



USE OF EDUCATIONAL MATERIAL IN PROMOTING THE FUNCTIONALITY OF PRETERM CHILDREN: FEASIBILITY STUDY

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ABSTRACT

Objective: To evaluate the feasibility and acceptability of a research protocol on the effects of the educational technology "History of Sofia" in the promotion of functional skills of preterm infants. **Method:** Controlled, randomized and single-blinded feasibility study, carried out in a follow-up service in the *Mata Mineira* Zone. The intervention group (GI) received printed educational material, and the control group (CG), guidance with the Children's Book. The child's functionality was evaluated in three moments with the Pediatric Disability Assessment Inventory (PEDI). Indicators of feasibility, acceptability and preliminary efficacy were analyzed. **Results:** Of the 120 potential participants, 39 families were contacted, 19 agreed to participate (48.72%) and 6 completed all phases (31.58%). All caregivers understood the material and reported improvements in child care. GI showed a significant increase in functional mobility skills after two months ($p=0.02$), but the gain was not maintained. There were no significant differences between groups. Barriers, such as outdated medical records and lack of funding, made recruitment difficult. **Final thoughts:** The educational material had good acceptance, with positive preliminary effects. Active methodologies, extended follow-up and evaluation of emotional and relational impacts in future research are recommended.

Keywords: Premature infant. Child development. Health education. Educational technology. Pilot projects.

INTRODUCTION

In 2023, there were 303,450 premature births in Brazil, which corresponds to 11.9% of the live births of the year⁽¹⁾. Preterm birth is an important risk factor for deficits in neurodevelopment⁽²⁻⁴⁾, especially when associated with other factors⁽⁴⁾, such as low birth weight⁽⁵⁾. Such deficits may manifest up to school age, with cognitive^(2,6), behavioral⁽⁷⁾ impairments, executive functions⁽⁸⁾, academic performance^(7,9), and acquisition of functional skills⁽¹⁰⁾.

Although the vast influence of biopsychosocial factors on children's health is known, as well as their consequences throughout life, there are few longitudinal and intervention studies focused on the integral health of preterm children⁽¹¹⁾. In addition to the neurological vulnerability of this public, the lack of adequate

stimuli contributes to developmental delays, whereas early stimulation promotes functional gains and better quality of life⁽¹²⁾.

Educational interventions focusing on verbal instruction tend to lose knowledge over time, and continuity in actions is important⁽¹³⁾. Structured materials can support families, acting as resources for consultation in case of doubts and omissions. Despite the importance and good cost-effectiveness of light technologies⁽¹⁴⁾, there is a lack of robust studies on the use of educational materials to promote functional development in preterm children. Thus, the objective of the study was to evaluate the feasibility and acceptability of a research protocol to investigate the effects of the use of educational technology "History of Sofia: Battles and achievements of the family in the care and

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development of the premature born child" in the promotion of functional skills of preterm infants.

METHOD

Controlled, randomized and single-blinded feasibility study, following the CONSORT guidelines for pilot and feasibility studies. It was approved by the Research Ethics Committee of the Federal University of Juiz de Fora (CAAE 74111417.0.0000.5147), with the participants signing a free and informed consent form.

The study was conducted in a multidisciplinary service of mixed care (primary and secondary) to child health, reference in the region, which concentrated the population of interest. The convenience sample consisted of consultation with medical records and list of pre-term graduates from two maternity hospitals in the region.

Inclusion criteria were: any level of prematurity and weight less than 2,500g⁽¹⁵⁾; have between 6 months and 3 years and 5 months of age corrected; not have a diagnosis of cerebral palsy, neurologic, orthopedic or respiratory disease severe, malformations or genetic alterations, congenital syphilis or known classification of atypical development. It was also a criterion to be under the responsibility of a caregiver aged over 18 years, literate and with (observed during the collection) ability to understand the interview and the assessment instrument used.

Randomization used the function "randomly" in the Excel 2016® program, generating simple grouping with random numbers. Sealed envelopes were used to maintain blinding of the researchers during the application of the tests. The intervention group (IG) received the printed version of "History of Sofia", a book with illustrated narrative, practical guidelines and framework for monitoring functional development⁽¹⁴⁾, produced with funding from previous research (*Fundação de Amparo à Pesquisa do Estado de São Paulo - FAPESP PROCESS 2014/08778-3*). This material was elaborated and validated based on literature and participation of caregivers and professionals⁽¹⁶⁾.

The intervention consisted in presenting the material chapter by chapter, with a summary of the key messages. Then, guidelines were given for the use of the functional skills framework,

which describes functional behaviors of the child from birth to 3 and a half years old, with suggestions for stimulating the skills expected for the current age group of the child. The control group (CG) received guidance on the use of the development monitoring instrument in the Children's Book. If the caregiver did not have in hand the notebook, a copy of the pages with the frames of the development milestones was delivered. The group also received the educational technology "History of Sofia" after the last evaluation of the study, providing access to all participants involved.

The functional capacity of the child was evaluated as a primary outcome, using the Pediatric Disability Assessment Inventory (PEDI), which covers the age range from six months to seven and a half years. It covers three dimensions: functional skills, caregiver assistance, and modifications of the environment (the latter was not used in the study). In each dimension, the domains of self-care, mobility and social function are addressed. The score is initially given by a gross total score, through which it is possible to obtain a normative score according to age group, which allows the classification of performance as normal (30-70); significantly lower (<30) or higher (>70)⁽¹⁷⁾.

PROCEDURES

After consent, sociodemographic data were collected with the Economic Classification Criterion Brazil (CCEB - *Critério de Classificação Econômica Brasil*)⁽¹⁸⁾, in addition to clinical and functional data (PEDI). The allocation was revealed after the collection of the baseline. The evaluations were scheduled according to the availability of families, trying to reconcile with the day of follow-up consultation in the service, with reminders and reminders via phone or WhatsApp®. The reevaluations occurred after two (follow-up 1 = S1) and four months (follow-up 2 = S2) of the baseline, with application of the PEDI by blind assessor to the allocation. At each meeting, there were health and insertion complications in specialized services. The CCEB was reapplied in S2. All participants received feedback on performance and guidance for stimulation of the child.

Acceptability and feasibility: The acceptability of the methodology was evaluated

considering the acceptance and retention rates of participants, qualitative analysis of the flow and recruitment strategies⁽¹⁹⁾. The perception of families about educational technology was also evaluated through a questionnaire developed for the research. The questionnaire consisted of four graduated sentences with a Likert scale, on the understanding and application of the guidelines described in the educational technology, identification of difficulties in use, and how it helped in the care of the child.

The feasibility was evaluated following recommendations⁽²⁰⁾ in the following dimensions: implementation (necessary resources and facilitation/difficulty factors in implementation); practice (application time and cost analysis); integration (possibility of insertion into existing system/program), effectiveness (preliminary effect of the intervention and adequacy of the methodology to measure the outcome of functionality).

DATA ANALYSIS

The statistical package used was SPSS®, version 20.0. The characterization of the sample was done by descriptive statistics. Shapiro-Walk test was performed, with definition of the use of parametric tests. Categorical variables were analyzed with the Fisher exact test or and Chi-square, when possible. To compare the groups along the three phases of collection, the analysis of variance (ANOVA) was used, verifying the

effects of the group, time and interaction between both on each domain of the PEDI. The Bonferroni test was used for peer-to-peer comparison, with a significance level of 0.05.

RESULTS

Acceptability aspects

Perception of the families about the educational material: The participants of the intervention group reported good understanding and acceptance of the material. All declared to have understood the material; 60% were able to follow the guidelines; 80% denied difficulties in use and all stated that the material helped in the care of the child, and 60% strongly agreed with this statement. There were also participants who reported emotional acceptance, by identifying with the emotions of the parents of Sofia, the main character of the book. There were also reports of positive changes in relations with the child, since the content promoted awareness about the damages of overprotection for children's development.

Acceptance and retention rates: Of the 39 families contacted, 19 agreed to participate in the study (48.72% acceptance rate). Retention was 31.58% for all phases of collection, with 42.11% participating in only two phases and 26.32% from the baseline only. Table 1 presents in detail the data related to participation by collection phase.

Table 1. Participants by data collection phase, Juiz de Fora, 2018

Phase	Intervention		Control		Total	
	n	%	n	%	n	%
Baseline (s0)						
Total of phase	8	100	11	100	19	100
Attended all stages.	2	25	4	36.36	6	31.58
Attended only s0	1	12.50	4	36.36	5	26.32
First follow-up (s1)						
Total of phase	4	50	4	36.36	8	42.11
Attended only s0 and s1	2	25	0	0	2	10.53
Second follow-up (s2)						
Total of phase	5	62.50	7	63.64	12	63.16
Attended only s0 and s2	3	37.50	3	27.27	6	31.58

Recruitment flow and strategies: Recruitment was hampered by physical records with outdated records, limiting contact with potential participants. Even with the addition of lists of newborns from two local maternity

hospitals, the flow was insufficient to reach a significant sample: out of 120 eligible participants, 39 families (32.5%) were successfully contacted.

Sample characteristics: The groups were

homogeneous in sociodemographic and clinical characteristics (Table 2) and initial functional (Table 3). It is observed that, even with the inclusion criterion of any level of prematurity, the children in the sample had a mild to

moderate risk profile for changes in development, being mostly late premature (68.4%) and low weight (63.2%), with up to three neonatal complications (73.7%).

Table 2. Characterization of study participants according to their affiliation group, Juiz de Fora, 2018.

Table 2. Characterization of study participants according to their admission group, June to July, 2016.							
Variable	Intervention (n=8 42.1%)		Control (n=11 57.9%)		Total (n=19 100%)		p
	n	%	n	%	n	%	
Weight, n (%)							
ELBW	1	12.5	2	18.2	3	15.8	0.66
VLBW	1	12.5	2	18.2	3	15.8	
LBW	6	75.0	6	54.5	12	63.2	
NBW	0	0.0	1	9.1	1	5.3	
Degree of prematurity							
EP	1	12.5	2	18.2	3	15.8	0.64
VP	2	25.0	1	9.1	3	15.8	
LP	5	62.5	8	72.7	13	68.4	
Complications in the neonatal period							
None	1	12.5	1	9.1	2	10.5	0.6
One to three	5	62.5	9	81.8	14	73.7	
Over three	2	25.0	1	9.1	3	15.8	
Incidents in the last year							
None	3	37.5	1	9.1	4	21.1	0.13
One to three	5	62.5	10	90.9	15	78.9	
Over three	0	0.0	0	0.0	0	0.0	
Attends daycare							
Yes	2	25.0	2	18.2	4	21.1	0.72
No	6	75.0	9	81.8	15	78.9	
Socioeconomic level							
B2	1	12.5	0	0.0	1	5.3	0.36
C1	3	37.5	6	54.5	9	47.4	
C2	4	50.0	5	45.5	9	47.4	

Caption: Descriptive data of the sample expressed as frequency (n) and percentage (%). ELBW: Extremely Low Birth Weight (<1000g); VLBW: Very Low Birth Weight (<1500g and >1000g); LBW: Low Birth Weight (<2500g and >1500g); NBW: Normal Birth Weight (>2500g). Degree of prematurity expressed in weeks; EP: Extremely Premature (<28 weeks); VP: Very Premature (>=28 - <32 weeks); LP: Late Premature (>=32 - <37). SD (standard deviation).

The predominant socioeconomic level was class C (94.8%). The means and standard deviation in the numerical variables for IG and CG were, respectively: current age of the child in months, 21.8 (± 8.2) and 19.2 (± 7.8), gestational age in months, 21.8 (± 8.2) and 19.2 (± 7.8), birth weight in grams, 1646.9 (± 434.2) and 1625.9 (± 503.8), and age of the primary caregiver in years, 31 (± 8.0) and 30.3 (± 7.8).

Feasibility Aspects

Practice: The data collection lasted an average of 60 minutes, and the operational costs were borne by the researchers themselves.

Implementation: The research required

material and structural resources, such as private physical space, printed materials and trained staff. The printed version of the educational material was made available as a result of previous research, generating no additional expenses in this study. In addition, the material is available virtually, which can ensure access in future studies. All families had the Children's Book. The previous training of the intervening authors and the use of a referral service with the support of the responsible pediatrician, who collaborated in the recruitment, were important facilitating factors for the implementation. In addition, the availability of private room service and location of this in the city center also facilitated the process. Finally, the use

of a material developed specifically for the target audience may have facilitated the identification of the family and consequent adherence to the guidelines. Complicating factors included the lack of up-to-date medical records, difficulty in moving families living in distant neighborhoods, and the lack of funding for transportation, potentially aggravated by the short interval between collections (two months).

Integration: The integration with the service was favored by previous links of one of the researchers, which facilitated the contact and articulation of the research process. Considering that the interveners were undergraduate students

and that their training with the PEDI instrument resulted in an ICC of 95%, it is pointed out that, in case of replication, the research has the potential to be inserted into the scope of extension projects or scientific initiation, thus facilitating the integration into pre-existing services.

Effectiveness: PEDI inventory is a validated instrument, suitable for measuring the outcome of functionality and widely used in research. As for the preliminary effects, Table 3 expresses data on functional development according to PEDI normative scores, by group, throughout the evaluations. There were no statistically significant differences between the groups.

Table 3. Longitudinal characterization of functional development according to the PEDI: Normative Scores

Domain	Intervencion						Control					
	Initial (n-8)		S1 (n-4)		S2 (n-5)		Initial (n-11)		S1 (n-4)		S2 (n-7)	
	Mean	IC	Mean	IC	Mean	IC	Mean	IC	Mean	IC	Mean	IC
	(DP)	95%	(DP)	95%	(DP)	95%	(DP)	95%	(DP)	95%	(DP)	95%
HFAC	47,0	[39,0- (±9,6)	56,3	[34,1- (±2,5)	54,1	[-95,1- (±16,6)	48,7	[41,0- (±10,8)	44,2	[22,9- (±13,4)	47,7	[31,0- (±10,5)
HFM	35,1	[24,4- (±12,9)	56,5	[32,3- (±2,7)*	47,0	[26,0- (±2,3)	35,2	[28,1- (±10,0)	36,9	[24,0- (±8,1)	41,0	[35,3- (±3,6)
HFFS	57,7	[52,3- (±6,5)	70,4	[32,3- (±4,2)	61,2	[35,8- (±2,8)	49,1	[37,5- (±16,3)	47,3	[25,9- (±13,4)	51,2	[44,1- (±4,4)
ACAC	34,9	[28,1- (±8,1)	39,4	[29,9- (±1,1)	48,2	[-89,6- (±15,3)	35,6	[31,3- (±6,0)	31,5	[15,1- (±10,3)	42,1	[34,0- (±5,1)
ACM	37,9	[28,5- (±11,2)	45,4	[33,1- (±7,7)	46,5	[5,2- (±4,6)	37,3	[31,9- (±7,6)	42,2	[14,0- (±17,7)	35,6	[24,1- (±7,2)
ACFS	42,6	[28,7- (±16,6)	45,2	[10,3- (±3,9)	52,9	[12,2- (±4,5)	46,3	[33,1- (±18,5)	37,8	[1,7- (±22,7)	39,0	[20,4- (±11,6)

Caption: HFAC: Functional self-care skills; HFM: Functional mobility skills; HFFS: Functional social function skills; ACAC: Caregiver assistance in self-care; ACM: Caregiver assistance in mobility; ACFS: Caregiver assistance in social function; DP: Standard Deviation; IC: Confidence Interval; S1 and S2: follow-ups 1 and 2. *Statistically significant difference after Bonferroni adjustment ($p < 0.05$).

The analysis of variance showed that time had a significant effect on HFM and ACAC variables. There was no significant group effect in any of the variables. Peer-to-peer comparisons indicated that the HFM score increased significantly in the first follow-up of the GI ($p = 0.02$), which was not maintained in the second follow-up. In HFFS, the ANOVA showed a significant group effect ($p = 0.0045$), but the paired comparisons did not reach statistical significance after Bonferroni adjustment ($p > 0.05$ in all comparisons).

DISCUSSION

The development of the study in the reference service facilitated the selection of the sample,

but logistical factors, such as the need for travel, may have contributed to the acceptance rate for entry into the research of 48.72% and retention of 31.58% for participation in all phases of collection. Despite this, methodological procedures such as team training, use of sealed envelopes and simple randomization proved viable for studies on a larger scale.

The sample presented a mild to moderate risk for changes in development, without aggravating biological factors, such as extreme prematurity, extreme low weight and multiple neonatal complications^(21,22). The environmental factor can be considered a potential risk factor, considering that more than 90% of the participants belonged to Class C, and that the

low socioeconomic level may negatively affect the functional development of this public⁽⁴⁾, besides being one of the main factors for absenteeism in health services⁽²³⁾.

In the initial evaluation of functional skills, although most children had scores within the expected for the age group (normative score between 30 and 70), it was observed that the values of most PEDI domains were close to the lower limit of this normal range, or below the mean value (50), which is in line with the findings from other studies with preterm children^(10, 21). This may suggest that in children who do not have a severe risk, such as those in the present sample, and in the average age of the children included (below 2 years) there are no clear differences in functional development skills. Or that children who are treated in follow-up services, such as those of this study, have access to treatments and guidance that minimize the negative effects of prematurity on development, as suggested by some authors^(21,24). This interpretation directly dialogues with contemporary evidence that child development results from the dynamic interaction between biological maturation, early experiences and environmental conditions⁽²⁵⁾.

The peer-to-peer comparison showed that the normative values of HFM increased significantly ($p=0.02$) in the baseline GI for the first follow-up after two months; this was not maintained in the second follow-up, and may indicate that the insertion of the material was perceived as a novelty factor, generating a greater initial engagement that, over time, decreased. This reinforces the hypothesis that punctual interventions may not be sufficient and that continuous approaches or active methodologies may have a greater impact on the outcome analyzed. In addition, it is possible that the follow-up time was not sufficient to capture important changes, especially considering that the age of most participants was less than 2 years. Considering that the damages of prematurity can last for some years, manifesting itself even in school age^(2,6-9), a long-term follow-up may be important to clarify and amplify the findings.

Also, the fact that there is no significant group effect on the HFM variable may indicate that the information contained in the child's

notebook (instrument used with the control group) are useful for promoting the development of functional mobility skills. These findings reinforce the importance of strategies such as parental education to promote development in the first years of life, which constitute a critical period for human development and society⁽²⁶⁾. Although underutilized in practice⁽²⁷⁾, the booklet is widely distributed and easily accessible to the population, being an important tool for promoting child development in general, and the stimulus for its use at the time of research may have contributed to its use by families.

However, it is considered that the use of a material designed specifically for the population of premature babies can bring additional benefits. Qualitative reports indicated emotional and relational impacts, such as the identification of the caregiver with the content of the material, mobilizing acceptance of their emotions and strengthening the family bond when shared between caregivers of the child. These effects have not been measured, but represent potential outcomes to be explored in future research, broadening the understanding of the benefits of humanized educational interventions in the context of prematurity.

The lack of updated medical records was an important obstacle, limiting contact with potential participants. To get around this problem, a diversified approach of the means of contact (such as e-mail, social networks and secondary telephones) can be used. However, in the medical records in question, this data was not available. This reinforces the growing discussion about adherence to unified electronic systems, as a measure for integrating services and facilitating comprehensive care⁽²⁸⁾.

Despite the good acceptance of the material by families, it is considered that in order to reach a relevant sample for research, it may be necessary to test different strategies, such as the expansion of the or coordination with field professionals to make the material available at the first consultation of the child. In this case, having research funding would be essential to ensure the logistics of this expansion, as well as offering tickets for participants to travel to the collection site, or to have viable technological resources, for example, for teleconsultation -

whose potential is pointed out by some studies to reduce the absenteeism of users and may be a viable approach strategy⁽²⁹⁾. In addition, the educational material used can also be accessed free of charge on digital media, which makes it possible to reproduce the research for a larger audience, even without making the printed educational material available.

Finally, the main limitation of the study was the small convenience sample. To achieve greater representativeness, it is suggested to broaden the search for participants, including, for example, active search strategies in Primary Care Units.

FINAL THOUGHTS

The study showed that the methodological design is viable and replicable on a larger scale, although it requires improvements, especially in terms of recruitment and retention of participants. The educational material was well accepted by families, and preliminary results indicate that educational interventions can favor the functional development of premature children. However, the observed gains were not sustained over time, suggesting the need for

continuous and more active family engagement strategies. Spontaneous reports pointed to possible positive emotional and relational effects, indicating new dimensions to be explored in future studies. The limitations found, such as sample loss and outdated records, reinforce the importance of considering logistical, structural and financial aspects in future research planning. Strategies, such as the use of digital technologies, teleconsultations, expansion of collection for other services and financial support for participation, should be considered to expand the scope and robustness of studies in this area.

It is concluded that the book "History of Sofia" is a promising tool to support child development and strengthen the role of caregivers, especially by considering the specificities of the experience of prematurity. It is recommended that future research adopt active methodologies, with monitoring of the use of material and evaluation of effects on multiple dimensions of child development, such as responsiveness and opportunities in the environment.

USO DE MATERIAL EDUCATIVO NA PROMOÇÃO DA FUNCIONALIDADE DE CRIANÇAS PRÉ-TERMO: ESTUDO DE VIABILIDADE

RESUMO

Objetivo: Avaliar a viabilidade e aceitabilidade de um protocolo de pesquisa sobre os efeitos da tecnologia educativa "História de Sofia" na promoção das habilidades funcionais de lactentes pré-termo. **Método:** Estudo de viabilidade controlado, randomizado e unicego, realizado em serviço de follow-up na Zona da Mata Mineira. O grupo intervenção (GI) recebeu material educativo impresso, e o grupo controle (GC), orientações com a Caderneta da Criança. A funcionalidade infantil foi avaliada em três momentos com o Inventário de Avaliação Pediátrica de Incapacidades (PEDI). Foram analisados indicadores de viabilidade, aceitabilidade e eficácia preliminar. **Resultados:** Dos 120 potenciais participantes, 39 famílias foram contatadas, 19 aceitaram participar (48,72%) e 6 completaram todas as fases (31,58%). Todos os cuidadores compreenderam o material e relataram melhorias no cuidado com a criança. O GI apresentou aumento significativo nas habilidades funcionais de mobilidade após dois meses ($p=0,02$), mas o ganho não se manteve. Não houve diferenças significativas entre grupos. Barreiras, como prontuários desatualizados e falta de financiamento, dificultaram o recrutamento. **Considerações finais:** O material educativo teve boa aceitação, com efeitos preliminares positivos. Recomenda-se metodologias ativas, acompanhamento prolongado e avaliação de impactos emocionais e relacionais em futuras pesquisas.

Palavras-chave: Recém-nascido prematuro. Desenvolvimento infantil. Educação em saúde. Tecnologia educacional. Projetos piloto.

USO DE MATERIAL EDUCATIVO EN LA PROMOCIÓN DE LA FUNCIONALIDAD DE NIÑOS PRETÉRMINO: ESTUDIO DE VIABILIDAD

RESUMEN

Objetivo: evaluar la viabilidad y aceptabilidad de un protocolo de investigación sobre los efectos de la tecnología educativa "Historia de Sofia" en la promoción de las habilidades funcionales de lactantes pretérmino. **Método:** estudio de viabilidad controlado, aleatorizado y ciego simple, realizado en un servicio de *follow-up* en la Zona da

Mata Mineira/Brasil. El grupo de intervención (GI) recibió material educativo impreso, y el grupo control (GC), orientaciones con la Libreta del Niño. La funcionalidad infantil fue evaluada en tres momentos con el Inventario de Evaluación Pediátrica de Discapacidad (PEDI). Se analizaron indicadores de viabilidad, aceptabilidad y eficacia preliminar. **Resultados:** de los 120 participantes potenciales, 39 familias fueron contactadas, 19 aceptaron participar (48,72%) y 6 completaron todas las fases (31,58%). Todos los cuidadores comprendieron el material e informaron de mejoras en el cuidado del niño. El GI presentó aumento significativo en las habilidades funcionales de movilidad tras dos meses ($p=0,02$), pero la ganancia no se mantuvo. No hubo diferencias significativas entre los grupos. Barreras, como historiales clínicos desactualizados y falta de financiación, dificultaron el reclutamiento. **Consideraciones finales:** el material educativo tuvo buena aceptación, con efectos preliminares positivos. Se recomiendan metodologías activas, seguimiento prolongado y evaluación de impactos emocionales y relacionales en futuras investigaciones.

Palabras clave: Recién nacido prematuro. Desarrollo infantil. Educación en salud. Tecnología educativa. Proyectos piloto.

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