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Social and emotional competence as key element to improve healthy lifestyles in children: Results from a randomized controlled trial

- **Short running title**

Preliminary effects of CRECES programme

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Criteria	Author Initials
Made substantial contributions to conception and design, or acquisition of data, or analysis and interpretation of data;	EBM, OL,AM, MJP,AI,CRZ,MB
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ABSTRACT

Aim: To show the results of an exploratory trial based on social and emotional learning to promote healthy lifestyles in 5-6 aged children.

Design: A randomized controlled trial.

Method: The study was conducted from 2015 - 2016. Thirty-seven children were allocated to the intervention group (N=19) and control group (N=18). A multi-method and multi-component evaluation approach was used to capture the preliminary efficacy, acceptability and feasibility of the programme. Repeat measures ANOVA followed by an ANCOVA tests were applied for the inferential analysis and for qualitative data a content analysis was used.

Results: Positive effects on emotional perception and resilience were found in children's intervention group. Children and families showed high programme's acceptability and a wide range of barriers and facilitators were identified during the implementation process.

Conclusion: predicted mechanisms to improve healthy lifestyles in children throughout social and emotional competence seem to be supported by some of the study's results. However more research is needed to replicate such results and confirm these mechanisms.

Impact:

What problem did the study address?

- To promote social and emotional skills as an important factor to adopt and maintain healthy habits.
- To include children as health agents and active participants in health education activities.

What were the main findings?

- Positive effects on dimensions of children's emotional knowledge and Health Profile.
- A high acceptability of the programme perceived by children and families.
- Key feasibility factors identified during the implementation process.

Where and on whom will the research have impact?

- This research can help to improve nurse's health education strategies in school and community contexts to achieve better health results in children's wellbeing.

ClinicalTrials.gov Identifier: NCT02975544

Key words: healthy lifestyles, children, health education, socio-emotional competence, school-based interventions, nursing, school nurse, exploratory trial, mental health, health promotion

INTRODUCTION

Optimal social and emotional competence is seen as a protective factor for healthy development in children, which will play a key role in their well-being in later stages (Aviles et al., 2006; Durlak et al., 2015; Linares et al., 2005; Thompson et al., 2006; Weare & Nind, 2011). Furthermore, its benefit might be also extended to the acquisition and maintenance of healthy lifestyles (Fuster, 2010; Malinauskas et al., 2018; Ortega-Navas, 2010, 2014; Weare, 2010), providing children with better learning, self-motivation, self-efficacy and self-confidence (Birch et al., 1997; Elias, et al., 1997; Linares et al., 2005; Zins et al., 2007).

Currently, most school-based interventions to promote healthy lifestyles have been focused on physical issues and not on emotional and social skills (Kobau et al., 2011; Colomer-Revuelta et al., 2004). Therefore, considering the interconnection between emotion, cognition and behaviour it is necessary to improve these strategies, to make them more beneficial (Gibson, 2006; Graybiel & Smith, 2014; Lemerise & Arsenio, 2000). Regarding these aspects, preschool age has been considered one of the most important stage to work on, since it is during these years when the most significant socio-emotional development take place (Denham & Brown, 2010; Saarni, 1999, 2000; Zins et al., 2007).

Background

Nurses have an important responsibility to promote healthy lifestyles in schools. However, there are few initiatives conducted by them which include emotional and social skills as central components of their programmes (McLachlan et al., 2009). A previous Spanish qualitative study conducted highlighted the importance of tackling these aspects and the need

to improve the communication between schools, families and primary care health professionals to carry out an integral child health promotion (Lopez-Dicastillo et al., 2012).

In contrast, social and emotional learning programmes have been mostly delivered by teachers in schools and evaluated by large-scale studies (Durlak et al., 2015; Durlak et al., 2010; 2011; Humphrey, 2013). Nevertheless, the lack of an appropriate and rigorous implementation and evaluation makes the application of such initiatives in other contexts difficult (Pérez-González, 2008, 2015; Humphrey et al., 2016). Despite research growing in this area, more studies are needed to identify their feasibility and acceptability (Lendrum & Wigelsworth, 2013). Furthermore, a multi-informant and multi-method assessment of social and emotional competence is required (Humphrey et al., 2011).

THE STUDY

Aim.

To explore the impact of the first unit of a health education programme (CRECES) based on the development of social and emotional competence in 5-6 aged children, as a mediator to adopt healthy lifestyles.

The objectives and hypotheses are:

Objectives.

1. To examine the preliminary effects of the first unit on the emotional knowledge, basic social skills and children' health profile variables.
2. To explore the social validity and feasibility of the intervention.

Hypothesis.

Compared with a control group, children in the intervention group will have improved emotional knowledge (primary outcome), basic social skills and health profiles (secondary outcomes) over time (from baseline, to 6 weeks post-test measure and 7-months follow-up), controlling for basal variability.

Design

A randomized controlled two-group pre-test–post-test and follow-up design was adopted. The study protocol has been published (Bermejo-Martins et al., 2017).

Methods

This paper reports empirical data on three critical aspects of an exploratory trial (following the Medical Research Council framework for complex interventions):

1. Preliminary estimation of the intervention effect size through comparison of outcomes in children receiving the intervention and those in a 'usual routine' control group.
2. Examination of feasibility using analysis of researcher's field diary after each session.
2. Examination of the intervention's acceptability and perceived impact on children and their families through qualitative interviews. Identifying social validity and subjective efficacy of a complex intervention is a critical precursor to a definitive trial (Campbell et al., 2007).

Participants

Children were recruited in January-March 2015 from a public school in Spain located in a multicultural area of the city with wide heterogeneity in terms of ethnicity, socio-economic situations and families' characteristics.

Inclusion criteria: (1) Children enrolled in a public school; (2) aged 5 and 6 years old; (3) taking part of the school's extracurricular activities; (4) able to read and/or speak in Spanish; and (5) with their caregivers' informed consent. Exclusion criteria: (1) Children aged above 7 years or below 4; (2) who are not taking part in the school's extracurricular plan; (3) known severe cognitive or language difficulties; and (4) not having their caregivers' informed consent.

Sample size calculation

Being exploratory trial, a conventional sample size calculation, appropriate for a full-scale intervention, is not required (Lovell et al., 2008). A minimum of 30 participants was considered necessary to answer the aim and objectives of this study. This estimation is in line with other similar studies (Conner & Fraser, 2011; Harvey-Berino & Rourke, 2003; Mujika et al., 2014). This study recruited 37 children.

Intervention

Control group. The control group continued their school routine. They and their families took part in a multi-activity day with the rest of participants as programme's closing event.

Intervention group. The intervention group received a health education programme; named CRECES programme, based on the development of social and emotional competence as a vehicle to adopt healthy lifestyles. The theoretical core of this programme is based on Denham's (2005) model of social and emotional competence development and its similar adaptation to Spanish language by (Bisquerra & Perez 2007).

This model includes five interconnected components: emotional awareness, emotional regulation, emotional independence, social skills and life skills. According to the gradual development of social and emotional competence, CRECES programme was designed in a pyramidal way. The first unit ('My Exciting Health'), was based on emotional awareness as the elemental component to develop other subsequent components of the competence. The theoretical framework is wider explained in the study protocol (Bermejo-Martins et al. 2018). The intervention consisted of eight sessions (40-50 minutes), twice weekly, delivered after-school. Topics covered included strategies and activities to identify, recognize, label and express acutely the six basic-emotions (anger, fear, joy, sadness, surprise, disgust/pleasure) around four healthy habits: eating, physical exercise, hygiene and sleeping. For example, active games were used to work on these emotions around eating habits, how to recognize and face fears before going to bed, building a positive self-concept and autonomy, using exercise to produce positive emotions. Home-extension activities (the 'emotions diary') were also used by children and their parents. This diary included a set of dynamic and fun games which were reviewed weekly by the deliverer.

A logic model was used to described how the intervention might work, linking its characteristics, key components or change mechanisms and its relationship with expected proximal and distal outcomes (Figure 1).

The intervention was conducted by the first author, a mental health nurse with the support of an infant teacher to supervise the classroom management and intervention fidelity, as well as, three volunteers to help with data collection and the multi-activity day with families.

Outcome measures

The primary outcome; emotional knowledge (EK), was measured in children by the ability test *Perceval v.2.0 test* (Mestre et al., 2011). Secondary outcomes: Basic social skills were measured by the parent-report *Preschool and Kindergarten Behavior Scale (PKBS-II;* Merrell, 2003) and the child and parents' versions of the questionnaire *Child Health and Illness Profile; Child and Parent-Edition (CHIP-CE/PE;* Riley et al., 2004) was used to assess children's wellbeing (including physical, emotional and social aspects).

Furthermore, children's verbal ability was also measured by *The Peabody Picture Vocabulary Test-Third Edition (PPVT-III;* Dunn & Dunn, 1997), as an important covariate of their emotional knowledge (Domitrovich et al., 2007). Socio-demographic data sheet was used to collect children and parent's socio-economic characteristics. Characteristics details of these tools and evaluations times are described in Table 1.

Subjective efficacy, acceptability and feasibility.

Semi-structured interviews with parents and children from the intervention group were conducted at the end of the intervention to assess parent's perceived impact and programme's acceptability. Critical barriers and facilitators affecting the implementation process were identified by the researcher in a field diary during the implementation process (see Table 1).

Data collection

Baseline data were collected from March to April 2015 after obtaining Research Ethics Committee approval and after parents/caregivers provided written consent. They were then block randomized (AABB) in a 1:1 ratio to either the intervention or control group based on

the set of generated by an external researcher using Research Randomizer© and then each block applied to the coded number list of participants. The same researcher who conducted the intervention collected the data, immediately after the intervention (May 2015) and 7 months later (February 2016), Figure 2 shows the CONSORT flowchart of the study.

Ethical considerations

Ethical approval was obtained from the University Ethics Committee on 24 July 2014. Permission to conduct the study was obtained from both, school head board and school's Parents Association. A multi-activity afternoon was organized with families and children and a colorful kite was gifted to children from both groups for their participation. All personal data relating to the participants were kept separate from the study data and these data were identified with a unique participant number.

Data analysis

SPSS Version 15 was used for data entry and analysis. Descriptive statistics summarized the social demographic data. To compare the mean differences between the intervention group and control group across time, repeated measure ANOVA was used followed by an ANCOVA pairwise comparisons test to detect the difference controlling for basal variability as described by Vickers (2001). Furthermore, age and verbal ability were included in the analysis model as covariates. Effect size and its confidences intervals (CI) at 95% were calculated for T2 and T3 results, according to Cohen's d formula (Cohen 1988). Partial eta square (η^2) was used for ANOVA test effect size (Levine & Hullet, 2002). Technical

manuals were used for PKBS-II AND Peabody-II standardized scores provided by Dunn, Dunn & Arribas, 2006, The Johns Hopkins University, respectively.

Qualitative data were analyzed using content analysis (Mayring 2014) where categories and thematic unit were identified. To manage the transcriptions and data processing, Dedoose software platform was used.

Validity and reliability

The content of the intervention is based on evidence- and research-based social and emotional learning strategies identified in a previous systematic review of the main interventions in this area (Bermejo-Martins, 2016). The content of the programme is novel in its health approach but similar to previous work in this area. To ensure the quality of the intervention application and evaluation we used the EEIPESE indicators for programmes based on social and emotional competence (Pérez-González, 2008). For integrity, a minimum of 75% of the session's attendance by children was established.

RESULTS

Comparison of socio-demographic and scores of three outcome variables between groups at baseline

The median age of the children was 6.1 years (range = 5.8-6.8 years) in the intervention group (N = 19) and 6.1 (range = 5.8-6.5 years) in the control group (N = 18). Most of the children were Spanish (N = 27; 75%); the rest were from a variety of ethnicities such as Chinese, Ukrainian, Bulgarian, among others (N = 11; 4.07%).

Almost half of children from the intervention group were from families with an annual household income lower than 32.662 euros per year (N = 8; 50%), considered the average in Spain in 2014 by The Spanish Life Conditions survey (2013). However, most families from the control group reported incomes similar or higher to the reference amount (N = 10; 66.7%), but this difference was not statistically significant between both groups.

The main reporters in caregivers' measures were children's birth mother (N = 26; 74.3%) with a mean of 40 years and 8 months (SD = 5.36). There were no statistically significant differences in demographic characteristics (Table 2) except for the percentage of caregivers who worked outside the home ($p = 0.041$), which was higher in the control group (N = 16; 94.1%) than in the intervention group (N = 11; 61.1%). Table 2 shows the means, standard deviations of three study outcome variables across three measurements (baseline, post-test-1 and post-test-2) in the intervention and control groups.

Comparison of the intervention effect from baseline between groups over time

Emotional knowledge

Results along the three measurement times suggested a statistically significant impact of the programme on children's emotional perception in favor of the intervention group ($F(2.68) = 4.43$; $p = 0.016$; $\eta^2 = 0.12$), as it is showed in Figure 3. After adjusting for basal variability (Table 4), the intervention group scores on emotional perception were slightly higher at post-test (T2) and with a moderate effect size ($d = 0.56$), compared with the control group. The difference between both groups was not statistically significant ($F(1.34) = 2.77$; $p = 0.105$) but increased at 7 months follow-up (T3) in favour of the intervention group, reaching statistical significance with a large effect size ($F(1.33) = 4.32$; $p = 0.045$; $d = 0.72$).

Results did not show any impact of the intervention on the emotional assessment dimension ($F(2,68) = 0.97$; $p = 0.385$; $\eta^2 = 0.03$). Scores increased slightly over time in both groups ($F(2,68) = 10.90$, $p < 0.001$; $\eta^2 = 0.24$) (Figure 3), but no statistically significant effect was found between groups after controlling basal variability (Table 4).

However, a gender subgroup analysis was conducted to explore the differences on emotional perception scores. The results suggested that girls might have benefited more from the intervention than boys, based on the large effect observed in favor of the intervention group at post-test ($F = 2.91(1.13)$; $p = 0.112$; $d = 0.89$; 95%CI 0.24 to 2.01), although it decreased slightly at T3 ($F = 1.22(1.12)$; $p = 0.292$; $d = 0.60$; 95%CI 0.58 to 1.78).

Social skills

Scores obtained from the social skills parent-report, showed no important changes over time in either group ($F(2,60) = 0.02$; $p = 0.980$; $\eta^2 = 0.00$) (Figure 3). Likewise, analysis of the different dimensions (cooperation, positive interaction, independence and behaviour difficulties) did not show any important differences between groups over time. These results were confirmed on the mean comparison test, after adjusting basal variability (Table 4)

Health profile

The total score obtained from the children-report health profile was like the normative mean (50; $DE = 10$) over the three measurement times, which suggested that both groups' basal health profile was high from the start (Table 3). Similar results were found on the parent-report children's health profile, which did not show any variation from the baseline (Table 3). Adjustment of the model to eliminate the basal variability did not alter this finding (Table 4).

However, when different dimensions were analyzed separately, a statistically significant effect of the intervention was found on resilience dimension ($F(2,68) = 3.63$; $p = 0.032$; $\eta^2 = 0.10$); at T3 and the difference between groups became more noticeable. While data showed an increase in both groups over time, at T3 an important decrease was observed in the control group, which expanded the difference between both groups. After controlling basal variability (Table 4), results confirmed there was an important difference between both groups on the resilience dimension at T3, which showed a large effect size in favor the intervention group ($d = 0.83$; 95% CI 0.14 to 1.52). Results from parent-reports did not support the findings, as their scores did not show any variation over time (Table 4).

Acceptability and subjective efficacy of the intervention

In terms of perceived impact and social validity the quotes obtained from qualitative data shown in Table 5 show that children and parents were very positive about the intervention.

Feasibility of the intervention

Feasibility represents a key element to evaluate the process of application during the exploratory trial. Data were collected by the researcher using a field diary, volunteers' observations and session evaluation charts focusing on issues such as, participation, children motivation and external factors influencing the sessions, communication, difficulties and improvements of the content and classroom management, variations of games, children's anecdotes and experiences.

On one hand, some of the barriers identified during the school recruitment process were: - Beliefs were concerning health, mental health and emotional intelligence terms, which influenced the programme's reception and expectations about it. - The timetable (after-

school) where sessions were conducted was also a challenge, since it influenced how the groups were organized, being necessary a subdivision of the intervention groups which entailed a lack of teacher's implication and children's tiredness after the school day which in turn affected their attention and performance.

Regarding the aspects that influenced positively the intervention process were: the coherence between the programme's approach and the school ethos; the simplicity and low cost of the materials and resources used during sessions; the supervision of a external preschool teacher during the implementation of the sessions to ensure the quality and appropriateness of the teaching, as well as the deliverer competence to conduct the sessions.

Last, quality indicators were assessed in the initial, process and final evaluation of the programme included in the EEIPESE scale (Pérez-González, 2008). The programme conducted reached a high fidelity and integration with the protocol.

Discussion

The aim of this study was to explore the preliminary effects, acceptability and feasibility after the piloting of the CRECES programme's first unit. Results from the quantitative analysis showed a statistically significant difference on emotional perception scores between intervention group and control group after 7 months of follow-up ($d = 0.72$; 95% CI 0.02 to 1.42; $p = 0.045$). Although, data did not support such difference at post-test assessment, they showed a medium size effect, including large values whose clinical significance was at the superior limit of its confidence interval ($d = 0.56$; 95% CI -0.12 to 1.25; $p = 0.105$). However, regarding the emotional assessment dimension, a statistical difference between both groups was not found either at post-test or follow-up.

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These findings are consistent with previous studies which conducted a similar evaluation of emotional knowledge (Bierman et al., 2008; Domitrovich, Cortes & Greenberg, 2007; Mestre et al., 2011) where scores on emotional perception were higher than on a total score of emotional knowledge or emotional assessment. This could be due to the characteristics of the measure used. The PERCEVAL v2.0 test might have been confusing for recognizing some basic emotions on the pictures provided (for example, fear, anger or surprise) using items that contains more than one emotion as a response, which makes its mistakes rate higher. Furthermore, according to the measure's authors (Mestre et al., 2011), the simplicity and clarity of the questions on the emotional perception scale, could make it more precise. However, the emotional assessment scale might be more ambiguous, which requires more cognitive effort from children (perceiving, understanding the question and then distinguishing which person is expressing such emotion asked).

Some socio-demographics differences between groups at baseline time, such as gender, cultural and socio-economics level could have influenced on the children abilities to perceive and express emotions, according to the existing literature (Alonso-Alberca et al., 2012; Ekman, 1992; Friedlmeier, Corapci & Cole, 2011; Izard, 2002, 2011). Results suggested a better performance of girls in the emotional perception test compared with boys and in favor of the intervention group at post-test. This finding is congruent with other studies which have shown that girls use to get higher scores on emotional perception tests (Bennett et al., 2005; Brown & Dunn, 1996; McClure, 2000; Widen & Russell, 2010). Regarding cultural differences, 25% of participant children were from very diverse cultures. Furthermore, more than a half of the children in the intervention group were originally from other countries, meanwhile this percentage was lower in the control group. Some studies have supported that cultural differences could affect the impact of the intervention on the emotional knowledge, since cultural standards influence directly on the emotional expression (Alonso-Alberca et al.,

2012; Cole & Tan, 2007) and the emotional recognition of the basic emotions could be more acute when the facial expression on the pictures are from people with similar cultural characteristics (Ekman, 1992; Friedlmeier, Corapci & Cole, 2011). In relation to the socio-economic status, families in the intervention group had a lower annual home-income in comparison with the control group, which could have influenced on the children performance on emotional knowledge test, according with other studies (Ekman 1992b; Izard, 2002) where children from lower socio-economical contexts had lower performance on nonverbal abilities tests and specifically when facial expressions are used.

Statistically, this sub-analysis by groups could be considered an inaccurate method for trials with low statistical power to detect such difference (Petticrew et al., 2012). However, exploring interactions effects between subgroups let us identify tendencies that could inform about important clinical differences which should be confirm in future studies with a higher statistical power (Moore et al., 2015).

The second hypothesis related to social skills could not be supported by data, where both groups did not show important changes on their social skills scores from baseline to follow-up measurements. This could be explained by the fact that both groups showed high scores on PKBS-II reported by parents since baseline test, according to the normative mean (100; SD = 15), which is congruent with other studies which highlights that universal children populations, in general terms, show often optimal levels of social functioning and behavioral problems or social skills difficulties are showed less frequently (Merrell, 2002). This is coherent with the aim of this study, which was not targeted at a child population at risk or showing specifics problems and its content was less sensitive on this aspect. The lack of effect on this variable is consistent with previous studies (Bierman et al., 2008; Domitrovich, Cortes & Greenberg, 2007; Kramer et al., 2010).

Regarding the impact of the intervention on the resilience dimension at 7 months of follow-up is congruent with other studies in mental health promotion (Payton et al., 2008; Tennant et al., 2007; Wells et al., 2003), since it has been seen as a main beneficial aspect from programmes aimed to promote positive mental health in children (Barry & Jenkins, 2007; Friedli, 2009; Herrman, Saxena & Moodie, 2005; Jané-Llopis et al., 2005). Despite this study did not find an impact on the total score of children health profile, it is important to highlight, once again, that using a nonclinical population could have made difficult to detect improvement changes on their scores. However, these results cannot be contrasted with previous studies based on emotional education due to the lack of inclusion in their evaluations of a global health assessment (Haggerty et al., 2006; Peñalvo et al., 2013, 2015).

Despite quantitative data not supporting all hypothesis established regarding social and emotional skills, qualitative data from parent's interviews showed that they appreciated an important improvement on their children's social and emotional competence after the intervention. Although it is not possible to demonstrate any causality from these statements, evaluating the perceived impact is essential to obtain a completed picture of an intervention's reach and impact (Datta & Petticrew, 2013). Parent's perceptions suggested a link between an emotional knowledge improvement and a better healthy habits acquisition, especially in relation to eating, sleeping and hygiene daily routines. It could be explained by an improvement of children's health consciousness, which has shown a mediating role in the relation between emotional intelligence and health behaviours in adults (Espinosa & Kadic-Maglajlic, 2018). However, evidence exploring the link between socio-emotional competences and healthy behaviours is lacking (Zeidner et al, 2012). Future research using appropriate longitudinal designs, both with adults and children, would help for causal interpretations.

This finding contrast between quantitative and qualitative results in intervention studies is usual (Drescher, Warren & Norton, 2004; Paterson & Britten, 2004); this can be due to the own difficulty of the evaluation of complex interventions, since specific outcomes can be influenced and interconnected with different bio-psycho-social aspects. The intervention's success might be not equivalent to participant's improvement perception which could lead to an underestimation of participant perceived impact (Campbell et al., 2007). This holistic evaluation is one of the main strengths of this study.

An unexpected outcome was found on the improvement of parent and children relationship, perceived by parent and children. In future studies it would be relevant and interesting to test the impact of this kind of interventions on positive parenting and family relationships.

The intervention was highly acceptable to children and parents. This is a key aspect of the programme, as satisfaction and positive appraisal has been very important element to ensure participant's involvement and retention (Humphrey, 2013; Stallard et al., 2014; Webster-Stratton et al., 2002). This study got a response rate of 89.2% at T2 and 94.6% at 7 months of follow-up, which is considerably higher than similar previous studies (Bierman et al., 2008; Domitrovich et al., 2007; Stallard et al., 2014; Webster-Stratton et al., 2002). This finding can be also linked to the inclusion of family extension activities into the logic model, as a key change mechanism of the intervention.

Likewise, the intervention reach was high, since all children from the intervention group completed the minimal set of session number (75%), of whom 68.4% attended to the whole programme. This result is essential to analyze the intervention's effect (August et al., 2006) and which is often omitted by most of programmes in this area (Durlak & DuPre, 2008).

The main strengths of the study lie in its theory-based intervention program and the methodology. Most nursing interventions are of complex nature including several components, acting either independently or inter-dependently. This study followed the MRC framework which outlines the development and evaluation of complex interventions in detail and emphasizes the importance of a theory driven the development of the intervention, pilot testing and mixed methods evaluation (Blackwood, 2006). Despite the numerous benefits of following this methodological framework, there are few interventions in this area which have followed this recommendation (Lendrum & Humphrey, 2012; Lendrum & Wigelsworth, 2013; Wigelsworth et al., 2016). As result, there is a lack of rigorous programmes evaluation, even before they are widely extended and implemented, which entails their failure in the process of achieving the same positive results than previous similar studies (Humphrey et al., 2010). Therefore, elaborating a logic model for the intervention's design and evaluation is a critical aspect to understand the whole process of an intervention, through which the theory, key components, change mechanisms and expected outcomes are interconnected and articulated (Moore et al., 2014). This logic model provides the most relevant information about how this intervention could be replicated or improved in future studies (Bonell, et al., 2012). However, it is rarely reported (Adi et al., 2007; Blank et al., 2009; McCabe & Altamura, 2011).. Another strength of this study is its multi-component, multi-method and multi-informant evaluation. Most interventions with young children use measures based only on a typical behavior approach and reported by parents or teacher and very few of them include direct measures of children's abilities and skills (Humphrey et al., 2011). This is an essential aspect when social and emotional competence is being evaluated (Denham et al., 2009).

Limitations

The sample size of the study was small, which compromised the statistical power to detect significant differences. Nevertheless, this was an exploratory study (Hertzog, 2008). A second limitation is the possibility of the contamination in the control group. It could have decreased the mean differences between both groups and hence, the possibility of an Error type II. This biased could be avoided using a block randomization (e.g Bierman et al., 2008; Domitrovich, Cortes & Greenberg, 2007). However, it entails other difficulties such as the recruitment due to the need of a bigger sample size and the time-consuming, cost and complexity of the trial (Campbell et al., 2000; Torgerson, 2001).

Another possible limitation is the validity of the PERCEPVAL v 2.0 test, which development is still in process (Mestre et al., 2011). Some of its limitations have not been shown in the Spanish version of EMT (EMT: *Emotional Matching Task*: Alonso-Alberca et al., 2012). However, the administration time of the EMT (30' per child) limited the possibility its use in this study.

Last, the involvement of the main researcher as the deliverer of the intervention could have influenced the intervention effect. However, it is worth mentioning that it was inevitable, since the efficacy study (under control conditions) proceeds to the effectiveness trial (real context) in the intervention development (Campbell, 2000; Flay et al., 2005) which allows achieving high implementation fidelity (Eisner, 2009).

CONCLUSION

The first unit of CRECES programme showed a beneficial effect on children's emotional perception and the resilience dimension of children's health profile. Children and parents showed high acceptability of the programme and a wide range of barriers and facilitators were identified during the implementation process. The intervention's logic model facilitated to identify the mechanisms of action and therefore the understanding of how the actual intervention worked. These aspects are essential for the development of theory and future interventions designs. However, before a definitive version of CRECES programme can be developed, future research should explore the underlying mechanisms between socio-emotional competence and healthy behaviours.

It is also necessary to find out whether similar results are observed in a full scale final randomized controlled trial, as advice by the MRC framework for complex interventions. Some flagged issues should be accounted for when observing definitive randomized controlled trials: according to available literature could be influential to this population group, such as gender, age, verbal ability, culture and socio-economic status, as well as parent's free time playing with their children. Besides, finding tools for the measurement of the effect of this intervention, keeping in mind the above-mentioned aspects, was a challenge. Most of the existing tools were either disease focused or not adjusted to children's development. Therefore, using the existing instruments to measure outcomes might have resulted in not capturing the effect of the intervention carried out in a comprehensive way.

Conflict of interest statement

Professor Roger Watson in his capacity as a visiting professor at the University of Navarre was involved in advising and revising the English.

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Table 1. Summary of outcomes measures characteristics of the study

Outcomes	Measures and informants	Characteristics	Evaluation Time		
			T1	T2	T3
Socio-demographic	Socio-demographic questionnaire/ Caregiver	Short questionnaire regarding family characteristics including: the age of the child and the primary caregiver, ethnicity of family members, language spoken at home and family income, health history of their child and whether they are attending or had attended to a similar programme.	X		
Verbal ability	Test PEABODY-II Children	Measure of children's receptive vocabulary. Across age groups, the internal consistency for the Spanish validated PPVT-III standard scores range from 0.92-0.99 (Dunn, Dunn & Arribas 2006).	X		
Emotional knowledge	Test PERCEVAL v.2.0/ Child	A maximum behaviour test which assess receptive emotion vocabulary and emotional understanding in social situations. It has 16 items divided into two 8-points Likert scales: emotional perception and emotional assessment. It has shown a good inter-rater reliability in a preliminary testing with a sample of 138 Spanish children (Mestre et al., 2011)	X	X	X
Social skills	PKBS-II scale / Caregiver	A 42 items parent-report scale with three 4-point Likert subscales: Social Cooperation, Social Interaction and Social Independence). Each subscale is standardized to a normative mean (100; SD=15). This measure has shown a good reliability and validity (Cronbach's 0.88-0.97) in a Spanish sample (Fernandez et al., 2010).	X	X	X
Health profile	CHIP-CE/PE questionnaire Child/Caregiver	A questionnaire based on health perceptions from children and parents. Includes 44 items and five domains: Satisfaction, Comfort, Resilience, Risk Avoidance and Achievement. Domains are scored in the positive meaning of health and total scores are standardized to an arbitrary mean of 50 and a standard deviation (SD) of 10. The Spanish version has shown acceptable reliability and validity (0.70 of internal consistency and 0.69 to 0.80 for the intraclass correlation coefficient) (Estrada et al., 2012).	X	X	X
Impact perceived	Semi-structured interview/ Caregiver	Questions related to children's social and emotional skills improvements and its impact on healthy behaviours acquisition.		X	
Acceptability	Semi-structured interview/ Caregiver and children	Participants' satisfaction and social validity of the intervention (regarding content, materials and deliverer profile).		X	
Feasibility (Barriers and facilitators)	Field diary/ Researcher	Recruitment process, dosage delivered, programme reach, resources and materials used, context characteristics, session's duration, developing and management and participant responsiveness.		X	

Table 2 Children and families' socio-demographics characteristics

Variables		Intervention	Control	P value	X ²	95% CI
Child						
Age (years)	<i>Median (P₂₅, P₇₅)</i>	(n=19) 6.1 (5.8-6.8)	(n=18) 6.1 (5.8-6.5)	0.620 ^b		(-0 to 0.9)
Age (months)	<i>Media (SD)</i>	74.32(6.8)	73.5 (7)	0.720 ^a		(-3.8 to 5.5)
PPVT-III IQ	<i>Media (SD)</i>	98.4(11.3)	98.8(15.3)	0.936 ^a		(-8.6 to 8.7)
PPVT-III Age	<i>Median (P₂₅, P₇₅)</i>	5.1 (5.1-6.1)	5.1 (5-7)	0.799 ^b		(-1 to 1)
Sex	<i>n (%)</i>					
Boy		12 (63.2%)	9 (50%)		0.515 ^d	
Girl		7 (36.8%)	9 (50%)			
School year	<i>n (%)</i>					
Pre-school (4-5)		10 (52.6%)	12 (66.7%)			
Primary School (6-7)		9 (47.4%)	6 (33.3%)		0.385 ^c	
Language						
Spanish		14 (73.7%)	12 (66.7%)			
Bilingual		5 (26.3%)	6 (33.3%)		0.641 ^c	
Origin	<i>n (%)</i>	<i>n=(18)</i>	<i>n=(18)</i>			
Spain		13 (72.2%)	14 (77.8%)			
Ukraine		1 (5.6%)	0			
Bulgaria		0	2 (11.1%)			
Ecuador		3 (16.7%)	0		0.119 ^d	
Costa Rica		0	1 (5.6%)			
China		1 (5.6%)	0			
Russia		0	1 (5.6%)			
Schooling support	<i>n (%)</i>	<i>n=(15)</i>	<i>n=(16)</i>			
Yes		2 (11.8%)	1 (5.9%)		1.000 ^d	
Health problems	<i>n (%)</i>	<i>n=(18)</i>	<i>n=(17)</i>			
Yes		5 (27.8%)	3 (17.6%)		0.691 ^c	
		Allergy, Celiac disease, Hypothyroidism, harelip atopic dermatitis	Celiac disease, Acute intermittent porphyria, Hemophilia			
Participation in a similar activity	<i>n (%)</i>	<i>n=(16)</i>	<i>n=(17)</i>			
Yes		1 (6.3%)	0		0.485 ^d	
Year of schooling	<i>Median (P₂₅, P₇₅)</i>	(n=18) 3 (3-4)	(n=17) 3 (3-4)	0.832 ^b		(0 to 1)
Caregivers						
Informant	<i>n (%)</i>	<i>(n=18)</i>	<i>(n=17)</i>			
Birth mother		14(77.9%)	12(70.6%)			
Birth father		4 (22.2%)	4 (23.5%)		1.000 ^d	
Grandmother		0	1(5.9%)			
Origin	<i>n (%)</i>	<i>(n=18)</i>	<i>(n=17)</i>			
Spain		8 (29.9%)	13(37.1%)			
Ukraine		1 (2.9%)	0			
Bulgaria		0	1 (2.9%)			
Morocco		1 (2.9%)	0			
Guinea		1 (2.9%)	0		0.126 ^d	
Bolivia		2 (5.7%)	1 (2.9%)			
Ecuador		5 (14.3%)	1 (2.9%)			
Costa Rica		0	1 (2.9%)			
Age	<i>Mean (SD)</i>	<i>(n=18)</i> 40.4(4.2)	<i>(n=17)</i> 41.2(6.5)	0.648 ^a		(-4.6 to 2.9)
Nº of children	<i>Median (P₂₅,P₇₅)</i>	<i>(n=18)</i> 2 (1-2)	<i>(n=17)</i> 2 (2-3)	0.503 ^b		(-1.0 to 0)
Education level	<i>n (%)</i>	<i>(n=17)</i>	<i>(n=17)</i>			
Primary school		0	1 (5.9%)			
Secondary school		5 (29.4%)	1 (5.9%)			
Professional training		5 (29.4%)	2 (11.8)		0.121 ^d	
University degree		4 (23.5%)	9 (52.9%)			

<i>Postgraduate degree</i>		3 (17.6%)	4 (23.5%)		
N° people living at home	Median (P₂₅ P₇₅)	(n=18)	(n=17)		
		4 (3-4)	4 (3-4)	0.883 ^b	(-1 to 1)
Annual family income (32,662 euros)	n (%)	(n=16)	(n=15)		
<i>Lower</i>		8 (50%)	5 (33.3%)		
<i>Similar</i>		2 (12.5%)	3 (20.0%)	0.706 ^d	
<i>Higher</i>		6 (37.5%)	7 (46.7%)		
Work outside home	n (%)	(n=18)	(n=16)		
<i>Yes</i>		11 (61.1%)	16 (94.1%)	0.041 ^{d*}	
N° hours of work weekly	n (%)	(n=11)	(n=16)		
<i>< 20h</i>		1 (9.1%)	1 (6.3%)		
<i>20-40h</i>		9 (81.8%)	13 (81.3%)	1.000 ^d	
<i>> 40h</i>		1 (9.1%)	2 (12.5%)		
Free time to spend with family	n (%)	(n=17)	(n=17)		
<i>Do not have time during the week</i>		1 (5.9%)	0		
<i>Only weekends</i>		2 (11.8%)	1 (5.9%)	0.213 ^d	
<i>From 1 to 2h per day</i>		2 (11.8%)	7 (41.2%)		
<i>> 2h per day</i>		12 (70.6%)	9 (52.9%)		

a= t-student test with Levene homogeneity of variance test.

b= Mann-Whitney U test.

c= Chi-square test.

d= Fisher exact test.

*p < 0.005

Table 3 Means and Standard Deviations of outcomes variables

		I mean (SD)	C mean (SD)
Emotional Knowledge (PERCEPVAL 2.0)			
Emotional perception	T1	3.5 (0.8)	4.2 (1.7)
	T2	5.9 (1.4)	5.1 (1.6)
	T3	6.1 (1.4)	5.2 (1.4)
Emotional assessment	T1	4.8 (0.8)	5.1 (1.1)
	T2	5.7 (1.3)	5.4 (1.1)
	T3	6.1 (1.0)	5.9 (1.2)
Social skills (PKBS-II)*			
Total score	T1	104.1 (7.0)	103.3 (11.9)
Total score	T2	107.2 (7.3)	105.8 (9.0)
Total score	T3	104.3 (10.9)	104.7 (9.4)
Health profile perceived by children (CHIP-CE) †			
Total score	T1	48.8 (5.7)	48.4 (5.5)
Total score	T2	51.5 (5.1)	50.3 (7.6)
Total score	T3	53.3 (4.5)	52.5 (5.6)
Health profile perceived by parents (CHIP-PE) †			
Total score	T1	49.7 (4.0)	51.1 (6.1)
Total score	T2	51.0 (4.9)	52.0 (5.6)
Total score	T3	49.8 (5.3)	50.9 (5.1)

I=Grupo Intervención; C=Grupo Control. T1=Baseline; T2=Post-test; T3=7 months follow-up.

*Standardized scores to the normative mean (100; DE=15), a high score shows a high level of social skills.

†Standardized scores to the normative mean (50; SD=10); a high score shows a high level of health profile.

Table 4 ANCOVAs mean comparison

Emotional Knowledge		Dif.(I-C)	95% CI	F (df)	p	d Cohen	95% CI
Perception	T2	0.85	(-0.19 to 1.90)	2.77 (1.34)	0.105	0.56	(-0.12 to 1.25)
	T3	1.03	(-0.02 to 2.03)	4.32 (1.33)	0.045*	0.72	(-0.02 to 1.42)
Assessment	T2	0.38	(-0.49 to 1.19)	0.91 (1.34)	0.346	0.32	(-0.36 to 0.99)
	T3	0.14	(0.65 to 0.92)	0.14 (1.33)	0.712	0.13	(-0.56 to 0.81)
Basic Social Skills							
Cooperation	T2	1.72	(-2.01 to 5.45)	0.88 (1.30)	0.355	0.33	(-0.38 to 1.04)
	T3	-2.96	(-10.49 to 4.56)	0.65 (1.31)	0.428	-0.28	(-0.98 to 0.42)
Interaction	T2	0.04	(-4.88 to 4.96)	0.00 (1.30)	0.988	0.01	(-0.72 to 0.73)
	T3	-0.23	(-4.49 to 4.03)	0.01 (1.31)	0.913	-0.04	(-0.75 to 0.67)
Independence	T2	0.14	(-4.52 to 4.79)	0.00 (1.30)	0.953	0.02	(-0.69 to 0.73)
	T3	-0.22	(-7.09 to 6.64)	0.00 (1.31)	0.948	-0.02	(-0.73 to 0.68)
Total	T2	0.61	(-3.84 to 5.07)	0.08 (1.30)	0.780	0.10	(-0.61 to 0.81)
	T3	-1.11	(-7.21 to 5.00)	0.14 (1.31)	0.714	-0.13	(-0.83 to 0.57)
Health perceived by children							
Comfort	T2	3.19	(-2.98 to 8.36)	1.02 (1.34)	0.301	0.35	(-0.32 to 1.01)
	T3	-1.40	(-6.19 to 3.39)	0.35 (1.33)	0.556	-0.20	(-0.88 to 0.48)
Satisfaction	T2	0.65	(-4.22 to 5.52)	0.07 (1.34)	0.788	0.09	(-0.59 to 0.77)
	T3	-0.30	(-4.43 to 3.83)	0.02 (1.33)	0.883	-0.05	(-0.73 to 0.63)
Resilience	T2	-0.86	(-9.34 to 2.36)	0.24 (1.34)	0.628	-0.16	(-0.83 to 0.51)
	T3	8.00	(1.69 to 14.31)	6.65 (1.33)	0.015*	0.83	(0.14 to 1.52)
Risk avoidance	T2	0.38	(-3.13 to 3.89)	0.05 (1.34)	0.827	0.07	(-0.60 to 0.74)
	T3	-3.10	(-8.24 to 1.93)	1.57 (1.33)	0.218	-0.42	(-1.10 to 0.26)
Achievement	T2	-0.82	(-5.72 to 4.08)	0.12 (1.34)	0.737	-0.11	(-0.78 to 0.56)
	T3	-0.20	(-5.48 to 5.08)	0.01 (1.33)	0.938	-0.03	(-0.71 to 0.66)
Total	T2	0.99	(-2.74 to 4.73)	0.29 (1.34)	0.592	0.02	(-0.66 to 0.69)
	T3	0.72	(-2.69 to 4.13)	0.19 (1.33)	0.670	0.14	(-0.54 to 0.82)
Health perceived by parents							
Comfort	T2	-0.92	(-6.09 to 4.24)	0.13 (1.30)	0.718	-0.13	(-0.86 to 0.60)
	T3	-1.86	(-8.92 to 5.19)	0.29 (1.31)	0.594	-0.19	(-0.91 to 0.53)
Satisfaction	T2	0.03	(-4.18 to 4.23)	0.00 (1.30)	0.990	0.00	(-0.71 to 0.72)
	T3	2.92	(-2.89 to 8.72)	1.05 (1.31)	0.314	0.36	(-0.35 to 1.07)
Resilience	T2	-2.59	(-6.91 to 1.72)	1.51 (1.30)	0.229	-0.43	(-1.16 to 0.29)
	T3	-1.52	(-7.02 to 3.98)	0.32 (1.31)	0.577	-0.20	(-0.91 to 0.51)
Risk avoidance	T2	-0.44	(-4.87 to 3.98)	0.41 (1.30)	0.840	-0.07	(-0.79 to 0.65)
	T3	-2.82	(-7.74 to 2.10)	1.37 (1.31)	0.251	-0.41	(-1.12 to 0.30)
Achievements	T2	1.27	(-2.99 to 5.53)	0.37 (1.30)	0.547	0.21	(-0.50 to 0.93)
	T3	2.24	(-2.26 to 7.11)	0.88 (1.31)	0.355	0.32	(-0.38 to 0.02)
Total	T2	-0.31	(-2.85 to 2.24)	0.06 (1.30)	0.808	-0.09	(-0.80 to 0.63)
	T3	-0.38	(-3.66 to 2.90)	0.06 (1.31)	0.813	-0.08	(-0.79 to 0.62)

. Adjusted model for baseline variability (T1). I= Intervention; C= Control

* $P < 0.05$

Emotional Knowledge (Perceval v 2.0), Basic Social Skills (PKBS-II); Health Perceived by children and parents (CHIP-CE; PE)

Table 5 Qualitative data from children and families interviews

Outcomes and categories	Quotes examples
Perceived impact	
Social and emotional competence improvement	(1) <i>“She now talks more...about how she feels...whether she is happy or sad...now She expresses it and tell you, which she didn’t use to do before...” (mother 14)</i>
Healthy lifestyles changes	(2) <i>“ It helped him to improve his health habits...because he now says that this food contains vitamins, gives strength to you, he values what he eats...and the activity of...relaxing before going to bed...he does it frequently and it has become a nice practice for all of us” (mother 5)</i>
Children’s satisfaction	
Children’s positive response to activities and games	(3) <i>“ Because it was so cool...that I even cannot forget it and I want to repeat the diary and play again the games we did...and going to the primary school and so we won’t say goodbye...” (child18)</i>
Family time	(4) <i>“ I liked so much playing with my parents, like that game that we had to capture our fears...or that one that we had to say nice things to each other (...)we hadn’t done something like that before” (child 6)</i>
Families’ satisfaction	
Positive experience	(5) <i>“It has been a very nice experience for me, as a mother, it has been very interesting; and for children, it was fantastic, because they have enjoyed a lot, or at least my daughter showed that (...) you have worked very well, and have given a lot to children, and mainly, to parents, to families, letting their know how to work these things with their children” (mother 3)</i>
Programme deliverer’s positive characteristics	(6) <i>“it depends on how you deliver these kind of activities...because you can carry out a project, or activities, but if then your person doesn’t match with this, your character or your style to work with children... she was always happy to work with you and all children seemed to be enthusiastic about the activities with you.. “(mother 21)</i>
Emotional diary as a family time mediator	(7) <i>“Above all, it has been a time with family, spending time together and doing something nice and fun...” (mother 2)</i>

Figure 1 CONSORT flowchart of the study.

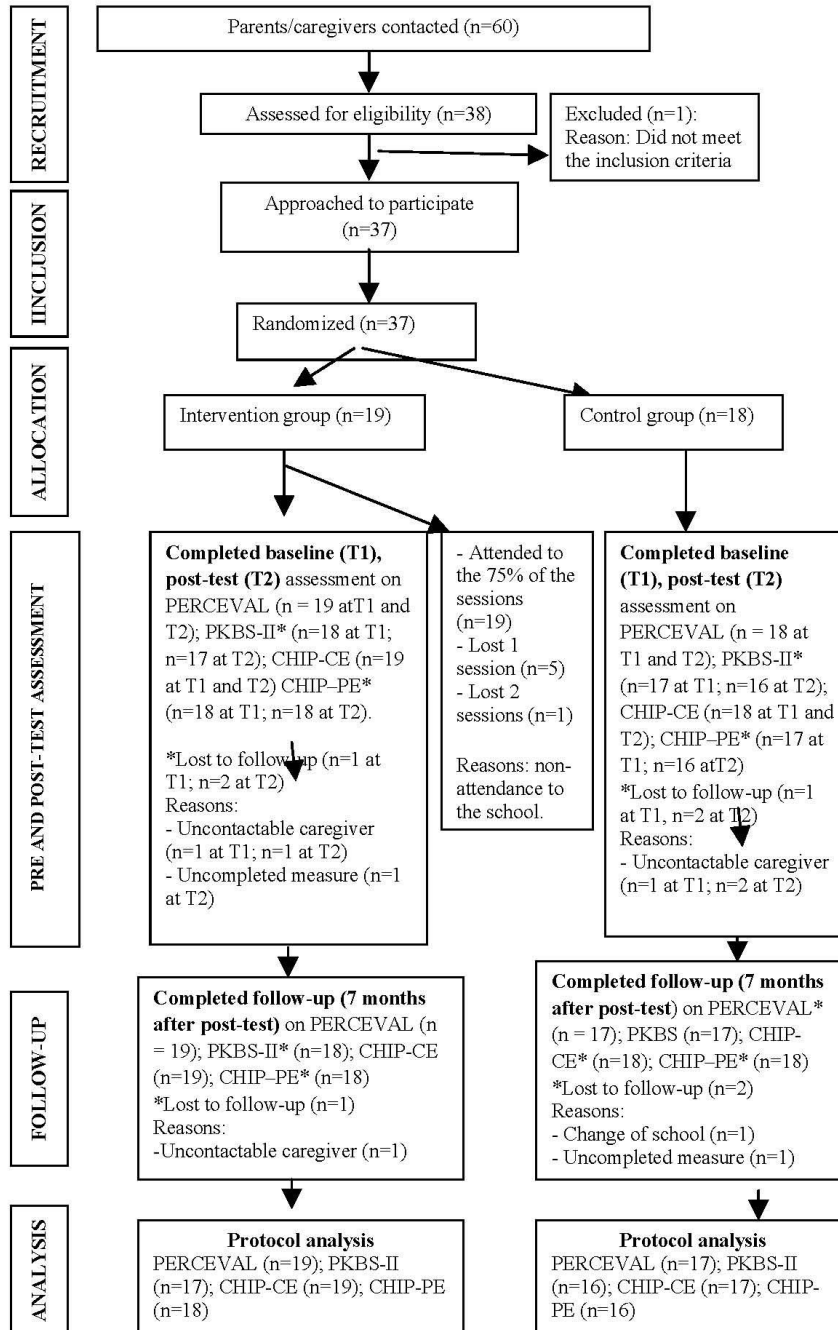


Figure 2 CRECES Programme's logic model

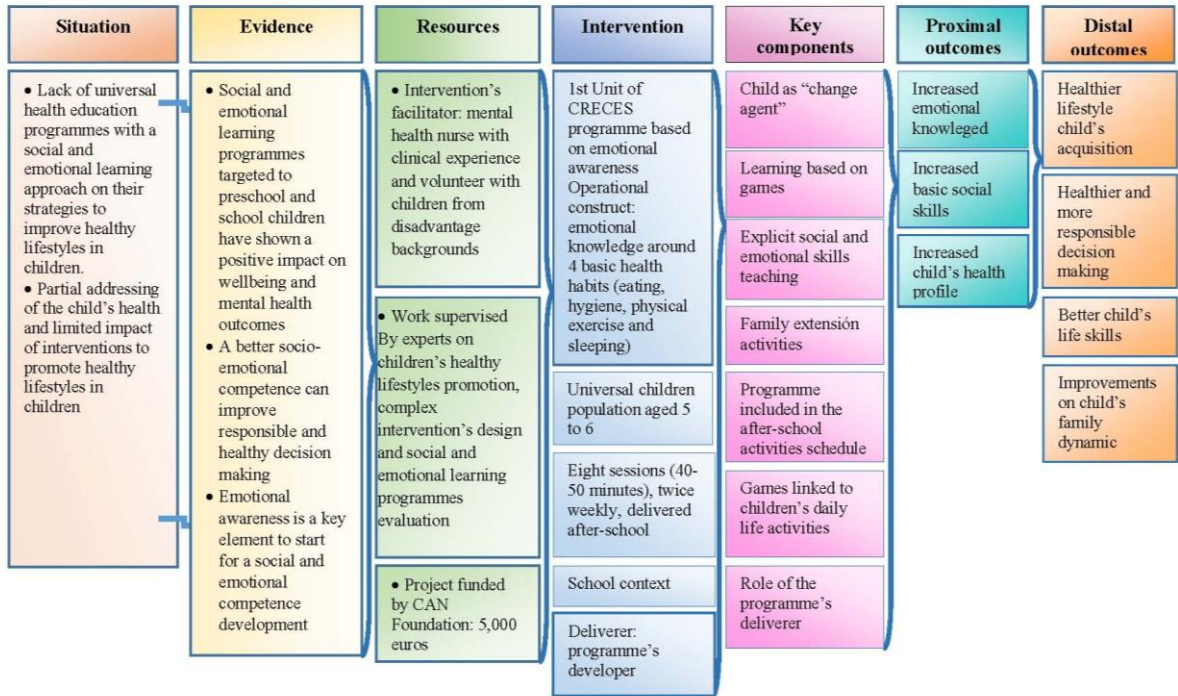


Figure 3 ANOVA results on the level of Emotional Perception and Assessment, Basic Social Skills and Health perceived by children and parents at T1, T2 and T3

