

# Medical clowns ease anxiety and pain perceived by children undergoing allergy prick skin tests

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## Keywords

anxiety; medical clowns; pain; skin prick test.

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## Abstract

**Background:** Intervention of medical clowns (MC) during various medical procedures performed in children has been used to relieve anxiety and pain. Their role in allergy skin testing has never been evaluated.

**Objective:** To evaluate whether MC can diminish pain and anxiety perceived by children undergoing allergy skin prick tests (SPT).

**Methods:** In a prospective, randomized, controlled, and blinded study, children undergoing SPT were or were not accompanied by MC. All parents and children  $\geq 8$  years completed the State-Trait Anxiety Inventory (STAI) before and after SPT. Videotapes recorded during the procedure were scored for anxiety (m-YPAS) for all children and for pain (FLACC) for children 2–7 years old by a psychologist who was unaware of the MC's presence. After SPT, children  $\geq 8$  years completed a visual analog score (VAS) for pain.

**Results:** Ninety-one children (mean age 8.2 years, M/F = 54/37) were recruited of whom 45 were accompanied by clowns. A significant reduction in state-STAI was found in the clowns group, in both parents and children, when compared with the regular group ( $26.9 \pm 6.6$  and  $32.3 \pm 10.0$ ;  $P = 0.004$ , and  $27.1 \pm 4.2$  and  $34.3 \pm 7.6$ ;  $P = 0.002$ , respectively). Both m-YPAS and FLACC were reduced in the clowns group compared with the regular one. In the clowns group, m-YPAS positively correlated with both VAS and FLACC ( $P = 0.000$  and  $0.002$ , respectively). m-YPAS was positively correlated with FLACC in the regular group ( $P = 0.000$ ).

**Conclusion:** Medical clowns significantly decrease the level of anxiety perceived by both children undergoing allergy SPT and their parents, as well as the pain perceived by young children.

The health benefits of humor and laughter have gained growing interest and research over the past three decades although conclusive evidence about their benefits have still not been completely established (1, 2). Hunter 'Patch' Adams as a physician and Michael Christensen as a professional clown are often considered to be the founders of the medical clown movement (3, 4), and their number in pediatric settings has grown significantly over the last decade (5). A recent comprehensive publication addressing MC in pediatric practice provided a review of the pediatric literature, and reviewed studies examining the effect of clown interventions on various practical procedures and individual medical conditions (6). Most studies on MC have focused on medical procedures associated with pain and anxiety, especially in the preopera-

tive setting (7–12). The effect of MC has also been assessed out of the operation room in other medical procedures such as sexual abuse examination (13, 14), intra-articular injection for juvenile rheumatoid arthritis (15), and various medical interventions in pediatric malignancies or during cardiac biopsies performed during cardiac catheterization in heart transplant recipients (16) or in inpatients at a pediatric rehabilitation hospital (17). Most of these studies suggested that MC are a valuable tool in relieving pain and anxiety in children undergoing frightening or painful procedures.

Allergy skin prick tests (SPT) are the staple and the most common diagnostic procedure, performed in almost every allergic evaluation. Children, and occasionally their parents, often express anxiety and fear from the procedure, either

before, during, or after it was performed. We attempted to assess whether MCs may alleviate these emotions.

## Methods

### Patients

All consecutive children aged 2–17 years in whom SPT were required by the allergist were invited to participate in the study. During enrollment, the potential clown involvement was explained to children and parents. We suspected that a recent painful or frightening experience might have added an unwanted bias to the study results, by causing increased anxiety with regard to similar medical procedures. Therefore, children who had undergone painful medical procedures, such as surgery, venipuncture, intramuscular injection, or dental treatment, within 3 months prior to the SPT and children who suffered from fear of clowns (coulrophobia) were excluded. After parent's signing an informed consent approved by the Institutional Ethics Committee, parents and children completed the study questionnaires. Then, patients were randomly allocated to undergo SPT, accompanied or not by professional MC belonging to the 'Dream Doctors' organization, Israel.

### Study protocol

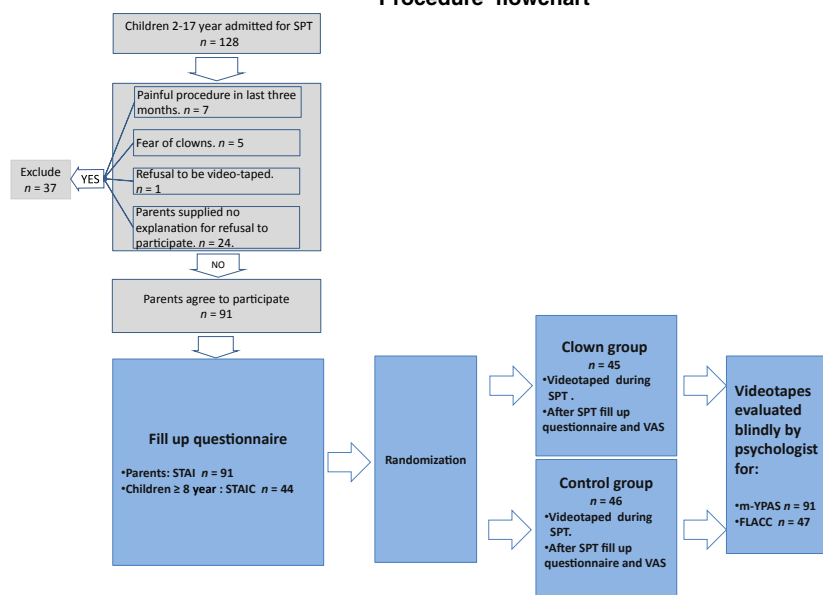
Parents of all children and children aged 8–17 years completed the State-Trait Anxiety Inventory (STAI and STAIC for children) questionnaires (18, 19) before they were allocated to one of the groups. The Hebrew versions of the STAI and STAIC questionnaires had been validated previously for both adults and children (20). Children were then accompanied by the allergist to the locations where SPT were performed. These sites were completely separated and located

within a one-minute walk from the allergist's office, thus providing for a minimal anticipation effect with regard to either procedure. Children accompanied by the clowns could not see the site where SPT were performed without clowns and vice versa. On both sites, children were video-taped throughout the procedure: in the waiting room, before meeting the nurse, while SPT were performed on the volar aspect of the arm and 15 min later, when SPT results were measured. Clowns accompanied the children belonging to their group from the moment they entered the waiting room until SPT results were read. While videotaping, the camera-men were instructed to focus on the patient only and to avoid any indication of clown presence nearby. Videotapes were edited later on, and special attention was once again provided so as to conceal the presence of the clowns. Two–three minutes of edited videotapes representing the time spent in the waiting room, during SPT performance and result reading were referred to a child psychologist who was unaware of the presence or absence of clowns from the video setting. Based on these videotapes, the psychologist filled the modified Yale Preoperative Anxiety Scale (m-YPAS) (21) for all children and the FLACC score (face, legs, activity, cry, and consolability) (22) for children aged 2–7 years.

Fifteen minutes after measuring SPT results, parents of all children and children aged 8–17 years completed once again the STAIC questionnaires and children  $\geq 8$  years old also filled a visual analog score (VAS) for pain. A flowchart of the study protocol is depicted in Fig. 1.

Skin prick tests were performed with ALK-Abello extracts (Horsholm, Denmark). Largest diameters of wheal and flare of all allergens were recorded. The largest diameter of the reaction to either *Dermatophagoides farinae* or *Dermatophagoides pteroyissinus* was considered as the representative value for house dust mites result.

### Procedure flowchart



**Figure 1** Flowchart of study protocol.

### Questionnaires and scores

The STAI and STAIC questionnaire is a self-reportable anxiety inventory which contains two separate 20-item subscales that measure state (situational) and trait (baseline) anxiety. There are specific inventories for adults (STAI) and children (STAIC) (21). The results of the inventories may range between 20 and 80 for adults and between 20 and 60 for children. The higher the score, the greater the anxiety expressed by the responder. This inventory has been widely used as a subjective measure in studies examining anxiety in various situations (18). Questionnaires that contained  $\geq 3$  unanswered items were rejected and were not included in the results.

The m-YPAS is an objective observational instrument which measures children's anxiety in the preoperative holding area and during anesthesia induction (23). The m-YPAS distributes 27 items into five categories that suggest anxiety in children: activity, emotional expressivity, state of arousal, vocalization, and use of parents. Each category is scored from 1 to 4, with the exception of vocalization which is scored from 1 to 6. Partial weights for each category are calculated and then added together to obtain a total score that may range between 0 (not anxious) and -100 (very anxious). Using the weighted  $k$  statistics for overall chance-corrected agreement ( $k_w$ ), the observer reliability has been shown to be good ( $k$  of 0.60–0.74) to excellent ( $k$  of 0.75–1.00) as well as having high concurrent and construct validity, compared with the gold standard of STAI and STAIC (8, 21).

FLACC is an objective observational scale which measures young children's pain (22). Results may range between 0 (no pain) and 10 (very painful).

### Statistical analysis

Nominal data were described as numbers and percentage and continuous parameters – as mean and standard deviation. Comparisons between treatment groups (Clowns vs Regular) or between subgroups of each of the treatment groups were analyzed according to type of data. For nominal parameters, chi-square test was used. Shapiro–Wilk's test was performed for testing normal distribution for continuous variables.  $T$ -test or Mann–Whitney nonparametric test was used, as well as paired  $t$ -test or Wilcoxon nonparametric test, each when appropriate. Repeated-measures ANOVA were used to test changes by time and group.

A difference was considered statistical when  $P < 0.05$ . All statistical analyses were performed using SPSS-21 software (IBM Corporation, Armonk, NY, USA).

### Results

One-hundred and twenty-eight children were screened, of whom 37 declined to participate. Reasons for avoidance of participation included refusal to be video-taped (one patient), fear of clowns (five patients) and having experienced a painful medical intervention within the previous 3 months (seven patients). Twenty-four patients provided no explanation for their refusal (Fig. 1). Thus, 91 patients were enrolled.

**Table 1** Patients' characteristic

|                            | Clowns<br><i>n</i> (%) | Regular<br><i>n</i> (%) | Refused<br><i>n</i> (%) |
|----------------------------|------------------------|-------------------------|-------------------------|
| Male                       | 29 (64)                | 25 (54)                 | 20 (54)                 |
| Female                     | 16 (36)                | 21 (46)                 | 17 (49)                 |
| Age, mean $\pm$ SD (years) | 8.02 $\pm$ 4.65        | 8.33 $\pm$ 4.58         | 7.3 $\pm$ 4.6           |
| 2–7 years                  | 24 (53)                | 23 (50)                 | 18 (49)                 |
| 8–17 years                 | 21 (47)                | 23 (50)                 | 19 (51)                 |
| Total                      | 45                     | 46                      | 37                      |

Patients' characteristics are presented in Table 1. There was no difference between the regular group and the clowns group with regard to age, gender and medical diagnosis.

The number of scratches performed in the clowns and regular groups was  $\leq 15$  in 17 and 24 patients (38% and 52%), respectively and  $> 15$  scratches in 28 and 22 patients (62% and 48%), respectively ( $P = 0.17$ ).

### STAI and STAIC

When the STAI and STAIC results of parents and children ( $\geq 8$  years old only) were compared between regular and clown groups (Tables 2 and 3), there was no difference between state anxiety before or trait anxiety both before and after SPT were performed. However, a significant reduction in state anxiety after SPT was found in the clowns group compared with the regular group, in parents as well as in children ( $26.9 \pm 6.6$  and  $32.3 \pm 10.0$ ;  $P = 0.004$ , and  $27.1 \pm 4.2$  and  $34.3 \pm 7.6$ ;  $P = 0.002$ , respectively). The effect of the clowns could also be demonstrated in the reduction of parents state-STAI before SPT compared with their state-STAI after SPT ( $31.3 \pm 7.7$  and  $26.9 \pm 6.6$ , respectively;  $P < 0.0001$ ) only in the clowns group whereas in the regular group parents state-STAI remained unchanged between before and after SPT ( $33.6 \pm 10.4$  and  $32.3 \pm 10.0$ , respectively). Similar differences could be noted in children's state-STAI where only in the clowns group a significant reduction was demonstrated between before and after SPT ( $30.3 \pm 5.4$  and  $27.1 \pm 4.2$ , respectively;  $P = 0.014$ ). No change was recorded in the regular group ( $33.6 \pm 5.7$  and  $34.3 \pm 7.6$ , respectively). Analyzing the data by repeated measures, we took into consideration time effect (before and after), group effect (clowns and regulars), and the interaction between time and group. The results were similar to those found in the univariate analysis within time and between groups. No significant interaction between time and group was found.

When the groups were subdivided according to their age, similar significant difference between the clowns and the regular group was present in the younger group (2–7 years) with regard to the parents' state anxiety after SPT ( $27.2 \pm 6.6$  and  $35.0 \pm 9.8$ ;  $P = 0.003$  in the clowns and regular group, respectively). As for the older age group (8–17 years), there was no difference between the two treatment groups in the trait or state anxiety of the parents, either before or after SPT. However, there was a significant difference in the children's state anxiety after SPT between the clowns and the

**Table 2** Parents' STAI

|                                 | Clowns |   |                 | Regular |   |                    | <i>P</i> -value |
|---------------------------------|--------|---|-----------------|---------|---|--------------------|-----------------|
| Parents' state-STAI before SPT  |        |   |                 |         |   |                    |                 |
| All children                    | 31.3   |   |                 | 33.6    |   |                    | 0.33            |
| Children age 2–7 years          | 32.2   | } | <i>P</i> = 0.39 | 35.8    | } | <i>P</i> = 0.18    | 0.27            |
| Children age 8–17 years         | 30.1   |   |                 | 31.5    |   |                    | 0.62            |
| Number of scratches in SPT < 15 | 31.6   | } | <i>P</i> = 0.79 | 34.6    | } | <i>P</i> = 0.51    | 0.48            |
| Number of scratches in SPT ≥ 15 | 31.0   |   |                 | 32.5    |   |                    | 0.58            |
| Parents' trait-STAI before SPT  |        |   |                 |         |   |                    |                 |
| All children                    | 34.0   |   |                 | 33.7    |   |                    | 0.94            |
| Children age 2–7 years          | 32.5   | } | <i>P</i> = 0.30 | 34.4    | } | <i>P</i> = 0.71    | 0.57            |
| Children age 8–17 years         | 34.8   |   |                 | 33.4    |   |                    | 0.57            |
| Number of scratches in SPT < 15 | 31.8   | } | <i>P</i> = 0.21 | 33.0    | } | <i>P</i> = 0.45    | 0.70            |
| Number of scratches in SPT ≥ 15 | 34.7   |   |                 | 35.0    |   |                    | 0.91            |
| Parents' state-STAI after SPT   |        |   |                 |         |   |                    |                 |
| All children                    | 26.9   |   |                 | 32.3    |   |                    | *0.004          |
| Children age 2–7 years          | 27.2   | } | <i>P</i> = 0.74 | 35.0    | } | <i>P</i> = 0.07    | *0.003          |
| Children age 8–17 years         | 26.5   |   |                 | 29.6    |   |                    | 0.24            |
| Number of scratches in SPT < 15 | 26.9   | } | <i>P</i> = 0.99 | 35.2    | } | * <i>P</i> = 0.045 | *0.009          |
| Number of scratches in SPT ≥ 15 | 26.9   |   |                 | 29.2    |   |                    | 0.30            |
| Parents' trait-STAI after SPT   |        |   |                 |         |   |                    |                 |
| All children                    | 32.0   |   |                 | 33.6    |   |                    | 0.40            |
| Children age 2–7 years          | 31.1   | } | <i>P</i> = 0.46 | 33.9    | } | <i>P</i> = 0.93    | 0.36            |
| Children age 8–17 years         | 33.0   |   |                 | 33.6    |   |                    | 0.81            |
| Number of scratches in SPT < 15 | 29.4   | } | <i>P</i> = 0.09 | 32.4    | } | <i>P</i> = 0.33    | 0.31            |
| Number of scratches in SPT ≥ 15 | 33.6   |   |                 | 35.2    |   |                    | 0.52            |

STAI, State-Trait Anxiety Inventory; SPT, skin prick test.

\* $P < 0.05$ .**Table 3** Children's STAIC

|                                  | Clowns |   |                  | Regular |   |                 | <i>P</i> -value |
|----------------------------------|--------|---|------------------|---------|---|-----------------|-----------------|
| Children's state-STAI before SPT |        |   |                  |         |   |                 |                 |
| All children (age 8–17 years)    | 30.3   |   |                  | 33.6    |   |                 | 0.10            |
| Number of scratches in SPT < 15  | 22.0   | } | <i>P</i> = 0.12  | 32.2    | } | <i>P</i> = 0.49 | 0.097           |
| Number of scratches in SPT ≥ 15  | 30.9   |   |                  | 34.1    |   |                 | 0.15            |
| Children's trait-STAI before SPT |        |   |                  |         |   |                 |                 |
| All children (age 8–17 years)    | 31.0   |   |                  | 32.0    |   |                 | 0.70            |
| Number of scratches in SPT < 15  | 42.0   | } | <i>P</i> = 0.12  | 28.5    | } | <i>P</i> = 0.20 | 0.13            |
| Number of scratches in SPT ≥ 15  | 30.2   |   |                  | 33.5    |   |                 | 0.30            |
| Children's state-STAI after SPT  |        |   |                  |         |   |                 |                 |
| All children (age 8–17 years)    | 27.1   |   |                  | 34.3    |   |                 | *0.002          |
| Number of scratches in SPT < 15  | 26.0   | } | <i>P</i> = 0.86  | 34.5    | } | <i>P</i> = 0.93 | 0.17            |
| Number of scratches in SPT ≥ 15  | 27.3   |   |                  | 34.2    |   |                 | *0.011          |
| Children's trait-STAI after SPT  |        |   |                  |         |   |                 |                 |
| All children (age 8–17 years)    | 27.4   |   |                  | 28.8    |   |                 | 0.66            |
| Number of scratches in SPT < 15  | 39.5   | } | <i>P</i> = 0.051 | 23.0    | } | <i>P</i> = 0.09 | *0.044          |
| Number of scratches in SPT ≥ 15  | 25.8   |   |                  | 31.0    |   |                 | 0.21            |

STAI, State-Trait Anxiety Inventory; STAIC, State-Trait Anxiety Inventory for Children; SPT, skin prick test.

\* $P < 0.05$ .

regular group ( $27.1 \pm 4.2$  and  $34.3 \pm 7.6$ ;  $P = 0.002$ , respectively).

The number of scratches performed during SPT might have affected the level of anxiety. Indeed, in children undergoing small number of scratches (<15), when the regular

group was compared with the clowns group, there was a significant decrease in parents' state-STAI after SPT ( $35.2 \pm 10.8$  and  $26.9 \pm 6.8$ ;  $P = 0.009$ , respectively). When this parameter was analyzed separately for the two groups, in the clowns group, no difference was observed in parents or

children's STAIC between children experiencing small or large ( $\geq 15$ ) number of scratches during SPT. In the regular group, parents' state-STAI after SPT was the only parameter that differed significantly between children experiencing small and large number of scratches ( $35.2 \pm 10.8$  and  $29.2 \pm 8.0$ ;  $P = 0.045$ , respectively).

#### modified Yale Preoperative Anxiety Scale

The m-YPAS was significantly reduced in the clown group compared with the regular group ( $31.8 \pm 12.1$  and  $45.6 \pm 22.8$ ;  $P = 0.001$ , respectively) (Table 4). The reduction in m-YPAS in the clowns group was significant for younger children (2–7 years) ( $36.0 \pm 13.5$  and  $58.5 \pm 24.8$ ;  $P = 0.0001$ ) as well as for the older children (8–17 years) ( $27.0 \pm 8.1$  and  $32.7 \pm 10.1$ ;  $P = 0.009$ , respectively). Upon analyzing the two treatment groups separately, younger children had significantly higher m-YPAS when compared with the older ones, both in the clowns group ( $36.0 \pm 13.5$  and  $27.0 \pm 8.1$ ;  $P = 0.009$ , respectively) as well as in the regular group ( $58.5 \pm 24.8$  and  $32.7 \pm 10.1$ ;  $P < 0.0001$ , respectively).

In the entire study population, a small number of scratches performed during SPT was associated with higher m-YPAS and vice versa. Thus, mean m-YPAS was  $33.5 \pm 11.9$  when  $\geq 15$  scratches were performed and  $45.2 \pm 24.6$  when  $< 15$  scratches were performed ( $P = 0.008$ ). Nevertheless, the reduction in m-YPAS in the clowns group compared with the regular group remained significant for small number of scratches ( $30.8 \pm 9.8$  and  $55.3 \pm 26.9$ ;  $P = 0.000$ , respectively) and nearly significant for large number of scratches ( $32.4 \pm 13.4$  and  $35.0 \pm 9.8$ ;  $P = 0.065$ , respectively). When m-YPAS was compared separately for the two treatment groups, this difference between children experiencing small or large number of scratches was evident only in the regular group ( $55.3 \pm 26.9$  and  $35.0 \pm 9.8$ ;  $P = 0.002$ ), whereas in the clowns group, there was no such difference ( $30.8 \pm 9.8$  and  $32.4 \pm 13.4$ , respectively).

#### Face, legs, activity, cry, and consolability

The FLACC score which was evaluated only for children 2–7 years old was significantly reduced in the clowns group compared with the regular group ( $1.58 \pm 1.89$  and  $4.39 \pm 3.16$ ;  $P = 0.001$ , respectively). In children undergoing SPT with small number of scratches, FLACC was significantly reduced in the clowns group when compared with the regular group ( $1.0 \pm 1.8$  and  $5.0 \pm 3.2$ ;  $P = 0.000$ , respectively). There was no difference in FLACC in the whole group or in the clowns group regarding the number of scratches performed during SPT. However, in the regular group, there was a tendency for higher FLACC in children experiencing small number of scratches ( $< 15$ ) as compared with children experiencing large number of scratches ( $\geq 15$ ) ( $5.0 \pm 3.2$  and  $2.2 \pm 1.8$ ;  $P = 0.08$ , respectively).

#### Visual analog score

Although the VAS for pain which was evaluated only for children 8–17 years old was lower in the clowns group compared with regular group, this difference was not statistically significant ( $1.94 \pm 2.10$  and  $2.57 \pm 1.94$ ;  $P = 0.34$ , respectively). Small or large number of scratches did not affect the VAS of the whole group or that of the clowns group. It tended to be lower in patients of the regular group who underwent small as compared with large number of scratches, but this difference did not reach statistical significance ( $1.3 \pm 1.0$  and  $3.1 \pm 2.0$ ;  $P = 0.062$ , respectively).

#### Correlations

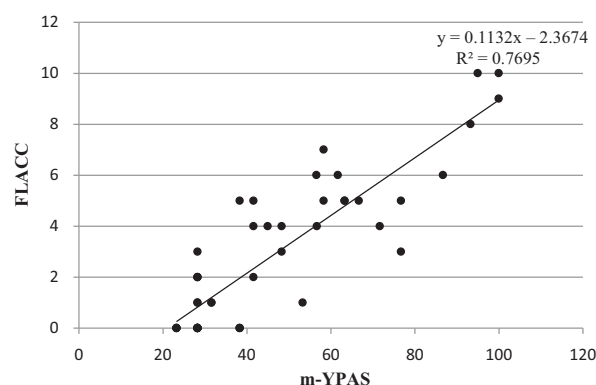
The entire group exhibited a positive significant correlation ( $P < 0.0001$ ) between m-YPAS and FLACC in the younger children (Fig. 2) and m-YPAS and VAS ( $P = 0.001$ ) in the older children. Upon evaluating these correlations separately for the two different groups, these correlations remained

**Table 4** m-YPAS, FLACC, and VAS

|                                      | Clowns |                 | Regular |                  | P-value |
|--------------------------------------|--------|-----------------|---------|------------------|---------|
| m-YPAS                               |        |                 |         |                  |         |
| All children                         | 31.8   |                 | 45.6    |                  | *0.001  |
| Children age 2–7 years               | 36.0   | } * $P = 0.009$ | 58.5    | } * $P < 0.0001$ | *0.001  |
| Children age 8–17 years              | 27.0   |                 | 32.7    |                  | *0.009  |
| Number of scratches in SPT $< 15$    | 30.8   | } $P = 0.68$    | 55.3    | } * $P = 0.002$  | *0.000  |
| Number of scratches in SPT $\geq 15$ | 32.4   |                 | 35.0    |                  | 0.065   |
| FLACC                                |        |                 |         |                  |         |
| All children (age 2–7 years)         | 1.58   |                 | 4.39    |                  | *0.001  |
| Number of scratches in SPT $< 15$    | 1.0    | } $P = 0.10$    | 5.0     | } $P = 0.08$     | *0.000  |
| Number of scratches in SPT $\geq 15$ | 2.3    |                 | 2.2     |                  | 0.94    |
| VAS                                  |        |                 |         |                  |         |
| All children (age 8–17 years)        | 1.94   |                 | 2.57    |                  | 0.34    |
| Number of scratches in SPT $< 15$    | 1.3    | } $P = 0.64$    | 1.3     | } $P = 0.06$     | 0.93    |
| Number of scratches in SPT $\geq 15$ | 2.0    |                 | 3.1     |                  | 0.19    |

mYPAS, modified Yale Preoperative Anxiety Scale; VAS, visual analog score; SPT, skin prick test; FLACC, face, legs, activity, cry, and consolability.

\* $P < 0.05$ .



**Figure 2** Correlation between m-YPAS and FLACC in the whole group. mYPAS, modified Yale Preoperative Anxiety Scale; FLACC, face, legs, activity, cry, and consolability.

significant in the clowns group ( $P = 0.002$  and  $0.000$ , respectively), whereas in the regular group, only the correlation between m-YPAS and FLACC was positively significant ( $P = 0.000$ ).

There was a positive significant correlation ( $P = 0.016$ ) between m-YPAS and parents' state-STAI after SPT in the whole group. The entire group also demonstrated a significant correlation ( $P < 0.0001$ ) between m-YPAS and children's state-STAI after SPT in children 8–17 years old. Upon evaluating these correlations separately for the two different groups, m-YPAS correlated significantly with older children's state-STAI before SPT only in the clowns group and with older children's state-STAI after SPT only in the regular group ( $P = 0.006$  and  $0.004$ , respectively).

Visual analog score positively correlated with state-STAI in older children (8–17 years) both before and after SPT ( $P = 0.001$  and  $0.047$ , respectively) only in the clowns group but not in the regular group.

When correlations between VAS, m-YPAS, and FLACC were examined, there was a positive significant correlation between m-YPAS and both VAS and FLACC in the clowns group ( $P = 0.000$  and  $0.002$ , respectively) and between m-YPAS and FLACC in the regular group ( $P = 0.0001$ ).

### Skin prick tests

Largest diameters of wheal and flare results of various allergens were compared between the clowns and the control groups. Age and gender of the children whose SPT results were compared did not differ between the two different groups. Data on the most common positive allergens and the histamine positive control are presented in Table 5. Milk wheal was significantly larger in the clowns group compared with the regular group. Histamine wheal in the clowns group was also larger when compared to the regular group, but this difference was only nearly statistically significant ( $P = 0.054$ ). There was no difference between flares sizes of all antigens or between house dust mite wheals.

**Table 5** Prick skin tests results

| Allergen/group              | Patients number | Mean size $\pm$ SD | <i>P</i> -value   |
|-----------------------------|-----------------|--------------------|-------------------|
| Histamine wheal (mm)        |                 |                    |                   |
| Regular                     | 41              | $4.8 \pm 2.0$      | $\dagger 0.054$   |
| Clowns                      | 39              | $4.1 \pm 1.5$      |                   |
| Histamine flare (mm)        |                 |                    |                   |
| Regular                     | 41              | $17.1 \pm 6.8$     | $\dagger 0.420$   |
| Clowns                      | 39              | $16.1 \pm 7.8$     |                   |
| House dust mites wheal (mm) |                 |                    |                   |
| Regular                     | 31              | $5.9 \pm 6.1$      | $\dagger 0.836$   |
| Clowns                      | 33              | $6.5 \pm 7.0$      |                   |
| House dust mites flare (mm) |                 |                    |                   |
| Regular                     | 31              | $17.5 \pm 17.5$    | $\dagger 0.750$   |
| Clowns                      | 33              | $19.2 \pm 18.8$    |                   |
| Milk wheal (mm)             |                 |                    |                   |
| Regular                     | 10              | $6.7 \pm 4.5$      | $*\ddagger 0.048$ |
| Clowns                      | 6               | $2.3 \pm 2.6$      |                   |
| Milk flare (mm)             |                 |                    |                   |
| Regular                     | 10              | $18.9 \pm 11.8$    | $\ddagger 0.128$  |
| Clowns                      | 6               | $9.0 \pm 11.9$     |                   |

\* $P < 0.05$ .

$\dagger P$ -value in Mann–Whitney nonparametric test.

$\ddagger P$ -value in *t*-test.

### Discussion

Almost every allergic evaluation includes SPT. Like many other medical procedures, SPT may induce anxiety and pain in children undergoing this procedure. Several trials have been made to alleviate these shortcomings of SPT, including various devices for skin testing (24–30), prior application of local anesthetic cream (31–36), vapocoolant spray (37), local antihistamine (32), distraction techniques (38), and hypnosis (39). Some of the techniques are still debated, and some were associated with adverse reactions (36).

Although MC have been used successfully in various frightening and painful medical procedures in children (7–16), their roles have never been evaluated in prick skin testing which is the most common diagnostic procedure in allergy. The present study clearly demonstrates the superiority which medical clown have over conventional methods in alleviating both pain and anxiety in children undergoing allergy SPT, as well as alleviating the anxiety perceived by their parents.

The STAI and STAIC are considered the gold standard in evaluating anxiety (21). Although there was no difference between the regular and the clowns groups in parents' state or trait-STAI before performance of SPT or in their trait-STAI after SPT performance, there was a significant decrease in the parents' state-STAI after SPT in the clowns group when compared with the regular group. The decrease in parental anxiety in the clowns group is also reflected in the significant decrease of their state-STAI before SPT compared with the one after SPT. When evaluating these results separately for younger or older children and for large or small number of scratches performed during the SPT, this difference between the clowns

and the regular groups remained significant only for younger children (2–7 years) and for a small number (<15) of scratches (Table 2). Similar results were obtained for the anxiety perceived by the children themselves (age 8–17 years): only state-STAI after SPT was significantly decreased in children accompanied by clowns when compared to the regular group (Table 3). In contrast to the results in parents' STAI after SPT, children's STAI after SPT was significantly decreased in the clowns group only when a large number ( $\geq 15$ ) of scratches was performed during SPT.

The subjective decreased anxiety in the clowns group, presented by the state-STAI after SPT, was similarly reflected in the objective expression of anxiety, the m-YPAS. This parameter, evaluated by a blinded indifferent observer, was also significantly decreased in the clowns group when compared with the regular group. These differences in favor of the clowns group were significant not only for the whole group but also for younger and older children, as well as for large and small numbers of scratches performed during SPT. As might be expected, in both the clowns and regular groups, m-YPAS was significantly increased in younger children. However, and in contrast to intuitive and initial assumptions, a small number of scratches compared with a large number was associated with a significantly increased m-YPAS only in the regular group. This resembles parents' state-STAI before SPT which was also significantly higher when small compared with large numbers of scratches was performed during SPT, only in the regular group. Although there is no good explanation for these findings, their reliability is demonstrated when similar results were obtained for both the objective and the subjective parameters of anxiety in the same subgroup of patients. This reliability is also reflected in the correlation found between m-YPAS and both parents' and children's state-STAI and STAI post-SPT in the whole group.

The VAS, which represents the subjective pain perceived by older children, also correlated significantly with the subjective children's state-STAI, but only in the clowns group. Three possible explanations may account for this. First, fundamentally, as pain and anxiety are different emotions, there is most likely no correlation between the two in the first place. Second, the number of participants was not big enough, and third, in objectively measured experimental pain assessment, VAS was found to be unreliable (40). The FLACC, which is an objective assessment of the degree of pain perceived by younger children, did not correlate with STAI. This could also be explained similarly. Nevertheless, when these three parameters were compared, a significant correlation was found between m-YPAS and both VAS and FLACC in the clowns group and between m-YPAS and FLACC in the regular group. These correlations as well as the correlation mentioned above between m-YPAS and state-STAI post-SPT in children of the regular group all support the reliability of our results.

Stress and anxiety have been shown to increase wheal size in immediate SPT (41). In our study, a significant increase in the wheal size of milk skin test was noted in the control group compared with the clowns group and a nearly statistically

significant difference ( $P = 0.054$ ) was noted upon comparing the histamine wheal size between the two treatment groups. These results provide still more indirect evidence for the stressogenic effect of regular SPT as compared with SPT accompanied by clowns. As we did not observe similar difference upon comparing house dust mite wheals, these results ought to be assessed cautiously.

The current study is the first prospective study addressing the impact of medical clowns on pain and anxiety perceived by children undergoing allergy SPT. Pain and anxiety might be perceived differently in various cultures and societies. Therefore, the beneficial effects of MC found by us should be re-evaluated in other countries. In addition, we evaluated 91 children. Larger groups of children might be needed to substantiate our findings. Video-taped MC for a child to watch or other means such as audiotaped, animated, and televised cartoons with clowns might provide cheaper and more accessible alternatives to live MC. These possibilities should be investigated in future studies.

The data presented here clearly demonstrate the efficacy of MCs in alleviating anxiety and pain in children under going SPT as well as the anxiety perceived by their parents. Obviously, adding MC to the routine team of allergy clinic will be associated with additional expenses as well with possible impact on other members of the health care team (6). This point has been investigated in other medical situations, and in general, it was found to be beneficial. Its role in SPT ought to be examined specifically, but nevertheless, children and parents will definitely benefit from the contribution of MC to allergy skin prick testing.

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### Author contributions

A.G. and R.CC. designed the study with input from T.S., O.P., P.H., and L.E.; A.G. and R.CC. analyzed the data and drafted the manuscript and together with T.S. were responsible for the clinical care of the patients; P.H. and L.E. were the medical clowns; O.P. evaluated the m-YPAS and the FLACC. All authors contributed to and approved the final version of the manuscript.

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### Conflicts of interest

PH and LE are employees of 'Dream Doctors' which is funded by the Magi Foundation, Israel. All other authors declare no conflict of interest.

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