Protocol

Study design and participants

This is a single-center prospective quasi-randomized controlled trial, recruiting children aged 2 to 18 years who require hospitalization for CAP in the Department of Pediatrics, The Lady Davis Carmel Medical Center in Haifa, Israel. The study has been approved by the Carmel Medical Center institutional review board (approval number CMC-0170-16), and a parent has to give a written informed consent before recruitment. Exclusion criteria comprised of children who are hemodynamically unstable or required transfer to an intensive care unit; children with other systemic comorbidities or chronic respiratory diseases, including but not limited to congenital bronchopulmonary malformations, Cystic Fibrosis, immune compromise, genetic malformations, and congenital heart disease (excluding patent foramen ovale and atrial septal defect); children from families unable to comprehend and sign an informed consent form.

To determine the sample size required to establish a difference in the hospitalization duration in the study population, given confidence level of 95% and power of 80%, to detect a difference of 0.8 standard deviation (SD) in hospitalization duration between the intervention group and the control group, a sample size of 26 subjects in each group is needed.

Following a senior doctor's diagnosis of CAP based on the combination of clinical, laboratory and radiological results in the Emergency Department, the criteria for admission included at least one of the following: hypoxemia, dehydration, inability to take oral medications, moderate-to-severe respiratory distress, toxic appearance, complicated pneumonia (such as medium-to-large pleural effusion, empyema, lung abscess, pneumatocele, or necrotizing pneumonia), or failure of oral antibiotic treatment (2,28). All these patients were presumed to have bacterial pneumonia and

were treated with antibiotics though we did not specifically test for viral or bacterial origin.

The hospitalazed childeren are randomly assigned to either the intervention or control group based on their order of arrival in a 1:1 case–control and were treated in separate rooms. Both groups receive comparable medical treatment (as needed intravenous (IV) antibiotics, adequate respiratory support, hydration, pain and antipyretic treatment) and investigations, with the intervention group additionally receiving 15-minute visits from MCs twice daily during the first two days of admission.

The medical clowns in this study are part of 'The Dream Doctors Project', a unique Israeli non-profit organization that integrates professional medical clowns into Israeli hospitals, training them to work as members of multidisciplinary care teams. These clowns used various techniques to relax the patients (e.g. music, singing, playing, humor, guided imagination) and helped encourage children to begin drinking and eating on their own.

All laboratory and radiology tests, as well as treatment decisions, including admission and discharge, are based solely on clinical judgment by pediatricians who were blinded to the study and not involved in it (the clinical team was separate from the research team). Criteria for discharge are based on the IDSA Clinical Practice Guidelines for CAP. In our department, discharges occur at the same rate on weekends as on weekdays, so the length of hospitalization should not be affected by weekend admissions.

Study assessments

A doctor’s daily case report form (CRF) (Supplementary 1) and a parent CRF (Supplementary 2) must be completed on the first two days of admission. In both groups, the child’s primary caregiver, who accompanies them during the hospital stay

should answer the parent CRF. These forms document details of child's treatment, clinical assessment, vital signs, symptoms, and overall well-being as perceived by a parent (regarding respiratory state, mood and vitality) and the treating doctor (regarding pain, mood and vitality). The well-being variables will be evaluated by a visual analogue scale (VAS) in the CRF's grading their opinion between 1 (lowest score) to 10 (best score) except for pain where VAS meaning was 1= not suffering at all to 10 = most suffering.

The primary outcome parameter is length of hospitalization in hours, determined by the duration between admission and discharge from the pediatric department. Secondary outcome parameters include the duration of IV treatment, need for chest tube insertion, changes in well-being scores as reported by both the parent and the treating physician, and alterations in vital signs and laboratory results.

Statistical analysis

Statistical analyses will be performed using IBM statistics (SPSS) vs 24. The continuous variables will be presented by mean and SD or Median and IQR, as appropriate. The categorical variables will be presented in percentages. To check differences between the two groups, Chi square test will be used for the categorical variables and independent t-test, or Mann Whitney for the continuous variables. $P < 0.05$ is considered statistically significant.