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Educational and Practical Research

Effect of Hugs on Promoting Relaxation in Children with Severe Motor and Intellectual Disabilities in Medical Care Dependent Groups (SMID-MCDG): Results of a Single-arm, Multicenter, Intervention Trial

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Abstract

Children with severe motor and intellectual disabilities in medical care dependent groups (SMID-MCDG) are exposed to chronic stress due to their unstable state of health and daily medical care. The purpose of this study was to verify the effectiveness of stress release through hugging. The intervention consisted of singing and rocking with hugs once a week for 24 weeks. The practitioner sang a song and slowly rocked the child's upper body up and down. The primary endpoint was the high-frequency (HF) component, an index of parasympathetic nervous system activity, based on frequency analysis of heart rate variability. Secondary endpoints included the ratio of the low frequency (LF) to HF component (LF/HF) as an index of sympathetic nervous system activity, salivary amylase activity (sAA) as an index of eustress / distress, incidence of adverse events, and change in appearance. Results of those analyses of 16 cases showed that changes in mean values of HF, LF/HF, and sAA were not statistically significant. Results of additional analyses showed that no child experienced a serious adverse event and that when the child had a pleasant facial expression, the HF component was statistically significantly lower and the LF/HF component was higher.

1. Introduction

The term "severe motor and intellectual disabilities (SMID)" is a classification based on degree of disabilities, but not a name of disease. A group of children requiring continuous dense medical care over a long period was defined as the SMID-medical care dependent group (MCDG)[1]. According to the scores of SMID-MCDG[2], children with a score of 10 to 24 for medical care items continued for ≥ 6 months were classified into sub-SMID-MCDG, and those with a score of ≥ 25 into SMID-MCDG.

According to a survey involving 8 prefectures in Japan in 2008[3], the number of children in SMID-MCDG or sub-SMID-MCDG aged 19 years or younger was approximately 0.3 per 1,000 children of the same age. The total number of those children in Japan is estimated to be approximately 7,000, of which 70% are living at home. It is pointed out that this number has annually increased. In particular, the number of children requiring advanced care, including mechanical ventilation, has relatively increased in children aged 5 years

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or younger.

The term "profound intellectual and multiple disabilities (PIMD)" is used abroad as an entity similar to the SMID-MCDG. Although there are no criteria for medical care differing from Japan, children with PIMD are defined as those having both severe intellectual disability and motor dysfunction[4]. In addition, they have a wide range of health disorders including severe sensory disturbance, chronic pulmonary infection, and gastroesophageal reflux[5,6].

Children may always be exposed to a state of tension by receiving required care daily in the SMID-MCDG or PIMD group[7]. In particular, chronic stress derived from an unstable health status under daily medical care and acute mental stress related to medical care are issues specific to SMID-MCDG children. Therefore, it is important to approach those issues for the maintenance of their lives and quality of life.

To approach those issues, supportive interventions aimed at stress relief and evaluation using physiological indices have been attempted in the educational practice research on children with SMID or SMID-MCDG.

A study of storybook reading to a child with SMID showed a statistically significant decrease in salivary amylase activity (sAA) after reading[8]. A study in which an infant with SMID-MCDG was given rocking play by hug also showed a statistically significant decrease in sAA after play[9]. sAA is considered an indicator of stress state, with decreased values reflecting eustress and increased values reflecting distress[10].

In a study of footbath intervention of a child with SMID-MCDG, frequency analysis of heart rate variability showed that LF/HF, the ratio of the high frequency component (HF; 0.15-0.4 Hz) to the low frequency component (LF; 0.04-0.15 Hz), increased significantly after intervention[11]. In a study in which children with SMID were treated with hot-pack warm baths to both upper and lower extremities, HF increased during the intervention compared to before, and LF/HF decreased[12]. HF responds to parasympathetic activity, while LF/HF is said to be influenced by sympathetic activity[13].

Those physiological indicators are used as indices of autonomic nervous system activity or stress, and interpreted as primarily reflecting emotional responses of children with disabilities.

However, since all of those were case studies involving a small number of children, neither effective and safe supportive interventions for stress reduction nor the effectiveness of physiological indicators were fully demonstrated.

There are few studies that scientifically demonstrated the relaxation effect on children with SMID or SMID-MCDG, but recent studies have shown that heart rates of infants transported by a hug was reduced significantly in only a few seconds (i.e., the parasympathetic nerve was in a significantly-relaxed state). Also, it was shown that children in the group hugged while being transported rarely moved or cried and their heart rates were lower than those in the group hugged while sitting[14].

Therefore, we conducted a multicenter intervention study using hugs, which are expected to have a relaxing effect, to provide temporary relief from chronic stress in SMID-MCDG children. In this study, frequency analysis of heart rate variability and sAA were used as physiological indices to examine the effectiveness of hugs in promoting relaxation.

2. Methods

2.1 Participants

Among children with SMID-MCDG admitted to medical-type welfare facilities, those requiring continuous dense medical care were enrolled in this study. Children who satisfied the eligibility criteria (Table 1) were enrolled.

2.2 Trial design and intervention

This is a single-arm, open-label, multicenter, exploratory study. Intervention by a hug with singing and rocking was performed once a week for 24 weeks (Figure 1). The 24-week intervention for each participant was conducted by the nursery teacher in charge. The intervention took place in the participant's room, in

Table 1 Eligibility criteria

Inclusion criteria
1) Multiple and severely handicapped children with a SMID-MCDG score of 25 or more.
2) Children who need a tracheotomy or mechanical ventilation.
3) Children aged 17 years or younger.
4) Children with body weight lower than 20 kg.
5) Children whose consent for participation in this study is provided by the representative.
Exclusion criteria
1) Children recognized as inappropriate by the principal investigator or other investigators.
2) Children who became severely handicapped due to traffic injury, etc.
3) Children who need sustained continuous suction.
4) Children with a history of bone fractures within 3 years until the time of registration.

as quiet an environment as possible. To avoid influencing sAA levels, nutritional infusion was prohibited within one hour before the intervention.

The procedure for the intervention was as follows. First, before intervention, we measured sAA using a salivary amylase monitor (NIPRO, Osaka), and subsequently measured the heart rate for 5 minutes using a portable heart rate variability measurement device (TRYTECH, Tokyo). Before the measurement, suction was performed as necessary, and a three-minute rest period was provided to ensure a calm state. Subsequently, the practitioner performed the following type of hug. They held the child in their arms, confirmed that the child's physical and mental state had calmed, and gently rocked the child's upper body up and down while singing a song. The rocking rhythm was set at approximately 45-50 beats per minute (BPM), with adjustments made according to the individual child's responses. The second heart rate measurement was conducted during the first five minutes after starting this intervention. Immediately after the intervention, the second sAA measurement was taken while maintaining the holding posture. The child was then laid on the bed, and after confirming that their physical and mental state had calmed, the third heart rate measurement was conducted over a five-minute period.

Figure 1 Intervention by a hug with singing and rocking

2.3 Endpoints

The primary endpoint was HF components by frequency analysis of heart rate variability. Secondary endpoints were LF/HF components by frequency analysis of heart rate variability, activity value of salivary amylase, incidence rate of adverse events, and appearance changes (in facial expression as well as body movements).

2.4 Statistical methods

Because the number of children with SMID-MCDG was limited, sample size was determined based on the feasibility rather than statistical analysis. The target sample size was 20 children.

Efficacy analyses were performed on the full analysis set (FAS), consisting of all enrolled participants who received intervention at least once without any critical protocol violation. A critical protocol violation was defined as any practice judged to deviate from the procedures established to ensure the health and safety of the participants. Such judgments were made by the efficacy and safety evaluation committee, which included co-researchers and doctors from each facility. Safety analyses were performed on the safety population, consisting of all enrolled participants who received intervention at least once.

For efficacy endpoint, HF components data were reported by mean and standard deviation, and mean change from baseline and its 95% confidence interval (CI) were estimated. The baseline was defined as the measurement value obtained before the intervention in the first week, and a paired t-test was used for statistical analyses. Also, we performed analysis by the linear mixed-effects model with week as fixed effect, participants as random effect and baseline value as covariate. As LF/HF components and sAA showed skewed distribution, the baseline was defined as the measurement value obtained before the intervention in the first week, and those data were summarized by geometric mean (GM) and coefficient of variance (CV), and geometric mean ratio to baseline and its 95% CI were estimated. In those endpoints, the same test for HF components was performed on logarithmically transformed data.

In cases where baseline data were missing, analyses were conducted without imputing the missing values. However, for the 24-week time point used to calculate changes, analyses that accounted for missing data were performed, and the specific method was determined after reviewing the status of the missing data during the data review process. Outliers were not excluded from the analysis, considering that children with SMID-MCDG are often highly sensitive to environmental stimuli and may exhibit involuntary movements. It was deemed difficult to clearly define the criteria for identifying outliers under these conditions.

All analyses were performed using the SAS statistical software, version 9.4 (SAS Institute, Cary, NC). A p-values of less than 0.05 were considered to indicate statistical significance.

2.5 Additional analyses

In order to evaluate the relationship between appearance changes (facial expression and body movement) of children interpreted by the practitioners and their examination values at the same point, boxplot diagrams of the values were shown corresponding to each condition and compared by using the linear mixed effects model with children as random effects. Changes in appearance were assessed by the practitioner during the pre-, mid-, and post-intervention period, and an assistant recorded the observations. Facial expressions were evaluated as pleasant, unpleasant, or unknown, and body movement was evaluated as voluntary, involuntary, or unknown.

3. Results

3.1 Study participants

Seventeen children in 14 centers in Japan were enrolled. One child did not receive the study intervention at all, and therefore 16 children were included in both FAS and the safety population. Median follow-up period was 162 days (range: 98 to 169).

3.2 Baseline data

The baseline characteristics were summarized. Median age was 5.5 years (range: 2 to 17), 5 participants were male, median SMID-MCDG score was 32.5 points (range: 26 to 42), and all children underwent tracheotomy and received nutrition through a feeding tube.

3.3 Outcomes and estimation

Table 2 shows the main results of heart rate variability and salivary amylase activity.

Table 2 Comparison between 24-week and baseline in HF components, LF/HF components and sAA

	Analyzed patients (N=16)							
	1-week/ pre-intervention (Baseline)		24-week/ pre-intervention		24-week/ mid-intervention		24-week/ post-intervention	
HF components								
Mean (SD)	n=10	51.8 (20.0)	n=9	58.7 (15.5)	n=8	53.9 (20.2)	n=10	47.3 (18.3)
Mean change from baseline (95% CI)			n=7	12.0 (-5.9 to 30.0)	n=7	-8.1 (-31.0 to 14.7)	n=8	-5.0 (-20.5 to 10.5)
P-value				0.152		0.418		0.472
Adjusted mean change from baseline (95% CI)*				11.9 (-0.3 to 24.2)		-7.7 (-21.6 to 6.2)		-6.0 (-17.8 to 5.9)
P-value*				0.057		0.277		0.32
LF/HF components								
GM (CV)	n=10	0.87 (1.30)	n=9	0.70 (0.76)	n=8	0.79 (1.30)	n=10	1.09 (0.91)
GMR to baseline (95% CI)			n=7	0.59 (0.28 to 1.25)	n=7	1.52 (0.50 to 4.65)	n=8	1.29 (0.60 to 2.74)
P-value				0.138		0.393		0.456
Adjusted GMR to baseline (95% CI)*				0.60 (0.34 to 1.05)		1.50 (0.68 to 3.30)		1.36 (0.76 to 2.40)
P-value*				0.071		0.311		0.296
sAA								
GM (CV)	n=7	18.5 (1.44)	n=8	15.5 (1.79)			n=11	24.4 (1.29)
GMR to baseline (95% CI)			n=4	1.35 (0.20 to 9.02)			n=4	1.08 (0.07 to 17.18)
P-value				0.647				0.939
Adjusted GMR to baseline (95% CI)*				1.03 (0.32 to 3.29)				0.80 (0.28 to 2.26)
P-value*				0.959				0.669

* linear mixed-effects model; SD, standard deviation; CI, confidence interval; HF, high-frequency; LF, low-frequency; sAA, salivary amylase activity; GM, geometric mean; CV, coefficient of variance; GMR, geometric mean ratio.

The mean changes in HF components from baseline to 24-week were 12.0 (95% CI, −5.9 to 30.0) for pre-intervention, −8.1 (95% CI, −31.0 to 14.7) for mid-intervention, and −5.0 (95% CI, −20.5 to 10.5) for post-intervention, and those changes were not statistically significant. Moreover, the results of linear mixed-effects model analysis were similar to those of plain analysis. In LF/HF components, the geometric mean ratios of 24-week to baselines were 0.59 (95% CI, 0.28 to 1.25) for pre-intervention, 1.52 (95% CI, 0.50 to 4.65) for mid-intervention, and 1.29 (95% CI, 0.60 to 2.74) for post-intervention, and those changes were not statistically significant. Moreover, the results of linear mixed-effects model analysis were similar to those of plain analysis. In sAA, the geometric mean ratios of 24-week to baselines were 1.35 kU/L (95% CI, 0.20 to 9.02 kU/L) for pre-intervention and 1.08 kU/L (95% CI, 0.07 to 17.18 kU/L) for post-intervention, and those changes were not statistically significant. Moreover, the results of linear mixed-effects model analysis were similar to those of plain analysis. Figure 2 shows that there was no time trend in the three endpoints above.

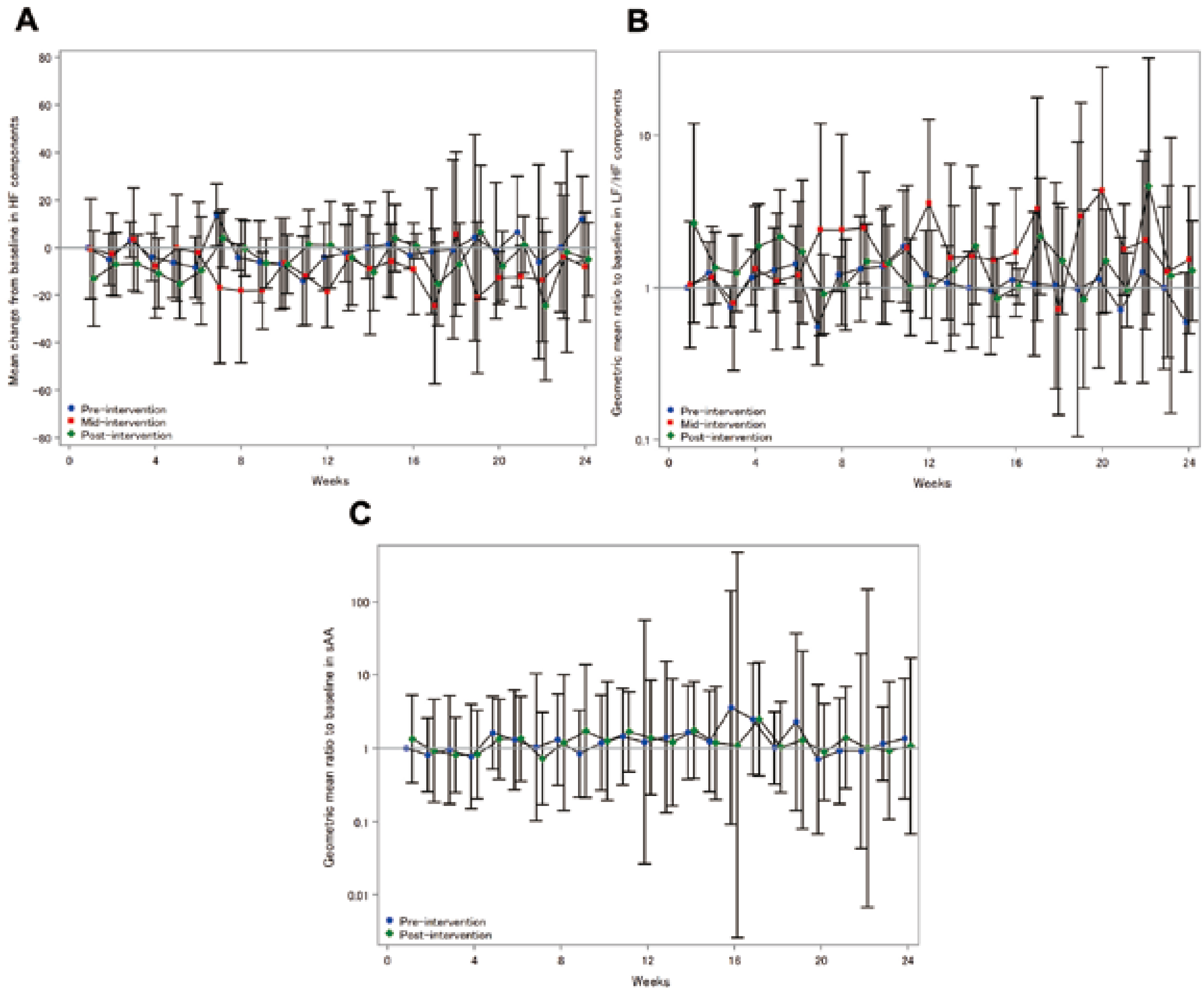

Figure 2 Time course of mean change from baseline in HF components (A), geometric mean ratio to baseline in LF/HF components (B), and geometric mean ratio to baseline in salivary amylase activity (C). Error bars indicate 95% CI.

The results of the relationship between appearance change and HF, and between LF/HF and sAA is shown in Figure 3. There were significant differences between pleasure and displeasure of facial expression in HF and LF/HF (p=0.009 and p=0.004, respectively). On the other hand, there was no significant difference between body movements and other endpoints.

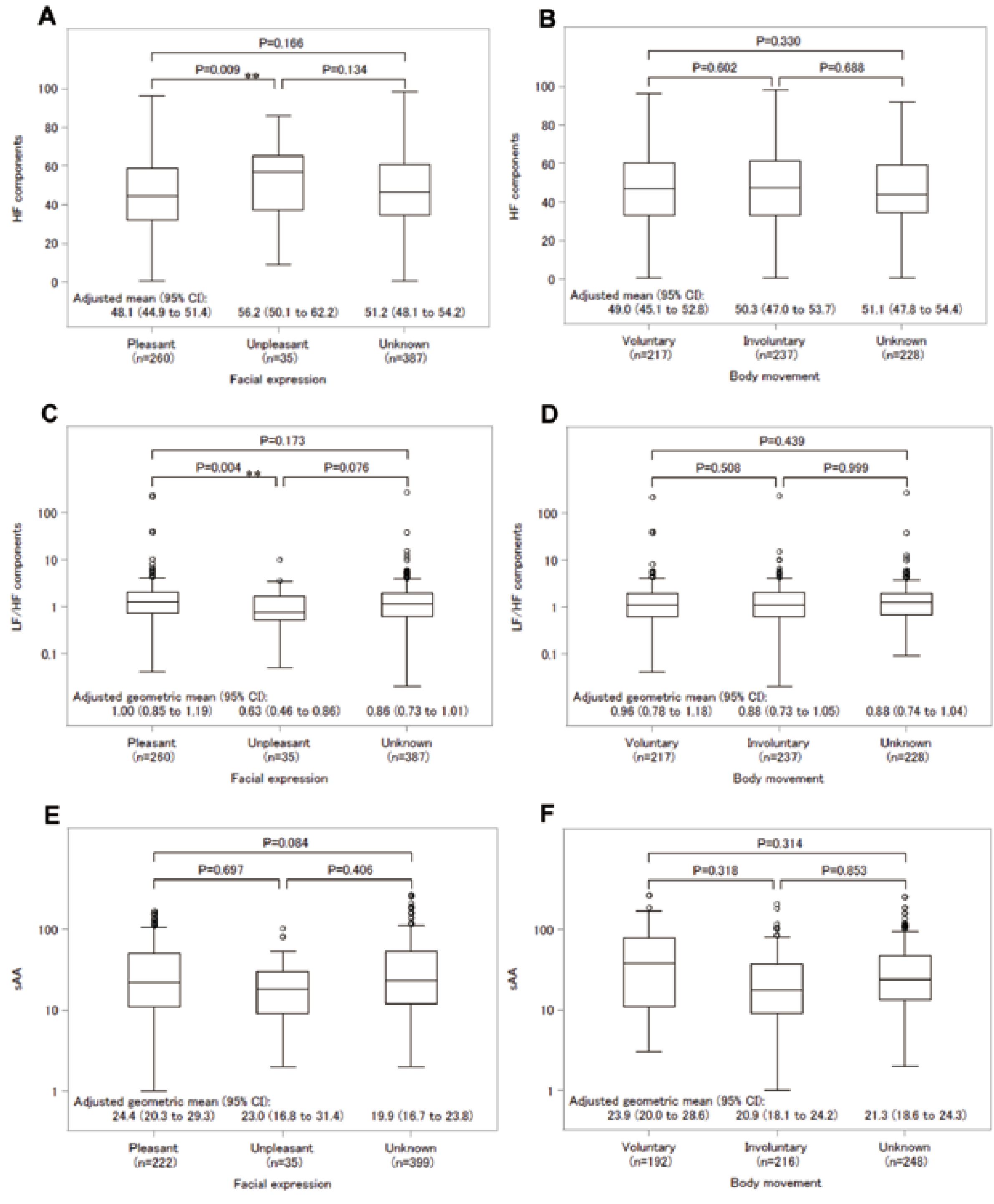

Figure 3 Box plots of HF components by facial expression (A), and body movement (B); those of LF/HF components by facial expression (C) and body movement (D); those of sAA by facial expression (E) and body movement (F).

3.4 Harms

Any serious adverse events were not observed.

4. Discussion

The mean change in the HF component, a measure of parasympathetic activity, was not statistically significant. The mean change in the LF/HF component, a measure of sympathetic activity, was also not significant. These results may suggest either that HRV was not a valid indicator or that interventions for children with SMID-MCDG are inherently challenging. Regarding the former, it highlights the difficulty of applying HRV as an intervention indicator for children with SMID-MCDG. A previous study has pointed out that HF and LF components are easily influenced by respiratory rhythm[15], and although those components are useful as indicators of the state of activation of autonomic nervous system activity, the factors that cause their fluctuation are complex, and it is necessary to consider reflexes due to respiratory status and changes in posture and position[14]. In this study, 17.4% (range: 0.0 to 38.5) of the participants on average each week sucked during the heart rate measurement throughout the intervention. This suggests that suctioning may have destabilized the respiratory status, which in turn affected the component values. Although LF/HF values in non-handicapped persons are considered to be smaller than 2.0 at rest and greater than 4.0 when parasympathetic activity is suppressed or sympathetic activity is excited[16], 2 of the participants in this study had significantly higher mean values of the LF/HF component of 25 or greater. Regarding the latter, it highlights the uncertainty of interventions resulting from the unstable health conditions of children with SMID-MCDG. Due to this instability, it is difficult to maintain consistent interventions. In fact, in the present study, interruptions in the intervention and missing data were not uncommon, and 3 out of 16 cases discontinued the intervention before completing the full 24 weeks. In such unstable interventions, it is inevitable that obtaining consistent data is challenging.

The mean change in sAA was also not statistically significant between pre-intervention and post-intervention. Similar to the findings for HRV, this result may also suggest that sAA was not a valid indicator. One possible reason is related to issues associated with saliva collection, which serves as the sample for sAA measurement. In the present study, the average rate of suctioning in the 3 minutes before saliva collection before the intervention was 32.1% (range: 11.1 to 50.0). This result may be due to the invasive nature of suctioning and higher level of stress immediately prior to the intervention, which may have prevented the effect of stress relief from being seen as a change in sAA values.

In a study of the effect of a bed bath with skin care that acts as a stress reliever in 20 subjects with SMID, no statistically significant differences were detected in both heart rate variability and sAA[17]. From those results, it is concluded that a high level of skill and care that leads to a pleasant state is necessary in assisting children with SMID.

In the present study, condition-controlled interventions were carried out with the latest attention. However, it was conceivable that giving a hug, i.e., change in posture and position, may itself be stressful for children with SMID-MCDG. In addition, the magnitude and tempo of rocking stimulation by hugging the child may vary from person to person in terms of comfort. We assumed that the practitioner would be able to find a method of sway stimulation that was comfortable for the subject child during the 24-week period, but it is possible that this period was not long enough.

The results of the additional analysis showed that when the practitioner perceived the subject child as having pleasant facial expressions, the HF component was statistically significantly lower and the LF/HF component was higher than when the subject child was having unpleasant facial expressions. Those results suggest that the parasympathetic nervous system was more inhibited during pleasant than unpleasant facial expressions in participants. We had hypothesized that rocking stimulation by hugging would promote parasympathetic activity and inhibit sympathetic activity in the children with SMID-MCDG. However, the results of the present study were the opposite, suggesting that the rocking stimulus acted on excitation rather than sedation. The reason for the effect toward excitation may be attributed to stimulation from postural changes or emotional excitement derived from positive feelings. Although it is not easy to determine what specifically triggers the HRV response, analysis in conjunction with facial expressions suggested that the responses observed in participants were associated with positive emotions.

A previous study similar to this research investigated the relaxation effects of foot baths in 4 children with severe motor and intellectual disabilities (SMID). As a result of the intervention, a significant decrease in the LF/HF component was observed in 2 of the 4 participants, while a significant increase in the HF component was observed in only 1 participant. Thus, the expected effects were not obtained in all cases[18]. Based on the results of this study and previous research, it is suggested that in intervention trials involving children with SMID or SMID-MCDG, the stimuli provided do not necessarily produce the expected effects. Because many SMID or SMID-MCDG children are congenitally bedridden, they have limited experience with a variety of stimuli and may take some time to stabilize and accept the stimuli presented to them. Therefore, we believe that when intervening with SMID or SMID-MCDG children with specific stimuli, it is important to start with the exploration of the target child's preferred stimuli.

Finally, in the present study, no adverse events were observed during the hug with singing and rocking intervention. This is thought to be due to the participants' stable health conditions prior to the intervention and the establishment of intervention guidelines that carefully accounted for connections such as ventilators and infusion lines[19].

5. Limitations

Through this study, several methodological limitations were identified. To standardize the intervention procedure, guidelines were established covering every step from pre-intervention preparation to post-intervention bed rest. Nevertheless, difficulties remained in fully unifying the experimental conditions.

One such difficulty concerned the timing of measurement for the indicators. HRV and sAA were measured at a pre-, mid-, and post-intervention period; however, the exact timing of measurement within each period was determined based on when each participant's physical and mental state had stabilized. This guideline was inevitable, given that children with SMID-MCDG are prone to temporary instability in their physical and mental states due to physical contact or posture changes during the intervention. Consequently, the timing of measurements varied slightly among participants. This variability represents one of the challenges in designing intervention studies for children with SMID-MCDG.

The second issue concerned the timing of saliva sampling for sAA and the recording of factors that may influence sAA levels. Although sAA is known to exhibit diurnal variation[20], it was difficult to standardize the timing of intervention and measurement across facilities because of the participants' daily care routines and health conditions. Moreover, factors that could affect sAA—such as suctioning immediately before intervention, body posture during measurement, and epileptic seizures—were only partially observed; aside from whether suctioning was performed, other potential influencing factors could not be adequately recorded. Some participants assumed lateral or prone positions due to drooling, suggesting that posture during measurement should be recognized as an important influencing factor.

Regarding epileptic seizures, some participants exhibited unexplained tremors, making it difficult to distinguish between tremors and seizures and thus to accurately observe the presence or absence of seizure activity.

For future studies, it would be desirable to record measurement timing and body posture during data collection and to consider these variables as covariates in subsequent analyses.

6. Conclusion

In this study, the effects of a hug with singing and rocking play in promoting relaxation were examined using heart rate variability analysis and the physiological index of salivary amylase activity. Results did not show statistically significant differences. Possible reasons for those results were the effects of interruption of the intervention due to suctioning or instability of health before or during the intervention.

Additional analysis showed that the parasympathetic nervous system was inhibited when the subject child showed pleasant facial expressions. We hypothesized that rocking would have a sedative effect on the subject, but the results showed the opposite. Thus, the results suggest that the stimuli presented to SMID children do not always have the expected effects.

We believe that when intervening with SMID or SMID-MCDG children using specific stimuli, it is important to begin by exploring the target child's preferred stimuli.

Ethical considerations

This trial was approved by the National Hospital Organization's central review board for clinical trials (approval number: H28-0902002).

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