

The Bronchiolitis Follow-up Intervention Trial (BeneFIT)

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1 INTRODUCTION

1.1 STUDY RATIONALE AND BACKGROUND

Bronchiolitis is the leading cause of hospitalization in infants and the fourth leading cause of hospitalization overall in children.¹ The condition is self-limited with few therapeutic interventions demonstrating meaningful benefit.² As such, hospitalization generally consists of supportive care with hydration, oxygen, and other forms of respiratory support as needed.

Given the current unsustainable pace of US healthcare spending, close examination of costly but unproven practices is essential.³ Because of the high prevalence of bronchiolitis and the abundant evidence of overuse of unnecessary tests and treatments,⁴⁻⁸ bronchiolitis care has been the focus of numerous recent high-value care improvement efforts.^{5,6,8-11} However, none of these efforts have addressed routine outpatient follow-up after hospital discharge, a common but understudied intervention.

While routine follow-up after hospitalization is often recommended, regardless of the condition, the benefits, harms, and overall value of this core component of healthcare delivery are only just starting to be evaluated critically.¹²⁻¹⁴ Potential benefits include increasing parental reassurance, strengthening the relationship between a family and the child's primary care provider (PCP), and modifying treatment to speed disease resolution or prevent disease exacerbation. On the other hand, routine follow up visits cost money, may be burdensome for families, and may precipitate additional, unnecessary medical care. For example, a recent randomized trial involving 1,500 patients discharged from Cincinnati Children's Hospital demonstrated that the intervention (a nurse-led home visit after discharge) was unexpectedly associated with an increased risk of acute healthcare reutilization (including readmission and emergency department visits) compared with no home visit.¹⁵ Overdiagnosis (the detection of conditions where such detection does not benefit patients¹⁶) may be one explanation for these findings. In other words, exposure to a medical encounter may uncover abnormalities that otherwise would have gone undetected and not caused harm had such a visit not occurred. In bronchiolitis particularly, overdiagnosis of hypoxemia detected by routine pulse oximetry is a well-described phenomenon.^{7,17-20}

Our study will assess the relative benefits, risks, and costs of two different follow up strategies for children with bronchiolitis who are discharged from the hospital. Our findings will impact management of over 100,000 hospitalizations per year nationally.²¹ Furthermore, results from this study can be used to inform follow up practices for other common, self-limited pediatric conditions.

1.2 PILOT DATA

To prepare for BeneFIT, we conducted an observational pilot study²² of children hospitalized for bronchiolitis during the winter of 2016-17. All five BeneFIT medical centers (listed in section 3) participated. Among 199 enrolled subjects, a routine follow-up visit was either recommended or scheduled by the primary team in 84% of cases. Two-thirds of patients who completed the study attended a routine follow-up visit, including 87% of those who had a follow up appointment scheduled prior to hospital discharge and 33% of those for whom as needed follow up was recommended.

“Reassurance provided” (70%) and “education provided” (15%) were cited by parents as the most useful aspect of the follow-up visit. Hospital re-visits were uncommon (2%).

2 OBJECTIVES AND ENDPOINTS

2.1 PRIMARY OBJECTIVE AND ENDPOINT

The primary objective of the study is to determine whether as needed Primary Care Physician (PCP) follow-up is non-inferior to scheduled PCP follow-up in terms of reduction in parental anxiety.

Primary Outcome

Parental anxiety, as measured by the anxiety portion of the Hospital Anxiety and Depression Scale (HADS),²³ a validated tool used in a previous trial among parents whose children had been hospitalized for bronchiolitis.¹⁹ Parental anxiety will be measured by research coordinators at before hospital discharge (baseline) and at the first data collection phone call (5-9 days following discharge). The same parent will be interviewed for both the baseline and the follow up HADS. If the length of time between baseline HADS and actual discharge exceeds 2 days, the HADS will be repeated, such that each subject has a baseline HADS within 2 days of hospital discharge.

Justification of Primary Outcome

Our primary outcome was selected based on feedback from primary care providers and parents of children hospitalized for bronchiolitis. Among parents surveyed in our pilot study, “reassurance” was most commonly selected (70%) as the most valuable aspect of the follow up visit.²² Parental reassurance was also mentioned repeatedly by primary care providers from Stanford, Intermountain, and elsewhere via informal discussions with the investigators.

2.2 SECONDARY OBJECTIVES AND ENDPOINTS

Secondary objectives of the study include determining whether as needed PCP follow-up, compared to scheduled PCP follow-up:

- Does not adversely impact satisfaction with care?
- Does not adversely impact the relationship between the child’s primary caregiver and the child’s PCP?
- Does not prolong time to resolution of symptoms?
- Does not increase risk of hospital re-admissions and emergency department visits?
- Results in a fewer number of post-discharge ambulatory visits?
- Results in less ambulatory testing (pulse oximetry, chest x-ray) and fewer prescriptions (albuterol, antibiotics, steroids)?
- Results in fewer missed days from daycare and work?
- Results in lower medical costs?

Secondary Outcomes

Measured by parent report via weekly research coordinator phone calls, until symptoms resolved or 50 days after discharge, whichever occurs first:

- Time from hospital discharge to cough resolution
- Time from hospital discharge to child reported back to normal

Measured by parent report via weekly research coordinator phone calls, until symptoms resolved or 50 days after discharge, whichever occurs first:

- Number of hospital re-admissions and emergency visits
- Number of ambulatory visits
- Number of missed daycare and work days
- Ambulatory prescriptions (albuterol, antibiotics, steroids)
- Ambulatory testing (i.e. pulse oximetry, chest x-ray)- only measured at first ambulatory visit

Measured by parent report via research coordinator phone call at 1 month from discharge:

- Relationship with PCP measured by the Patient-Doctor Depth-of-Relationship Scale²⁴
- Satisfaction with care, measured by applicable questions from the Patient Satisfaction Questionnaire Short Form (PSQ-18)²⁵
- Immunizations received

Measured among patients cared for at Intermountain clinics and those who have Select Health insurance:

- Total charges for ambulatory medical care from discharge until:
 - 14 days after discharge
 - symptom resolution

Measured at the time of discharge and during the first follow up phone call:

- Perceptions about pulse oximetry monitoring

3 STUDY DESIGN

The BeneFIT trial will be a multicenter, unblinded randomized trial. The study will take place within the inpatient units at 2 tertiary children's hospitals (Primary Children's Hospital, Lucille Packard Children's Hospital- Palo Alto, CA) and 3 affiliated community hospitals (Riverton Hospital, UT; John Muir Hospital, CA; Packard El Camino Hospital, CA). Data will also be collected via phone calls from the research team after patients have been discharged from the hospital.

3.1 END OF STUDY DEFINITION

The participant is considered to have completed the study after the final follow-up phone call has been conducted or at the time they withdraw from continued study participation.

4 STUDY POPULATION

4.1 INCLUSION CRITERIA

Children less than two years of age who are hospitalized with an attending physician diagnosis of bronchiolitis will be considered for enrollment.

4.2 EXCLUSION CRITERIA

- Chronic lung disease (any baseline supplemental oxygen need or on diuretics, including CF or other bronchiectasis)
- Complex or hemodynamically significant heart disease (planned surgery, medications)
- Immunodeficiency
- Neuromuscular disease
- Discharged home with medication for withdrawal (narcotic or benzodiazepine)
- Inpatient team believes the child should follow up with their PCP
- Patient enrolled during previous hospitalization (does not need to be re-enrolled)

4.3 SUB-POPULATION

Patients discharged home with supplemental oxygen will not be randomized and will not be included in the main analyses. However, a separate analysis of these patients will be conducted (section 7.2.2).

4.4 STRATEGIES FOR RECRUITMENT AND RETENTION

Research coordinators will identify eligible patients. Families will be approached by a research coordinator for consent and enrollment, within 2 days of anticipated discharge. Families will receive a \$25 gift card for enrollment and a \$325 gift card for study completion. These incentives will also be provided to families of children who are enrolled and then discharged home with supplemental oxygen.

5 PARTICIPANT DISCONTINUATION/WITHDRAWAL

5.1 PARTICIPANT DISCONTINUATION/WITHDRAWAL FROM THE STUDY

Participants are free to withdraw from participation in the study at any time upon request. The investigator may also choose to discontinue or withdraw a participant from the study. The reason for participant discontinuation or withdrawal from the study will be recorded in the research chart.

5.2 LOSS TO FOLLOW-UP

A participant will be considered lost to follow-up if the study staff are unable to contact the parent or legal guardian for the follow-up phone calls. In an effort to decrease loss to follow up, study coordinators will ask parents at enrollment the best days and times of the week to reach them for follow up phone calls. Parents will be provided with the phone number from which they should expect research coordinator phone calls. Where possible, three messages will be left before considering the participant lost to follow-up. The coordinator will document the failed attempts to contact the parent in the research chart.

6 STUDY ASSESSMENTS AND PROCEDURES

6.1 STUDY INTERVENTION

Scheduled follow up

At the time of hospital discharge, parents will be instructed to have their child follow up with their PCP within 4 days of discharge regardless of improvement and/or symptom resolution. Research coordinators will verify that the child has a scheduled follow up appointment prior to discharge and will help with scheduling if necessary.

As needed follow up

At the time of hospital discharge, parents will be instructed that the child does not need to automatically follow up with his/her primary care physician. Rather, the child should follow up on an as needed basis: if the child does not improve or if new concerns arise.

6.2 STUDY PROCEDURES

Consent, screening and study enrollment will occur while the participant is hospitalized for bronchiolitis. Eligibility confirmation will be obtained from the electronic medical record along with parent interview as applicable. Prior to randomizing the eligible patient, the child's parent will be asked to complete the anxiety portion of the HADS, administered verbally by research coordinators. When a RedCap enrollment checklist has been completed, RedCap will supply the local research coordinator with the patient's randomization assignment. The parents will be notified of their randomization group and instructed on the study plan for follow-up as discussed in section 6.1. Patients discharged home with supplemental oxygen will not be randomized, with follow up plans determined by the child's medical team.

Prior to hospital discharge, a research coordinator will call the child's PCP to notify them of the child's enrollment in the trial and their randomization assignment. The research coordinator will fax a one page summary of the trial to the PCP. PCPs will be notified at the time of the call and in the one-page summary that the protocol allows for and encourages PCPs to check-in over the phone with families enrolled in the trial.

Demographic and hospitalization details will be obtained via electronic medical record review. Data for the primary endpoint will be collected by administering the anxiety portion of the HADS survey prior to randomization and at the first post discharge follow-up phone call (5-9 days after discharge). Data for the secondary endpoints will be collected via phone calls from a research coordinator and will occur weekly until symptom resolution or 50 days after discharge, whichever comes first. Research

coordinators will follow a script for all data collection phone calls. Electronic medical record review will supplement information collected by phone calls for patients who re-visit the emergency department or are re-admitted to the hospital. In addition, a one month post discharge phone call will be made to administer the Patient-Doctor Depth-of-Relationship Scale questionnaire. Study participation will conclude with the final discharge phone follow up call.

Table 1: Schema of study procedures

Screening/Enrollment	Within 2 days of anticipated hospital discharge
<ul style="list-style-type: none"> •Screen potential participants by inclusion and exclusion criteria •Obtain informed consent and enroll •Obtain demographics and relevant medical history •After consent and eligibility verification, but before randomization, parent or legal guardian will complete anxiety portion of HADS 	
Randomization	Day of discharge (patients discharged on oxygen will not be randomized)
<ul style="list-style-type: none"> •Coordinator will obtain patient randomization assignment •Coordinator will notify child's PCP of child's enrollment in study and randomization assignment •Scheduled follow up: Family instructed to follow-up with PCP (appointment made prior to discharge) •As needed follow up: Family will be instructed to follow-up with PCP on as needed basis 	
7 day phone call	Follow-up assessments of study endpoints
<ul style="list-style-type: none"> •Parent will complete anxiety portion of the Hospital Anxiety and Depression Scale (HADS) •Parent assessment for secondary outcomes collected via phone interview (see script) 	
Subsequent weekly phone calls	Follow-up assessment of study endpoints
<ul style="list-style-type: none"> •Parent will be contacted weekly to collect secondary endpoint data until symptom resolution or 50 days after discharge whichever comes first (see script) 	
1 month follow-up	Follow-up Telephone Call
<ul style="list-style-type: none"> •Patient-Doctor Depth-of-Relationship Scale will be administered •Participant considered off study at this timepoint or when final weekly phone call occurs (if needed beyond 4 weeks) 	

6.3 MEASURES TO MINIMIZE BIAS: RANDOMIZATION AND BLINDING

Randomization

After consent and enrollment, a research coordinator at the site will obtain a site-specific computer-generated randomization assignment for each patient. Patients will be randomized with equal (1:1) allocation to either the scheduled PCP follow up group or to the as-needed PCP follow up group, using randomly permuted blocks of random sizes. Randomization sequences will be stratified by site but not by any additional baseline factors. The research coordinator will inform the patient's family, inpatient

medical team, and PCP of the patient's assignment.

Blinding

BeneFIT will be an unblinded trial because it will not be feasible to blind parents or research coordinators to intervention assignment, as the reason for any follow-up visit (i.e. routine vs new concern) that occurs needs to be documented. However, investigators responsible for analyses will be blinded to individual patient intervention assignments.

7 STATISTICAL METHODS

7.1 SAMPLE SIZE DETERMINATION

A previous bronchiolitis trial of 615 patients¹⁹ found a standard deviation for HADS scores of 4.1 and a serial correlation of the HADS score between an admission and 7-day assessment that exceeded 0.80 (S. Cunningham, personal communication, October 18, 2017). To provide as conservative assessment of statistical power, we assume that the serial correlation over 7 days will equal or exceed 0.65 in the present study. We designated a non-inferiority margin on the anxiety portion of the HADS of 2 points, the smallest clinically meaningful change. Based on the non-adherence to recommended follow-up encountered in our pilot study,²² we estimated that up to 33% of patients randomized to as needed follow up would still follow up and that 13% of patients randomized to scheduled follow up would not attend follow up appointments. Hence, the non-inferiority margin for the ITT analysis of all randomized patients was adjusted to be $2 \times (1 - 0.33 - 0.13) = 1.08$. We also assumed that the follow-up anxiety assessment would be obtained for at least 90% of subjects. Under these assumptions, a total sample size of 294 patients (147 patients in each group) will provide 80% power with 1-sided $\alpha = 0.025$ for the analysis of covariance planned for the primary analysis to demonstrate non-inferiority of as needed follow up if in fact as needed follow up and scheduled follow up lead to equal levels of anxiety. Because children discharged home with supplemental oxygen are not being randomized and are not being analyzed in the main analysis, these patients are not included in the power calculation.

7.2 STATISTICAL ANALYSES

7.2.1 ANALYSIS OF THE PRIMARY AND SECONDARY ENDPOINT(S)

Intent-to-treat analysis for primary outcome

The primary non-inferiority analysis will be an analysis of covariance comparing HADS scores approximately 7 days after discharge between patients randomized to scheduled PCP follow up or as needed PCP follow up, controlling for baseline HADS scores. A 1-sided upper 97.5% confidence bound for the difference in mean HADS score between the intervention and control groups will be constructed, and non-inferiority will be inferred if the upper confidence limit excludes the intent-to-treat non-inferiority (ITT) bound of 1.08 points.

ITT comparisons for secondary outcomes

A log-rank test will be used to compare the time from discharge to the first report of symptom resolution between the randomized treatment groups. Follow-up for symptom resolution will be right-censored at 50 days after discharge or at the time of loss-to-follow-up. Charges will be compared between the two intervention groups using two-part models, given that charge data will likely be semi-continuous. Other secondary outcomes will be compared between the randomized groups using Poisson or negative binomial models with robust standard errors for statistical inference.

Instrumental variable analysis of the effect of the routine follow-up visit

The primary ITT analyses evaluate the effect of a recommendation for scheduled PCP follow up or as needed follow up, irrespective of whether the PCP visit actually occurs. We will supplement the ITT analyses with an instrumental variable analysis, using randomization as the instrument, which will approximate the average causal effect on parental anxiety of actually receiving routine PCP follow up. The goal of this analysis is to estimate the local average causal effect of the treatment among the subgroup of patients who would attend the PCP visit if randomized to the scheduled follow up group but not if randomized to as needed follow up.²⁶ The validity of instrumental variable analysis depends on an “exclusion” assumption which requires that the randomized intervention affects parental anxiety only through the occurrence or nonoccurrence of the PCP visit and not by other pathways. It also depends on a monotonicity assumption that requires that randomization to the as needed follow up intervention could not cause any subjects to attend a PCP visit when they would not have attended a PCP visit if randomized to the scheduled follow up intervention. Because these assumptions are not fully testable, the instrumental variables analysis will be exploratory.

7.2.2 ANALYSIS OF CHILDREN DISCHARGED HOME WITH SUPPLEMENTAL OXYGEN

All of the same outcomes discussed above will be measured among the subpopulation of un-randomized children discharged home with supplemental oxygen. We will describe parental anxiety and resource utilization among this subpopulation and compare them to patients who are not discharged home on oxygen, using the same statistical tests used for the main analysis.

8 SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

8.1 REGULATORY, ETHICAL, AND STUDY OVERSIGHT CONSIDERATIONS

8.1.1 STATEMENT OF COMPLIANCE

The study will be conducted in accordance with the applicable United States Code of Federal Regulations (CFR) and the International Conference on Harmonization Good Clinical Practice (ICH GCP). The Principal Investigator will assure that the protocol, informed consent form(s), and all participant questionnaires will be submitted to the IRB for review and approval. Approval of the study materials will be obtained before any participant is enrolled. No deviation from or amendment to the protocol will take place without prior approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All changes to the consent form will be IRB approved.

8.1.2 INFORMED CONSENT PROCESS

This study involves children as a vulnerable population and therefore adequate measures will be taken to ensure that the parent or legal guardian of the child is adequately informed of the study and an Informed Consent Form (ICF) is appropriately signed prior to enrolling the child in the trial. The parent or legal guardian will be given adequate time to read the ICF and ask questions prior to signing. A copy of the ICF will be given to the parent once signed. Assent from the child will not be sought due to the age of the participant population.

8.1.3 CONFIDENTIALITY AND PRIVACY

The Institutional Review Board (IRB) or regulatory agencies or other Quality Assurance monitors may request to inspect all documents and records pertaining to the trial, including medical records (office, clinic, or hospital). The clinical study sites will permit access to such records.

Study participant's contact information, necessary for phone call data collection, and study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at Stanford University via the RedCap data system. The study data entry and study management systems used by clinical sites will be secured and password protected.

8.1.4 QUALITY ASSURANCE AND QUALITY CONTROL

Quality control (QC) procedures will be implemented beginning with the data entry system and data QC checks that will be run on the database will be generated by the Principal Investigator or Clinical Research Coordinator at Stanford University. Any missing data or data inconsistencies will be communicated to the site(s) for clarification/resolution.

When requested, the investigational site will provide direct access to all trial related source data/documents, and reports for the purpose of monitoring and auditing by the sponsor, or inspection by local and regulatory authorities.

A Data Safety and Monitoring Board will not be utilized for the trial as this is a minimal risk, non-therapeutic trial.

8.1.5 DATA HANDLING AND RECORD KEEPING

Data collection is the responsibility of the clinical trial staff at the site under the supervision of the Principal Investigator. Aside from electronic medical review, all data will be collected via verbal interview of parents by research coordinators, adhering to a pre-specified script. All of the validated questionnaires will be read aloud to the parent or legal guardian by research coordinators. The anxiety portion of the HADS, for example, will be read aloud both at baseline and phone follow up, to maintain consistency. Research coordinators will record responses in RedCap. The investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

8.1.5.1 STUDY RECORDS RETENTION

At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB or Institutional policies.

8.1.6 PROTOCOL DEVIATIONS

A protocol deviation is any departure from the defined procedures as outlined in the protocol version submitted and previously approved by the IRB. Protocol deviations have the potential to place participants at risk and can also undermine the scientific integrity of the study thus jeopardizing the justification of the research.

It is the responsibility of the site investigator to use continuous vigilance to identify and document deviations in the research records. Protocol deviations must be sent to the reviewing Institutional Review Board (IRB) per their policies.

8.2 ABBREVIATIONS

CRF	Case Report Form
CTO	Clinical Trials Office
eCRF	Electronic Case Report Forms
GCP	Good Clinical Practice
HADS	Hospital Anxiety and Depression Scale
HIPAA	Health Insurance Portability and Accountability Act
ICF	Informed Consent Form
ICH	International Conference on Harmonisation
IRB	Institutional Review Board
ITT	Intention-To-Treat
OHRP	Office for Human Research Protections
PCP	Primary Care Physician
PI	Principal Investigator
QA	Quality Assurance
QC	Quality Control

9 REFERENCES

1. Keren R, Luan X, Localio R, et al. Prioritization of comparative effectiveness research topics in hospital pediatrics. *Arch Pediatr Adolesc Med* 2012;166:1155-64.
2. Ralston SL, Lieberthal AS, Meissner HC, et al. Clinical practice guideline: the diagnosis, management, and prevention of bronchiolitis. *Pediatrics* 2014;134:e1474-502.
3. Berwick DM, Hackbarth AD. Eliminating waste in US health care. *JAMA* 2012;307:1513-6.
4. Knapp JF, Simon SD, Sharma V. Variation and trends in ED use of radiographs for asthma, bronchiolitis, and croup in children. *Pediatrics* 2013;132:245-52.
5. Parikh K, Hall M, Teach SJ. Bronchiolitis Management Before and After the AAP Guidelines. *Pediatrics* 2013.
6. Ralston SL, Garber MD, Rice-Conboy E, et al. A Multicenter Collaborative to Reduce Unnecessary Care in Inpatient Bronchiolitis. *Pediatrics* 2016;137.
7. Schroeder AR, Marmor AK, Pantell RH, Newman TB. Impact of pulse oximetry and oxygen therapy on length of stay in bronchiolitis hospitalizations. *Arch Pediatr Adolesc Med* 2004;158:527-30.
8. Van Cleve WC, Christakis DA. Unnecessary care for bronchiolitis decreases with increasing inpatient prevalence of bronchiolitis. *Pediatrics* 2011;128:e1106-12.
9. Quinonez RA, Garber MD, Schroeder AR, et al. Choosing wisely in pediatric hospital medicine: five opportunities for improved healthcare value. *J Hosp Med* 2013;8:479-85.
10. Ralston S, Garber M, Narang S, et al. Decreasing unnecessary utilization in acute bronchiolitis care: results from the value in inpatient pediatrics network. *J Hosp Med* 2013;8:25-30.
11. Mittal V, Hall M, Morse R, et al. Impact of inpatient bronchiolitis clinical practice guideline implementation on testing and treatment. *J Pediatr* 2014;165:570-6 e3.
12. Koelink E, Schuh S, Howard A, Stimec J, Barra L, Boutis K. Primary Care Physician Follow-up of Distal Radius Buckle Fractures. *Pediatrics* 2016;137.
13. Uitti JM, Tahtinen PA, Laine MK, Ruohola A. Close Follow-up in Children With Acute Otitis Media Initially Managed Without Antimicrobials. *JAMA Pediatr* 2016;170:1107-8.
14. Collier RJ, Klitzner TS, Saenz AA, et al. Discharge Handoff Communication and Pediatric Readmissions. *J Hosp Med* 2017;12:29-35.
15. Auger KA, Simmons J, Sucharew H, et al. Hospital to Home Outcomes Study: A Randomized Controlled Trial to Evaluate the Effectiveness of a Single Nurse Home Visit after Routine Pediatric Discharge. *Pediatric Academic Societies National Meeting* 2017;San Francisco.
16. Coon ER, Quinonez RA, Moyer VA, Schroeder AR. Overdiagnosis: how our compulsion for diagnosis may be harming children. *Pediatrics* 2014;134:1013-23.
17. Principi T, Coates AL, Parkin PC, Stephens D, DaSilva Z, Schuh S. Effect of Oxygen Desaturations on Subsequent Medical Visits in Infants Discharged From the Emergency Department With Bronchiolitis. *JAMA Pediatr* 2016;170:602-8.
18. Schuh S, Freedman S, Coates A, et al. Effect of oximetry on hospitalization in bronchiolitis: a randomized clinical trial. *JAMA* 2014;312:712-8.
19. Cunningham S, Rodriguez A, Adams T, et al. Oxygen saturation targets in infants with bronchiolitis (BIDS): a double-blind, randomised, equivalence trial. *Lancet* 2015;386:1041-8.
20. Shay DK, Holman RC, Newman RD, Liu LL, Stout JW, Anderson LJ. Bronchiolitis-associated hospitalizations among US children, 1980-1996. *JAMA* 1999;282:1440-6.
21. Goto T, Tsugawa Y, Mansbach JM, Camargo CA, Jr., Hasegawa K. Trends in Infectious Disease Hospitalizations in US Children, 2000 to 2012. *Pediatr Infect Dis J* 2016;35:e158-63.
22. Schroeder AR, Destino L, Brooks R, Wang CJ, Coon ER. Outcomes of follow-up visits after bronchiolitis hospitalizations. *JAMA Pediatrics*;Accepted for publication.

23. Zigmond AS, Snaith RP. The hospital anxiety and depression scale. *Acta Psychiatr Scand* 1983;67:361-70.
24. Ridd MJ, Lewis G, Peters TJ, Salisbury C. Patient-doctor depth-of-relationship scale: development and validation. *Ann Fam Med* 2011;9:538-45.
25. Thayaparan AJ, Mahdi E. The Patient Satisfaction Questionnaire Short Form (PSQ-18) as an adaptable, reliable, and validated tool for use in various settings. *Med Educ Online* 2013;18:21747.
26. Dunn G, Maracy M, Tomenson B. Estimating treatment effects from randomized clinical trials with noncompliance and loss to follow-up: the role of instrumental variable methods. *Stat Methods Med Res* 2005;14:369-95.