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Impact of an mHealth intervention on parents' emotional health and on the neurodevelopment of high-risk infants

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Abstract

We assess the prenatal and postnatal effect of the High-Risk Pregnancy and Baby Parenting programme, which is complemented with two mHealth (app-based) resources. The GLM Repeated Measures Model technique was used to explore differences in the emotional health of the participants and in their infants' neurodevelopment, comparing programme versus usual care groups, composed of 150 and 195 participants, respectively. The mothers presented lower levels of depression (mean difference 1.74, $p = 0.04$, 95% CI 0.07, 3.40) and higher levels of resilience (mean difference 4.09, $p = 0.004$, 95% CI 1.40, 6.78). For the fathers, positive effects on resilience were recorded ($p < 0.001$). A positive treatment effect was perceived in the infants' cognitive ($p = 0.014$), language ($p < 0.001$) and motor ($p = 0.006$) development. These findings suggest application of the programme can benefit maternal emotional health and infant neurodevelopment. M-Health technology could make this programme more accessible.

Keywords

mHealth, premature infant, psychological distress, resilience, small-for-gestational-age infant

Introduction

A pregnancy with neurological risk can be traumatic for the parents, and intervention to protect their emotional health is often indicated (Glover, 2020). Such an intervention should span the period not only prior to birth but also afterwards, in order to optimise the parents' abilities to interpret the behaviour and meet the needs of their baby, regardless of health status. Achieving this goal would help develop the

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baby's potential and strengthen the bond between the parents (Haeusslein et al., 2023; Mause et al., 2022; Spinelli et al., 2016) and their child (Porreca et al., 2016).

Active participation by the family is essential if lasting positive effects on neonatal physical, cognitive and psychosocial development are to be obtained. Many studies have observed that the mental health of the main caregiver and the relationship between the parents can influence the development of children born with neurological risk (Crovetto et al., 2021; Nordheim et al., 2018; O'Donnell and Meaney, 2017; Tuovinen et al., 2021).

However, a major problem is that, despite the enormous efforts made and the gradual incorporation of parents into this process, the families of babies born prematurely and treated in Neonatology Units may not receive care themselves during the infant's hospitalisation, during preparation for discharge or during the next few months of parenting (Polizzi et al., 2021). Family-centred neurodevelopmental care is a philosophy of care based on an alliance between the health team and the families concerned (Quiroga, 2018). However, very few studies have included the fathers in the intervention programmes considered (Padilla-Muñoz et al., 2024). In the context of neonatology there is a need for systematic interventions to reduce stress, to strengthen the parent-child interaction (Sgandurra et al., 2019; Urech et al., 2019) and to consider protective factors such as family resilience (Caruso and Mikulic, 2010; Escartí et al., 2016). When resilience is supported, the family is more likely to overcome the traumatic experience of a high-risk pregnancy (Tedeschi and Calhoun, 2004). According to Jayawickreme et al. (2021), traditional research in this field has too often consisted of methodologically flawed cross-sectional studies with retrospective assessments of post-traumatic growth, an approach that is open to criticism. Therefore, further prospective studies should be conducted, based on methodologies that are accessible to the parents involved. The need for accessibility is one reason why the demand for virtual healthcare is now increasing. Mobile health, or mHealth, is an app-based virtual healthcare resource, which with changing lifestyles and the almost universal use of smartphones is becoming increasingly popular. This approach represents a new model of supported health intervention that facilitates behavioural change in users, enabling them to improve their health status via a straightforward, convenient resource (Voorheis et al., 2022). This type of approach offers many advantages, for example by enabling the medical office to monitor interventions without requiring the user's physical presence (Silva-Jose et al., 2022).

However, despite the advantages offered by mHealth, for patients and health professionals alike, not all interventions generate statistically significant changes (Junker et al., 2024; Kusyanti et al., 2022). Moreover, with the scientific evidence currently available it is not possible to specify the areas of intervention in which mHealth might be beneficial and those in which an in-person intervention would be more appropriate (Hussain et al., 2020).

It has been reported that the parents of premature and/or Small for Gestional Age (SGA) babies are especially suited to make good use of apps designed to reduce the stress and anxiety derived from the traumatic experience of being separated from their baby immediately after birth due to the necessity of neonatal intensive care unit (NICU) hospitalisation. This separation can lead to difficulties in later establishing attachment, heighten uncertainty regarding the infant's health and/or provoke emotional challenges between the parents (Castelar-Ríos et al., 2022; Sabuncuoglu and Basgul, 2016; Sadeghi et al., 2021; Worrall et al., 2023).

Parenthood is in itself a complex situation, and this is accentuated if the baby is born prematurely and/or SGA. Therefore, a purpose-built, scientifically endorsed app could be highly useful, providing these mothers and

fathers with much-needed information and coping strategies.

To date, most of the mobile apps designed for this population have focussed on providing information about the basic care of premature and/or SGA babies (Khoshnood et al., 2023; Rau et al., 2020; Zahedpasha et al., 2019), paying little attention to the prenatal stage.

Objectives and hypotheses

In view of these considerations, our research team has developed a programme termed High-Risk Pregnancy and Baby Parenting (HRP&BP), supported by two mHealth apps (CAREpregnancy and CAREparenting). The aim is to help parents protect their emotional health during pregnancy and to promote the child's health and development during the first year of life. To assess the outcomes achieved with this programme, two study groups were compared: those who participated in HRP&BP from the prenatal stage until the infant reached 12 months of life, versus those who received usual care.

We hypothesised that the study group would achieve better results, in terms of the emotional health of the parents and the neurodevelopment of the infant during this period.

Methods

A prospective longitudinal study with intervention and control groups was conducted to determine the effect of an app-based care programme (HRP&BP) used during pregnancy and the post-natal period by parents of infants at risk (due to premature and/or SGA birth).

Participants

The study population was recruited from two tertiary referral hospitals, one in SE Spain (Hospital 1) and the other in SW Spain (Hospital 2), within the same Autonomous Community (administrative region). Both samples were recruited according to the same inclusion and exclusion criteria.

In every case, the participants were parents of infants identified as SGA and/or at risk of preterm birth (WHO, 2006). Hospital 1 mainly studies SGA infants (birth weight below the 10th percentile according to gestational age), while Hospital 2 focuses more on those at risk of premature birth.

Babies who were not high risk at the time of birth (i.e. they did not meet the criteria for SGA or prematurity) and the parents of babies who died were excluded from the study. All participants received support and training in the use of the programme and the associated apps and gave signed informed consent to take part.

Hospital 1. The participants were selected from the 78 mothers, together with the same number of fathers and live-born infants, attended from April 2017 to July 2018. The recruitment was sequential. Half of the couples with foetuses diagnosed as SGA were randomly assigned to the HRP&BP psychological care programme and the other half, of similar characteristics, were assigned to the control or non-treatment group, which received usual care.

23 couples (12 from the HRP&BP programme and 11 from the usual care group) dropped out of the study for reasons such as change of address, lack of interest or incompatibility with their work. The resulting sample from Hospital 1 thus consisted, in the HRP&BP programme, of 27 mothers, fathers and infants, and in the usual care group, of 28 mothers, fathers and infants.

Hospital 2. The participants were selected from the 94 mothers, together with their partners, who met the inclusion criteria and were treated at this hospital during the period from June 2017 to March 2019.

Following the indications of Ruiz et al. (2005), who considered a similar sample, a delayed recruitment of cases was conducted for 22 months. Thus, during the first 10 months, all parents who met the criteria were recruited to the usual care group; then, after a 2-month

break, recruitment for the HRP&BP programme began. This differentiated approach to study group assignment was adopted considering the specific characteristics of the patients attended at this hospital (a higher proportion of premature infants, with long hospitalisation times), where both study groups would share spaces and experiences, due to their proximity in space and time during hospitalisation. Without delayed recruitment, these confounding factors would have nullified the internal validity of the study (Chacón-Moscoso et al., 2008; Cook et al., 2002).

35 couples (16 from the HRP&BP programme and 19 from the usual care group) declined to participate, for reasons such as lack of interest, lack of time, excessive distance from home to attend the evaluation sessions, lack of means to attend appointments, unwillingness of the partner to collaborate or transfer to another hospital closer to home for follow-up. The resulting study sample for Hospital 2, therefore, consisted of 23 mothers (and the same number of fathers and infants) assigned to the HRP&BP programme, and 37 mothers, fathers and infants in the usual care group.

Total Participants. The study population for the two hospitals, thus, consisted of 50 mothers, 50 fathers and 50 infants (HRP&BP group) and 65 mothers, 65 fathers, and 65 infants (usual care). The recruitment process for the cases selected for each group and hospital, together with details of the cases excluded from follow-up at all measurement times, indicating the reasons for exclusion, are shown in Figure 1 (see Annexe).

Instruments and measures

The five validated, scaled measurement instruments described below were used to analyse the effect of the HRP&BP programme and to determine the influence of stressors (depression, perceived stress and anxiety) and protectors (resilience) on the study population. These instruments have been used extensively in prior international research with similar population samples. The full protocol was applied in person to all mothers and their partners at three moments during the study period: T1, the second trimester of pregnancy (when the level of risk was determined); T2, at 6 months' corrected age (CA); and T3, at 12 months CA. The infants' degree of neurodevelopment was assessed at T2 and T3.

The *Edinburgh Postnatal Depression Scale* (EPDS; Cox et al., 1987; Garcia-Esteve et al., 2003) was applied to assess the subject's mood during the previous 7 days. In our sample, the Cronbach's α value obtained ranged from 0.89 (T1) to 0.78 (T3).

The *Perceived Stress Scale* (PSS; Cohen et al., 1983), Spanish version (Remor, 2006) measures the extent to which life situations are considered to be stressful. The Cronbach's α value obtained was 0.89 – 0.92 (T1-T3).

The *Connor-Davidson Resilience Scale* (CD-RISC; Connor and Davidson, 2003) was used to assess the ability of the parents, in each group, to cope with adversity. The Cronbach's α value obtained was 0.85 – 0.80 (T1-T3).

The *SCL-90 Anxiety subscale* (Derogatis, 2002) detects and assesses the presence of general anxiety. The Cronbach's α value obtained was 0.91 – 0.90 (T1-T3).

The *Bayley Scales of Infant and Toddler Development* –Third Edition (Bayley, 2006) assess the mental, psychomotor and behavioural development of children aged between 1 and 42 months. The Cronbach's α values obtained were 0.85 for the cognitive area, 0.85 for receptive language, 0.87 for expressive language, 0.85 for fine motor skills and 0.85 for gross motor skills.

Description of the HRP&BP programme

The HRP&BP intervention programme incorporates two mHealth apps (CAREpregnancy and CAREparenting) to be used with a smartphone. The programme was created by psychologists, gynaecologists, paediatricians and midwives (in

a group formed specifically for this project and funded by the Andalusia Ministry of Health (Junta de Andalucia, Spain) Ref. PC-0526-2016-0526). The programme is intended to promote the physical and emotional health of mothers and fathers during pregnancy and the neonatal period, and at the same time to optimise infant neurodevelopment, from the initial detection of a risky pregnancy and throughout the first year of life.

Specifically, the programme offers care guidelines to the parents of premature and/or SGA babies, addressing the emotional problems that may arise and providing resources and suggestions to achieve a strong maternal/paternal bond. The programme content was developed from the above-mentioned integrative models on child and family care (the Neonatal Integrative Developmental Care Model, the Routine-Based Model and the Family-Centred Care Model). Motivations that were common to all these models, and that were considered in developing the programme and its associated apps, were: a) to encourage parental participation; b) to enable parents to become the main support for their children. The prenatal phase consisted of 20 sessions, distributed according to the parents' preferences, in a cycle that was repeated until the baby was born. In the postnatal phase, the 26 programme sessions were distributed according to the needs of the parents and their babies. The parents were asked to complete a self-assessment questionnaire after each session, and some were also asked to comment on the usability of the programme (Balderas-Díaz et al., 2022).

In line with Zahedpasha et al. (2019), in this study we consider the family as a system, in which the baby is an integral part. An important aspect of the HRP&BP programme is that it seeks to improve parent-infant communication and enhance the parents' confidence in caring for their baby. Figure 2 (see Annexe) summarises the contents of the HRP&BP programme.

Procedure

At each of the participating hospitals, healthcare personnel (nurses, midwives and gynaecologists) facilitated contact with all the mothers and their partners who met the inclusion criteria for this study. Variables related to the parents' emotional health (risk and protection factors) were determined at five time points: during the second trimester of pregnancy, at birth, and at 3, 6 and 12 months CA. However, for the purposes of this study, only the data obtained during gestation (in the second trimester, T1) and at 6 and 12 months (T2 and T3, respectively) were considered, as these are the most significant for detecting changes in infant development. Both hospitals were fully equivalent regarding all evaluation conditions, that is, the inclusion and exclusion criteria applied, the instructions given regarding access to the cases selected, the evaluation conditions (that the room used should be well-ventilated, spacious and equipped with everything necessary) and, of course, the measurement protocol applied (using the same evaluation booklet and locating the instruments in the same positions).

Finally, both hospitals used the same version of the HRP&BP programme, and were supplied with the same instructions for use, to facilitate digital literacy (World Health Organization, 2019), drafted by the IT Engineer that collaborated in the design of the apps.

The coordinated project and its two subprojects, with differentiated recruitment between the two hospitals, was approved by the corresponding Ethics Committees and by the regional authorities, reference 29d1f3f9bf2b2ffbfd6b25d7136d7ab7a7558494, in a decision dated 30 November 2016. The provisions of the Declaration of Helsinki were rigorously always followed, and the participating fathers and mothers all gave signed informed consent to the procedure.

Data analysis

Statistical analyses were performed with SPSS v26 software (IBM SPSS Statistics for

Windows, Version 26.0, 2019). Descriptive statistics (means, standard deviations, frequencies and percentages) were used to describe the participants and all the study variables. Cronbach's alpha statistic was used to test the reliability of the measurement instruments. Student's t-test and Pearson's chi-square test were used to analyse bivariate associations between the study variables.

Possible bias due to missing data was analysed by applying Student's t-test to the sociodemographic variables for the couples that completed the study and those who dropped out. No significant differences were detected, from which we conclude that the study findings are not affected by missing data bias. For the participants' education background, the following results were obtained: Hospital 1 (mothers, $t = -0.50$, $p = 0.30$; fathers $t = 1.04$, $p = 0.15$); Hospital 2 (mothers, $t = -0.65$, $p = 0.25$; fathers, $t = -0.60$, $p = 0.27$).

The General Linear Repeated Measures Model (RM-GLM) was used to test the study hypotheses on the effects of the HRP&BP programme on parental emotional health and infant neurodevelopment, taking the relevant scores at the three time points established (T1, T2 and T3) as the within-subjects variable, together with participation in the HRP&BP programme versus usual care. Contrasts of interaction between intrasubject and intersubject variables were also analysed. For all these analyses, the level of statistical significance was set at $p < 0.05$ and the size of the η^2_{partial} effect was calculated, considering this effect small from 0.010, medium from 0.059 and large from 0.138.

Results

Quantitative (Student's t test) and qualitative (chi-square test) comparisons were made to detect possible differences between the participants at the two hospitals regarding the sociodemographic and clinical variables considered. These tests showed that the two populations were similar with respect to the parents' level of education and (for the baby) the type of delivery, the birth weight, arterial pH at birth and sex (Table 1). However, there were some differences in the variables related to the type of population. In Hospital 2, where the population mainly consists of premature infants, the parents tended to be older, and there was a lower proportion of primiparous women, a greater risk of premature rupture of the membrane, a greater number of miscarriages, a lower gestational age and more prolonged hospitalisation (Table 1).

On the other hand, there was a degree of overlap between the two populations. In our study sample, of 115 premature and/or SGA babies, 23 (20%) were both premature and SGA. In this respect, Turcan et al. (2020) reported that 5.6% of the study population were both preterm and SGA.

At Hospital 1, differences between the two study groups were only observed for the study variable 'Type of delivery'. At Hospital 2, no differences between the groups were observed for any of the study variables (Table 1).

The emotional health of the parents when the pregnancy risk was determined (i.e. the T1 measurement) was also examined. In this respect, there were no significant differences between the hospitals for any of the measures considered (Table 2, see Annexe). In other words, the populations at both hospitals obtained similar scores for emotional health before entering the HRP&BP programme, and therefore can be considered a single sample in this respect, thus improving the power of the analyses performed.

Having established the homogeneity of the two samples as regards the participants' emotional health, the effects of the HRP&BP programme were analysed jointly.

Effect of the programme on the parents' emotional health

Table 3 shows the RM-GLM results for the emotional health variables of the mothers at each of the time points considered and

Table 1. Details of the hospital populations. Sociodemographic characteristics (mothers and fathers), pregnancy and perinatal outcomes.

	Hospital 1		Hospital 2				
	HRP&BP program N = 27	Usual care N = 28	HRP&BP programme N = 23	Usual care N = 37	*p*	*p**	*p*†
Maternal age (years)	32.11 (5.85)	29.89 (5.42)	33.91 (4.99)	33.73 (5.00)	0.003	0.08	0.44
Paternal age (years)	32.70 (6.67)	32.11 (7.34)	35.65 (5.15)	37.47 (5.65)	<0.001	0.38	0.10
Maternal education							
Primary school	8 (29.6)	9 (32.1)	5 (21.7)	3 (8.1)	0.08	0.79	0.11
High school	7 (25.9)	9 (32.1)	6 (26.1)	16 (43.2)			
College/university	12 (44.5)	10 (35.8)	12 (52.2)	18 (48.7)			
Paternal education							
Primary school	6 (22.2)	6 (21.4)	4 (17.4)	4 (10.8)	0.40	0.98	0.58
High school	13 (48.1)	13 (46.5)	12 (52.2)	19 (51.4)			
College/university	8 (29.7)	9 (32.1)	7 (30.4)	14 (37.8)			
Pregnancy risk							
PRM	0 (0)	1 (3.6)	18 (78.3)	26 (70.3)	<0.001	0.11	0.77
SGA	23 (85.2)	18 (64.3)	3 (13.0)	6 (16.2)			
PRM + SGA	4 (14.8)	9 (32.1)	2 (8.7)	5 (13.5)			
Types of delivery							
Vaginal	17 (63.0)	13 (46.4)	13 (56.5)	13 (35.1)	0.11	0.01	0.10
Assisted vaginal	8 (29.6)	4 (14.3)	8 (34.8)	16 (43.3)			
Caesarean	2 (7.4)	11 (39.3)	2 (8.7)	8 (21.6)			
Miscarriage	0.22 (0.50)	0.29 (0.71)	0.52 (0.99)	0.59 (0.89)	0.02	0.35	0.38
Primiparous							
Yes	20 (74.1)	16 (57.1)	8 (34.8)	10 (27.0)	<0.001	0.18	0.52
No	7 (25.9)	12 (42.9)	15 (65.2)	27 (73.0)			
Gestational age at delivery (weeks)	37.29 (2.36)	37.28 (2.32)	34.52(3.50)	34.52(4.18)	<0.001	0.49	1.00
Birth weight (grams)	2234 (523)	2272 (518)	2181 (856)	2145 (914)	0.25	0.39	0.88
5-min Apgar score	8.56 (0.97)	8.89 (0.87)	9.15 (1.06)	9.37 (1.01	0.06	0.09	0.28
Vena artery pH	7.18 (0.15)	7.20 (0.12)	7.21 (0.14)	7.31 (0.09)	0.23	0.24	0.07
Risk to baby							
Still birth	5 (18.5)	2 (7.1)	0	2 (5.4)	<0.001	0.24	0.78
Risk-free	1 (3.7)	3 (10.7)	7 (30.4)	12 (32.4)			
Premature	0	3 (10.7)	9 (39.1)	15 (40.5)			
SGA	17 (63.0)	15 (53.6)	1 (4.4)	1 (2.7)			
SGA + premature	4 (14.8)	5 (17.9)	6 (26.1)	7 (19.0)			
Hospitalisation (days)	8.25 (7.70)	11.50 (7.29)	31.69 (20.50)	33.74 (36.17)	<0.001	0.20	0.42
Gender of baby							
Male	16 (59.3)	14 (50.0)	14 (60.9)	17 (45.9)	0.75	0.49	0.26
Female	11 (40.7)	14 (50.0)	9 (39.1)	20 (54.1)			

Data are given as *n* (%), mean (SD). *p*-values were calculated using Student's *t*-test and Pearson's chi-square test.
p Hospital 1 versus Hospital 2. *p** Hospital 1 HRP&BP programme versus usual care. *p*† Hospital 2 HRP&BP programme versus usual care.
PRM: premature rupture of membranes; SGA: small for gestational age.

according to whether or not they participated in the HRP&BP programme.

Maternal depression. Differences were observed between the different measures at T1, T2 and T3, with a large time effect $F_{(1.44)} = 63.01$, $p < 0.001$, $\eta^2 = 0.49$, $\beta\text{-}1 = 1.00$. A significant treatment effect for depression was also found. Comparisons by time show that this effect was significant at T2 (6 months CA), since the depression scores for the HRP&BP programme group (M = 4.77, SD = 3.25) were significantly lower than those for the usual care group (M = 6.85, SD = 4.58, $p = 0.03$, [95% CI 0.15, 4.01]). At T3 there were no differences in maternal depression between the two groups, but the improvement achieved at T2 compared to T1 was more strongly maintained at T3 in the programme group (11.07 mean T1 vs 5.10 mean T3) than in the usual care group (9.59 mean T1 vs 6.93 mean T3; Figure 3, see Annexe).

Maternal stress. Similarly, differences were observed between the various measures of maternal stress over time, with a large time effect $F_{(1.66)} = 19.64$, $p < 0.001$, $\eta^2 = 0.25$, $\beta\text{-}1 = 1.00$. A significant treatment effect on the stress experienced by the mothers was detected at T2; in other words, the stress scores for the HRP&BP programme group (M = 13.57, SD = 7.40) were significantly lower than those for the usual care group (M = 15.23, SD = 9.99, $p = 0.01$, [CI 95% 0.86, 9.13]). At T3, the same effect was found as for depression, with unchanged differences in stress between the two study groups (Figure 3, see Annexe).

Maternal anxiety. Differences were observed at T1, T2 and T3, with a large time effect $F_{(1.3)} = 32.48$, $p < 0.001$, $\eta 2 = 0.37$, $\beta\text{-}1 = 1.00$. Although for both groups levels of anxiety fell between T1 and T2 ($p = 0.006$ HRP&BP programme group, $p < 0.001$ usual care group), there was no such variation, in either group, between T2 and T3. No differences in anxiety were observed between the HRP&BP programme group and the usual care group, for any of the times evaluated (Table 3, see Annexe).

Maternal resilience. Differences were also found in the different measures of resilience, at each of the times considered, with a large time effect $F_{(2)} = 6.21$, $p = 0.003$, $\eta 2 = 0.11$, $\beta\text{-}1 = 0.88$. In addition, a treatment effect was recorded at each time point ($p = 0.004$); in other words, the mothers in the HRP&BP programme group were more resilient than those in the usual care group, at T1 ($p = 0.02$), T2 ($p = 0.01$) and T3 ($p = 0.001$; Figure 3, see Annexe).

Paternal emotional health. Table 4 (see Annexe) shows the RM-GLM results for the emotional health variables of the fathers at the different time points, and according to whether or not they participated in the HRP&BP programme.

Over time, levels of depression ($p < 0.001$) and stress ($p < 0.001$) fell among these men, that is, there was a time effect. However, no treatment effect in this respect was observed at any of the time points. For anxiety, no time or treatment effect was found. For resilience, no time effect was observed, but there was a treatment effect ($p < 0.001$), highlighted by intergroup differences at all time points evaluated. Thus, the HRP&BP programme group was more resilient than the usual care group at T1 ($p = 0.02$), T2 ($p = 0.002$) and T3 ($p < 0.001$). In other words, resilience increased over time among the HRP&BP programme group but remained unchanged in the usual care group (Table 4, see Annexe).

Effect of the programme on the baby's development during the first year of life

The effect of the HRP&BP programme on infant neurodevelopment is summarised in Table 5 (see Annexe), which shows the RM-GLM results for relevant variables at each time

point considered and according to participation or otherwise in the HRP&BP programme. In brief, the infants' development had improved in all areas at 6 months and at 12 months, except in that of gross motor skills.

Furthermore, a time effect was observed in all areas of development, that is, cognitive skills ($p < 0.001$), language expressivity ($p < 0.001$), language receptivity ($p < 0.001$), total language skills ($p < 0.001$), gross motor skills ($p < 0.001$) and fine motor skills ($p < 0.001$). In addition, a positive effect of the HRP&BP programme was found at both T2 and at T3 in all areas of development evaluated, except in that of gross motor skills, which presented differences between the HRP&BP programme group and the usual care group at T2 ($p = 0.02$, CI 95% [0.33, 5.49]) but not at T3 ($p = 0.32$).

Discussion

The study results obtained indicate that application of the HRP&BP programme has a positive effect on emotional health, especially that of the mothers, and on infant neurodevelopment, compared to usual care. The main improvements were observed at T2. Thus, the programme's effect on the risk variables for emotional health (depression and stress) became evident at 6–8 months after the start of the programme and remained present until (at least) 12-15 months after the start. As regards the protective variables (resilience), the programme's influence remained apparent throughout the study period. Its positive effect on infant neurodevelopment was observed at 6 and 12 months' CA.

Certain differences were detected in the sociodemographic variables, according to the type of population recruited, which differed from one hospital to the other. Thus, at Hospital 2, the maternal and paternal ages were greater than at Hospital 1 and the babies treated were mainly premature. This finding coincides with Fuchs et al. (2018), who observed a positive relationship between maternal age and the percentage of premature births. Regarding the clinical characteristics, differences were observed in gestational age, pregnancy risk and length of hospitalisation. These were all greater at Hospital 2, as was to be expected due to its larger population of premature infants. Magro-Malosso et al. (2018) reported that the risk of premature birth was associated with that of miscarriage. This was also the case in our own study sample. By type of delivery, operative deliveries were more common at Hospital 1 than at Hospital 2, since most of the babies treated were SGA and thus more likely to require this approach (Rhoades et al., 2017). Other factors that varied between the two hospitals were the type of risk to the baby, the 5-minute Apgar score and the proportion of mothers who were primiparous. Our bibliographic search did not reveal other studies corroborating this finding.

However, despite the above differences corresponding to the type of sample recruited at each hospital, at both sites the families that participated in the programme were similar to those who received usual care, and similar patterns of behaviour were observed, with the exception of the type of delivery, which at Hospital 1 was less surgical, with fewer caesarean sections, among the mothers who took part in the programme.

Effect of the programme on the parents' emotional health

Our findings show that when appropriate resources are offered to mothers and their partners as soon as a risk to the pregnancy is detected, and a systematic follow-up is carried out, positive changes can be produced in terms of enhanced maternal emotional health, reduced levels of stress and depression, and heightened resilience. These changes, moreover, could enhance the mother's care of the child and contribute to optimising neurodevelopment.

In this respect, studies have shown that the mental health of the main caregiver, the

behaviour of the parents and the relationship between parents and children, when they interact with other risk factors, influence the development of preterm infants (Nordheim et al., 2018; Tuovinen et al., 2021) and that of SGA infants (Glover, 2020; Ibrahim and Lobel, 2020). This is an important understanding because, as O'Donnell and Meaney (2017) point out, hypotheses on the evolutionary origins of health and disease suggest that the quality of foetal development determines individual differences in the lifetime risk of chronic disease. For example, prenatal symptoms of anxiety or depression are associated with a more difficult infant temperament, regardless of postnatal maternal mental health. Accordingly, the HRP&BP programme could help prevent these kinds of negative consequences for child development.

According to Craig et al. (2015), the standardised use of family-centred developmental care (FCDC) within the NICU would optimise infant development and help establish a solid foundation for the family's relationship with the child. Studies of intervention programmes applied with this model have highlighted the positive effects of this approach in areas such as early interaction (Porreca et al., 2016), enhanced parenting skills (Sgandurra et al., 2019) and stress reduction (Urech et al., 2019). However, there is a significant problem, namely that most such programmes have had insufficient resources with which to continue providing long-term support for parents. However, the programme we describe is reinforced by the provision of two mobile apps, CAREpregnancy and CAREparenting, which provide users with the means to improve their emotional health and stimulate the development of their babies. These mHealth apps also facilitate periodic self-assessment of the progress made towards these goals, via questionnaires about the family's daily routines (Balderas-Díaz et al., 2022).

In line with our own findings on the programme, and also using a tool based on new technologies, Sgandurra et al. (2019) reported that the participation of parents in early intervention programmes seems to have positive effects both for the parents and for their children.

Regarding the study outcomes, the mothers who participated in our programme achieved a higher level of improvement than the fathers, especially at 6 months' CA. This finding is in line with Sgandurra et al. (2019), whose results showed that the CareToy intervention was managed mainly by the mothers. These authors also measured a significant reduction in the parental distress subscale among the mothers in the CareToy group compared to usual care, but no such difference for the fathers.

Our study did not reveal any effect of the programme on the risk factors considered for the fathers (depression, stress and anxiety), which suggests that the mothers, on average, achieved a stronger post-traumatic growth (Tedeschi and Calhoun, 2004). This difference may be because the fathers have not yet assumed a parental role, and hence feel less involved in terms of emotional health and in promoting the baby's neurodevelopment, or it may reflect their lesser involvement in the programme. Hearn et al. (2020) suggest that if the fathers were present in the NICU this would give them greater confidence and knowledge about childcare, and hence encourage them to take a more active part in this respect. The programme does include specific sessions for fathers, but their participation remained lower than that of the mothers. In other words, the treatment effect was smaller for fathers. Thus, in accordance with Hearn et al. (2020), we believe that fathers should be further encouraged to actively participate in caring for their newborn children.

Effect of the programme on the baby's development during the first year of life

The study results show that the infants whose parents followed the HRP&BP programme presented a higher degree of neurodevelopment than those in the usual care group, and that this difference was maintained over time. The only

exception to this was in the development of gross motor skills; in this area, no differences between the groups were observed at 12 months of life.

The study findings highlight the value of the programme for health, both before and after birth. It not only benefits the emotional state of the mothers taking part, but also enhances the infants' neurodevelopment. Unlike previous proposals in this field (Khoshnood et al., 2023; Rau et al., 2020), our programme not only provides psychoeducation and emotional support to parents, but also fosters the implementation of their discoveries for emotional management, self-care, and development stimulation. This, together with the fact that the programme spans the period during pregnancy and the first 12 months of postnatal life, seems to provide greater benefit than interventions which focus more narrowly on the prenatal or the postnatal stage. Thus, its impact could extend to the medium and long-term neurodevelopment of children, their emotional regulation and academic performance (Glover, 2020).

Finally, the programme provides a family-focussed and natural environment-centred approach to care, as each family can adapt the programme to their needs and schedule. Although the evidence suggests that methods such as Family-Centred Developmental Care Practices and Family-Centred Early Intervention provide the best results, their implementation in real-world contexts remains challenging. Our programme seems to offer the necessary resources to equip parents for the new tasks facing them, enabling them to put into daily practice skills that promote and optimise the child's development (Valero et al., 2020).

Conclusions, limitations and implications

The main outcome of the present study is the development of a practical instrument, the HRP&BP programme, that facilitates the participation of parents who might otherwise have difficulty in engaging with an in-person training programme. The programme incorporates two differentiated sub-programmes: one focussed on pregnancy and the other on caring for infants at risk. The prenatal and postnatal follow-up maintained for 15 months, with a range of control measures, increases the potential of our study. In addition, the programme offers a guided, structured intervention with practical exercises in each module, together with in-person sessions designed to assess the emotional state of the parents during the pregnancy and subsequent childcare, and also to monitor the neurodevelopment of the child. This dual approach promotes adherence and enhances the effect of the programme, as well as enabling the early detection of any difficulties that may arise.

Despite the strengths indicated, this study is not without limitations. The first is the limited size of the study sample, which was partly due to the difficulties encountered in obtaining an appropriate population sample, together with the 15-month follow-up period involved. Furthermore, the differentiated recruitment system employed for each of the hospitals at which the study took place, although explained and justified, is not free of bias. However, analysis of the inter-group comparison showed that the patients recruited at both hospitals were similar in terms of their emotional health, and that the groups that participated in the programme were of a similar nature to those who received usual care, at each hospital.

These findings encourage us to extend this line of research, with a longer follow-up to determine whether the changes initially observed become consolidated or decay over time. In addition, the results underpin the use of new, readily accessible technologies for couples with a risky pregnancy, to provide a useful tool for Family-Centred Early Intervention.

In future work, it would also be desirable to assess the influence of certain clinical variables, such as birth weight, CA, previous gestational

losses or the type of delivery, on maternal emotional health and on infant neurodevelopment. In addition, we should assess which variables are most closely related to mental health during follow-up, with more sensitive instruments (in particular for anxiety) and include an analysis of the parents' discourse. Finally, if the analysis were based on a larger sample, this would allow other hypotheses to be formulated, such as the impact of participation in this type of programme during pregnancy on the type of delivery subsequently performed.

To conclude, we believe that studies of intervention programmes such as HRP&BP, focussed on family routines, should be assigned high priority, since they may contribute significantly to enhancing the emotional health of mothers and benefit the neurodevelopment of babies at risk of being SGA. However, a better understanding is needed of the mechanisms that might increase the involvement and active participation of fathers during pregnancy and early childhood.

Author contributions

Conceptualization MBG, EMPM, MJCR, MADL, JML, MDLF; methodology MBG, EMPM MADL, JML, MDLF; software, MBG, EMPM, MJCR, MADL, JML, MDLF; formal analysis, MBG, MDLF; research, MBG, EMPM, MJCR, MADL, JML, MDLF; writing and supervision, MBG, EMPM, MJCR, MADL, JML, MDLF; project management, MBG, EMPM; fund acquisition, MBG, EMPM. All authors have read and agree with the published version of the manuscript.

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Data sharing statement

The data generated during and/or analysed during the current study are not publicly available due to Protection of health and medical data (BOE» no. 294, December 6, 2018) but are available from the corresponding author on reasonable request.

Declaration of conflicting interests

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Ethics approval

The study was approved by the Ethics Committee Autonomous Community of Andalusia, Spain, date 30/11/2016 (code/29d1f3f9bf2b2ffbfd6b25d7136d7ab7a7558494), and informed consents were obtained from the participants to be included in the study.

Consent for publication

All authors have approved the manuscript and agree with its submission to Journal of Health Psychology.

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Supplemental Material

Supplemental material for this article is available online.

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