STUDY PROTOCOL

Effects of clown visits on stress and mood in children and adolescents in psychiatric care—Protocol for a pilot study

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Abstract

Scientific evidence has shown that healthcare clowning can decrease the level of stress and anxiety in pediatric patients. However, little attention has been devoted to the potentially beneficial impact of clown visits in the child and adolescent psychiatry setting. Therefore, this pilot study aims at investigating short-term effects of clown visits by RED NOSES Clown doctors Austria on stress and mood levels of children and adolescents in psychiatric care. The sample will consist of approximately 50 children and adolescents in inpatient psychiatric wards who receive clown visits on a weekly basis over four consecutive weeks. The examined intervention, i.e., the clown visits, is an integral part within the selected psychiatric institutions. Using a non-controlled pre-/post-test design, the level of salivary cortisol and self-reported stress and mood will be measured as primary outcomes before and immediately after each clown visit. Additionally, self-reported effects on care staff at the health care facilities will be assessed based on a questionnaire after each clown visit within the same time period of four weeks. Secondary outcome measures (i.e., health-related quality of life, emotional and conduct problems, perceived chronic stress) will be assessed at baseline and at close-out assessment after the four intervention weeks. Further control variables and potential moderators are included at baseline. Due to the nested data structure, multilevel modeling will be used to analyze the data. To our knowledge, this is the first study to examine the stress-reducing and mood-improving effects of clown visits on inpatients in child and adolescent psychiatry. Results will be relevant for the design of future large-scale RCTs and might provide valuable implications for the use of healthcare clowning to reduce stress and improve mood in children and adolescents in psychiatric care. The study is registered at ClinicalTrials.gov (Identifier: NCT04844398).
Background

Hospitalized children often face a range of demanding experiences. Stress and anxiety are prevalent phenomena during hospital stays [1, 2]. Preoperative anxiety in pediatric patients is one of the primary outcomes investigated in previous research [3–5], although children report other problems as well; for example, hospitalized children often feel “alone, […] mad, and sad” [6]. Pain, loss of control, and disconnection from family and relatives can lead to physical and psychological impairments [7]. Even after discharge, children may exhibit symptoms of distress, such as restlessness and lower self-esteem [8]. In children in psychiatric care, stress and anxiety can be even more pronounced, as they might be part of the symptoms requiring inpatient treatment in the first place, and the process of adaptation to the context of hospitalization can exacerbate primary symptoms [9].

To address these issues and alleviate their impact on the patients’ well-being, humor interventions have been identified and used as an effective treatment in hospitals for decades [10, 11]. Most commonly, these take the form of professional hospital clowns and are either carried out in independent visits or integrated into hospital routines. In Austria, such interactive clown performances are offered, inter alia, by RED NOSES Clowndoctors Austria, which is part of RED NOSES International (RNI), a non-profit association providing professional clown programs in the medical and social care settings. RNI identifies three target areas of healthcare clowning for clinical patients stemming from common problems associated with hospitalization: (a) Social disconnection: patients may be separated from family and friends for a prolonged period of time, resulting in feelings of loneliness and exclusion; (b) Painful emotions: patients may experience heightened levels of stress, fear, and anxiety; (c) Challenging environments: hospital environments may be unable to provide adequate psychosocial support, leading to feelings of boredom and powerlessness [12]. Healthcare clowning aims at addressing these issues by offering individual attention to patients in need, switching focus away from negative emotions to humorous play, and valuing a patient’s unique strengths in an otherwise possibly impersonal environment. These encounters lead to improved communication, attention, energy, and mood [13]. Moreover, healthcare clowning has been conceptualized as a model for a more self-compassionate way of dealing with one’s own shortcomings and hardships [14]. Presumably, a particularly suitable target group for the clowning approach are children and adolescents, who might respond especially well to clowning due to the immediate, non-intellectual approach [14]. Clown interventions in hospital settings are therefore assumed to be highly effective among pediatric inpatients.

Previous research on the effectiveness of healthcare clowning has mainly focused on interactive clown performances for children and adolescents in intensive care or undergoing medical surgery. Specifically, clown visits have been shown to reduce preoperative anxiety [15, 16] and stress [17], salivary cortisol [18], pain during medical procedures [19, 20], and the need for sedation [21] in pediatric patients. With the exception of a few pilot studies with adult patients [22–24], little attention has been paid to potential benefits of clowns in the psychiatric setting. For adult patients in a closed psychiatric ward, an interactive clown performance during a period of bi-weekly clown visits led to reduced disruptive behaviors, including less agitation, aggression, and self-injury [24]. To our knowledge, there is no prior study that has investigated the impact of clown visits in the setting of child and adolescent psychiatry. Hence, the current pilot study aims at addressing this gap.

A small number of studies have demonstrated positive effects not only for patients, but for medical staff as well. Anesthetists appreciated the presence of clowns accompanying their medical rounds [25], and professionals performing venipuncture benefitted from less anxiously agitated patients when assisted by clowns [26]. Most prominently, strong effects were...
observed on nursing staff, where clown interventions have been shown to improve nurse-patient interactions [27, 28] as well as professional communication throughout their workday [28]. Ghaffari et al. [29] found that humor enhanced nurses’ mental and emotional well-being; the authors further highlighted its ability to promote an energetic and creative state for nurses in clinical settings as well as help them to overcome sadness and despair [30]. This finding was supported by other studies reporting reduced negative mood in nurses experiencing the clown performances [28]. In a pilot study, Wild et al. [31] described pediatric psychiatric care staff reports about the helpfulness of healthcare clowning in their daily routine and their expressed support to continue the program—a finding that other scholars have reported similarly [28, 32].

Study aims and hypotheses

To our knowledge, this pilot study is the first to investigate the impact of clown visits on stress and mood of children and adolescents in inpatient psychiatric care, examining patients’ salivary cortisol in addition to self- and staff-reports on stress and mood perception. A second novelty is that we assess effects on stress and mood over the course of multiple visits, allowing for insight into dose-response relationships. We expect that children and adolescents involved in an interaction with the clowns will experience a decrease in their subjective and physiological stress levels as well as improved mood by redirecting their attention to the current pleasurable moment. Specifically, we hypothesize that (1) children and adolescents will report less perceived stress and improved mood and that (2) they will display a reduced cortisol level after the experience of a clown visit compared to before. We further expect that (3) the more frequently children and adolescents experience the weekly clown visits over the course of the four-week intervention, the stronger the stress-reducing and mood-improving effects will be. Last, we assume that (4) perceptions of care staff will indicate positive effects of the clown visits on their own individual mood, the atmosphere within the staff team, and the patients’ well-being.

Materials and methods

Participants

This pilot study will be conducted with children and adolescents of any gender and psychiatric diagnoses who currently are inpatients in Austrian child and adolescent psychiatric institutions cooperating with RED NOSES Clowndoctors Austria. Specific inclusion criteria are (1) being aged between 7 and 18 years and (2) regular participation in clown visits at the relevant health care facility on a weekly basis. Exclusion criteria are (1) potential negative impacts of clown visits or study participation on participants’ mood or well-being according to medical or paramedical care staff of the relevant health care facility and (2) insufficient command of German (for self-administered questionnaires only).

Participants will be recruited from two cooperating psychiatric healthcare facilities in Austria. The visits will take place in at least two different wards of each participating psychiatric care facility. In each ward, a maximum of 10 participants will be targeted. The four-week intervention assessments will take place twice in both clinics with different patients (time interval of approximately four to seven weeks between the two assessment phases). The first recruitment phase is initiated by a staff member of RED NOSES Clowndoctors, who regularly visits those clinics. Within the clinics, the recruitment process will be assisted by the care staff of the relevant wards. After being informed about the study goals and data collection process, care staff will evaluate the eligibility of specific patients regarding potential negative impacts of clown visits or study participation. If there are no anticipated negative consequences on
participants’ health or well-being, informed consent will be obtained from participants and, in case of underage participants, their parents or legal guardians prior to the start of data collection.

Based on effect sizes reported in reference studies [18, 33–39] we computed the minimum sample size needed for identifying the expected effects assuming rudimentary paired one-tailed t-tests using G’Power [40]. Calculating with $\beta = .20$, $\alpha = .05$, and expected effect sizes for cortisol levels ($f = .25$), self-administered measures of stress ($f = .44$), anxiety ($f = .47$), and emotional state ($f = .23$), a minimum sample size of about 30 participants in total (children and adolescents together) is needed. It is of note that the effect sizes for emotional state were derived from adult samples due to a lack of child and adolescent data. All other estimates were based on child samples. Accounting for dropout and random variation, a sample size of at least 50 children and adolescents will be targeted.

**Trial design**

This pilot study uses a non-controlled pre-/post-test design. There is no control group and no variation in intervention to be evaluated; thus, the study contains only one arm. See Fig 1 for an overview of the study schedule according to the SPIRIT 2013 Statement [41].

**Procedure**

At baseline, standardized questionnaires will be used to assess participants’ sociodemographic data, general mental and physical health status, emotional and conduct problems, perceived stress, and coping mechanisms. Participants will be administered paper-pencil versions of the undermentioned measures and will be asked to fill them out by themselves under supervision of the examiners. Additionally, the assigned care staff will provide basic clinical information for each participant in form of a self-administered questionnaire. In this session, participants will be assigned a pseudonymized code. Following baseline assessment, salivary cortisol as well as self-administered questionnaires on stress and mood states of participants will be collected before and after each clown visit on a weekly basis over four consecutive weeks. Immediately after the fourth clown visit, the self-administered questionnaires from the baseline assessing secondary outcome measures will be presented a second time. Effects on care staff at the health care facilities will be assessed within the same time period of four consecutive weeks based on a self-administered questionnaire completed after each clown visit. Fig 2 outlines the study procedure and assessments per time point.

**Intervention**

Clown visits will be carried out routinely by two professional clown artists from RED NOSES Clowndoctors Austria once a week for four consecutive weeks either in a group setting or an individual setting. The selection of artists, type of setting (group or individual), duration of clown visits, and specific artistic sequences will correspond to usual clown visits in those institutions, following internally organized routines instead of being standardized. The essence of the clown visit is to catch the patient’s attention proactively and reach the highest possible level of engagement. The specific artistic sequences and type of setting are implemented spontaneously according to the situational atmosphere and current condition of participants. One clown visit in the group setting will last between 1 and 2 hours including individual as well as collective attention depending on age, number of participants, and situational atmosphere. In the individual setting, each participant will be engaged individually between 5 and 20 minutes by the clown, depending on the situational mood and condition of the patients. The clown artists are not involved in any study-related research activities.
Primary outcome measures

Perceived stress. Subjective stress levels of children and adolescents will be assessed in a self-administered manner with one item (“Right now I am feeling stressed.”) using a 100-mm
visual analogue scale (VAS) before as well as immediately after each of the four clown visits. The item asks participating children and adolescents to draw a line where they would currently place themselves on the VAS ranging from 0 (not at all stressed) to 100 (very much stressed). Age-appropriate anchor graphics are placed at both extremes to support comprehension. The VAS approach has been used and validated in a number of previous studies in stress research [42, 43].

**Perceived mood.** The original German short version of the self-administered Multidimensional Mood Questionnaire (MDMQ) [44] will be used to measure adolescents’ different dimensions of current mood states (pleasant–unpleasant; awake–sleepy; calm–restless) before as well as immediately after each of the four clown visits. The MDMQ provides four-item scales to measure each dimension. Participants respond to the statement "At this moment I feel . . ." by means of adjectives (e.g., "content"; "tired"; "agitated"; "well") on a 5-point Likert scale from 1 (not at all) to 5 (very much). The validity and reliability of the measure have been shown [45]. For children aged between 7 and 11 years, we adapted the scale to an age-appropriate picture-based version with two items per dimension rated on a similar 5-point Likert scale from 1 (not at all) to 5 (very much).

**Salivary cortisol.** Saliva samples of cortisol are collected as a marker for the physiological stress response of children and adolescents. Salivary cortisol reflects the activity of the HPA axis. We will use Salicaps collection devices consisting of collection tubes and straws. Samples will be collected immediately before as well as immediately after each of the four clown visits in a self-administered way, but under the supervision of the examiners. Participants will be thoroughly instructed to collect accumulated saliva for two minutes without swallowing. After the two minutes, participants will transfer the accumulated saliva into the Salicap tube via the straw. Tubes are then stored locally at the health care facility at -20˚C prior to transport to and analysis in the biochemical laboratory.

**Secondary outcome measures**

**Health-related quality of life.** Children’s and adolescents’ health-related quality of life will be assessed at baseline and at close-out assessment immediately after the fourth clown visit by the self-administered German revised questionnaire Health-Related Quality of Life (KINDL-R) [46, 47]. We will use the three subscales physical health (sample items: “During the past week I felt ill” or “. . . I had a headache or tummy-ache”), mental health (sample items: “. . . I had fun and laughed a lot” or “. . . I was bored”), and self-esteem (sample items: “. . . I was proud of myself” or “. . . I felt pleased with myself”). Each subscale consists of four items rated on a 5-point Likert scale from 1 (never) to 5 (always). Age-appropriate versions of the
questionnaire are used for children and adolescents. The validity and reliability of the German self-administered version have been demonstrated [48].

**Emotional and conduct problems.** Children and adolescents will complete the five-item emotional problems and conduct problems subscales of the self-administered Strengths and Difficulties Questionnaire (SDQ) [49] adapted for use in German [50] at baseline and at close-out assessment immediately after the fourth clown visit. Sample items assessing emotional problems are: “I am often unhappy, depressed, or tearful” or “I have many fears; I am easily scared”. Sample items measuring conduct problems are: “I take things that are not mine (from home, school, or elsewhere)” or “I get very angry and often lose my temper.” Responses are 0 = not true, 1 = somewhat true, and 2 = certainly true. The validity and reliability of the German self-administered version have been supported in past research [51, 52].

**Perceived chronic stress.** The self-administered Perceived Stress Scale (PSS) [53] assesses one’s own subjective stress in the last month. Participants will be asked to evaluate the ten items on how often they experienced certain states, e.g., “In the last month, how often have you been angered because of things that were out of your control?” or “In the last month, how often have you found that you could not cope with all the things you had to do?” on a 5-point Likert scale ranging from 0 (never) to 4 (very often), once at baseline and at close-out assessment immediately after the fourth clown visit. A global value of perceived stress is obtained from summing up all responses after reversing positive items. The German version of the PSS will be used [54], which has been proven valid and reliable within a German sample including adults and adolescents [54]. Only adolescents from the age of 11 years will complete this questionnaire, as it is not age-appropriate for younger children.

**Evaluation of care staff.** A self-administered questionnaire for care staff at the health care facilities assesses effects of clown visits on their own mood, the atmosphere within the care team, and the patients’ well-being after each of the four clown visits. The questionnaire was developed by the authors specifically for the study purpose on the basis of previously implemented research tools [32, 55]. The items were partly self-developed and partly translated into German, adopted according to the study’s objectives, newly designed and formulated in accordance with previous research [32, 55]. The questionnaire includes 20 items. Using a 4-point Likert scale from 1 (very negative) to 4 (very positive) with an additional fifth option (no change perceived), assigned care staff will assess the extent of individual changes according to specific emotion-related domains like energy level, concentration, sense of sympathy, or serenity. Following the same scaling, care staff is further asked to evaluate the impact of the clown visits on work related items like general atmosphere in the ward, teamwork within the care staff, or ability to provide empathic care to the patients.

**Potential control variables and moderators**

**Control variables (examiners).** The examiners that will carry out data collection procedures on-site will complete a self-administered questionnaire assessing the date of assessment, name of examiner, name of the health care facility, type of setting (group or individual), number of participants (if group setting), pseudonymized identification codes of participating children and adolescents, start and end time of the clown visit (duration), time of saliva sample collection (pre and post), and special incidents for each clown visit.

**Sociodemographic and clinical data and control variables for salivary cortisol (children and adolescents).** A self-administered questionnaire to assess children’s and adolescents’ sociodemographic data includes information about gender, age, type of school attended before psychiatric admission, first language, and number of previously experienced clown visits. Further, psychiatric diagnoses or reasons for treatment, admission date at the clinic, number of
previous clinic stays, current treatment (forms of therapy), current medication, attending in-house clinic schooling, and somatic comorbidities are assessed by a self-administered questionnaire filled out by care staff. Control variables for salivary cortisol are measured by a self-administered questionnaire completed by children and adolescents (i.e., intake of food, chewing gums, or relevant drinks (i.e., coffee, tea, cola, juices, and alcohol); tooth brushing or smoking within an hour before the collection of the saliva samples; whether they did sport in the last 48 hours; whether they took medication on the same day; and whether they feel healthy).

**Sociodemographic data (care staff).** A self-administered questionnaire to assess care staff’s own sociodemographic data includes information about type of care staff, age, gender, extent and duration of employment in the relevant clinic, and first language.

**Perceived enjoyment.** A self-developed and age-appropriate self-administered 5-point Likert scale with one item assesses how participants and care staff enjoyed the clown visit from 0 (not at all) to 4 (very much) after each of the four clown visits.

**Coping with stress.** The self-administered Stress and Coping Questionnaire for Children and Adolescents (SSKJ 3–8) [56] is a German measure to assess stress and coping styles in children and adolescents. At baseline, participating children and adolescents will complete the coping style scale of the SSKJ 3–8, encompassing 30 items that describe coping strategies to reduce stress. Participants are prompted in written form to evaluate how regularly they exhibit the described behaviors on a 5-point Likert scale ranging from 1 (never) to 5 (always). These correspond to five subscales consisting of six items each, namely seeking social support (e.g., “I tell one of my family members what happened”), problem-focused coping (e.g., “I decide for a way to solve the problem”), avoidance (e.g., “I act as if everything was o.k.”), constructive-palliative coping (e.g., “I try to do something relaxing”), and destructive-anger-focused coping (e.g., “I get angry and destroy something”). The SSKJ has shown good validity (convergent, discriminant) and reliability (Cronbach’s alpha, retest) for all subscales [57].

**Statistical analysis**

Due to the nested data structure (outcomes being nested within time points and in turn nested within participants), change in primary outcome measures (i.e., perceived stress and mood, salivary cortisol) will be analyzed by means of multilevel modeling using R packages (e.g., lme4 package [58]) to disentangle within-subject and between-subject variance. Level 1 comprises variables that are assessed repeatedly (i.e., the primary outcomes assessed before as well as immediately after each of the four clown visits), whereas level 2 specifies time points. Level 3 comprises of individual participants. Note that to prevent convergence issues, the best-fit model out of the following models will be used to test hypotheses: Fixed slope, random intercept for level 2 and 3 (Model 1); random slope at level 3 (Model 2); random slope at level 2 (Model 3); random slope at levels 2 and 3 (Model 4).

Given the complexity of the models, further analyses are to be considered exploratory in view of the small sample size of this pilot study. Potential moderator effects (number of visits, enjoyment, baseline variables) will be examined by testing cross-level interactions, provided the best-fit model allows for these analyses.

Missing data will be handled with full-information maximum likelihood (FIML) estimation, which uses all available information in the variance/covariance matrix to compute model parameters and produces less biased estimates than listwise or pairwise deletion or mean substitution [59]. Statistical significance will be assumed at $\alpha \leq .05$, as conventional. To reduce the chance of false discovery, alpha error correction will be applied using the Benjamini-Hochberg procedure [60].
Ethics, data management and dissemination

Research ethics approval

The present study has been reviewed and approved by the institutional review boards of the University of Vienna (Reference number: 00675; Date of approval: 3 May 2021; see S1 File) and the Medical University of Innsbruck (Reference number: 1272/2021; Date of approval: 24 November 2021). We comply with APA ethical standards and the Code of Ethics of the World Medical Association (Declaration of Helsinki) for research involving humans.

Consent or assent

All clown artists, clinic staff and participants interested in participation will receive verbal and written information from the study staff. Prior to the start of data collection, written consent must be obtained from all participants and one legal guardian of each underaged participant, as well as an assent from the care staff.

Confidentiality

We comply with statutory provisions concerning the collection, storage, and use of data in order to preserve full confidentiality (e.g., participants’ and their legal guardians’ written informed consent before participation). Data will be pseudonymized by a self-generated identification code. Documents with identifying information, such as signed consent forms, will be stored separately from the study data. Only authorized project staff members, who are subject to the obligation of secrecy, can identify an individual by linking a participant’s name to the identification code.

Data management

Collected data will be treated and stored in a pseudonymized form. All identifying information of participants will be removed from the datasets. Documents with identifying information, such as signed consent forms, will be stored securely and separately from the study data. One month after study completion all data are fully anonymized and hence contact details are irrevocably deleted. Data will be stored on a secured data server of the University of Vienna.

Data monitoring

A data monitoring committee (DMC) is usually formed to monitor patient safety and treatment efficacy during an ongoing clinical trial. Since the intervention has no known risk and does not involve blinding, no DMC is formed. Furthermore, no interim analysis is conducted and no stopping guidelines are formulated.

Harms

The intervention has a low risk of negative effects. Medical or paramedical care staff will independently evaluate the eligibility of current inpatients regarding potential negative impacts of clown visits or study participation on participants’ health or well-being. Participants are only enrolled if there are no anticipated adverse consequences. During the intervention sessions participants are monitored by the care staff and examiners. If there are unexpected adverse effects, the present care staff takes care of the concerned participant. With regard to the measurements, no risk or complications are expected. All procedures used in the study are painless and harmless to health.
Auditing
No auditing is planned.

Access to data
Only authorized project staff members will have access to collected data, who are subject to the obligation of secrecy. Access to individual data is possible only in case of participants’ study withdrawal for data deletion or if access is requested by participants or legal guardians.

Dissemination policy
Study results will be made available to the scientific community and the cooperating health care facilities’ staff. All reports of study results will be anonymous. Further, anonymized data and syntaxes of this study will be made openly available in OSF Storage (https://osf.io/) after completion of data collection.

Discussion
To the best of our knowledge, the present pilot study will be the first to investigate the effects of interactive clown performances on children and adolescents in inpatient psychiatric care. Previous studies demonstrated that clown visits in healthcare settings reduce anxiety, stress, salivary cortisol, and pain of hospitalized children [15–20]. However, there is a lack of research on children and adolescents in the psychiatric setting who might especially be in need of and benefit from such clown visits. This pilot study aims at addressing this gap by examining the potential effects of clown interventions on stress reduction and mood improvement (primary outcomes) as well as longer-term changes in health-related quality of life, emotional and conduct problems, and perceived chronic stress (secondary outcomes). Since similar target variables have successfully been improved by healthcare clowning in pediatric patients in other clinical settings, it is important to explore whether children and adolescents in psychiatric treatment also benefit from such interventions. Scientific insights gained through this study can improve appropriate care in child and adolescent psychiatry, preventing negative outcomes typically elicited by inpatient stays, such as loneliness, loss of control, and other psychological impairments [6–8]. Findings will further provide knowledge about how clown visits influence patients’ mental state and well-being from their own and the care staff’s perspectives.

There are several strengths of this study. We will assess children’s and adolescents’ stress levels by subjective (self-report) as well as physiological measures (salivary cortisol), which enables us to measure the immediate effect on stress on two different levels, enhancing the validity of assessments. The inclusion of secondary outcomes provides further insights of the overall impact of the four-week intervention. As staff reports are collected as well, conclusions can be drawn from various perspectives. Experiences of care staff have only been included in a limited number of studies so far. More attention to this area is needed, as those few studies found positive effects of healthcare clowning on care staff and their working conditions in psychiatric settings [28, 31, 32]. Additionally, control and moderator variables are assessed. Thereby, we will be able to account for statistical controls as well as to identify potential subgroups benefiting most from interventions. Moreover, the repeated measures design (i.e., one clown visit on a weekly basis over four consecutive weeks) allows the investigation of cumulative effects as a result of repeated clown visits.

Although this pilot study aims at closing an important research gap, we are also aware of its limitations. First, the lack of an untreated control group will preclude causal inferences. Thus, there is a chance that alternative explanations such as other temporal developments could
account for found effects rather than the intervention per se. However, as assessments take place before and after each clown visit, within-subject temporal trends can still be examined. Second, due to the target sample size of approximately 50 children and adolescents and the circumstance that the study only takes place in two facilities, generalizability of study results is inherently limited. Third, not all questionnaires used in this study have been validated in previous research. We must therefore first examine whether the instruments in question, which were developed on the basis of theoretical considerations, also prove themselves empirically.

Nevertheless, depending on the outcomes and insights gained from this pilot study, future research including large-scale randomized controlled trials might prove worthy of investigation. Results will expand knowledge on the use of healthcare clowning to reduce stress and improve mood in children and adolescents in psychiatric care and might inform us about future clinical research within health-promoting measures in the context of child and adolescent psychiatry.

Supporting information
S1 Table. SPIRIT checklist. (DOC)
S1 File. Ethics committee protocol (German original version and English translation). (PDF)

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References
1. Delvecchio E, Salcuni S, Lis A, Germani A, Di Riso D. Hospitalized children: Anxiety, coping strategies, and pretend play. Front Public Health. 2019;7.
2. Tiedeman ME, Clatworthy S. Anxiety responses of 5- to 11-year-old children during and after hospitalization. J Pediatr Nurs. 1990; 5: 334–343. PMID: 2213477
3. Kain ZN, Mayes LC, O’Connor TZ, Cicchetti DV. Preoperative anxiety in children: predictors and outcomes. Arch Pediatr Adolesc Med. 1996; 150: 1239–1245. https://doi.org/10.1001/archpedi.1996.02170370016002 PMID: 8953995
4. McCann ME, Kain ZN. The Management of preoperative anxiety in children: An update. Anesth Analg. 2001; 93: 98–105. https://doi.org/10.1093/00000539-200107000-00022 PMID: 11429548
6. Ahmed MI, Farrell MA, Parrish K, Karla A. Preoperative anxiety in children—Risk factors and non-pharmacological management. 2011; 21: 153–164.

7. Wilson ME, Megel ME, Enenbach L, Carlson KL. The voices of children: Stories about hospitalization. J Pediatr Health Care. 2010; 24: 95–102. https://doi.org/10.1016/j.pedhc.2009.02.008 PMID: 20189061

8. Price J, Kassam-Adams N, Alderfer MA, Christofferson J, Kazak AE. Systematic review: A reevaluation and update of the integrative (trajectory) model of pediatric medical traumatic stress. J Pediatr Psychol. 2016; 41: 86–97. https://doi.org/10.1093/jpepsy/jsv074 PMID: 26319585

9. Rennick JE, Rashotte J. Psychological outcomes in children following pediatric intensive care unit hospitalization: a systematic review of the research. J Child Health Care. 2009; 13: 128–149. https://doi.org/10.1177/1367493509102472 PMID: 19458168

10. Ladois-Do Pilar Rei A, Bui E, Bousquet B, Simon NM, Rieu J, Schmitt L, et al. Peritraumatic reactions and posttraumatic stress disorder symptoms after psychiatric admission. J Nerv Ment Dis. 2012; 200: 88–90. https://doi.org/10.1097/NMD.0b013e31823fab9 PMID: 22210368

11. Kim K-H, Lee M-H. Effects of humor intervention program on anxiety, depression and coping of humor in hemodialysis patients. Korean J Rehabil Nurs. 1999; 2: 95–108.

12. Koller D, Grzycki C. The life threatened child and the life enhancing clown: Towards a model of therapeutic clowning. Evid-Based Complement Altern Med ECAM. 2008; 5: 17–25. https://doi.org/10.1093/ecam/nem033 PMID: 18317544

13. RED NOSES CLOWndoctors International. Our Theory of Change. [cited 24 Apr 2021]. In: Red Noses [Internet]. https://www.rednoses.eu/who-we-are/our-theory-of-change/

14. Markova G, Houdek L, Kocabova Z. To the operating room! Positive effects of a healthcare clown intervention on children undergoing surgery. Front Public Health. 2021; 9: 653884. https://doi.org/10.3389/fpubh.2021.653884 PMID: 33959583

15. Ruckgaber C. Das Glück des Stolpers [The bliss of stumbling]. In: Wild B, editor. Humor in Psychiatrie und Psychotherapie: Neurobiologie—Methoden—Praxis [Humor in psychiatry and psychotherapy: Neurobiology—Methods—Practice]. Stuttgart: Schattauer; 2016. pp. 290–306.

16. Sridharan K, Sivaramakrishnan G. Therapeutic clowns in pediatrics: a systematic review and meta-analysis of randomized controlled trials. Eur J Pediatr. 2016; 175: 1353–1360. https://doi.org/10.1007/s00431-016-2764-0 PMID: 27605131

17. Diogini A, Sangiori D, Flangini R. Clown intervention to reduce preoperative anxiety in children and parents: A randomized controlled trial. J Health Psychol. 2014; 19: 369–380. https://doi.org/10.1177/1359105314520971 PMID: 23362335

18. Vagnoli L. Clown doctors as a treatment for preoperative anxiety in children: A randomized, prospective study. PEDIATRICS. 2005; 116: e563–e567. https://doi.org/10.1542/peds.2005-0466 PMID: 16199685

19. Saliba FG, Adiwandana NS, Uehara EU, Silvestre RN, Leite VV, Faleiros FTV, et al. Salivary cortisol levels: the importance of clown doctors to reduce stress. Pediatr Rep. 2016; 8. https://doi.org/10.4081/pr.2016.6188 PMID: 27114816

20. Goldberg A, Stauber T, Peleg O, Hanuka P, Eshayek L, Confino-Cohen R. Medical clowns ease anxiety and pain perceived by children undergoing allergy prick skin tests. Allergy. 2014; 69: 1372–1379. https://doi.org/10.1111/all.12463 PMID: 24943088

21. Goldberg A, Stauber T, Peleg O, Hanuka P, Eshayek L, Confino-Cohen R, Medical clowns ease anxiety and pain perceived by children undergoing allergy prick skin tests. Allergy. 2014; 69: 1372–1379. https://doi.org/10.1111/all.12463 PMID: 24943088

22. Ben-Pazi H, Cohen A, Krozyer N, Lotem-Ophir R, Shvili Y, Winter G, et al. Clown-care reduces pain in children with cerebral palsy undergoing recurrent botulinum toxin injections- A quasi-randomized controlled crossover study. PLoS ONE. 2017;12. https://doi.org/10.1371/journal.pone.0175028 PMID: 28414728

23. Viggiano MP, Giganti F, Rossi A, Di Feo D, Vagnoli L, Calcagno G, et al. Impact of psychological interventions on reducing anxiety, fear and the need for sedation in children undergoing magnetic resonance imaging. Pediatr Rep. 2015; 7. https://doi.org/10.4081/pr.2015.5682 PMID: 25918624

24. Gruber A, Levin R, Lichtenberg P. Medical clowning and psychosurgery: A case report and theoretical review. Isr J Psychiatry Relat Sci. 2015; 52: 20–23. PMID: 27357551

25. Chammas F, Potyrccha A, Moulier V, Thomas M, Bouaziz N, Januel D. L’activité clown: outil thérapeutique au sein d’un service de psychiatrie adulte fermé ? Étude pilote de faisabilité. Ann Med-Psychol Rev Psychiatr. 2021; 179: 487–491. https://doi.org/10.1016/j.amp.2020.11.003

26. Higuera S, Carretero-Dios H, P M, Idini E, Ortiz A, Rincón F, et al. Effects of a humor-centered activity on disruptive behavior in patients in a general hospital psychiatric ward. Int J Clin Health Psychol. 2006; 6: 53–64.

27. Smerling AJ, Skolnick E, Bagiella E, Rose C, Labinsky E, Tager F. Perioperative clown therapy for pediatric patients. Anesth Analg. 1999; 88: 306S. https://doi.org/10.1213/00000539-199902001-00030

28. Wolyniec I, Rimon A, Scolnik D, Gruber A, Tavor O, Haviv E, et al. The effect of a medical clown on pain during intravenous access in the pediatric emergency department: A randomized prospective pilot study.
study. Clin Pediatr (Phila). 2013; 52: 1168–1172. https://doi.org/10.1177/000992813502257 PMID: 24028842

27. Gelkopf M, Sigal M, Kramer R. Therapeutic use of humor to improve social support in an institutionalized schizophrenic inpatient community. J Soc Psychol. 1994; 134: 175–182. https://doi.org/10.1080/00224545.1994.9711380 PMID: 8201815

28. Blain S, Kingsnorth S, Stephens L, McKeever P. Determining the effects of therapeutic clowning on nurses in a children’s rehabilitation hospital. Arts Health. 2012; 4: 26–38. https://doi.org/10.1080/17533015.2011.561359

29. Ghaffari F, Dehghan-Nayeri N, Shali M. Nurses’ experiences of humour in clinical settings. Med J Islam Repub Iran. 2015; 29: 182. PMID: 26034735

30. Blain S, Kingsnorth S, Stephens L, McKeever P. Determining the effects of therapeutic clowning on nurses in a children’s rehabilitation hospital. Arts Health. 2012; 4: 26–38. https://doi.org/10.1080/17533015.2011.561359

31. Wild B, Wetzel P, Gottwald U, Buchkremar G, Wormstall H. Clowns in der Psychiatrie?: Ein Pilotprojekt [Clowns in psychiatry?: A pilot project]. Nervenarzt. 2007; 78: 571–574.

32. Barkmann C, Siem A-K, Wessolowski N, Schulte-Marcowitz M. Clowning as a supportive measure in paediatrics—a survey of clowns, parents and nursing staff. BMC Pediatr. 2013; 13: 166. https://doi.org/10.1186/1471-2431-13-166 PMID: 24112744

33. Auerbach S, Ruch W, Fehling A. Positive emotions elicited by clowns and nurses: An experimental study in a hospital setting. Transl Issues Psychol Sci. 2016; 2: 14–24. https://doi.org/10.1037/tps0000055

34. Costa Fernandes S, Arriaga P. The effects of clown intervention on worries and emotional responses in children undergoing surgery. J Health Psychol. 2010; 15: 405–415. https://doi.org/10.1177/13591050950310

35. Romero Leguizamon C, Osorio Castaño A, Guarin Morales C, Neira Cifuentes L. Humour therapy intervention to reduce stress and anxiety in paediatric anaesthetic induction, a pilot study. Br J Anaesth. 2017; 119: 847–848. https://doi.org/10.1093/bja/aex278 PMID: 29121307

36. Lopes-Junior LC, Silva Seco DSC, Olson K, Bomfim EO, Veronez LC, Santos JC, et al. Clown intervention on psychological stress and fatigue in pediatric patients with cancer undergoing chemotherapy. Cancer Nurs. 2020; 43: 203–209. https://doi.org/10.1097/NCC.0000000000000690 PMID: 30801267

37. Simon A, Shalom S, Wolnyez I, Gruber A, Schachter-Davidov A, Glatstein M. Medical clowns and cortisol levels in children undergoing venipuncture in the emergency department: A pilot study. 2016; 18: 680–683.

38. Zhang Y, Yang Y, Lau WY, Garg S, Lao J. Effectiveness of pre-operative clown intervention on psychological distress: A systematic review and meta-analysis. J Paediatr Child Health. 2010; 53: 237–245. https://doi.org/10.1111/j.1365-2516.2009.03685.x PMID: 20090261

39. Sánchez JC, Echeverri LF, Londoño MJ, Ochoa SA, Quiroz AF, Romero CR, et al. Effects of a humor therapy program on stress levels in pediatric inpatients. Hosp Pediatr. 2017; 7: 46–53. https://doi.org/10.1542/hpepd.2016-0128 PMID: 27908974

40. Faul F, Erdfelder E, Lang A-G, Buchner A. G*Power 3: a flexible statistical power analysis program for the social, behavioral, and biomedical sciences. Behav Res Methods. 2007; 39: 175–191. https://doi.org/10.3758/BF03193146 PMID: 17695343

41. Chan A-W, Tetzlaff JM, Altman DG, Laupacis A, Götzsche PC, Krinzinger K, et al. SPIRIT 2013 Statement: Defining standard protocol items for clinical trials. Ann Intern Med. 2013; 158: 200–207. https://doi.org/10.7326/0003-4819-158-3-201302050-00583 PMID: 23295957

42. Thoma MV, Zemp M, Kreienbühl H, Hofer D, Schmidlin PR, Attin T, et al. Effects of music listening on pre-treatment anxiety and stress levels in a dental hygiene recall population. Int J Behav Med. 2015; 22: 498–505. https://doi.org/10.1007/s12529-014-9439-x PMID: 25200448

43. Zhang Q, Ma J, Nater UM. How cortisol reactivity influences prosocial decision-making: The moderating role of sex and empathic concern. Front Hum Neurosci. 2019; 13: 415. https://doi.org/10.3389/fnhum.2019.00415 PMID: 32038194

44. Steyer R, Schwenkmezger P, Notz P, Eid M. Der Mehrdimensionale Befindlichkeitsfragebogen (MDFB). Handanweisung [The multidimensional mood questionnaire (MDFB). Manual]. Göttingen: Hogrefe; 1997.

45. Steyer R, Schwenkmezger P, Notz P, Eid M. Testtheoretische Analysen des Mehrdimensionalen Befindlichkeitsfragebogens (MDFB). [Theoretical analysis of a multidimensional mood questionnaire (MDFB)]. Diagnostica. 1994; 40: 320–328.

46. Ravens-Sieberer U, Bullinger M. News from the KINDL-Questionnaire—A new version for adolescents. Qual Life Res. 1998; 7: 653.
47. Ravens-Sieberer U, Bullinger M. Assessing health related quality of life in chronically ill children with the German KINDL: first psychometric and content-analytical results. Qual Life Res. 1998; 7: 399–407. https://doi.org/10.1007/s00787-008-1014-z PMID: 9691720

48. Bullinger M, Brütt AL, Erhart M, Ravens-Sieberer U, the BELLA Study Group. Psychometric properties of the KINDL-R questionnaire: results of the BELLA study. Eur Child Adolesc Psychiatry. 2008; 17: 125–132. https://doi.org/10.1007/s00787-008-1014-z PMID: 19132312

49. Goodman R. The Strengths and Difficulties Questionnaire: A research note. J Child Psychol Psychiatry. 1997; 38: 581–586. https://doi.org/10.1111/j.1469-7610.1997.tb01545.x PMID: 9255702

50. Lohbeck A, Schulteß J, Petermann F, Petermann U. Die deutsche Selbstbeurteilungsversi on des Strengths and Difficulties Questionnaire (SDQ-Deu-S): Psychometrische Eigenschaften, Faktorenstruktur und Grenzwerte [The German self report version of the Strengths and Difficulties Questionnaire (SDQ-Deu-S): psychometric properties, factor structure and cutoff values]. Diagnostica. 2015; 61: 222–235. https://doi.org/10.1026/0012-1924/a000153

51. Becker A, Hagenberg N, Roessenr V, Woerner W, Rothenberger A. Evaluation of the self-reported SDQ in a clinical setting: Do self-reports tell us more than ratings by adult informants? Eur Child Adolesc Psychiatry. 2004; 13: 17–24. https://doi.org/10.1007/s00787-004-2004-z PMID: 15243782

52. Woerner W, Becker A, Friedrich C, Rothenberger A, Kliesn H, Goodman R. Normierung und Evaluation der deutschen Elternversion des Strengths and Difficulties Questionnaire (SDQ): Ergebnisse einer repräsentativen Felderhebung [Norming and evaluation of the German parent version of the Strengths and Difficulties Questionnaire (SDQ): Results of a representative field study]. Z Für Kinder-Jugendpsychiatrie Psychother. 2002; 30: 105–112. https://doi.org/10.1024/1422-4917.30.2.105

53. Cohen S, Kamarck T, Mer sterilein R. A global measure of perceived stress. J Health Soc Behav. 1983; 24: 385–396. https://doi.org/10.1177/002215168302400213

54. Klein EM, Brähler E, Dreier M, Reinecke L, Müller KW, Schmutzer G, et al. The German version of the Perceived Stress Scale—psychometric characteristics in a representative German community sample. BMC Psychiatry. 2016; 16: 159. https://doi.org/10.1186/s12888-016-0675-9 PMID: 27216151

55. Masetti M, Caires S, Brandão D, Vieira DA. Confirmatory factor analysis of the Questionnaire on the Health Staff’s Perceptions Regarding Douroes da Alegria’s Interventions. J Health Psychol. 2019; 24: 166–174. https://doi.org/10.1177/1359105319851892 PMID: 30921630

56. Lohaus A, Eschenbeck H, Kohlmann C-W, Klein-Heßling J. Fragebogen zur Erhebung von Stress und Stressbewältigung im Kindes- und Jugendalter (SSKJ 3–8) [Questionnaire for assessment of stress and stress coping in childhood and adolescence (SSKJ 3–8)]. Göttingen: Hogrefe; 2006.

57. Eschenbeck H, Kohlmann C-W, Lohaus A, Klein-Heßling J. Die Diagnostik von Stressbewältigung mit dem “Fragebogen zur Erhebung von Stress und Stressbewältigung im Kindes- und Jugendalter” (SSKJ 3–8) [Diagnosis of stress and stress coping with the ‘Questionnaire for assessment of stress and stress coping in childhood and adolescence (SSKJ 3–8)’]. Diagnostica. 2006; 52: 131–142. https://doi.org/10.1026/0012-1924.52.3.131

58. Bates D, Mächler M, Bolker B, Walker S. Fitting linear mixed-effects models using lme4. J Stat Softw. 2015; 67: 1–48. https://doi.org/10.18637/jss.v067.i01

59. Johnson DR, Young R. Toward best practices in analyzing datasets with missing data: Comparisons and recommendations. J Marriage Fam. 2011; 73: 926–945. https://doi.org/10.1111/j.1741-3737.2011.00861.x

60. Benjamini Y, Hochberg Y. Controlling the false discovery rate: A practical and powerful approach to multiple testing. J R Stat Soc Ser B Methodol. 1995; 57: 289–300.