

Clowns in Paediatric Surgery: Less Anxiety and More Oxytocin? A Pilot Study

Clowns in der Kinderchirurgie: weniger Angst und mehr Oxytocin? Eine Pilotstudie

Authors

Tabea Scheel¹, Dorothea Hoepfner², Anne Grotevendt³, Winfried Barthlen⁴

Affiliations

- 1 Work and Organizational Psychology, FernUniversität in Hagen, Hagen, Germany
- 2 Health Psychology, Universität Potsdam, Potsdam, Germany
- 3 Clinical Chemistry, Universitätsmedizin Greifswald, Greifswald, Germany
- 4 Pediatric Surgery, Universitätsmedizin Greifswald, Greifswald, Germany

Key words

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Bibliography

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Correspondence

Dr. Tabea Scheel

Work and Organizational Psychology

FernUniversität in Hagen


Universitätsstraße 33D

58097 Hagen

Germany

Tel.: +49/2331/987 2157, Fax: +49/2331/987 2179

tabea.scheel@fernuni-hagen.de

 Supplementary Fig. 1, Supplementary Table 1 finden Sie unter <http://dx.doi.org/10.1055/s-0043-106854>.

ABSTRACT

Background Hospital stays and medical interventions are accompanied by worries and anxiety in children and parents. Recent studies show that hospital clowns may reduce anxiety

and enhance well-being. However, so far studies are based solely on subjective measures and clowns are usually not integrated in medical routine. With this pilot study, we aim to provide both psychological and physiological evidence of positive effects of clowns' interventions in hospitalized children.

Patients/Method In a consecutive randomized intervention-control group design with 31 children aged 4 to 13 years, 17 patients were accompanied by a clown prior to surgery or during ward round (intervention group) and 14 were not (control group). Saliva samples for oxytocin measurement were taken from all patients before hospitalization (T1) and prior to surgery or after ward round (T2). Self- and parents-reports were obtained at T1, T2 as well as at time of discharge from hospital (T3) regarding children's anxiety (STAI), worries and well-being. Clowns evaluated their success in cheering up the child. Health professionals were asked for their acceptance of clowns in hospitals.

Results Children in the intervention group had lower anxiety ratings and a higher oxytocin concentration at T2 as compared with T1; the control group showed no changes. Parents rated the well-being of their children higher if their child had clown's contact and were more willing to recommend the hospital. The staff judged the clowns as helpful for patients.

Discussion Consistent psychological and physiological results suggest the positive impact of a clown's intervention in hospitalized children.

ZUSAMMENFASSUNG

Hintergrund Krankenhausaufenthalte und medizinische Behandlungen sind bei Kindern und Eltern mit Sorgen und Ängsten verbunden. Aktuelle Studien zeigen, dass Krankenhausclowns Angst reduzieren und Wohlbefinden steigern können. Allerdings basieren Studien bisher nur auf subjektiven Maßen und Clowns sind üblicherweise nicht in die medizinische Routine integriert. Daher soll unsere Pilotstudie psychologische und physiologische Belege für die positiven Effekte von Clownsinterventionen bei Kindern im Krankenhaus liefern.

Patienten/Methode In einem konsekutiven randomisierten Interventions-Kontrollgruppen-Design mit 31 Kindern (4–13 Jahre) wurden 17 Patienten vor der Operation bzw. während der Visite (Interventionsgruppe) von Clowns begleitet, während 14 nicht begleitet wurden (Kontrollgruppe). Speichelproben für die Oxytocin-Messung wurden von den Kindern vor

der Einweisung (T1) und vor der Operation/Visite (T2) genommen. Selbst- und Elterneinschätzung zu T1, T2 sowie bei Entlassung (T3) wurden bezüglich Angst der Kinder (STAI), Sorgen und Wohlbefinden erhoben. Clowns schätzten ihren Erfolg bei der Aufheiterung der Kinder ein. Das medizinische Personal wurde nach ihrer Akzeptanz von Clowns im Krankenhaus gefragt.

Ergebnisse Kinder in der Interventionsgruppe hatten zu T2 geringere Angstwerte sowie eine höhere Oxytocinkonzentra-

tion als zu T1; die Kontrollgruppe zeigte keine Änderung. Die Eltern der Kinder in der Interventionsgruppe schätzten das Wohlbefinden ihrer Kinder höher ein und waren gewillter, das Krankenhaus zu empfehlen. Das Personal bewertete die Clownsinterventionen als hilfreich für Patienten.

Diskussion Konsistente psychologische und physiologische Befunde weisen auf die positive Wirkung von Clowns für Kinder im Krankenhaus hin.

Introduction

Hospital stays or medical interventions are highly straining for children and their parents [18]. It has been shown that, awaiting surgery, children usually are tense, nervous and anxious [15, 17]. Parents' anxiousness in turn increases childrens' anxiety [15, 28].

Therefore, methods have been searched to reduce this vicious circle. Beside pharmacological intervention (e. g., midazolam), other coping strategies have been investigated, for instance, psychological preparation [16], parental acupuncture or playing video-games [22]. Also, clown interventions may be used [2, 11, 14, 29].

Clown interventions in medical treatment showed positive effects in the reduction of childrens' stress symptoms [3, 19, 26]. Laughing with clowns is said to have effects on 3 levels: neurochemically, by the release of endorphins, cognitively by distraction from pain, and socially by enhancement of the communication and trust between physician and children [1]. Studies reported that laughing relaxes muscles [25], increases oxygen uptake [12], the levels of salivary immunoglobuline A [20] as well as pain thresholds [31], and stimulates the immune system [4].

However, concerns about the acceptance of clowns in hospital routine by medical personnel have been expressed [29].

Aim of our study was to evaluate the effects of clowns as members of the therapeutic team in a tertiary pediatric surgical unit by combined psychological and physiological assessment. Psychological results were obtained by validated psychological scores and physiological data by measurement of oxytocin in children's saliva. Oxytocin is known for its physiological role in lactation and parturition, enhances wound healing [7], modulates stress [8] and indicates well-being [9]. However, its role in clown interventions for children has not been evaluated before. We hypothesized that clowns are able to reduce anxiety and enhance well-being in children, resulting in more satisfaction with the hospital experience.

Material and Methods

Patients

The data were collected in a tertiary pediatric surgical ward and outpatient department. A total of 31 children aged 4–13 years were included of whom 18 children had ambulatory surgery and 13 children had stationary treatment. Of these groups, 28 children had valid oxytocin samples. While 14 children (6 girls) were consecutively assigned to the control group, 17 children (3 girls) were included in the intervention group. Mean age of all children was

8.93 years (standard deviation (*SD*) = 2.57; $M_{\text{control}} = 8.07$ years, $SD_{\text{control}} = 2.73$; $M_{\text{intervention}} = 9.69$ years, $SD_{\text{intervention}} = 2.24$). One parent per child answered the parents surveys ($n = 31$).

Written informed consent was obtained from all children and their parents. The study was conducted according to the declaration of Helsinki and has been approved by the ethics committee of the University Medicine Greifswald (No. BB075/15).

Study design

In a consecutive randomized intervention – control group design the first measurement (T1) took place at the admission talk in the outpatient or stationary environment, respectively. The second measurement (T2) was conducted, after clown intervention or not, right after the ward round or prior to surgery, respectively. The third measurement (T3) was at time of discharge from hospital.

Procedure

During three weeks, children in the intervention group were accompanied by 2 clowns prior to surgery or during the ward rounds, while clowns were not present in these situations in the control group, which took place several weeks before and after the intervention phase.

Saliva samples were taken from all patients twice (T1, T2). Psychological evaluation by means of paper-pencil questionnaires were obtained at T1, T2 and T3 from children and parents regarding their anxiety, emotions, worries and well-being (see below). Clowns evaluated their success in cheering up the child after each visit. Similarly, hospital professionals were asked for their acceptance of clowns in hospitals prior to and past the intervention phase.

Proceedings differed slightly between outpatient and stationary patients. Psychological assessment and a saliva sample were taken at T1 during preliminary talk (outpatient) respectively admission procedure (stationary). Patients for outpatient surgery returned several days later in the morning for treatment. If participating in the intervention group, clowns entertained them in a separate room until the patient was brought to the operation theater. Immediately before anesthesia induction (or any pharmacological premedication), a questionnaire for children and parents was delivered and a saliva sample was taken from the child (T2).

T2 evaluation for stationary patients including questionnaires and saliva acquisition took place directly after the morning ward round. For the intervention group, clowns entered the patients' room first and prepared the child mentally for the physicians' come. They supported the children during the physical examinations associated with the ward round. The control group was

assessed identically but had no clown contact. Length of clown intervention varied from 5 to 120 min. The third measurement (T3) took place right before the discharge from the hospital in both groups; outpatients in the afternoon of the same day and stationary patients usually after a 2 days hospital stay.

Psychological assessment

Anxiety

The State-Trait Anxiety Inventory [21] was used at T1 in the trait version (STAI-T) and at T1, T2, and T3 in the state version (STAI-S) for children's and parents' self-ratings. The trait subscale measures rather stable personality differences in anxiety proneness; the state subscale measures situation-dependent transitory anxiety states (e. g., apprehension, tension, worry). In the trait version, 13 items (e. g., "I feel depressed") had to be rated from 1 = almost never to 4 = almost always, and in the state version, 10 items (e. g., "I feel tense") had to be rated from 1 = not at all to 4 = very much. Cronbach's α reliability ranged from 0.80 to 0.92 for STAI-T and from 0.78 to 0.92 for STAI-S.

Emotion

The Self-Assessment Manikin [6] (SAM) measures emotional states. Five graphic figures (mannequins) have to be rated for each of three dimensions: valence (ranging from happy to unhappy), arousal (reversed, ranging from highly aroused to calm) and dominance (from small/no control to large/control). SAM is theoretically based in the semantic differential, easy to implement and culture- and language-free. The children were asked to cross out the picture which was most like how they feel (T1, T2, T3).

Worries

Worries were assessed specifically for the hospital context, using the Child Surgery Worries Questionnaire [27] (CSWQ). Children were asked to answer 11 items regarding worries about hospitalization (e. g., "I worry about how they'll anesthetize me") and 6 items regarding worries about the medical procedure (e. g., "I worry about whether or not my parents can stay with me in hospital") at T1 and T2. For ethical reasons, a third subscale (illness and its negative consequences) was excluded. Ratings had to be given on a 5-point Likert scale from 0 = not at all to 4 = extremely worried. Cronbach's α reliabilities for both subscales and both measurement times ranged from 0.83 to 0.92.

Well-being

Prior to discharge from the hospital (T3) children were asked how well they felt during hospital stay (from 1 = not at all to 4 = very much). Also, their parents were asked how well his/her child felt during hospital stay on the same scale.

Parent's satisfaction

At T3, parents were asked regarding 1) their own satisfaction with the treatment, 2) whether they would recommend the hospital to others, and 3) whether they would choose the hospital again (from 1 = not at all to 4 = very much).

Health professional's acceptance

The Questionnaire for Health Professionals [29] obtains the medical staff's opinion of the presence of clowns in the hospital routine.

Health professionals were asked twice, before and right after the intervention phase, for their opinion of the presence of clowns in hospital routine (1 = very favorable to 5 = very contrary), whether they perceived the clowns as useful for children, for parents, for staff (1 = yes, 2 = no, 3 = I do not know), whether clowns were a disturbance for the medical treatment (1 = yes, 2 = no, 3 = sometimes), and whether they are favorable of a continuance of the clowns activity at the ward (1 = yes, 2 = no).

Clown effectiveness

Clowns filled in the Clown Effectiveness Self-Evaluation Form [29] about their interaction with the child immediately after their contact. Four items covered the extent to which the child looked interested, participated, reacted positively, and smiled (from 1 = for nothing to 5 = very much). 2 additional items asked for the extent that the child laughed and the extent that contact with the child could be established. Time of intervention and incidents in form of an open question were also reported.

Physiological assessment

Saliva samples were taken from each participant at 2 time points (T1, T2) with a median length of 2 days in-between. No stimulant was used for saliva sampling. Participants were asked to chew on a cotton swab (Salivette®; Sarstedt, Nuembrecht, Germany) for one minute. As the half-life period of this neuropeptide is short (< 2 min in plasma), the samples were stored immediately on dry ice. All samples were stored at -80°C and analyzed batch-wise for oxytocin concentration in saliva using an EIA (Enzyme Immuno Assay) Kit (Caymen Chemicals, Ann Arbor, USA) as described by manufacturer's recommendation. Ultrapure water (Berlin Pharma, Germany) was used to prepare all EIA reagents and buffers. Temperature of all phases of the work-up did not exceed 6°C . Centrifugation was performed at 4211 g for 15 min. For further stabilization and analyses, 50 mmol/l sodium citrate solution (PPS Natrium Citricum 3.13%, MediPac) were added to the centrifuged sample. Furthermore, a solid phase extraction was performed using a reversed-phase, silica-based octadecylsilane cartridge (pore size 70 Å, particle size 50 μm) to reduce matrix effects. The solution was reduced to dryness by a constant stream of argon gas and resuspended with EIA buffer. All samples were measured in triplicates using a Sunrise™ microplate absorbance reader (Tecan, Maennedorf, Switzerland). Absorbance was transferred into an oxytocin concentration in pg/mL by applying a reference curve. The EIA kit displayed a detection limit of approximately 18 pg/mL. Internal quality control measures were performed each run using two levels of control materials. The inter-assay coefficient of variation was 18.7% at low level (mean value = 107.1 pg/mL) and 13.6% at high level (mean value = 287.9 pg/mL).

Statistical Analyses

Data with respect to psychological assessment were analyzed with the use of SPSS 22.0 for Windows (IBM). Significance was accepted at $p < 0.05$. Beside descriptive statistics, *t*-tests for between-group comparisons (i. e., between intervention and control group) were conducted. To compare changes in psychological parameters/salivary oxytocin levels between T1 and T2 in each group separately, paired *t*-tests were used. Additionally for the physiological data, a repeated

measure analysis of variance (ANOVA) was performed to test for an effect of time, treatment as well as an interaction between both.

Results

Anxiety

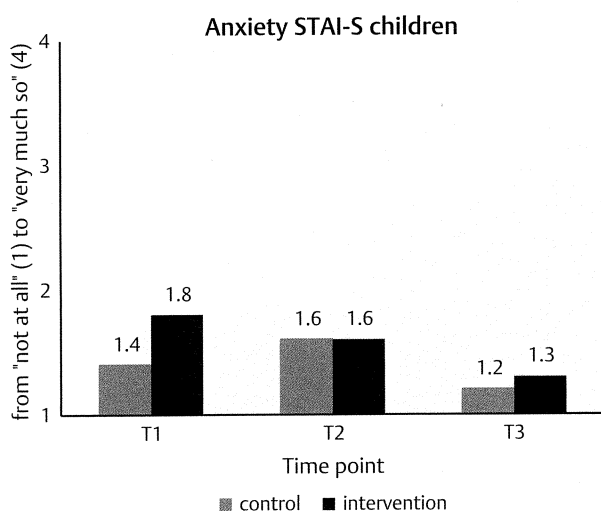
Children in the intervention group had lower anxiety ratings (STAI-S) at T2 than at T1 ($M_{T1} = 1.83, SD_{T1} = 0.66$, vs. $M_{T2} = 1.58, SD_{T2} = 0.4$, $t/16 = 2.089, p = 0.053$, ► **Fig. 1**), while the control group was unchanged from T1 to T2 ($M_{T1} = 1.41, SD_{T1} = 0.32$, vs. $M_{T2} = 1.55, SD_{T2} = 0.47, t/12 = -0.905, ns$). Interestingly, the control group reported initially significantly lower anxiety at T1 as compared to the intervention group (STAI-S and STAI-T). Parent's anxiety was not significantly different between groups (STAI-T, STAI-S). At T3 (discharge), anxiety and worries were lowest in all groups (► **Fig. 1**).

Emotion

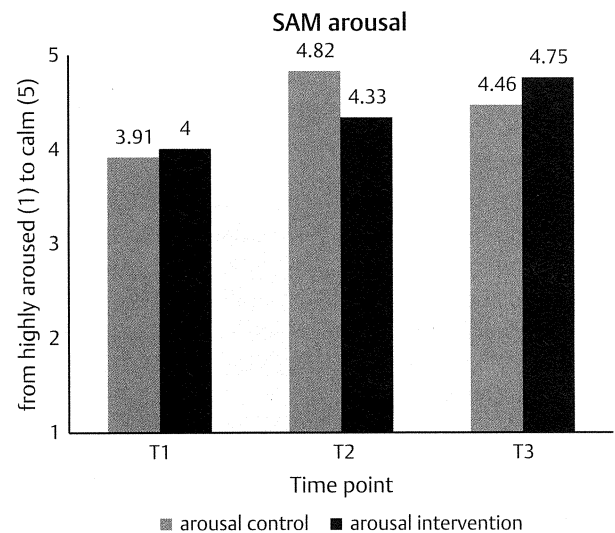
SAM ratings of arousal were higher (reverse coded, refers to "calmer") at T2 as compared to T1 for the control group ($M_{T1} = 3.91, SD_{T1} = 1.22$, vs. $M_{T2} = 4.82, SD_{T2} = 0.41, t/10 = -2.319, p = 0.043$, ► **Fig. 2**) but not within the intervention group ($M_{T1} = 4.0, SD_{T1} = 1.28$, vs. $M_{T2} = 4.38, SD_{T2} = 0.87, ns$). Ratings for valence or dominance showed no significant differences neither between groups nor measurement times (► **Fig. 3**).

Worries

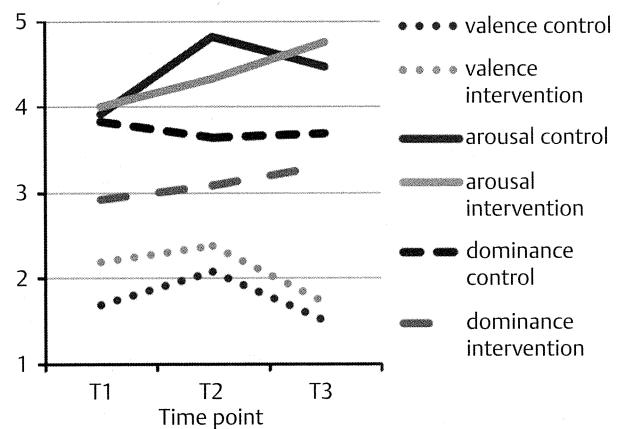
Children in the intervention group ($n = 13$) reported by trend lower worries about hospitalization at T2 as compared to T1 ($M_{T1} = 1.01, SD_{T1} = 0.71$, vs. $M_{T2} = 0.63, SD_{T2} = 0.7, t/12 = 2.032, p = 0.065$), while the worries of the control group ($n = 8$) remained unchanged ($M_{T1} = 0.50, SD_{T1} = 0.44$, vs. $M_{T2} = 0.27, SD_{T2} = 0.36, ns$) (data not shown). Again, like in the STAI-S, the intervention group showed



► **Fig. 1** Anxiety STAI-S children of intervention and control group T1, T2, T3. Mean of STAI-S (children; from 1 = „not at all“ to 4 = „very much so“) at admission to the hospital (T1), prior to surgery/ after ward round (T2) and at discharge from the hospital (T3). The intervention (clown) group is more anxious primarily than control group but decreases to the level of the control group at T2.



► **Fig. 2** SAM arousal children of intervention and control group T1, T2, T3. Mean of Arousal (SAM, children; from 1 = „highly aroused“ to 5 = „calm“) at admission to the hospital (T1), prior to surgery/ after ward round (T2) and at discharge from the hospital (T3). The control group is significantly less aroused (i.e., more calm) at T2 compared to T1.



► **Fig. 3** SAM (arousal, dominance, valence) children of intervention and control group T1, T2, T3. Mean of SAM subscales Arousal (from 1 = „highly aroused“ to 5 = „calm“), Valence (from 1 = „unhappy“ to 5 = „happy“), Dominance (from 1 = „no control“ to 5 = „control“) at admission to the hospital (T1), prior to surgery/ after ward round (T2) and at discharge from the hospital (T3). The control group is significantly less aroused (i.e., more calm) at T2 compared to T1.

by trend initially higher worries about hospitalization at T1 as compared to the control group. The ratings of worries about medical procedure were not significantly different between groups or measurement times (T1 and T2).

Further results

While **children's self-ratings** of how well they felt during hospital stay were comparable between groups ($M_{intervention} = 3.59, SD_{intervention} = 0.62$ vs. $M_{control} = 3.50, SD_{control} = 0.52$), **parent's ratings** were

higher for children in the intervention group than for the control group ($M_{intervention} = 3.71$, $SD_{intervention} = 0.59$ vs. $M_{control} = 3.14$, $SD_{control} = 0.86$, $t/29 = -2.15$, $p = 0.04$) (data not shown). Satisfaction with treatment (parent-rating) was comparable between groups.

Hospital recommendations

At T3, parents from the intervention group had higher ratings of the intention to recommend the hospital to others than parents of the control group ($M_{intervention} = 3.88$, $SD_{intervention} = 0.49$ vs. $M_{control} = 3.14$, $SD_{control} = 0.86$, $t/29 = -2.85$, $p = 0.01$) and reported a higher tendency of choosing the hospital again ($M_{intervention} = 3.82$, $SD_{intervention} = 0.53$ vs. $M_{control} = 3.36$, $SD_{control} = 0.84$, $t/29 = -1.88$, $p = 0.07$) (data not shown).

Medical staff opinion

Eight health professionals answered at T1 and ten at T2. Although the presence of the clowns in hospital routine was judged as unfavorable at T1 ($M_{T1} = 3.88$, $SD_{T1} = 0.83$) and at T2 ($M_{T2} = 3.90$, $SD_{T2} = 0.74$), 7 out of 8 staff members judged the clowns to be useful for children at T1 ($n = 1$ did not know) and 10 out of 10 at T2.

Six out of 8 team members judged clowns to be useful for parents at T1 ($n = 2$ did not know) and 8 out of 10 at T2 ($n = 2$ did not know). Concerning usefulness for their own work, staff members answered yes at T1 in 5 cases ($n = 1$ no, $n = 2$ did not know), however, at T2 7 persons said no. Clowns were no disturbance for the medical treatment at T1 for 4 persons, and at T2 for 6 persons. The continuance of clown activity at the ward was advocated by most health professionals.

Control clown effectiveness

The average rating for all items of the Clown Effectiveness Self-Evaluation Form ranged between 3.71 ($SD = 1.26$) for laughing and 4.47 ($SD = 0.62$) for smiling and contact. Time of intervention was on average 37.81 min ($SD = 36.82$).

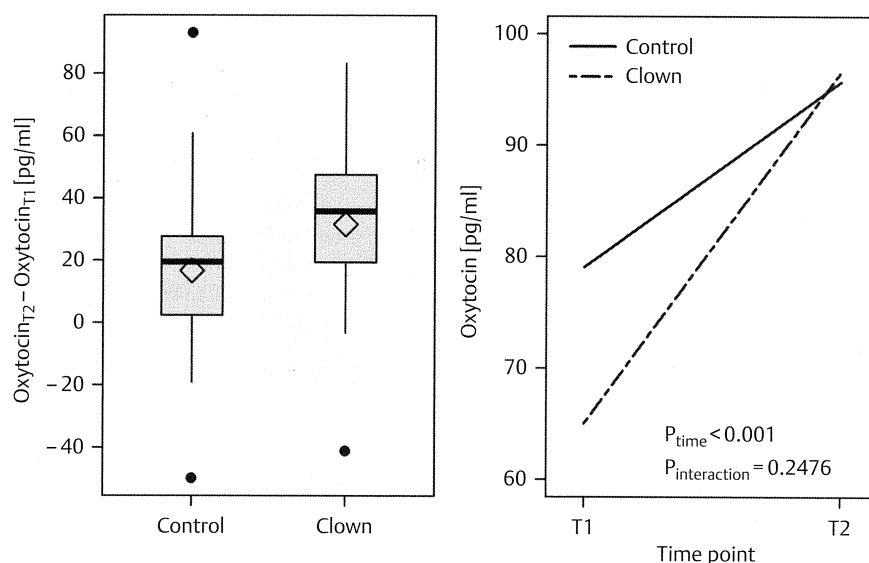
Oxytocin laboratory analysis

Simple group comparison revealed a significant effect of the clown intervention between both time points ($p = 0.002$, see Supplementments), whereas no trend in the control group became apparent ($p = 0.117$). However, a combined analysis of time and treatment revealed time ($p < 0.001$) as the main effect, whereas the clown intervention led to no significant improvement (► Fig. 4, left panel) (Supplementary Fig. 1) (Supplementary Table 1).

Discussion

In our study, we confirmed the results of previous studies that clown intervention results in a decline in anxiety in children prior to surgery [11, 14, 29] as compared with children treated without clowns. However, our intervention group showed a higher level of anxiousness already initially at T1 which is explainable only by a random distribution in a small size group. Although the clown intervention was said to be unfavorable for routine work by the health professionals, and judged to be not useful for their own work at T2, most of them think that it is useful for children and parents and the intervention should be continued. This positive acceptance is mirrored by prior studies [2], but stands in contradiction to Vagnoli et al. [29] where the majority of staff was opposed to continuing the program. This reflects the difficulty in establishing new methods in hospitals. The clowns reported a high success rate in inducing laughter and making contact with the children. These hospital clowns at issue are organized as a registered association, with obligatory self-organized workshops and trainings. However, the clowns are heterogeneous with regard to their background (theater training vs. self-taught), and their work experience as clowns.

We observed a more pronounced increase in oxytocin saliva levels after intervention (as compared with T1) in the clowns group than in the control group. The latter group is of course also treated



► Fig. 4 SAM (arousal, dominance, valence) children of intervention and control group T1, T2, T3. Mean of SAM subscales Arousal (from 1 = „highly aroused“ to 5 = „calm“), Valence (from 1 = „unhappy“ to 5 = „happy“), Dominance (from 1 = „no control“ to 5 = „control“) at admission to the hospital (T1), prior to surgery/ after ward round (T2) and at discharge from the hospital (T3). The control group is significantly less aroused (i.e., more calm) at T2 compared to T1.

kindly and care-giving by nurses, physicians and parents. Furthermore, the clowns group showed a lower oxytocin level in saliva and a concomitant higher anxiety level already initially at the first contact with the hospital. The incremental effect of clowns interventions needs to be investigated in an enlarged, age- and sex-matched cohort, to carve out the beneficial effect that is suggested by our results. The endogenous neuropeptide oxytocin has recently been shown to reflect psychological well-being, feeling of security and tenderness [9, 10, 24]. As a noninvasive extraction mode, sputum samples are preferable to blood samples in children. Though investigated intensely [13, 5, 30], oxytocin measurement in saliva poses a challenge for itself [23], for instance regarding the half-life period in sputum samples and intra/interindividual variation, which needs to be addressed to validate oxytocin as biomarker in saliva.

Besides the simultaneous evaluation of psychological and neuroendocrinological parameters before and after clown intervention, which to the best of our knowledge has not been evaluated in children in this setting before, a further strength of this study consists in establishing clowns as normal members of the medical team. In most former studies [3] clowns visited the children in the afternoon, in idle moments when all medical measures had subsided. Additionally, our clown intervention time has been much longer than in most previous studies. The main weaknesses of our pilot study are the small patient number and the heterogeneity of both children and clowns. That is, given the initial differences between the samples with regard to anxiety and (though nonsignificant) age and the non-standardized qualification program for clowns in combination with their variance in experience, we strongly recommend a large-scale standardized study to draw firm conclusions.

Conclusion

In a small controlled pilot study, we could show for the first time a simultaneous decrease in anxiety and a more pronounced increase in oxytocin saliva levels after clown intervention in children waiting for surgery or after the ward round. Further controlled randomized high-volume multicenter studies are needed to underline the necessity in establishing clown doctors as normal members of the medical team as they are already present for instance in Switzerland and Argentina.

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Contributor's Statement

Study conceptualization: Barthlen, W. Study, instrument design: Scheel, T. Coordination/supervision data collection: Barthlen, W. Data analyses: Hoepfner, D. Supervision data analysis: Scheel, T. Oxytocine

analyses: Grotevendt, A. Initial draft: Scheel, T. Revision manuscript: Scheel, T., Hoepfner, D., Grotevendt, A., Barthlen, W.

Conflict of interest

The authors have no conflict of interest to disclose.

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