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Reducing children's pain and distress towards flu vaccinations: A novel and effective application of humanoid robotics☆

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ABSTRACT

Objective: Millions of children in North America receive an annual flu vaccination, many of whom are at risk of experiencing severe distress. Millions of children also use technologically advanced devices such as computers and cell phones. Based on this familiarity, we introduced another sophisticated device – a humanoid robot – to interact with children during their vaccination. We hypothesized that these children would experience less pain and distress than children who did not have this interaction.
Method: This was a randomized controlled study in which 57 children (30 male; age, mean ± SD: 6.87 ± 1.34 years) were randomly assigned to a vaccination session with a nurse who used standard administration procedures, or with a robot who was programmed to use cognitive-behavioral strategies with them while a nurse administered the vaccination. Measures of pain and distress were completed by children, parents, nurses, and researchers.
Results: Multivariate analyses of variance indicated that interaction with a robot during flu vaccination resulted in significantly less pain and distress in children according to parent, child, nurse, and researcher ratings with effect sizes in the moderate to high range (Cohen's d = 0.49–0.90).
Conclusion: This is the first study to examine the effectiveness of child–robot interaction for reducing children's pain and distress during a medical procedure. All measures of reduction were significant. These findings suggest that further research on robotics at the bedside is warranted to determine how they can effectively help children manage painful medical procedures.

1. Introduction

Vaccinations have an enormous benefit, yet create significant pain and distress for children [1]. This paradox has spurred the development and evaluation of strategies to reduce distress experienced by many children during vaccinations [2]. Cognitive-behavioral interventions show promise with considerable, but not consistent, empirical support [3–9]. In fact, utilization of some strategies such as encouraging caregivers to reassure their children and demonstrate empathy may result in higher levels of pain/distress compared to baseline control [10,11], and children are not likely to use coping strategies they are taught [12]. A frequently used intervention is to instruct children to blow. Although it reduces researchers' ratings of children's pain behaviors, children's, nurses', and parents' ratings of children's pain are not lower when compared to a control group [5]. There are many studies that report significant pain reduction when blowing is combined with a visual stimulus as a form of distraction, such as party blowers; however, ratings of pain are not consistently lower [7,8]. Drawing on limited attentional capacity theory [13], it is possible that cognitive-behavioral intervention will have a limited impact on reducing children's pain when these stimuli are not as intense as the painful stimulus. In other words, the valence towards the distraction and blowing has to be stronger than towards the needle. Another advanced form of technology, virtual reality, has been explored for procedural-related distraction [14], but has shown mixed results, with associated nausea and headaches [15,16]. To address these challenges we evaluated the use of a humanoid robot as a highly engaging and novel method of facilitating distraction and blowing for reducing distress during childhood immunizations with the goal of reducing the burden to children, their families, and health care professionals.

1.1. Robotics in health care

Research on children's use of technologically advanced computer driven machines (e.g., cell phones) across the age spectrum

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throughout many countries in the world is well underway [17,18]. The study of other computer driven devices, such as robots and their contact with children, has recently emerged [19,20]. These studies indicate that children are eager, receptive, and "pre-programmed" to engage with robots. Many children, for example, would befriend a robot and tell it secrets [19]. Indeed, robots are being designed to exhibit socially engaging and entertaining behaviors, a field known as developmental robotics [21].

The use of robots in health care began in 2001 with the introduction of a specialized robot arm to perform surgery on patients at Children's Hospital Boston. Robots have also been used to dispense and transport medication and materials in hospitals [22]. Mobile robot systems are also being tested as a means for physicians to communicate remotely with their patients and for lifting patients. Another type, humanoid robots, is designed to resemble human characteristics such as appearance and movement. Many are uniquely programmed to work with people, capable of both verbal and nonverbal communication. With emerging research suggesting that mobile robot systems and robot arms improve patient care [23,24], it seemed timely to examine whether a humanoid robot could reduce pediatric pain and distress.

We introduced a small humanoid robot in a pediatric hospital to implement cognitive-behavioral strategies while children received a flu vaccination. The robot utilized strategies (distraction and blowing) that have some empirical support, and seem as effective as other forms of psychological intervention, for reducing children's pain distress while undergoing vaccination [4,9]. Given the propensity of children for engagement with a robot, it was expected that they would enthusiastically respond to one in a hospital setting. Thus, it was hypothesized that children who were distracted by a robot during their flu vaccination would experience lower levels of pain and distress than children without such distraction.

2. Method

2.1. Participants

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and was approved by the Conjoint Health Ethics Research Board of the University of Calgary. The steps followed in the conduct of the research design are found in the Consort E-Flowchart. Children admitted to, or attending outpatient clinics at the Alberta Children's Hospital in October 2011 were referred for flu vaccination, provided by the Infectious Diseases Clinic by their physicians, or signed up for the vaccination through posters at these locations. This setting, rather than a family doctor's office or public health clinic, was selected to access a large number of children within a short time frame. All children received the vaccination, but only those between the ages of 4 and 9 years were included in the study. This lower age limit was chosen to ensure that they were able to complete the ratings, and the upper age limit was set to restrict the developmental heterogeneity of the sample and ensure that the robot's actions were developmentally appropriate for the age range. All children received either Agriflu® (Novartis Vaccines and Diagnostics, Inc.) or Fluviral® (GlaxoSmithKline Inc.) with 0.5 ml administered intramuscularly in the deltoid muscle of either their right or left arm with a 25 gauge 1 in. needle. The latter was administered when supply of the former was limited. The vaccines were maintained at the same temperature for all children. Research nurses administered both vaccines in both groups and were not blinded to the conditions.

2.2. Measures

The Faces Pain Scale-Revised (FPS-R) [25] depicts six faces expressing increasing levels of pain on a scale from 0 (no pain) to 10 (most pain). It was completed by children, parents, nurses, and researchers who were asked to consider the children's strongest expression of pain during the injection. This scale was printed on separate sheets of paper so each person could independently complete it (with parents providing some assistance in reading the instructions for their children when necessary, but all children gave their own response). Concurrent validity and inter-rater reliability of scores on this scale are high [26]. In addition, all sessions were videotaped and coded using the Behavioral Approach-Avoidance Distress Scale (BAADS) [27]. Children's behaviors were scored at nine time points that correspond to specific steps during the medical procedure (e.g., movement towards chair, skin cleansing) on two subscales, distress and approach-avoidance. The former consists of items such as "moderate muscle tension, some crying", and the latter has items such as "turns away, tries to escape." Scores range from 1 to 5. To obtain a single score for each subscale, the mean of these scores across all nine time points was calculated with high scores reflecting more distress on one subscale and more avoidance on the other. Studies show that scores on the avoidance subscale are a good indicator of distress according to concurrent validity estimates of 0.37–0.57 when compared with other measures of distress [28,29]. Also, interrater and inter-item reliability estimates are in the acceptable range [28,29]. Moreover, it continues to be recommended as a good measure of distress [30]. Two raters, who were blinded to the purpose of the study, coded all 57 videos and obtained good inter-rater reliability according to intraclass correlation coefficients of 0.78 on the distress and 0.89 on the approach-avoidance subscales. In addition to measuring distress, in the robot group we administered the following question to the children and parents separately, "Would you want to have the robot next time you (your child) have (has) a flu vaccination?" Responses were given on a 5-point scale from "not at all" to "very much."

2.3. Procedure

Upon arrival at the clinic, parents completed demographic questions. Then they rated their children's level of pain during their previous vaccination using the FPS-R. Their children were also asked to complete this scale when thinking of their prior vaccination. This scale was re-administered to parents and children after the vaccination and was also completed by the nurse who gave the vaccination, and the researcher who observed the session.

Children were randomly assigned to either the robot (14 boys, 14 girls) or comparison condition (16 boys, 13 girls) (see Fig. 1) by using a computer generated random-number sequence. A stratified randomization table was used to assign each participant into groups balanced by sex and age. Allocation was conducted as children arrived to the clinic. A researcher was present in the room for both conditions (to ensure that the robot and camera were turned on but did not interact with anyone, and to ensure that no other medical interventions were used). In the robot condition (Fig. 2), each child sat beside the nurse and also beside or on the lap of a parent, in front of a three-foot tall humanoid robot. It was seated at the child's eye level on a bed with several toy objects on a table resting on its legs. It was pre-programmed to execute distraction strategies before, during, and after the injection, and to instruct the child to blow during the injection. These three injection phases occurred as follows. (1) As the child approached the chair to sit down, the researcher touched a button for the robot to introduce itself and begin talking about general interests such as music and movies. It also motioned with its arm and asked children for a "high five." During this activity, the nurse prepared the vaccination. (2) Once the

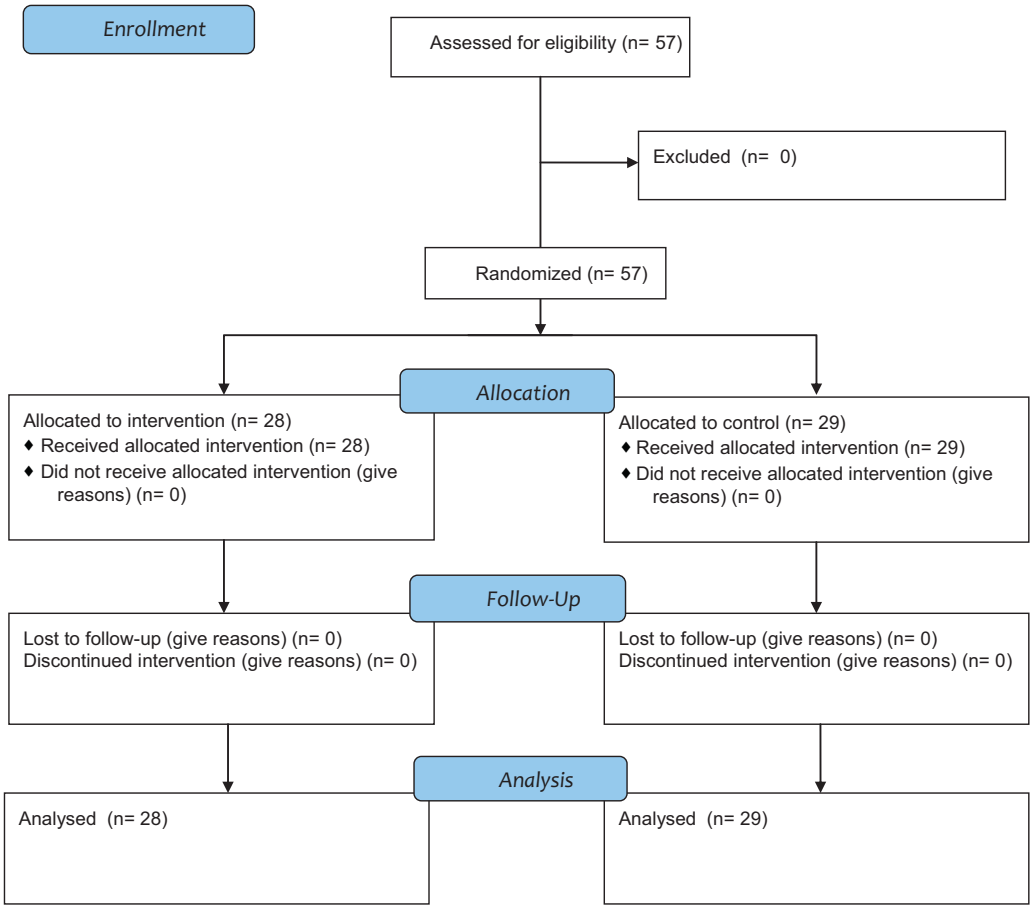

Fig. 1. Depiction of procedure.

nurse was finished, the researcher activated the robot again to pick up one of the toys and place it in a container. While doing so, it was programmed to state that one toy was dusty and asked the child to blow on it. In the meantime, the nurse positioned the child, raised the child's sleeve, cleansed the skin overlying the deltoid muscle, and administered the vaccine. The robot repeated the request to blow to ensure that if the nurse required more time to execute these tasks, the child would still have an opportunity to blow at least once. (3) After the injection, the researcher again activated the robot. It thanked the child for helping with the toy, made some encouraging statements to the child, and waved good-bye. During this time, the nurse placed an adhesive bandage on the child's arm. The robot was re-activated for each phase only when the child and nurse were ready. In the comparison condition children were also seated with their parent, and in front of the nurse. Several toy objects were also on a table beside the child. The nurse administered the vaccine using current immunization guidelines [31]. This included minimal distraction (e.g., "Look at the dinosaurs on the wall."). The nurses and parents were given no specific instructions about how to act in either condition. Rather, nurses were asked to administer the vaccination using standard guidelines for both conditions.

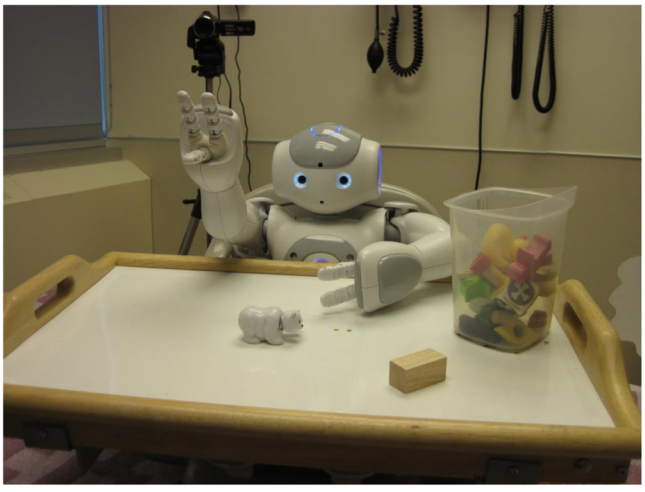

Fig. 2. Position of robot.

2.3.1. Description of robot

The robot NAO academic edition (Aldebaran Robotics®) was used ($12,000 CDN). Some of its features include an on-board fully programmable computer CPU: x86 AMD Geode with 500 MHz, 256 MB SDRAM and 1 GB flash memory, WiFi (802.11 g) and Ethernet, two cameras with up to 30 frames/s, two hands with self adaptive gripping abilities, force sensitive sensors on its arms and feet to perceive contact with objects, light emission diodes in its eyes and body, four microphones to identify the source of sounds, and two loud speakers for communication. It runs on a native Linux Operating system platform and can be programmed using a proprietary SDK called NaoQi, or in C, C++, Ruby and Urbi, which makes it compatible with other robot simulators such as Microsoft Robotics Developer Studio. It was programmed to execute the same series of commands for all children to ensure that everyone had the same experience with the robot.

Table 1
Demographic and medical characteristics by condition.

	Robot	Comparison	Statistic	*P*
Sex				
Boys	14	16	$\chi^2(1) = 0.15$	0.79
Girls	14	13		
Age	6.36 (1.34)	6.66 (1.65)	$F(1, 55) = 0.56$	0.46
Number of injections	0.54 (1.37)	0.45 (0.83)	$F(1, 55) = 0.08$	0.77
Distress at last vaccination				
Parent report	4.59 (1.52)	4.52 (1.62)	$F(2,53) = 0.02$	0.98
Child report	3.22 (2.10)	3.24 (1.92)		
Medical condition				
Yes	9	14	$\chi^2(1) = 0.11$	1.00
No	19	15		

Note: Means (SDs) are shown for age and number of injections.

Table 2
Means (SDs), *F* ratios, *P* values, and effect sizes of distress ratings.

	Robot	Comparison	*F*	*P*	Effect size
FPS-R ratings					
Parent	3.33 (3.37)	5.18 (3.73)	5.29	0.03	0.50
Child	2.44 (3.52)	4.37 (4.04)	4.46	0.04	0.49
Nurse	3.18 (3.34)	4.96 (3.52)	5.09	0.03	0.50
Researcher	3.48 (2.69)	5.48 (3.49)	6.89	0.01	0.62
BAADS					
Distress	1.68 (0.78)	2.61 (1.26)	9.76	0.003	0.79
Avoidance	2.40 (0.74)	3.24 (0.94)	11.22	0.001	0.90

2.4. Statistical analysis

A sample size of 57 was determined sufficient to achieve a power of 80% at a significance level of 0.05 to detect a conventional moderate effect size of 0.40 for between group comparisons [32]. Differences in demographic characteristics between the robot and comparison groups were first examined using chi square for nominal level data (i.e., sex, medical condition = yes/no) or analysis of variance (ANOVA) for ratio level data (i.e., age, number of injections). Differences in children's distress between the robot and comparison conditions were analyzed with a multivariate analysis of covariance (MANCOVA) for parent, child, nurse, and researcher scores on the FPS-R. The covariates were children's and parents' ratings of pain from their children's previous flu vaccination. The inclusion of these covariates allowed us to determine if the intervention led to reduced pain compared with the previous vaccination as well as with the control condition, thereby assessing whether previous distress accounts for any differences between conditions. Also, a MANOVA (multivariate analysis of variance) was used for scores from the two subscales of the BAADS. This method provides results considered robust for ordinal level data [33]. For all of the statistical tests, $p < 0.05$ was deemed significant. Statistical analysis was performed using SPSS 19.0 (SPSS Inc., Chicago, IL).

3. Results

3.1. Participant characteristics

This sample consisted of 30 boys and 27 girls ages 4–9 years ($M = 6.87$, SD = 1.34). The majority of children had no injections ($n = 44$, 77.2%), 9 (15.8%) had 1–2 injections, and 4 (7.1%) had 3 or more injections in the previous month. Many children ($n = 23$, 40.4%) had a chronic medical condition (e.g., asthma, cystic fibrosis). As shown in Table 1, there were no significant differences in participant characteristics between the two study conditions. In particular, age and sex were comparable. Also, the mean number of injections in the last month and the likelihood of having a chronic medical condition were similar for children in both conditions. In addition, there were no significant differences between the groups on children's or parents' ratings of pain at their previous vaccination according to ratings on the FPS-R.

3.2. Children's pain and distress

Ratings of pain and distress on the FPS-R and BAADS were first compared according to children's sex and age. There were no significant differences between boys and girls. Age was neither related with the exception of nurses' ratings of pain on the FPS-R, which were significantly and inversely correlated with age, $r = -0.26$, $p < 0.05$. The correlations of the FPS-R scores provided by parents, children, nurses and researchers of children's pain during the vaccination were high ($r = 0.83$–0.90, $p < 0.001$).

As shown in Table 2, parent, child, nurse, and researcher ratings of children's pain on the FPS-R were lower for the robot than the comparison condition, Wilks' Lambda = 0.88, $F(4,47) = 1.66$, $p < 0.05$. In addition, behaviors exhibiting distress and avoidance, according to the BAADS, were significantly lower for the robot than the comparison condition, Wilks' Lambda = 0.84, $F(2,46) = 6.13$, $p < 0.01$. All results were significant, and effect sizes, calculated as Cohen's *d*, were medium to large according to benchmarks [32].

Next, we examined whether the robot was effective with children who experienced the most pain to determine if the standardized delivery of distraction was as useful with them as with children who experienced less pain. Using data from the robot condition only, first we recoded children's pre-test FPS-R scores whereby values of 4–6 were coded as high, and scores of 1–3 were coded as low. Second, we calculated a change score by subtracting the children's post FPS-R scores from their pre scores. We used this change score as the dependent variable and compared the high and low pain groups using a one-way ANOVA. We found that there was a significant difference, $F(1,26) = 13.01$, $p < 0.01$, Cohen's $d = 1.40$, with children who reported higher pain at pre experiencing a greater reduction (mean = 2.33) than did children who reported lower pain at pre (mean = 0.19). Thus, it seems that it was more useful for children who reported more pain at their previous vaccination and that standardized programming of the robot was effective for them.

Responses to whether they would like the robot in the future were endorsed as follows. Children said "very much" (85.7%, $n = 24$), "a lot" (3.6%, $n = 1$), "unsure" (3.6%, $n = 1$), or "not at all" (7.1%, $n = 2$). Parents provided similar responses: "very much" (85.7%, $n = 24$), "a lot" (3.6%, $n = 1$), "unsure" (3.6%, $n = 1$), "a little" (3.6%, $n = 1$), or "not at all" (3.6%, $n = 1$).

4. Discussion

To our knowledge, no study has reported the application of a humanoid robot in the health care setting. This is a preliminary randomized controlled study, which determined that when distractions are facilitated by a robotic device, children experience significantly less pain and distress compared to children who are given little or no distraction during a commonly performed medical procedure, vaccination. With effect sizes in the moderate to high range, these effects are considered clinically significant [34]. Programmed to instruct children to blow and divert their attention to fun topics such as movies and music, it reduced children's pain and distress according to reliable and valid reports from parents, nurses, researchers, and children themselves. In addition to pharmacological and psychological interventions, this study suggests that technologically enhanced forms of distraction for management of pediatric pain be considered. Programmed with humanistic characteristics and to execute psychological strategies, a humanoid

robot shows promise of reducing procedural pain and distress in children.

Despite some reports of the effectiveness for psychological strategies [5,24], a review of approximately 30 studies concluded that their evidence is only "fair" when compared to no strategies [4]. With concerns about side effects of pharmacological treatment, psychological approaches are clearly desirable. They have not, however, been shown to be consistently effective for vaccination procedures [4]. A humanoid robot provides a highly engaging and entertaining distraction that is able to divert children's attention away from their worry of fear and pain of the vaccination. It was also able to illicit blowing behaviors from children. Moreover, the vast majority of children and parents indicated they would like to have the robot for future immunizations. Perhaps the novelty and surprise of seeing a robot strengthened the impact of the cognitive-behavioral strategies. Indeed, according to McCaul and Malott [13], the stronger the intensity of the distraction stimulus, the more effective the distraction will be, as it will remove children's attention more often from the painful stimulus.

There are several advantages to using a humanoid robot. It is programmed in advance of the procedure so that health care staff must only activate it when the child arrives. This requires minimal training (instruction on how to turn it on and off). Its speech and actions can be programmed according to the age of the child to ensure appropriate content and level of speech. Pending results from additional research, it may be beneficial for other medical procedures. Although more expensive than other distraction tools, such as videos and party blowers, it is versatile for other possibilities yet to be explored, such as educating families about disease and disease management. It can, moreover, be programmed with a variety of distractions such as music, stories, jokes, games, sounds, dance, and so on that are age appropriate and contemporary. Such programming can be done by simply dragging/copying icons from a library, or more complex actions can be created by copying and combining incremental movements into one fluid motion. These programming capabilities require minimal information technology support, which may be readily available at hospitals but perhaps not at clinics. Maintenance would include recharging the battery.

Results must be interpreted according to the following limitations. The study was conducted at a single center with experienced nurses who were interested in and not blinded to the purpose of the study (not possible as the robot was talking). In addition, the researchers who coded children's behaviors may have determined the purpose of the study from watching the videos and may have been biased, but their scores are consistent with the parents' and children's scores and yielded the same results. Data from multiple centers with more diverse staff are needed to determine if the results are generalizable. It is also unknown whether the distractions, the blowing, or their combination impacted distress. Also, although the cost is not prohibitive, it has yet to be determined whether it is more effective than other methods of distraction to justify the cost. However, academic and commercial developers are beginning to view robots as useful tools for helping children overcome the challenges posed by medical conditions such as autism [35]. Indeed, a recent report detailing diverse results on the use of robotics in health care shows that robotics can be one of the most important and cost-effective technologies to enter the health care system since Information Technology (IT) [36].

There are several avenues for further research needed to understand how children's engagement with a robot can reduce pain and distress. It is possible that the number of distractions, rather than the presence of the robot, is most engaging. Future research can examine whether the actions or the robot, per se, help children manage painful medical procedures by comparing a person's distracting behaviors with a robot's. Also, the relative importance of its physical appearance, comments, and actions must be further examined. Having determined that this novel intervention has a benefit to children, it is fitting to next compare it against other interventions and across children with varying characteristics such as type of illness, in-patient vs. out-patient status, and so on.

In the present study, the robot did not respond uniquely to children's behaviors. Rather, it was programmed to deliver the same behaviors for all children. We chose to standardize the robot in this way to make sure that all members of the experimental group had the same experience with the robot, and found that it is particularly effective for those who reported high levels of pain.

Feasibility studies must also determine if reduced pain and distress reduce procedural time. Although the cost may be prohibitive for some clinics, the durability of such robots can extend beyond 10 years, at which time the cost would be significantly lower (based on observed trends). Once programmed, minimal to no support would be needed, other than regular maintenance (i.e., $500/year). The dropping cost of robotic platforms and improvements in technology is setting the stage for significant growth and robot availability within the next decade or two. Considerable research is required to explore the role of humanoid robotics at the bedside, but this first study provides promising evidence from multiple sources that it can provide a beneficial impact.

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