A non-randomized controlled trial for the effectiveness of the 'aibo' intervention program for distraction in childhood vaccination

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Research article

Keywords: Artificial Intelligence, social robot, paediatric robot-assisted therapy, distraction, vaccination

Posted Date: February 23rd, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1101570/v2

Abstract

Background: Procedures and actions such as injections and immobilization cause pain and distress to children. In the pediatric field, there is a need for interventions and support to alleviate the pain and distress caused by such medical procedures. In recent years, the introduction of robots as a means of distraction has begun to be attempted.

Methods: In this study, we conducted a non-randomized controlled trial to examine the effect of intervention using ‘aibo’, a dog-like robot which has artificial intelligence (AI), to promote distraction in children after vaccination. Children between the ages of 3 and 13 years old eligible for the Japanese encephalitis vaccine, and their caregivers were assigned to intervention group or control group. Then, children evaluated their pain and children’s behavior were observed by observer. The mean values of Faces pain rating scale scores and observer pain scale scores were compared between groups using an unpaired *t*-test.

Results: Fifty-seven children (32 in the intervention group) participated in the study. Results of a *t*-test with the control group showed that the intervention group using aibo had significantly less pain following the post-vaccination intervention than the control group using stuffed dog (Face Scale, $t(55) = 2.582$, $p = .0125$; Behavioral Observation Scale, $t(55) = 2.772$, $p = .00759$). The results support the hypothesis that the aibo intervention group will be less distressed and able to calm down more quickly after vaccination than the control group.

Conclusion: AI-powered aibo interventions that allow for interactive interaction can be an effective distraction method during painful procedures such as vaccinations.

1. Background

Vaccination of children is widely used as a medical procedure for health care. However, procedures and actions such as injections and immobilization cause pain and distress to children. Intense pain and distress in medical procedures are known to cause medical trauma and behavioral problems such as anxiety, depression, fear, and non-compliance with treatment in children and their families [1], and there is a need for interventions and support aimed at alleviating pain and distress from medical procedures in the pediatric field.

Distraction is one of the ways to alleviate pain in medical treatment. Distraction is a method in which a parent attends an examination or procedure that the child finds "scary" to support the child's natural coping skills, or to help the child relax by focusing attention on something other than the medical procedure.

Beran et al. [2] conducted a study to evaluate the effects of distraction by a humanoid robot programmed to interact with 57 children receiving the influenza vaccine during the vaccination process. The distraction effect was examined using a control group. The results showed that compared to the control group, the children in the intervention group did not stop crying during vaccination, but they observed more smiling. Other studies have reported that humanoid robots intervening during the procedure can distract children [3], help reduce anxiety, cope with stress, and improve behavior during the procedure [4]. Such AI-based distraction, as a non-pharmacological method, can be widely applied in the field of pediatric medicine.

Tanaka et al. [5] conducted a pilot study of group robot intervention (GRI) using the AI robot aibo (Figure 1) on hospitalized chronically ill children (127 in total) and their caregivers (116 in total) and observed the language and behavioral characteristics of the children and their caregivers. We conducted a pilot study in which we observed the language and behavioral characteristics of children and their caregivers. As a result, about two-thirds of the total expressions of children and caregivers during GRI were positive, and we have reported that interaction through aibo may lead to children's acquisition of social skills, reduction of anxiety, and improvement of caregivers' mental health. The aibo was released by SONY Corporation ("SONY") in 2018. The robot aibo is a social entertainment robot with a rounded, dog-like appearance and the ability to develop through communication with those it interacts with. It was originally intended for use in daily-life situations. Although aibo was not originally developed to be used in clinical situations, its characteristics are similar to those of humanoid interaction and animal-assisted therapy, and it is expected to have the same distraction effect as animal-assisted therapy in pediatric medicine. In addition, AIBO, an older version of aibo, has been introduced into the medical field and is recognized as one of the SAR (Social Assistive Robot and Companion) [6].

The purpose of this study was to examine the psychosocial effects of intervention using aibo, a dog-like robot with artificial intelligence, specifically its ability to facilitate distraction during immunization.

Hypothesis

The aibo intervention group will be able to reduce distress and calm down more quickly after vaccination than the control group.

2. Methods

We conducted an intervention study using SONY's aibo, dividing caregivers and children who came to the hospital for Japanese encephalitis vaccination into an intervention group and a control group, in accordance with our objectives. The following is a description of the study subjects, survey period, intervention method, contents of the survey and analysis method in the study.

1. Study subjects

The subjects were children between the ages of 3 and 13 years old eligible for the Japanese encephalitis vaccine, and their caregivers.

2. Survey period

The survey period was February 2020 to December 2020.

3. Intervention method

One children's clinic in Mitaka City, Tokyo, which provides general pediatric care, was asked to cooperate in the study. The survey procedure is shown in Figure 2. A staff member (psychologist or physician) from the National Center for Child Health and Development (NCCHD) visited the clinic once a week as an observer and asked the caregivers and children for their cooperation while in a waiting room (small enough to accommodate 3 to 4 pairs of caregivers and children) exclusively for those scheduled for vaccination. Those who visited the clinic in odd-numbered months were assigned to the intervention group, and those who visited the clinic in even-numbered months were assigned to the control group. After obtaining caregiver’s consent, children and their caregivers were asked to spend time with aibo or a stuffed dog during the waiting time before and after child's vaccination (about 5 minutes each) in a waiting room, and children’s behavior was observed by professional observers. The children evaluated their pain experience after 5 minutes each whereas their caregivers proxy answered when child was not able to answered. If the aibo got stuck or the stuffed dog fell down, the observer adjusted the situation accordingly. The total survey time for each caregiver-child pair was about 15-20 minutes.

The dimensions of aibo (Figure 1) used in the intervention group were 180 × 293 × 305 mm and it weighed 2.2 kg. It was able to move freely around the waiting room. Its eyes were equipped with OLED displays, and it showed rich facial expressions as well as various voices and behaviors. It also responded to stimuli from touch sensors on its head, neck, and back with facial expressions and voices. The stuffed dog used in the control group was a gray-haired stuffed animal measuring 130 × 320 × 330 mm in length. It could change the angle of its limbs and neck but it did not move spontaneously and was not equipped with any special functions, such as voice or behavior.

4. Contents of the survey

The following indices were used to evaluate pain, distress, and restlessness.

(1) Primary index: Evaluation of pain and anxiety using Faces pain rating scale (FS)

The FS is a scale that describes a person's facial expressions at several levels, and evaluates feelings and states by facial expressions in addition words or numbers. In the present study, the Wong Baker faces pain scale [7] was used (Figure 3). It has six levels of facial expressions ranging from a smiling face to a crying face. Each expression was assigned a number on scale of 0, 2, 4, 6, 8, and 10, with a lower number indicating less pain and a higher number indicating more pain.

(2) Secondary indicator: Behavioral observations using the observer pain scale

The observer pain scale was translated from the scale reported by Gracely et al. [8] (Table 1). Children were observed interacting with aibo or a stuffed dog immediately after vaccination called “immediately following (IF)” and 5 minutes after vaccination called “post”, and the observer rated them. Each score and evaluation index is shown Table 1. The observer evaluates the child's behavior and state on a scale of 1 to 5, with 3 being normal and calm, a lower score indicating that the child is active and upset, and a higher score indicating that the child is in pain and distress. In order to ensure that there were no differences in observation and scoring among the raters, meetings were held within the raters to standardize the scores.

Table 1 The observer pain scale [8]

SCORE	OBSERVATION
1	LAUGHING, EUPHORIA
2	HAPPY, CONTENTED, SMILING, PLAYING
3	NEUTRAL: (ASLEEP OR CALM)
4	MILD-MOD: EXPRESSES, VOCALIZES PAIN, WRINKLES BROW, BUT CAN DISTRACT WITH TOY OR FOOD OR TV
5	MOD-SEVERE: EXPRESSES SEVERE PAIN, CRYING INCONSOLABLY, SCREAMING, HYSTERIA, SOBBING

5. Analysis method

The mean values of the FS and the observer pain scale scores at each time point before and after vaccination were calculated for each group, and the differences in the mean values at each time point were compared between groups using an unpaired *t*-test (significance level 5%, two-tailed test). All statistical analyses were performed with EZR [9] (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R (The R Foundation for Statistical Computing, Vienna, Austria). More precisely, it is a modified version of R commander designed to add statistical functions frequently used in biostatistics.

3. Results

A total of 57 children were included in the study, of which 32 were in the intervention group and 25 in the control group. The intervention group had a mean age of 4.41 years (3-12 years, median 3 years) and 10 boys (31%), whereas the control group had a mean age of 3.96 years (3-9 years, median 3 years) and 14 boys (56%) (Table 2).

Table 2 The participant's age and gender

	Age					Gender	
	Min.	Max	Med.	Avg.	*SD*	M	F
Intervention group (N=32)	3	12	3	4.41	2.69	10	22
Control group (N=25)	3	9	3	3.96	1.65	14	11

Table 3 compares the scores of the intervention group and the control group for each index. For the FS, there was no significant difference between the intervention and control groups before vaccination ($t_{(55)}$ = .657, p = .514). On the other hand, after vaccination, the intervention group was significantly lower than the control group ($t_{(55)}$ = 2.582, p = .0125). For the behavioral observation scale, there was no significant difference between the intervention and control groups immediately after vaccination ($t_{(55)}$ = 1.040, p = .303), but 5 minutes after vaccination, the intervention group was significantly lower than the control group ($t_{(55)}$ = 2.772, p = .00759).

Table 3 The average, standard deviation and t-score of FS and the observer pain scale in the intervention and control groups

	Intervention group		Control group		*t*
	Avg.	*SD*	Avg.	*SD*	
(*Pre*)Face scale	2.625	2.352	3.04	2.389	.657
(*Post*)Face scale	1.875	1.897	3.44	2.678	2.581†
(*IF*)The observer pain scale	3.344	0.787	3.56	0.768	1.040
(*Post*)The observer pain scale	2.125	0.609	2.68	0.9	2.772*

† p<.05, *p<.01

4. Discussion

In this study, we conducted an intervention study using aibo with the aim of examining the effect of AI distraction on vaccination. The results showed that compared to the control group using a stuffed animal, the aibo intervention group had significantly lower scores at the FS post vaccination and the behavior observation scale 5 minutes after vaccination. This result supports the hypothesis that the aibo intervention group will be able to reduce distress and calm down more quickly after vaccination than the control group.

Pediatric medical trauma can result in a strong pain response. In order to prevent this, the DEF protocol is recommended [10], and it is said to be effective in expressing the painful feelings. It involves explaining the situation clearly to the child, providing a way to ease the pain and distress, and also provides support to the family. Repeated injections during infancy can be a traumatic experience for children, and prevention of this is important for children's health literacy. In this study, we intervened by using aibo, which has AI, as a distraction to alleviate pain and anxiety.

In this study, the group difference in pain relief can be interpreted to suggest that the animal-type AI robot was more interesting to the children and was a friendly and smile-inducing stimulus. Beran et al. [2] intervened with a humanoid robot with interaction capabilities during a child vaccination procedure, and found that the group in which the humanoid robot intervened was more likely to smile than the group in which it did not intervene, but the degree of crying did not change. In contrast, Beran et al. [2] found that either the children recovered more quickly or that the robot minimized their distress, but that when robots are designed and programmed with human-like characteristics, they are very attractive to children and can elicit positive responses in the form of smiles. Our results agree with those of Beran et al. [2]. These reports also suggest that the intervention of artificially intelligent aibo may be effective as a distraction method during painful preventive injections.

Distress control for medical trauma prevention also includes cognitive behavioral therapy (CBT), distraction and meditation methods, and psychological preparation [11]. For infants and children, CBT and meditation methods using cognitive techniques are developmentally limited, so distraction through the five senses is more effective. According to Mitchell and Boss [12], pain experienced in childhood alters the formation of neural networks, when they encounter noxious stimuli. Taddio et al. [13] reported that in a large sample of immunized children, self-reported fear of needles was "strong" at 68% among 6-8 year-olds, 65% among 9-12 year-olds, and 51% among 13-17 year-olds. This suggests that many children experience the pain of injections as a fear. Distraction has been shown to be effective in reducing pain and fear related to needles [14,15]. Multisensory strategies that combine visual, auditory, and tactile sensations are thought to have a greater impact on pain than unisensory strategies [16], and one of the principles of attentional theory is that the distractor stimulus must be stronger than the pain stimulus in order to get the child's attention [17], and that novel, interactive, and multisensory distractions are necessary [2]. With this in mind, the intervention of aibo, which can communicate interactively and interactively with children's various responses such as voice, eye, and body movements, may be an effective method of distraction for children.

As a way to verify the effectiveness of aibo as a preventive measure against medical trauma during multiple medical procedures, such as preventive injections, it is necessary to verify to what extent aibo's intervention is effective in reducing anxiety and nervousness when going for medical tests or receiving preventive injections in the future.

Limitations

As the observer pain scale was evaluated by an investigator knowing the hypothesis, the investigator's expectations may have influenced the results. In addition, Some cases answered FS by caregivers' proxy. However, the result that we also found an effect in the children and caregiver did not know the hypothesis minimizes the possibility of observer bias. In this study, we were not able to adjust for confounding factors, such as the possibility that the children's attention was diverted elsewhere due to the accompanying caregiver's involvement in "distraction" and "chasing". In addition, in order to verify the effect of aibo with artificial intelligence as a preventive measure for medical trauma, it is necessary to examine the possibility that aibo may lead to a reduction in anxiety about subsequent medical treatment in the intervention group.

Abbreviations

AI: Artificial Intelligence

CBT: Cognitive Behavioural Therapy

FS: Faces Pain Rating Scale

GRI: Group Robot Intervention

NCCHD: National Center for Child Health and Development

SAR: Social Assistive Robot and Companion

SONY: SONY Corporation

Declarations

Ethics approval and consent to participate

Approval was given by the Ethics Committee in NCCHD. Written consent was obtained from the caregivers of the participants. If the child was available, we explained this survey and confirmed their willingness to participate.

Consent to publish

Not applicable

Availability of data and materials

The date that support the findings of this study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

Funding

All phases of this study were supported by National Center for Child Health and Development, grant number 30- 15 and AI Hospital Project, Cabinet Office, Government of Japan, grant number 2304080405. The funders did not participate in the design of the study; collection, analysis, and interpretation of data; and in writing the manuscript.

Authors’ contributions

KT designed the study design, analyzed and discussed the results, and wrote the paper. MH analyzed the results of this study and wrote the paper. AN, CN, and MN implemented the intervention in the clinic. CA supervised all interventions in this study. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

Acknowledgments

We would like to express our sincere gratitude to the staff of the Clinic for Children Akiyama Kodomo Clinic for generously providing the space and opportunity to conduct this research.

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Figures

Figure 1

aibo. Specification. Product name: aibo, Model number: ERS-1000, Processor: 64 bit Quad-Core CPU, Display: 2 OLEDs(eyes), Sound: Speaker, 4 Microphones, Camera: 2 Cameras (Front camera, SLAM camera), Communications: Mobile Network Communication Feature (Data transmission) LTE, Wi-Fi IEEE 802.11 b/g/n (2.4GHz), Outside dimensions: Approx. 180×293×305mm, Weight: Approx. 2.2kg, Power consumption Approx. 14W, Battery duration: Approx. 2 hours, Recharge time: 3 hours. You can download this image for free from the official aibo website following: https://aibo.sony.jp/download/

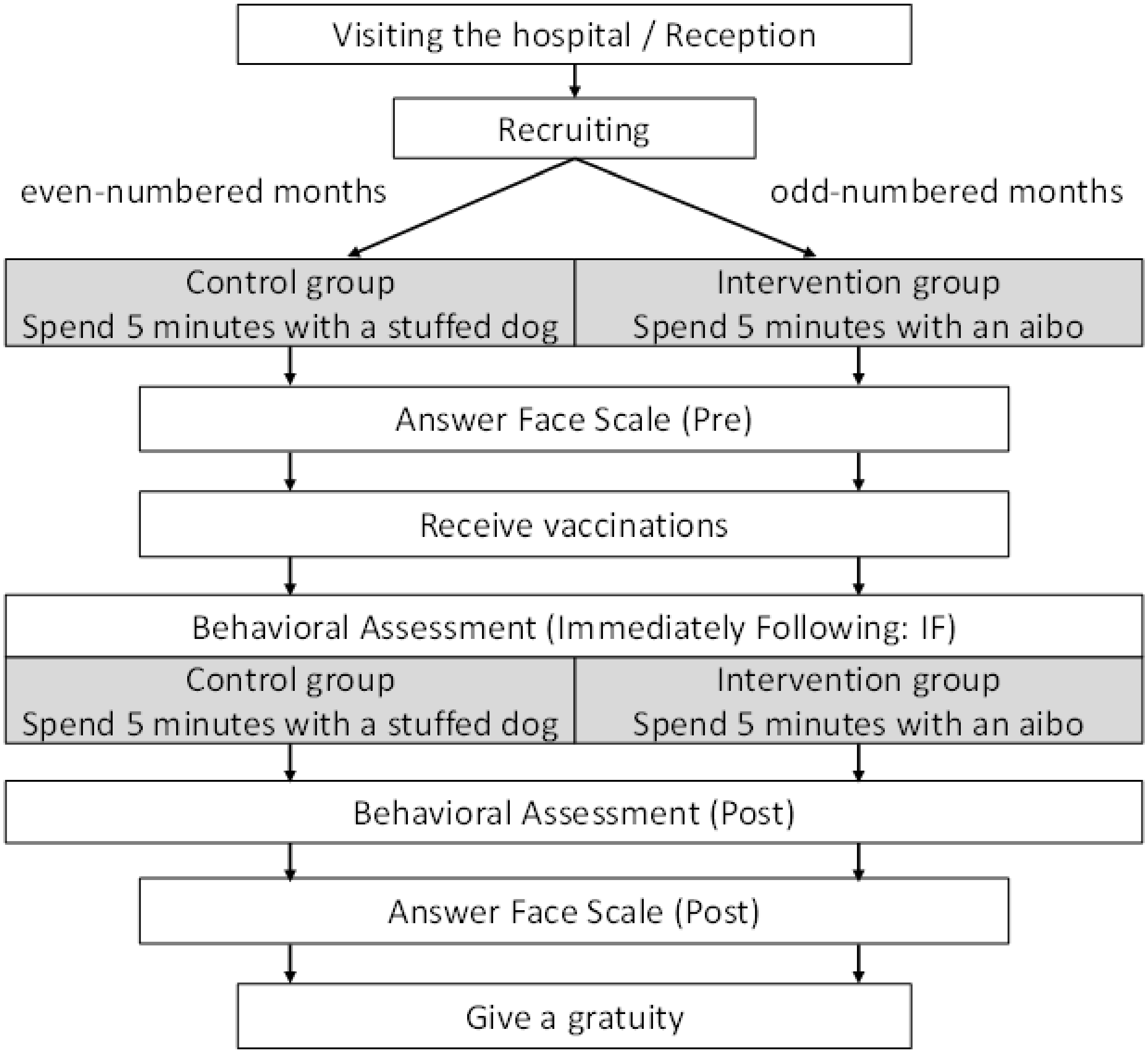

Figure 2

Flow of the investigation. Children and their parents who visited the hospital in even-number months were assigned to the control group, while children and their parents who visited in odd-numbered months were assigned to the intervention group. Intervention and observation conducted pre and post vaccination

Figure 3

Faces pain rating scale. The children's pain was assessed visuality scale, with 0 being the no hurt, increasing in pain as the number increased, and 10 being the hurts worst [7]