

# A pilot randomised controlled trial on the effectiveness of infant massage on the acceptance, commitment and awareness of influence in parents of babies with Down syndrome

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## Abstract

**Background** The emotional state of parents of babies with Down syndrome affects their babies' development and their parent–child bonding. The aim for this study was to conduct a pilot randomised controlled evaluation of the effect of infant massage on parents of babies with Down syndrome.

**Methods** This pilot study compared two groups (intervention and control), each with 16 parents of babies with Down syndrome. Indices of acceptance, engagement and awareness of influence were measured at two different time points (pre-test and after 5 weeks) using the 'This Is My Baby' Interview. The allocation of families to each group was randomised. The experimental group performed infant massage, applied by the parents, for 5 weeks, every day for at least 10 min. The massage protocol was based on the methodology created by Vimala

McClure. Parents in the control group received the intervention after completion of the study.

**Results** The indices of acceptance, commitment and awareness of influence improved in the experimental group and in the control group. The  $2 \times 2$  mixed-model analysis of variance indicates a statistically significant group-by-time interaction for all indices ( $P < 0.001$ ), which was significantly higher in the experimental group than in the control group.

**Conclusions** The application of infant massage, by parents to their babies, improves the rates of acceptance, commitment and awareness of influence of parents of babies with Down syndrome in the short term.

**Keywords** Down syndrome, interview, massage, parents

## Introduction

The influence of motherhood and fatherhood on neuroplasticity in two brain regions, the hippocampus and the prefrontal cortex, is highlighted; coupled with

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hormonal changes and the influence of the environment, emotional changes are recognised in parents of babies (Leuner *et al.* 2010), and this situation is further affected by child disability. Postpartum mental illness is often associated with inadequate infant care, which has been linked to impaired cognitive and emotional function in offspring (Nadel *et al.* 2005; Fihrer *et al.* 2009). Parents of children with intellectual disabilities report higher levels of stress, different experiences of personal growth and an impact on the family relationship. The study conducted by Sarimski (2020) with 30 mothers and fathers of children with Down syndrome on the family impact of childhood disability, parental stress and child behavioural symptoms suggests that the negative impact on the family is associated with the subjective level of stress and perception of the situation. Therefore, it is important to take into account the evaluation of the emotional situation of the parents when intervening with a family in family-centred models (Mas *et al.* 2019), since the individual perception of the parents towards their baby has a direct influence on the impact of the family. There is a bidirectional relationship between parents' emotional state and the parent-child relationship (Sarimski 2020). The acceptance process begins with the diagnosis of the child, and the experiences accumulated throughout infancy and childhood will mark the development of future skills (Marshall *et al.* 2015).

Infant massage, as an intervention tool carried out by parents and supervised by a professional, improves the mental health of children and their development in different areas (Purpura *et al.* 2017), in addition to increasing the skills of parents and encouraging the parent-child relationship (Barlow *et al.* 2015; Li *et al.* 2016; Pagnini *et al.* 2017; Lindensmith 2018). Specifically, the effects of infant massage on the development of skills and functions in infants with DS have been studied (Hernandez-Reif *et al.* 2006; Silva *et al.* 2012; Purpura *et al.* 2014; Pinero-Pinto *et al.* 2020); however, the effects produced by the practice of infant massage on the parents themselves when they are the ones who perform it have not been analysed to date. Nevertheless, it has been shown that practising infant massage is an effective intervention to facilitate mother-child interaction in mothers with postnatal depression (Onozawa *et al.* 2001; O'Higgins *et al.* 2008).

For all of the above, it is important to assess the emotional state of parents of babies with Down syndrome. In this sense, evaluations of the mental health of parents have been developed (Sánchez-Teruel and Robles-Bello 2015; Porreca *et al.* 2017), as well as tools to assess the impact of the arrival of a child with Down syndrome in a family (Skotko *et al.* 2011; Ridding and Williams 2019). The emotional state of parents is a dynamic construct that changes over time (Suzuki *et al.* 2015; Mas *et al.* 2019).

The 'This Is My Baby' (TIMB) Interview was created by Bates and Dozier (1998) to measure acceptance, commitment and awareness of parental influence. It is a semi-structured interview with an approximate duration of 5–15 min. There are three versions, designed for foster, adoptive and birth parents, each with eight questions. In the latter case, the first seven questions are about the mother/father-child relationship, and the last question is about their own experience as parents. The version for biological parents has been cross-culturally adapted to Spanish in a population of parents with children with DS (Pinero-Pinto *et al.* 2022).

The aim for this study was to conduct a pilot randomised controlled evaluation of the effect of infant massage on parents of babies with Down syndrome.

## Methods

### Study design

This pilot randomised controlled clinical trial evaluated the effects of infant massage therapy on the acceptance, commitment and awareness of influence of parents of babies with Down syndrome. This study was registered in Clinical Trials under Protocol No. NCT03126734.

This work followed the tenets of the Declaration of Helsinki. The parents who answered the interview were informed in written and oral form about the study characteristics, benefits and risks. The participants gave their written informed consent after the nature and possible consequences of the study were explained to them. The ethics committee of the University of Seville approved this research.

### Sample selection

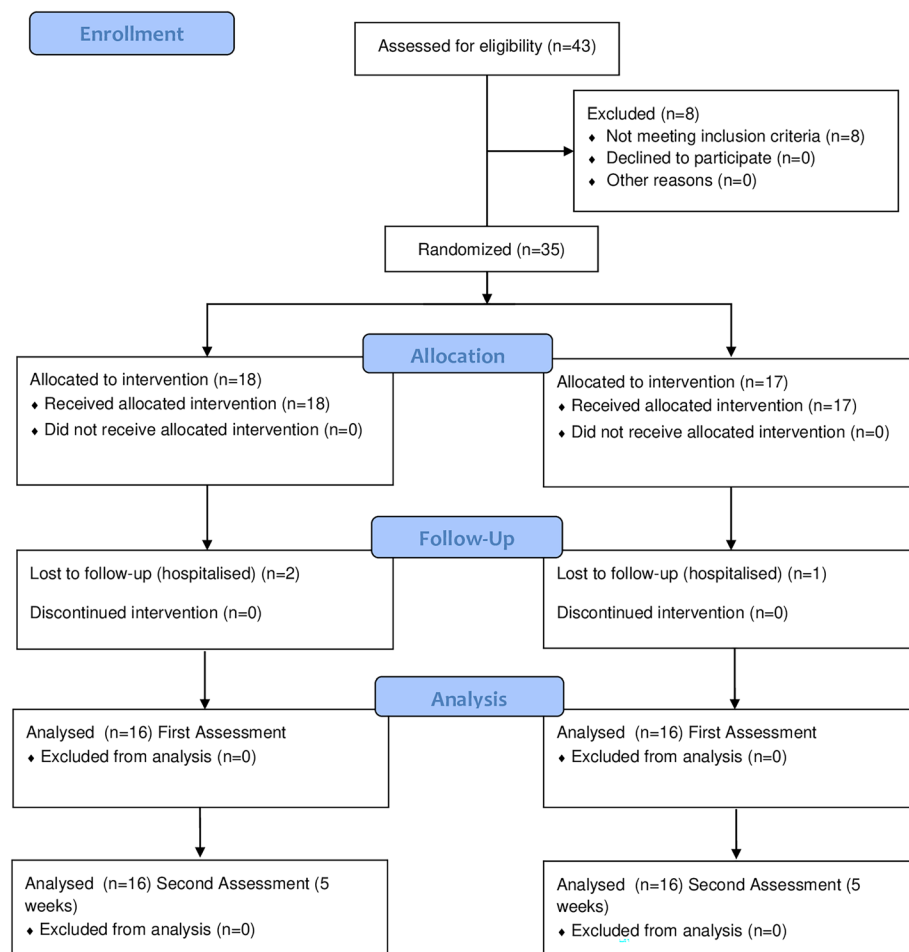
The sample consisted of parents of babies with Down syndrome. The participants attended associations of parents with children with Down syndrome and early care centres in several autonomous communities in Spain, and they were recruited from 2015 to 2020. Therefore, it is a multicentre study.

A consecutive non-probabilistic sampling was conducted by contacting 43 families, of whom eight did not participate, due to the age of the babies at the time of the first interview with the parents. Three other families whose babies were hospitalised were excluded because the second interview could not be conducted during the study period. Of these three

families, two belonged to the experimental group and one to the control group. Therefore, the sample was composed of 32 parents of babies with DS (Figure 1).

The babies of the participating families had an average age of 155.72 days [standard deviation (SD) = 39.46], with a minimum of 117 days and a maximum of 235 days. Of the 32 babies, 21 (65.6%) were boys, and 11 (34.4%) were girls. In four (12.5%) of the cases, the interviewees were the fathers, and in 28 cases (87.5%), the interviewees were the mothers. In addition, 17 (53.1%) of the babies had no siblings, whereas the other 15 (46.9%) had siblings.

Table 1 describes the initial characteristics of the subjects included in the study, as well as the initial homogeneity of the groups. As can be seen in said



**Figure 1.** Flowchart of progress through the phases of the clinical trial of the two groups, following the CONSORT 2010 Declaration.

**Table 1** Characteristics of the participants

Variable	Control group n = 16	Experimental group n = 16	P value
Baby age (days), median (Q1–Q3)	136.00 (125.00–202.50)	141.00 (126.00–157.50)	P = 0.836 <sup>†</sup>
Baby gender, n (%)			P = 0.710 <sup>‡</sup>
	Male 11 (68.8%)	10 (62.5%)	
	Female 5 (31.2%)	6 (37.5%)	
Interviewed parent gender, n (%)			P = 0.999 <sup>§</sup>
	Father 2 (12.5%)	2 (12.5%)	
	Mother 14 (87.5%)	14 (87.5%)	
Siblings, n (%)			P = 0.723 <sup>‡</sup>
	No 8 (50%)	9 (56.3%)	
	Yes 8 (50%)	7 (43.7%)	
Acceptance pre-test, mean (SD)	2.22 (0.89)	2.13 (0.97)	P = 0.779 <sup>¶</sup>
Commitment pre-test, mean (SD)	2.56 (0.73)	2.34 (0.94)	P = 0.468 <sup>¶</sup>
Awareness of influence pre-test, mean (SD)	2.72 (0.88)	2.72 (0.84)	P = 0.999 <sup>¶</sup>

SD, standard deviation; Q1–Q3, interquartile range.

<sup>†</sup>The Mann–Whitney *U* test.

<sup>‡</sup>Pearson's chi-square test.

<sup>§</sup>Fisher's exact test.

<sup>¶</sup>Student's *t*-test was used for independent samples.

table, there were no significant differences between the two groups in any of the variables analysed.

### Selection criteria

#### Inclusion criteria

Parents whose babies with DS were between 4 and 8 months of age. Parents whose babies with DS received early intervention treatment and had the parents attend with them. Parents who did not suffer from any type of disorder or illness that may prevent the understanding of the questions or the expression of the answers in the conversation.

#### Exclusion criteria

Parents of babies suffering from some pathology associated or not with DS. Families with only one parent, who were single parents. Families who had already received the Infant Massage course.

The free software G\*Power version 3.1 was used to calculate the required sample size. The data provided were  $\alpha$  error of 0.05 [confidence level (CI) of 95%],  $\beta$  error of 0.2 (power of the study: 80%), large Cohen effect size (1.56) using a pilot study (Piñero-Pinto *et al.* 2018), sample size ratio of the two groups ( $N_2/N_1$ ) equal to 1 and two-tailed hypothesis. Under these conditions, the estimated sample size was 28 parents (14 in each group). The effect size was

reduced to 1.05, since a total of 32 subjects (16 in each group) were included. The sample size was in line with that of similar studies, such as that of Purpura *et al.* (2014).

The participants were assigned to each group (intervention or control) by random sampling stratified by gender. Concealed allocation was performed using sequentially numbered sealed opaque envelopes. The person in charge of the data entry (assessor) remained blind to treatment allocation.

The mean age of the 32 babies was  $155.72 \pm 39.46$  days. Of the 32 babies, 21 (65.6%) were boys, and 11 (34.4%) were girls. The mean age of the 32 parents was  $31.52 \pm 4.25$  years. Of the 32 parents, 28 were mothers (87.5%), and four fathers (12.5%), divided equally in both groups.

### Measurement instrument

#### 'This Is My Baby' Interview: Characteristics of the interview

The TIMB Interview was created by Brady Bates and Mary Dozier at the University of Delaware in 1998.

This interview was designed to measure acceptance, commitment and awareness of influence in birth, foster and adoptive parents.

This is a semi-structured interview that requires approximately 5–15 min to be completed. There are two versions: one for birth parents, with eight questions, and one for foster and adoptive parents, with nine questions. The first eight questions, which are the same for both versions, tackle the mother/father–child relationship, and the last question is only for foster and adoptive parents, and it addresses one's own experience as a father or mother.

When administering any of the versions of the TIMB Interview, the tone of the interview should be conversational and should not sound like reading; therefore, the questions should be memorised. Parents should answer with little or no help from the interviewer, although in many cases, if responses are short or difficult to understand, help from the interviewer may be appropriate. It is important to use a tape recorder for subsequent transcription; moreover, due to the nature of the questions, children should not be present during the interview.

The coding system consists of three indices (acceptance, commitment and awareness of influence) that reflect how the mother or father feels about the child and the relationship with him/her. The review of the recorded audio of the interview and its transcription allow the interviewer to classify the three indices and codify them on a 5-point Likert-type scale. Point and half point scores (e.g. 2.5) are accepted in this system. The specific results are based on the weight of the positive and negative indicators of the level of acceptance, commitment and awareness of influence. These indicators may be the words used by the parents to describe the baby, the tone of voice they use, the degree of consistency in their responses, the independence as a person they convey about their baby, evidence of how important the baby is to his/her parents, experiences and examples in reflecting on their responses. The pauses to think about the answers are usually negative indicators in the three scales or indices, as well as the bad experiences as support for their answers.

This interview has been cross-culturally adapted to the Spanish population, specifically in parents with babies with DS (Pinero-Pinto *et al.* 2022). Intra-rater reliability, evaluated with intra-class correlation coefficient (ICC) was between 0.841 and 0.962, and inter-rater reliability was between 0.867 and 0.932. In addition, internal consistency (Cronbach's alpha) ranged between 0.564 and 0.739, and floor and

ceiling effects (there was no ceiling effect and a possible floor effect in the acceptance index) and responsiveness (showing good results) were studied.

### Study procedure

The families that met the selection criteria were contacted via early care centres and the Associations of Parents of Children with Down syndrome of Spain. The families interested in participating in the study were contacted by telephone to provide further information and clarify doubts. The families that accepted the terms of the study, and signed the informed consent, were randomly assigned to the intervention or control group using the sealed envelope technique. Randomisation was performed by one of the study investigators, who was independent of the investigators who performed the massage and assessments. When they were assigned to a group, the following data were collected and transferred to a record sheet prepared for this purpose: personal data from the child and parents, personal history of the child, early childhood intervention centre to which the infant was assigned, study group to which the child was assigned and tables with the scores of the interview. Both experimental and control groups were interviewed in two occasions with 5 weeks of difference. During those 5 weeks, the experimental group received a weekly infant massage session led by a physical therapist and applied, at least, 5 days/week at home. The control group did not receive this intervention. The parents who belonged to the control group did not perform any type of massage during the evaluation period, since they were informed that they would receive it after the said period. They were asked not to perform any type of massage at home during the period between the two evaluations (5 weeks). Both groups continued to attend their weekly early childhood intervention sessions (one session/week of physiotherapy in early family-centred care) during the 5 weeks of the study.

The physiotherapy intervention that both groups received only focused on the development of functional skills through play-based active work led by a physiotherapist. A researcher who was external to the intervention with infant massage applied the TIMB Interview.



Since massage therapy is considered beneficial for both parents and infants, for ethical reasons, the families from the control group were recommended to participate in the course after the 5 weeks of the study.

### Content and administration of infant massage intervention

After the initial interview, the parents from the experimental group participated in a 5-week infant massage therapy course, as was described by Pinero-Pinto *et al.* (2020).

The course, led by a physical therapist, consisted of five sessions (one per week) of 90 min each, with theoretical classes and practical sessions of infant massage. The parents practised it daily (or at least 5 days/week) at home. The first 15 min of each session was used to ask about the practice of the parents at home, as well as to solve possible doubts of previous weeks. Subsequently, the corresponding technique was taught to all families. The therapist had to confirm that everyone performed it correctly. Time was allowed to practise, specifically 45 min for session. Finally, the theory of infant massage (benefits, baby reflexes that appear during massage, contraindications and adaptations for older children through play) was explained. New doubts were also resolved. This was about 30 min of the session.

The massage protocol was based on the methodology and programme of the International Association of Infant Massage, created by Vimala McClure (Schneider 2008). The technique resulted in an overall massage time of approximately 10–15 min. In each session, the parents were asked to explain what they had practiced since the previous week. In addition, they received a booklet with the description and images of the movements learned after each session to practise at home.

After completing the massage therapy course, the parents were interviewed, for the second time.

### Data analysis

The data were organised and analysed using the statistical package SPSS version 24.0 for Windows (SPSS Science, Chicago, USA). The effectiveness of the applied intervention was compared between the two groups. For this purpose, the evaluations were made at the beginning (pre-test) and at the end of the

intervention [after 5 weeks of therapy (post-test)]. The Shapiro–Wilk test was used to assess the normality of the variables. The dependent and sociodemographic variables were analysed descriptively. The quantitative variables were expressed as means and standard deviations or medians and interquartile ranges, and the qualitative variables by means of absolute frequency and percentage. The homogeneity of the dependent variables at pre-test and the sample distribution by gender, age, presence of siblings and parents who actively participated in the therapy and who answered the interview were also analysed. Student's *t*-test for independent samples was used for quantitative variables with normal distribution, and the Mann–Whitney *U* test was used for quantitative variables with non-normal distribution. Pearson's chi-square test or Fisher's exact test was used for the qualitative variables. Finally, separate 2-by-2 mixed-model analyses of variance were used to examine the effects of the treatment on the dependent variables, with group (intervention or control) as the between-subjects variable and time (pre-test and post-test) as the within-subjects variable. The hypothesis of interest was the group-by-time interaction at an a priori alpha level of 0.05. The effect size of the observed differences was estimated by calculating the partial eta squared ( $\eta^2$ ). The effects of the applied intervention were evaluated on a per protocol basis. All statistical tests were performed using a 95% CI ( $P < 0.05$ ).

### Results

The  $2 \times 2$  mixed ANOVA (Tables 2,3) for Acceptance, Commitment and Awareness of influence revealed a significant time-by-group interaction: Acceptance ( $F_{1, 30} = 42.64$ ,  $P < 0.001$ ;  $\eta_p^2 = 0.587$ ), Commitment ( $F_{1, 30} = 50.37$ ,  $P < 0.001$ ;  $\eta_p^2 = 0.627$ ) Awareness of influence ( $F_{1, 30} = 10.71$ ,  $P = 0.003$ ;  $\eta_p^2 = 0.263$ ). In all cases (in acceptance, commitment and awareness of influence), there was a statistically significant increase in the values of the post-test compared to the pre-test in both the control and experimental groups. However, the experimental group showed a greater increase in acceptance, commitment and awareness of influence at post-test compared with the control group (Table 2), that is, in

**Table 2** Differences between the experimental group and the control group

Variable	Group	Pre-test Mean (SD)	Post-test Mean (SD)	Within-group changes from baseline, mean (95% CI)
Acceptance	Control ( <i>n</i> = 16)	2.22 (0.89)	2.78 (0.91)	0.56 (0.30; 0.83) <i>P</i> < 0.001
	Experimental ( <i>n</i> = 16)	2.13 (0.97)	3.88 (0.72)	1.75 (1.49; 2.01) <i>P</i> < 0.001
	Between-group differences, mean (95% CI)	-	1.10 (0.50; 1.69) <i>P</i> = 0.001 <i>d</i> = 1.38	-
Commitment	Control ( <i>n</i> = 16)	2.56 (0.73)	2.84 (0.77)	0.28 (0.04; 0.52) <i>P</i> = 0.024
	Experimental ( <i>n</i> = 16)	2.34 (0.94)	3.81 (0.54)	1.47 (1.23; 1.71) <i>P</i> < 0.001
	Between-group differences, mean (95% CI)	-	0.97 (0.49; 1.45) <i>P</i> < 0.001 <i>d</i> = 1.51	-
Awareness of influence	Control ( <i>n</i> = 16)	2.72 (0.88)	3.31 (0.70)	0.59 (0.29; 0.90) <i>P</i> < 0.001
	Experimental ( <i>n</i> = 16)	2.72 (0.84)	4.00 (0.71)	1.28 (0.98; 1.59) <i>P</i> < 0.001
	Between-group differences, mean (95% CI)	-	0.69 (0.18; 1.20) <i>P</i> = 0.010 <i>d</i> = 1.01	-

**Table 3** 2 × 2 mixed-model analyses of variance

Variable	Within-subjects factor (time)	Between-subjects factor (intervention)	Time-by-group interaction
Acceptance	$F_{1, 30} = 161.69$ <i>P</i> < 0.001 $\eta_p^2 = 0.843$	$F_{1, 30} = 2.82$ <i>P</i> = 0.103 $\eta_p^2 = 0.086$	$F_{1, 30} = 42.64$ <i>P</i> < 0.001 $\eta_p^2 = 0.587$
Commitment	$F_{1, 30} = 109.40$ <i>P</i> < 0.001 $\eta_p^2 = 0.785$	$F_{1, 30} = 2.16$ <i>P</i> = 0.152 $\eta_p^2 = 0.067$	$F_{1, 30} = 50.37$ <i>P</i> < 0.001 $\eta_p^2 = 0.627$
Awareness of influence	$F_{1, 30} = 79.65$ <i>P</i> < 0.001 $\eta_p^2 = 0.726$	$F_{1, 30} = 1.79$ <i>P</i> = 0.190 $\eta_p^2 = 0.056$	$F_{1, 30} = 10.71$ <i>P</i> = 0.003 $\eta_p^2 = 0.263$

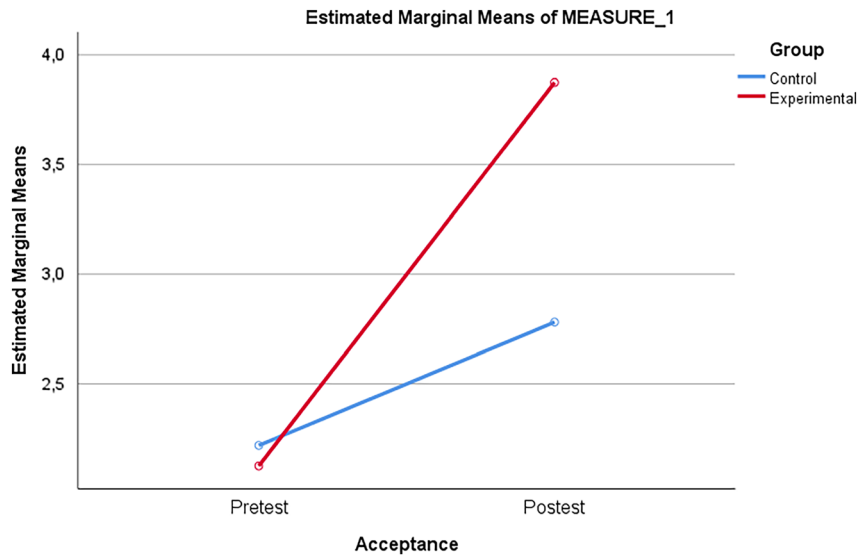
the post-test, the experimental group improved more than the control group.

Marginal mean graphs were made in order to illustrate the differences between the two groups for the three variables (Figures 2–4).

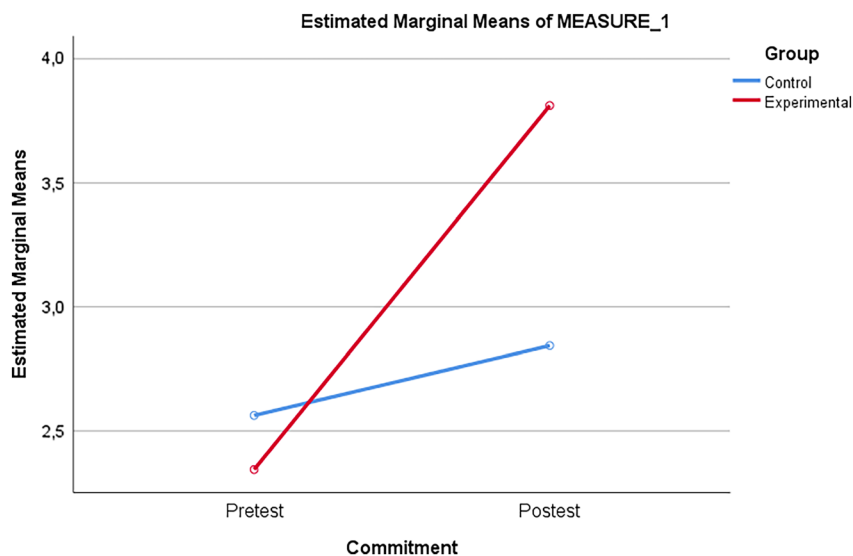
The results of the intention-to-treat analyses are included below. The results obtained in this case are similar to those previously described. Table 4

describes the initial characteristics of the subjects included in the study, as well as the initial homogeneity of the groups. As can be seen, there were no significant differences between the two groups in any of the variables analysed.

The 2 × 2 mixed ANOVA for Acceptance and Commitment revealed a significant time-by-group interaction [Acceptance ( $F_{1, 33} = 13.18$ , *P* = 0.001;



**Figure 2.** Difference between the two groups for the Acceptance.



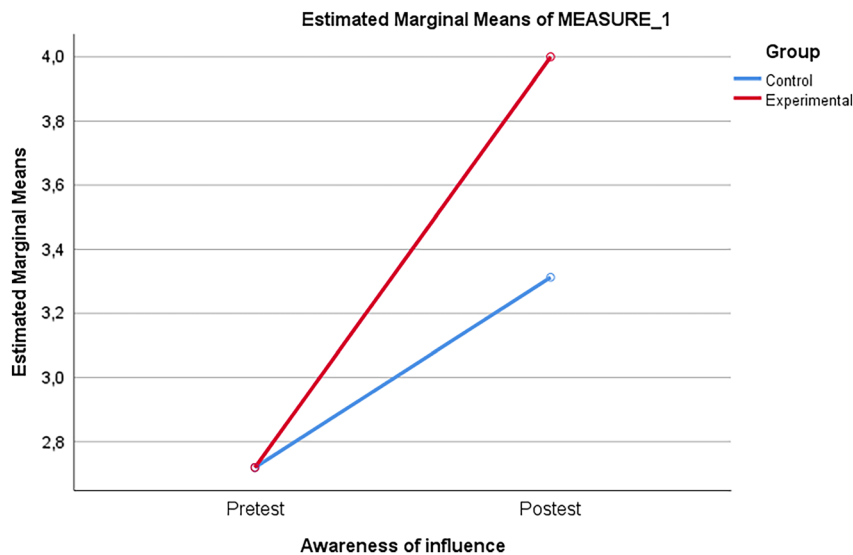
**Figure 3.** Difference between the two groups for the Commitment.

$\eta_p^2 = 0.285$ ), Commitment ( $F_{1, 33} = 15.18, P < 0.001$ ;  $\eta_p^2 = 0.315$ ) but not for Awareness of influence ( $F_{1, 33} = 2.48, P = 0.125$ ;  $\eta_p^2 = 0.070$ ). In all cases (in acceptance, commitment and awareness of influence), there was a statistically significant increase in the values in the post-test compared to the pre-test in both the control and experimental groups. However, the experimental group showed a greater increase in acceptance, commitment and awareness of influence in the post-test compared with the

control group (Tables 5,6), that is, in the post-test, the experimental group improved more than the control group, with this difference being statistically significant in the case of acceptance and commitment. On the other hand, in awareness of influence, this difference was not statistically significant.

Marginal mean graphs were made in order to illustrate the differences between the two groups for the three variables for 35 initial participants (Figures 5–7).





**Figure 4.** Difference between the two groups for the Awareness of influence.

**Table 4** Characteristics of the participants

Variable	Control group <i>n</i> = 17	Experimental group <i>n</i> = 18	<i>P</i> value
Baby age (days), median (Q1–Q3)	136.00 (126.00–194.00)	136.50 (126.00–147.00)	<i>P</i> = 0.704 <sup>†</sup>
Baby gender, <i>n</i> (%)			<i>P</i> = 0.903 <sup>‡</sup>
	Male 11 (64.7%)	12 (66.7%)	
	Female 6 (35.3%)	6 (33.3%)	
Interviewed parent gender, <i>n</i> (%)			<i>P</i> = 0.999 <sup>§</sup>
	Father 2 (11.8%)	2 (11.1%)	
	Mother 15 (88.2%)	16 (88.9%)	
Siblings, <i>n</i> (%)			<i>P</i> = 0.862 <sup>‡</sup>
	No 9 (52.9%)	9 (50.0%)	
	Yes 8 (47.1%)	9 (50.0%)	
Acceptance pre-test, mean (SD)	2.15 (0.91)	2.00 (0.99)	<i>P</i> = 0.651 <sup>¶</sup>
Commitment pre-test, mean (SD)	2.53 (0.72)	2.31 (0.89)	<i>P</i> = 0.421 <sup>¶</sup>
Awareness of influence pre-test, mean (SD)	2.68 (0.87)	2.64 (0.82)	<i>P</i> = 0.896 <sup>¶</sup>

SD, standard deviation; Q1–Q3, interquartile range.

<sup>†</sup>The Mann–Whitney *U* test.

<sup>‡</sup>Pearson's chi-square test.

<sup>§</sup>Fisher's exact test.

<sup>¶</sup>Student's *t*-test was used for independent samples.

## Discussion

The results obtained in the comparison of the control group with the experimental group of this study indicate that the levels of acceptance, commitment and awareness of parental influence increased significantly in favour of the experimental group. This means that these levels were better for this group. The

–d effect sizes are high for all three variables, according to Cohen's criteria (Cohen 2013). These results are consistent with those found in the study carried out by Lecannelier *et al.* (2009) with typically developing children, demonstrating the efficacy of infant massage to promote emotional bonding and, therefore, improve levels of acceptance, commitment and awareness of parental influence. In the same line,

**Table 5** Differences between the experimental group and the control group

Variable	Group	Pre-test Mean (SD)	Post-test Mean (SD)	Within-group changes from baseline, mean (95% CI)
Acceptance	Control ( <i>n</i> = 17)	2.15 (0.91)	2.82 (0.90)	0.68 (0.32; 1.03) <i>P</i> < 0.001
	Experimental ( <i>n</i> = 18)	2.00 (0.99)	3.56 (1.15)	1.56 (1.21; 1.90) <i>P</i> < 0.001
	Between-group differences, mean (95% CI)	-	0.73 (0.02; 1.45) <i>P</i> = 0.044 <i>d</i> = 0.71	-
Commitment	Control ( <i>n</i> = 17)	2.53 (0.72)	2.94 (0.85)	0.41 (0.08; 0.75) <i>P</i> = 0.017
	Experimental ( <i>n</i> = 18)	2.31 (0.89)	3.61 (0.78)	1.31 (0.98; 1.63) <i>P</i> < 0.001
	Between-group differences, mean (95% CI)	-	0.67 (0.11; 1.23) <i>P</i> = 0.020 <i>d</i> = 0.82	-
Awareness of influence	Control ( <i>n</i> = 17)	2.68 (0.87)	3.41 (0.80)	0.73 (0.36; 1.11) <i>P</i> < 0.001
	Experimental ( <i>n</i> = 18)	2.64 (0.82)	3.78 (0.93)	1.14 (0.78; 1.50) <i>P</i> < 0.001
	Between-group differences, mean (95% CI)	-	0.37 (-0.23; 0.96) <i>P</i> = 0.220 <i>d</i> = 0.43	-

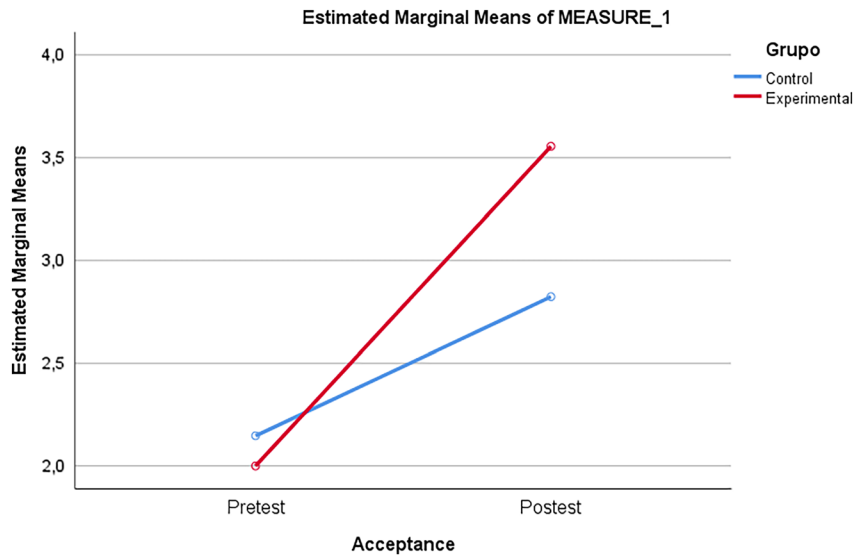
**Table 6** 2 × 2 mixed-model analyses of variance

Variable	Within-subjects factor (time)	Between-subjects factor (intervention)	Time-by-group interaction
Acceptance	$F_{1, 33} = 84.98$ <i>P</i> < 0.001 $\eta_p^2 = 0.720$	$F_{1, 33} = 0.87$ <i>P</i> = 0.358 $\eta_p^2 = 0.026$	$F_{1, 33} = 13.18$ <i>P</i> = 0.001 $\eta_p^2 = 0.285$
Commitment	$F_{1, 33} = 56.03$ <i>P</i> < 0.001; $\eta_p^2 = 0.629$	$F_{1, 33} = 0.80$ <i>P</i> = 0.378 $\eta_p^2 = 0.024$	$F_{1, 33} = 15.18$ <i>P</i> < 0.001 $\eta_p^2 = 0.315$
Awareness of influence	$F_{1, 33} = 53.45$ <i>P</i> < 0.001 $\eta_p^2 = 0.618$	$F_{1, 33} = 0.40$ <i>P</i> = 0.530 $\eta_p^2 = 0.012$	$F_{1, 33} = 2.48$ <i>P</i> = 0.125 $\eta_p^2 = 0.070$

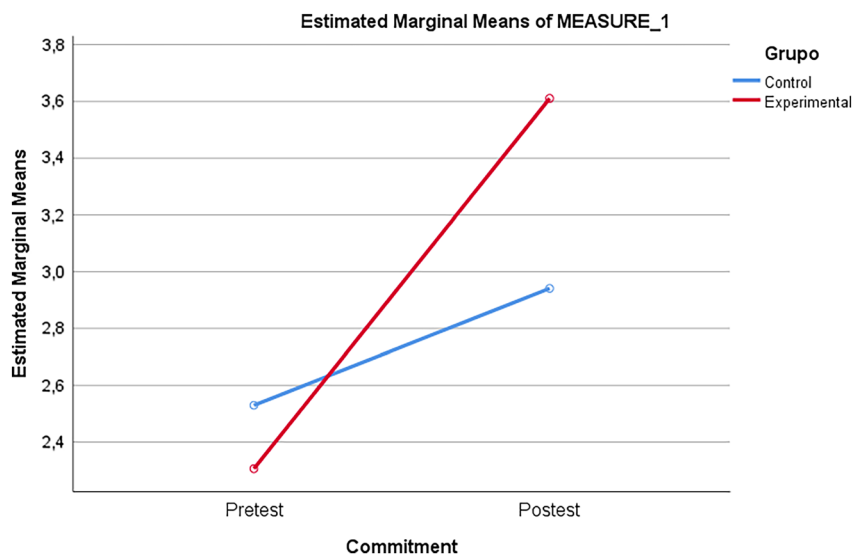
Campos Serrano *et al.* (2010) also stated that infant massage applied by parents to typically developing children improves the interaction between both, thus favouring the strengthening of the affective bond. The present study shows that this circumstance also occurs in parents of babies with Down syndrome. Thus, it seems that infant massage is a good tool to work with families for promotion of emotional bonding. In the study conducted by de Lima (2004)

with babies with DS, which analyses the benefits of 'Shantala' Infant Massage, mothers learned to accept the limitations of their children and described the importance of the contact with their baby.

On the other hand, both the control group and the experimental group, in the comparison made with the data obtained in the initial evaluation (pre-test) with respect to the final evaluation (post-test), significantly improved the levels of acceptance, commitment and



**Figure 5.** Difference between the two groups in Acceptance for 35 initial participants.



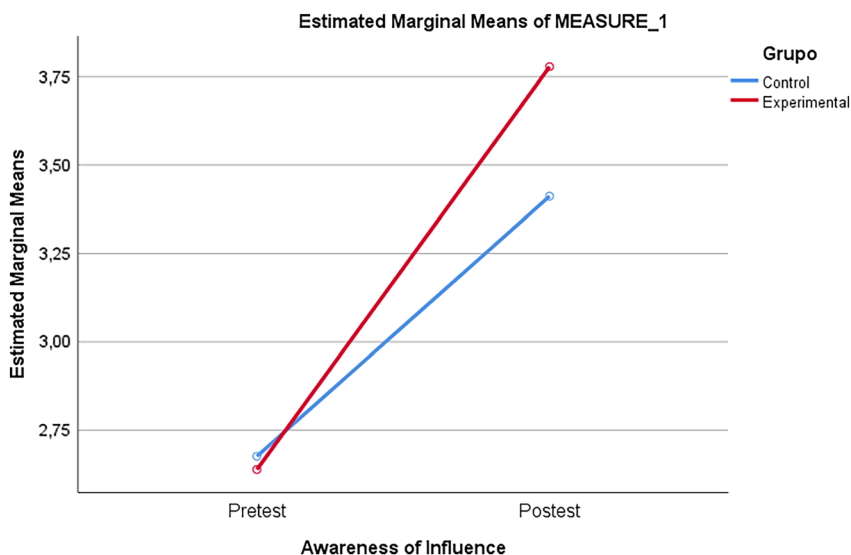
**Figure 6.** Difference between the two groups in Commitment for 35 initial participants.

awareness of influence. However, we must bear in mind that the time between one evaluation and another helps parents to bond with their baby and, therefore, to accept, commit and be aware of the influence they have on them. This aspect is also worked from the early care programme. In addition, one of the characteristics of the affective bond is that it arises and is fostered by continuous and prolonged interaction over time (Vicente *et al.* 2017).

Several studies have analysed the effect of infant massage on the development of babies with Down

syndrome (Silva *et al.* 2012; Purpura *et al.* 2014; Pinero-Pinto *et al.* 2020), and, in addition, in all of them, it is the parents who perform the massage. However, none of them analyse the effects of massage on the parents themselves, or their emotional state.

It is important to remember that the emotional state of the parents directly influences how they relate to their baby and, furthermore, that this relationship is directly related to the development of the child (Tran *et al.* 2017; Bujnowska *et al.* 2019). Bates and Dozier (2002) indicate that the maternal mental state



**Figure 7.** Difference between the two groups in Awareness of influence for 35 initial participants.

directly influences the emotional bond that is created. We know that, in the case of families with children with Down syndrome, the grieving process can affect the creation of the affective bond, since it is formed during pregnancy and is consolidated in the first months of the baby's life. In the case of families with children with disabilities, this process can be altered (Phillips *et al.* 2017; Marshak *et al.* 2019; Clark *et al.* 2020; Braga *et al.* 2021). It appears that parenthood involves experiential and hormonal changes that influence the hippocampus and prefrontal cortex, which are brain areas involved in cognition and mood regulation. If we better understand how having a baby, especially with a disability, affects the brain, it will allow us to program interventions to prevent, for example, parental depression, a condition that can have serious cognitive and mental health consequences for children (Leuner *et al.* 2010). The behaviours of the baby stimulate the parents to bond with him/her, and, in the case of babies with Down syndrome, they usually show some limitations, such as less initiative and difficulty in the emission of social and communicative signals (O'toole *et al.* 2018).

Numerous authors (Van Hooste and Maes 2003; O'toole *et al.* 2018; Pinero-Pinto *et al.* 2020; Sarimski 2020; Braga *et al.* 2021) argue that parents of children with Down syndrome offer the greatest opportunities to facilitate their children's learning and development, although they are not being active

participants in the intervention. During massage, babies can receive integrated information from their caregiver through different sensory channels and can focus their attention on these complex stimulations to learn and adapt to the environment (Purpura *et al.* 2017). However, healthcare systems are not constantly prepared to provide appropriate family-centred services to people with Down syndrome and their families (Marshall *et al.* 2015). That is why we must delve into how families of babies with Down syndrome work and how they respond to different interventions.

The results obtained in this research and those reported in other studies suggest that infant massage applied to babies with Down syndrome by their parents is an effective procedure to improve the levels of acceptance, commitment and awareness of parental influence.

#### Limitations and future research

The main limitation of this study is the sample size. It is necessary to expand the sample in future research in order to generalise these results. To calculate the sample size, an effect size was used from the same sample of this study that was analysed in a previous study. The same occurs with the data provided on inter-rater reliability, which were obtained in an initial study on the tool used; subsequently, an intervention

was applied in an experimental group to ascertain its effect.

In addition, in this investigation, we used a specific massage protocol; thus, the effect that other protocols may have on the results of this interview is unknown. It is necessary to continue delving into the effects of the interventions carried out on families with babies with Down syndrome in order to improve care practices.

### Conclusion

The infant massage applied by the parents to their baby with Down syndrome increases their levels of acceptance, commitment and awareness of influence in the short term in this sample.

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### Conflict of interest

The authors declare no conflict of interest.

### Data availability statement

All data from this research are available upon request to the corresponding author.

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