mother-infant interaction coding and early VFI interventions and it will be segmented into specific videoclip lasting up to 10 s. Each videoclip will be labelled with one of the thematic contents reported in table 1. During the sharing the focus sessions, the psychologist will propose to the mother to jointly review some of these segments, usually starting from potential curiosity, comments or requests from the mother herself. The specific order in which the themes will be discussed will be tailored on each specific case. The number of videoclips used for each thematic label in the TVFI of each family will be noted by the psychologist in a diary. The goal of the sharing the focus sessions is to develop insights about the infants' behavioural signals, the best ways to provide stimulations and get in touch, strategies to promote emotion regulation and to sustain cognitive and behavioural achievements. In the subsequent two 1 hour integration sessions, the mother will play with the infant while the psychologist will provide a dyadic-tailored guidance based on topics previously discussed during the first four sessions. The goal of the integration sessions is to promote a pragmatical translation of the insights developed during the sharing the focus sessions into the interactive exchanges between the mother and the infant. By doing so, the mother can introduce variations in her caregiving behaviour in a safe environment under the supervision of a trained specialist.

Intervention, PEB arm

Mothers assigned to condition B will receive an informative booklet addressing the same themes discussed in the experimental intervention (ie, responsiveness, physical stimulation, teaching and parenting experience), but not tailored on their own infant or specific parenting challenges.

Core variables and measures for the specific aims

Maternal sensitivity will be assessed using the Global Rating Scales (GRS)[31] from the first 5 min segment of videotaped mother-infant interactions at T0, T1 and T2.

The GRS provides indexes of maternal sensitivity and intrusiveness that ranges from 1 (low scores) to 5 (high scores) and require a holistic, macroanalytical coding of the interaction. Infants' emotional stress reactivity will be coded in terms of negative emotionality display (by voice and/or facial expression) across the FFSF procedure videotaped at T0, T1 and T2. Negative emotionality display will be coded according to previous system validated in FFSF research.[32] For both coding, students will be trained using available reference videoclips according to a gold standard 85% inter-rater agreement. Trained coders will be blind to the arm allocation and to the specific goals of the intervention.

Other measures (additional exploratory aims)

Information on the clinical characteristics and the diagnosis of the infant will be obtained from medical records. By filling in on-line questionnaires at T0, mothers will provide information on infants' neonatal characteristics (ie, sex, gestational age in weeks, birth weight in grams), sociodemographic variables (ie, maternal age, educational level and occupational status). In the same questionnaire as well as in the following questionnaires administered at T1 and T2, mothers will fill in the 36-item Parenting Stress Index-Short From,[33] the 21-item Beck Depression Inventory,[34] the 20-item state subscale of the State-Trait Anxiety Inventory[35] and the 91-item Infant Behaviour Questionnaire-Revised short form.[36] All these questionnaires have been validated in Italian and they are largely used in parent-infant research in experimental and clinical settings.

Statistical power and sample size estimation

The sample size was estimated for what pertains the first specific aim, that is, the effect of an early VFI intervention on maternal sensitivity. A minimum sample size of 59 subjects per group (alpha=0.05, beta=0.05, power=0.95, effect size, d=0.67) was estimated using G*Power software on the basis of meta-analytical evidence of online interventions focused on parenting.[37] Moreover, due to the longitudinal nature of the study, attrition rate of 20% for each phase was considered, therefore a starting sample size of 84 infants for each group (total sample size=168) has been estimated.

Plan of statistical analyses

R Studio packages[38] and IBM SPSS V.27[39] will be used for the statistical analyses. Participants with more than 20% missing data in the questionnaires as well as those who did not complete at least T0 and T1 assessments will be excluded from the analyses. TVFI and PEB dyads will be preliminarily compared for sociodemographic and neonatal characteristics. In order to respond to the specific aims of the SPHERE study, standard mixed analyses of variance will be used to test within-group and between-group differences in maternal sensitivity and infant's emotional stress reactivity. The difference between T0 and T1 measures will be considered as the primary output of these analyses and long-term maintenance of the effect will be tested by including a third time point (T2) in the model. Advanced modelling will be used to assess the effects of potential mediators/moderators (eg, infants' sex and age) on maternal and infants' outcome variables. Standard mixed analyses of variance will be used to test within-group and between-group differences in maternal parenting stress, depression, anxiety and infant's behavioural regulation across the three assessments time points.

Patient and public involvement

The intervention was not developed in concert with families or parents. Nonetheless, webinars and educational events dedicated to parents and rehabilitation care professionals will be organised to disseminate the findings of the SPHERE project and to promote a culture of family-centred care in the context of ND healthcare. Moreover, after the end of the RCT, the booklet of the PEB will be distributed within the clinical unit of the IRCCS Mondino Foundation and will become a freely available resource for parents and staff. The booklet will also circulate to families thanks to the engagement of parents' associations that collaborate with authors for educational and clinical purposes.

DISCUSSION

Limitations

First, the telemedicine nature of this study may imply technical problems during videorecording due to internet instability or to the loss of a good frame of the infant. For example, the quality of the internet signal may be in some cases low or moderate influencing the quality of the video output. Moreover, specific characteristics of the child (eg, high levels of physical activity) may pose challenges that can make it difficult to keep the interactive partners perfectly at the centre of the recording scene. Mothers will be asked to position the webcam or smartphone to have the widest possible view of the play area and to see the entire body of both the mother and the infant. However, it is possible that during the session infants may come out of the frame or that in some moments the face of participants is not visible. Therefore, portions of the videotapes might be only partially suitable for micro-analytic coding. However, the GRS coding system used for the assessment of the primary outcome of the intervention relies majorly on global scorings that can be performed with medium quality video output. Moreover, attrition rate has been included in the sample size estimation also to take care of potential loss of dyads due to technical problems.

Second, as dealing with the ND clinical condition of their son or daughter may be highly stressful for mothers, it should not be excluded that mothers may express the need of more specific emotional and psychological needs during the SPHERE project. In these cases, proper referral to specialists will be discussed with the mother. Third, NDs include a wide ensemble of clinical conditions

and the different levels of psychomotor delay as well as the different domains that may be impaired certainly play a role in affecting maternal sensitivity and well-being and also impact on the quality of parent–infant interaction. For example, the presence of a mild psychomotor delay or a severe sensory impairment may pose different challenges in the daily interactive exchanges. Nonetheless, the heterogeneity of the clinical conditions is an inherent characteristics of ND and it is often a limit to studies that are mainly focused on directly promoting specific infants' developmental outcomes. In this study, the main focus is on supporting maternal sensitivity as a proxy to further promote infants' development and well-being. Moreover, due to the early age at which infants are enrolled in the study, it is highly probably that they will partially share a risk condition for ND and they will not have already received a specific diagnosis. Notwithstanding, when available, a quantitative psychomotor developmental quotient with standardised scales will be obtained from medical records and will concur to define the enrolled sample.

Finally, despite the substantial variation in the paternal involvement in caregiving and the need for studies on fathers, the SPHERE project will enrol only mothers as participants, due to practical difficulties (eg, limited parental leave for fathers) in engaging fathers in the weekly videoconferences foreseen for the experimental arm.

Expected results and implications

The SPHERE project holds promises to test a new model for the telemedicine care and rehabilitation of infants with NDs. By investing in an early and family-centred intervention we aim to provide families with timely and efficient support to the rehabilitation journey, contributing to grow a sense of self-efficacy in the caregivers of infant with ND. Moreover, by promoting a TVFI we can contribute to reduce the healthcare inequalities for families who face challenges in accessing traditional rehabilitation programmes because they live in rural areas or because of long waiting lists. The SPHERE project may provide evidence-base support to the development and application of TVFI approaches that may maximise the benefit of early family-centred interventions for both parents' well-being and infant's development.

Ethics and dissemination

The study has received the approval of the Ethics Committee Pavia on 2 November 2020, Protocol number 20200096046. All the procedures are consistent with the Declaration of Helsinki ethical principles for research involving human subjects. The procedures do not imply any harm to the participating subjects. Moreover, the study interventions represent additional opportunities for families that do not imply changes in usual mother–infant care programmes. All infants will take part to all the diagnostic and therapeutic interventions that are planned in the child neurology and psychiatric unit IRCCS Mondino Foundation, Pavia, Italy. The dissemination plan includes the presentation of findings at national and international scientific meetings as well as the publication in scientific journals in the field of developmental psychology. The findings will also be disseminated to the public through reach-out activities involving families and healthcare specialists, in order to promote early family-centred intervention.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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