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ORIGINAL ARTICLE

Effect of Honey on Cough Symptoms in Children with Upper Respiratory Tract Infection: A Randomised Controlled Trial

Effet du Miel sur les Symptômes de la Toux chez les Enfants Atteints d'Une infection des Voies Respiratoires Supérieures : Un Essai Contrôlé Randomisé

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ABSTRACT

BACKGROUND AND OBJECTIVE: Cough from URTI is common, leads to discomfort, sleep loss and stress in caregivers, leading to use of ineffective and potentially harmful over-the-counter medications. Honey is cost-effective and safe for children above one year of age. It is readily available and is a potentially valuable demulcent for treatment of childhood cough. The study aimed to determine the effect of honey on cough frequency and severity among children with URTI in outpatient setting.

METHODS: A single-blind randomised control trial involving children presenting with cough from URTI attending the GOPC of FMC Keffi. Eighty-four children presenting with cough from URTI were recruited, randomised into two groups of 42 and administered Honey (intervention) and Diphenhydramine (control) in three consecutive bedtime doses. Socio-demographic and clinical data including cough frequency, severity and impact on children and caregivers was collected using Paediatric Cough Questionnaire and Kingston Caregiver Stress Scale tool. Data was analysed using SPSS version 25. A $p<0.05$ was considered statistically significant.

RESULTS: Majority (56.0%) of the participants were males, with a mean age +SD of 4±1.47 years. Median cough frequency score for intervention and control groups pre and post intervention decreased (5.00 and 0.00 vs 5.00 and 3.00, $p<0.001$). Median cough severity score decreased (4.00 and 0.00 vs 4.00 and 3.00, $p<0.001$), Post intervention pooled caregivers' burden significantly reduced, (5.00 and 11.00 for intervention and control respectively) and sleep pattern improved among children and caregivers (0.00, 2.00 $p<0.001$; and 0.00, 2.00 $p<0.001$, for children and caregivers respectively.

CONCLUSION: Night-time honey doses given to children with cough from URTI significantly reduces symptoms and improves children and caregivers sleep compared to Diphenhydramine DPH. **WAJM 2022; 39(9): 928–934.**

Keywords: Caregiver burden; Child; Cough; Demulcents; Diphenhydramine; Honey; Sleep; Upper respiratory tract infections.

RÉSUMÉ

CONTEXTE ET OBJECTIF: La toux due à l'URTI est courante, entraîne une gêne, une perte de sommeil et du stress chez les soignants, conduisant à l'utilisation de médicaments en vente libre inefficaces et potentiellement nocifs. Le miel est rentable et sans danger pour les enfants de plus d'un an. Il est facilement disponible et est un adoucissant potentiellement précieux pour le traitement de la toux infantile. L'étude visait à déterminer l'effet du miel sur la fréquence et la gravité de la toux chez les enfants atteints d'URTI en ambulatoire.

MÉTHODES: UNE Essai contrôlé randomisé en simple aveugle impliquant des enfants présentant une toux de l'URTI et participant au GOPC de FMC Keffi. Quatre-vingt-quatre enfants présentant une toux due à l'URTI ont été recrutés, randomisés en deux groupes de 42 et administrés du miel (intervention) et de la diphenhydramine (contrôle) en trois doses consécutives au coucher. Les données sociodémographiques et cliniques, y compris la fréquence, la gravité et l'impact de la toux sur les enfants et les soignants, ont été recueillies à l'aide du questionnaire Pediatric Cough Questionnaire et de l'outil Kingston Caregiver Stress Scale. Les données ont été analysées à l'aide de la version 25 de SPSS. Un $p<0,001$ était considéré comme statistiquement significatif.

RÉSULTATS: La majorité (56,0%) des participants étaient des hommes, avec un âge moyen de 4 ± 1,47 ans. Le score moyen de fréquence de toux pour l'intervention et le contrôle avant et après l'intervention a diminué (5,00 et 0,00 vs 5,00 et 3,00, $p<0,001$). Le score moyen de gravité de la toux a diminué (4,00 et 0,00 vs 4,00 et 3,00, $p<0,001$), le fardeau des soignants regroupés après l'intervention a été significativement réduit et le rythme de sommeil s'est amélioré chez les enfants et les soignants.

CONCLUSION: Les doses nocturnes de miel administrées aux enfants avec toux par URTI réduisent considérablement les symptômes et améliorent le sommeil des enfants et des soignants par rapport au DPH. **WAJM 2022; 39(9): 928–934.**

Mots clés: Fardeau du soignant; Enfant; Toux; Démulcents; Diphenhydramine; Miel ; Sommeil; Infections des voies respiratoires supérieures.

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INTRODUCTION

Respiratory tract infection refers to a number of infectious diseases involving the respiratory tract.[1] Based on anatomical origin, infections of the airway above the glottis or vocal cord is normally classified as an upper respiratory tract infection (URTI). This typically includes the nose, sinuses, pharynx, and larynx.[2] URTI, which is mainly viral in origin, represents a major public health problem due to global occurrence, ease of transmission and high morbidity and mortality among vulnerable populations.[1] Children are infected two to three times more frequently than adults, with acute respiratory tract infections (ARTI) being the commonest infection in childhood.[1] ARTI is most common in children under five years of age, and represents 30–50% of paediatric medical admissions, and 20–40% of hospitalisations in children.[1] ARTIs, the cause of both URTIs and LRTIs, are a major cause of death among children under 5 years of age particularly in developing countries where the burden of disease is 2–5 times higher than in developed countries.[1]

Cough due to URTI is one of the most frequent complaints encountered by primary care physicians and other frontline healthcare providers.[3] A cough is a normal protective mechanism of the respiratory system to eliminate excessive secretions and foreign bodies.[4] Cough is a common symptom in children, but can be a great source of concern to children and their parents.[5] It often results in discomfort to the child, loss of sleep for both the child and parents, and missed time in day care or school for children while parents also miss days of work.[5,6] In an attempt to treat cough, caregivers frequently administer over-the-counter (OTC) medications to their children, with attendant risks, lack of proven efficacy, and disapproval of professional and regulatory Organisations such as the American Academy of Paediatrics, and the Food and Drug Administration (FDA).[5,6]

The World Health Organisation (WHO) has described honey as a potential treatment for cough and cold symptoms, and considered honey as a demulcent that is inexpensive, popular, and safe for use in children above one year of age.[5] Honey has antioxidant properties and it increases cytokine release, which may explain its anti-microbial effects.[5,6] Despite all these properties of honey, there is paucity of studies that have established the effectiveness of honey on cough symptoms in children, especially in Nigeria.[6] The objective of this study was to compare the effect of three nocturnal doses of honey against that of Diphenhydramine (DPH) in children with nocturnal cough and sleep difficulty from URTI.

MATERIALS AND METHODS

The study was a single-blind, randomised-controlled trial (RCT), which compared the effect of Honey and DPH on cough symptoms among children with URTI attending the GOPC of FMC, Keffi. Convenience sampling method was used in participants allocation into intervention and control groups using computer randomly generated numbers from 01 to 84, with even and odd numbers for intervention and control groups respectively. The participants were blinded from the medication given (Honey for intervention and DPH for the control). The DPH was compounded in the hospital pharmacy department to look and taste like honey, and both were kept in two transparent containers and coded A (Honey) and B (DPH) for intervention and control respectively. The sample size was determined to detect a 2.5 difference in median cough score between intervention and control groups based on a previous study,[4] which reported a standard deviation of 3.9, with assumptions of power at 80%, alpha of 0.05, and 10% attrition rate.

Cough symptoms in this study refers to the frequency and severity of cough. The cough frequency and severity were determined using a validated Paediatric cough questionnaire with a 7- point Likert scale.[7] The study was designed and set to measure these primary outcomes. The study also assessed secondary outcomes of sleep and functional disruption of the children and their caregivers before and after intervention with honey and DPH respectively.

In this study sleep quality refers to the extent to which the children and their caregivers were deprived of sleep because of nightly cough, while the functional disruption is the extent to which the caregivers' daily activities in and out of the house was interfered with because of caregiving. These were measured using Kingston caregiver stress scale with a 5-point Likert scale.[8]

Children between 2 to 12 years of age who had nocturnal cough from URTI within a period of one week, and whose parents or caregivers had access to functional mobile phones and gave written consent were included in the study. Children with signs and symptoms of established lower respiratory tract infections, allergic rhinitis and asthma, temperature above 37.5°C and those on recent antibiotic treatment as well as those who had been on OTC cough and cold medications, were excluded from the study.

Participants who met the inclusion criteria and whose caregiver gave informed consent were recruited consecutively. Randomisation and group allocation were done using a computer-generated random number list. The validated paediatric cough questionnaire with a 7-point Rensis Likert Scale, which was developed by Paul et al, was adopted for the study.[7] A pre-test of this questionnaire (as pilot study) was conducted in the study environment, in a General hospital in Keffi to test its reliability. This pilot study showed a Cronbach alpha of 0.71 indicating high reliability of the questionnaire.

The Honey was purchased from registered distributors and was registered by National Agency for Food and Drug Administration and Control (NAFDAC). It was subjected to some simple home tests for authenticity as described by Ifiokobong.[9] The honey was dispensed into a transparent plastic container and given to caregivers to administer to the participants for three consecutive nights, 30 minutes before bedtime. Participants aged two to five years received 17mg/dose (5ml), while those aged six to 12 years received 34mg/dose (10ml). Dispensing spoons were supplied to the caregivers. Same volumes of honey or DPH were dispensed to participants in

the intervention or control groups depending on the ages. The caregivers were instructed not to give any other medication especially antibiotics to the children during the three-day honey administration at home, and instructed to repeat the same dose on event of vomiting immediately after any dose. The caregivers were reminded via a phone call between the hours of 20.00 and 20.10 daily for three days to ensure adherence. They were also told to watch out for any worsening of symptoms like dyspnoea and fever, which if present such children were to be brought back to the health facility immediately for reassessment and treatment. They were also told to come back with their honey containers after the third day to assess adherence.

On follow up, participants were assessed for cough frequency and severity again with the same cough questionnaires. Functional disruption of caregivers was assessed using the validated Kingston Caregiver Stress Scale tool.[8] This is a community-oriented tool to quickly assess the perceived stress on the caregiver while rendering care to loved ones. The same intervention was done for participants in the control group with DPH.

Data was checked for accuracy and completeness, then coded and inputted into the computer using the Statistical Package for the Social Sciences (SPSS) version 25. Data on primary outcome of cough frequency and severity of participants, as well as secondary outcome on sleep quality and effect on daily activities on participants and caregivers were analysed. Analysis was done on intention to treat basis. Continuous variables, including age of participants and caregivers, were analysed using student T-test, while non-parametric test like Wilcoxon Signed Ranked Test and Mann-Whitney U test were used to analyse ordinal variables. The association between categorical variables like participant's gender and education, and caregiver's religion, relationship with the child and occupation were tested using Chi square and Fisher's exact test. Statistical analysis was set at 95% confidence interval, and statistical significance at $p<0.05$.

RESULTS

The study was conducted from June to August 2018. A total of 125 participants and their caregivers met the inclusion criteria for the study and gave consent. Twenty-two participants were excluded for various reasons like pneumonia, temperature greater than 37.5°C and those already on antibiotics. A total of 19 subsequently withdrew consent for various reasons. A total of 80 participants concluded the study with 4 lost to follow up. The data was not evenly distributed, hence the use of comparison of medians rather than the means. Details are in Figure 1.

None of the participants reported any side effects or had other medications given within this period. Two participants developed pneumonia on follow up visit and were subsequently administered oral Amoxicillin/clavulanate. They got better on follow up visit five days later but were still included in the analysis on intention to treat basis.

Socio-demographic Characteristics

The mean age of the study participants was 4±1.47 years, and the median was 4 for the study population (Table 1). Majority (82.1%) of the study participants were between the ages of 2–5 years. Thirty-six of the participants (52.2%) in the intervention group were aged between 2–5 years, while only 6 (40%) were aged 6–12 years. In the control group 33 participants (47.8%) were between 2–5 years while 9 (60%) were aged 6–12 years. There was a total of 47 (56.0%) male participants and 37 (44.0%) females, while 53.6% of the participants were yet to be enrolled in any school. The significant school enrolment figure was due to the relatively younger ages of the participants. There was no significant difference in age and sex in the two groups. Other details are provided in Table 1.

Clinical Characteristics

The baseline clinical parameters of the caregivers showed comparable

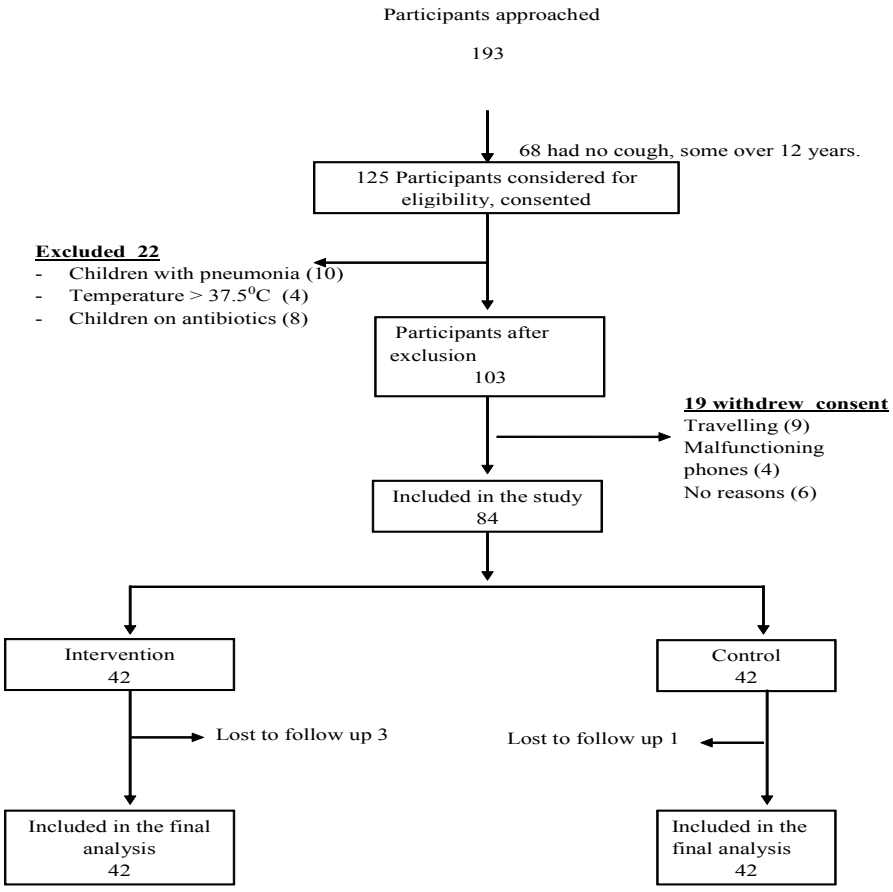

Figure 1: The Study Flow Chart.

pooled caregiver burden (17.5; interquartile range, IQR 5.00, versus 17.00; IQR 5.00, p=0.382) for intervention and control groups. Other details indicate the intervention and control groups were similar with regards to clinical characteristics at baseline as shown in Table 2. Table 6 shows the respective post intervention analysis.

The median baseline score for cough frequency of participants was 5.00, with IQR of 1.25 for the intervention group and 5.00 with IQR of 2.00, p=0.798 for the control group, while median pooled cough symptoms was 16.00 with IQR of 6.50 for the intervention and 16.00 with IQR of 5.25, p=1.000 for control groups, respectively at baseline (Table 3).

Post-Intervention Comparison

The post intervention median cough frequency was 0.00 with a range of 1.00 versus 3 with IQR of 2.00 $p < 0.001$ for intervention and control groups respectively. Table 3 in the appendices show other details of the respective baseline and post-intervention cough frequencies.

Table 5 shows the post intervention within group comparison of honey over DPH in the intervention and control groups, respectively. Although the difference was statistically significant for both groups, $p < 0.001$, the effect size comparison was more significant in the intervention group (honey). The other variables are displayed in Table 5.

DISCUSSION

Cough from URTI can be a distressing experience among children and their caregivers especially at night when cough symptoms become aggravated. This often leads to loss of school hours and substantial interference with daily activities for the children, and daily functional disruption of their caregivers. Adequate management of the cough symptoms with cheap and readily available medications substantially relieves suffering from URTI for children and their caregivers so that children can resume their daily activities including school hours, and productive working hours would be gained by their caregivers. This study compared the effect of honey and DPH on children with cough from URTI who attended the General Outpatient Clinic of FMC Keffi. The study revealed that the majority (82.14%) of participants with URTI were between the ages of 2-5 years confirming the high prevalence of URTI among the under 5 age group. This conforms with the two studies by Stover et al in 2014 and Ujunwa et al in 2014 where most of the participants were under 5 years.[10,11]

Most studies also report that the incidence of URTI declines with age with the highest incidence found between infancy to 4–5 years.[12] This study found out that 15 (17.86%) of the study population with URTI were between 6–12 years of age. The similarity of these studies is due to the relative poorly developed immunity in the under 5 years. The present study showed a comparable cough frequency score for control and intervention groups at baseline. The mean cough severity score and pooled cough symptom score were also comparable at baseline indicating that the randomization was adequate. However, the index study had a median cough frequency score of 5.00 with IQR of 1.25, at baseline compared to a mean score 3.7 ±0.8 reported by the Iranian study. This higher frequency could be as a result of the fact that the index study took place at the onset of the rainy season which is known to affect cough frequency.

Herman, *et al* in 2012 compared the effects of three types of honey; eucalyptus honey, citrus honey and Labiatae honey with a placebo like silan date extract on children with cough secondary to URTI.[8] They reported a baseline mean cough frequency and standard deviation of 3.72±1.02, 3.76±1.14, 3.68±0.9 and 3.58±0.82 respectively, and a mean cough severity

Table 1: Socio-demographic Characteristics of Participants and Caregivers

		Intervention (n=42)	Control (n=42)	
Variable	**Total**	**Freq. (%)**	**Freq. (%)**	
Mean age ±SD (years)	**3.61 ±1.99**	**3.49 ±1.47**	**3.67 ±2.40**	**0.58**
Median Age (yrs.)	**4**	**3**	**4**	
Grouped Age (Years)				**0.39**
2 – 5	69 (100)	36 (52.2)	33 (47.8)	
6 – 12	15 (100)	6 (40.0)	9 (60.0)	
Gender of the child				**0.51**
Male	47 (100)	25 (53.2)	22 (46.8)	
Female	37 (100)	17 (45.9)	20 (54.1)	
Child's Education+				**0.69**
Yet to start school	45 (100)	21 (46.7)	24 (53.3)	
Pre-nursery	10 (100)	6 (60.0)	4 (40.0)	
Nursery	15 (100)	9 (60.0)	6 (40.0)	
Primary	14 (100)	6 (42.9)	8 (57.1)	
Religion of Caregivers				**0.49**
Christianity	29 (100)	16 (55.2)	13 (44.8)	
Islam	55 (100)	26 (47.3)	29 (52.7)	
Relationship to the Patient				**0.28**
Mother	71 (100)	34 (47.9)	37 (52.1)	
Father	10 (100)	7 (70.0)	3 (30.0)	
Sister	1 (100)	0 (0.0)	1 (100.0)	
Brother	1 (100)	1 (100.0)	0 (0.0)	
Aunt	1 (100)	0 (0.0)	1 (100.0)	
Educational Level of Caregiver				**0.75**
Tertiary	45 (100)	25 (55.6)	20 (44.4)	
Secondary	23 (100)	11 (47.8)	12 (52.2)	
Primary	8 (100)	3 (37.5)	5 (62.5)	
No formal education	8 (100)	3 (37.5)	5 (62.5)	

Statistics: + Fisher's exact; Others: Chi square

Table 2: Comparison of Baseline Clinical Parameters of the Caregivers and Participants

	Intervention (n=42)	Control (n=42)	
	Median, IQR	Median, IQR	P-value
CAREGIVERS			
Cough effect on parents' daily functions at workplace	3.00(3.00)	3.00(2.00)	0.824
Cough bothersomeness on parent score	3.00(1.00)	2.00(1.00)	0.082
Effect on caregivers' relationship with the child	1.00 (0.00)	2.00 (1.00)	0.480
Effect on social life	2.00 (1.00)	2.00 (0.25)	0.625
Effect on previous daily work	2.00 (0.00)	2.00 (0.00)	0.052
Feelings of being trapped by demand of caregiving	2.00 (0.00)	2.00 (0.00)	1.000
Cough effect on caregivers' sleep	4.00 (2.00)	4.00 (2.00)	0.817
Pooled caregivers' burden	17.50 (5.00)	17.00 (5.00)	0.382
PARTICIPANTS			
Cough effect on child sleep	4.00 (2.00)	4.00 (2.00)	0.495
Cough effect on caregivers' sleep	4.00 (2.00)	4.00 (2.00)	0.817
Cough effect on overall daytime child activities	3.00 (2.00)	4.00 (2.00)	0.442

Statistics, Mann-Whitney U and Independent median tests.

Table 3: Comparison of Baseline and Post-Intervention Cough Frequency and Severity of Participants

Variable	Intervention (n=42) Median, IQR	Control (n=42) Median, IQR	Effect size	p-value
Baseline				
Cough frequency score	5.00 (1.25)	5.00 (2.00)	0.00	0.798
Cough severity score	4.00 (2.00)	4.00 (2.00)	0.00	0.822
Pooled cough symptoms	16.00(6.50)	16.00 (5.25)	0.00	1.000
Post-Intervention				
Cough frequency score	0.00 (1.00)	3.00 (2.00)	–3.00	<0.001
Cough severity score	0.00 (0.00)	3.00 (1.00)	–3.00	<0.001
Pooled cough symptoms	0.00 (1.00)	10.00 (5.00)	–10.00	<0.001

Statistics, Independent median test

Table 4: Comparison of Post Intervention Clinical Parameters of the Study Participants

Variable	Intervention (n=42) Median, IQR	Control (n=42) Median, IQR	p-value
Cough effect on child sleep	0.00 (0.00)	2.00 (1.25)	<0.001
Cough effect on parent sleep	0.00 (0.00)	2.00 (1.25)	<0.001
Cough effect on overall daytime child activities	0.00 (0.00)	2.00 (2.00)	.005

Statistic, Independent median test.

score and standard deviation of 3.66±0.96, 3.71±1.08, 3.75±0.91 for the honey types respectively, and 3.55±0.77 for the silan date extract.[5] However, in the present study there was no significant difference in the median cough symptoms score between the intervention and control at baseline.

In this study, the post intervention median cough frequency and severity score was statistically significant, $p < 0.001$, between the intervention and control. A similar study showed lower post intervention scores for honey group compared to DPH, but the effect size was much lower than the index study indicating a better response. This difference could be due to the cumulative effect of the three consecutive doses of honey administered in the present study as against only two consecutive doses administered to participants in the Parviz, *et al* study.[4]

Some constitutional differences in the composition of the types of honey administered in both studies from different geographical regions (Asia and Africa) could also account for the difference. However, the effect size of pooled median cough symptoms score in the current study of –10.00, $p <0.001$ was similar to the pooled mean cough symptoms score of 10.90±5.30 in the Parviz, *et al* study for the control groups in both studies.[4]

The findings in the present study was also comparable to Herman, *et al* at post intervention with a mean cough frequency and severity reduction of 3.7 to 2.0, 3.8 to 1.8, 3.7 to 1.9 for the honeys types, and 3.6 to 2.6 for silan date extract for cough frequency for the first and second night; and 3.7 to 1.9 for the eucalyptus honey, 3.7 to 1.9 for the citrus Honey and 3.8to 1.8 for the labiatae honey types, and 3.5 to 2.6 for the silan date extract for cough severity respectively for the first and second night.[5] Herman, *et al* also demonstrated a combined cough symptoms score reduction of 18.6 to 8.8, 18.6 to 8.5, 18.5 to 9.0 for the Honey types respectively; and 18.2 to 12.4 for the silan date extract for the first and second night respectively.[5] This finding was also similar to the present finding of between

Table 5:Within Group Comparison of Cough Symptoms of Participants and Caregivers

Participants Intervention Group	Effect Size Difference in the median	p-value
Cough frequency	5.00	<0.001
Cough severity	4.00	<0.001
Effect on child's ability to sleep	4.00	<0.001
Effect on child's overall activities	3.00	<0.001
Participants Control group		
Cough frequency	2.00	<0.001
Cough severity	1.00	<0.001
Effect on child's ability to sleep	2.00	<0.001
Effect on child's overall activities	2.00	<0.001
Caregivers Intervention Group		
Effect on parent's daily function at workplace	3.00	<0.001
Burdensomeness	2.00	<0.001
Relationship with the child	0.00	0.165
Change in social life	1.00	<0.001
Conflict with previous daily work	1.00	<0.001
Feelings of being trapped by caregiving demand	1.00	<0.001
Caregivers Control Group		
Effect on parent's daily function at workplace	3.00	<0.001
Burdensomeness	0.00	<0.001
Relationship with the child	0.00	0.102
Change in social life	0.00	<0.001
Conflict with previous daily work	1.00	<0.001
Feelings of being trapped by caregiving demand	0.00	<0.001

Statistic, 2 samples (paired) Wilcoxon Signed-Rank Test.

Table 6: Comparison of Post Intervention Clinical Parameters of Caregivers

Characteristics	Intervention (n=42) Median, IQR	Control (n=42) Median, IQR	P-value
Cough effect on parents' daily functions at workplace	0.00 (0.00)	3.00 (2.00)	<0.001
Cough bothersomeness on parent score	1.00 (0.00)	2.00 (1.00)	<0.001
Effect on caregivers' relationship with the child	1.00 (0.00)	1.00 (0.00)	0.960
Effect on social life	1.00 (0.00)	2.00 (1.00)	<0.001
Effect on previous daily work	1.00 (0.00)	1.00 (1.00)	<0.001
Feelings of being trapped by demand of caregiving	1.00 (1.00)	2.00 (1.00)	<0.001
Cough effect on caregivers' sleep	0.00 (0.00)	2.00 (1.25)	< 0.001
Pooled caregivers' burden	5.00 (0.00)	11.00 (4.00)	< 0.001

Statistics, Independent median test.

group post intervention combined median symptom score of 0.00 and 10.00 for the Honey and DPH groups respectively, p < 0.001. The Herman study also showed a significant post intervention sleep improvement for the children and their caregivers comparable with the present study.[5]

The present study was similar to a report by Shadkam, *et al* in 2010 which found a mean cough frequency score for Honey group of 4.09±0.72 and 1.93±0.65 before and after the intervention, respectively. After the intervention, the difference of the mean cough score of the variables in all groups was statistically significant in that study and the mean score of all variables in the honey group was significantly higher than those in control group.[13]

In Nigeria, Oduwole et al reviewed the effect of honey and Dextro-methorphan (DXT), honey and DPH, honey with no other treatment and Honey and placebo, on children with cough from URTI in three previous studies. The honey and DPH group showed some improvement of in cough frequency and severity with little or no effect in the honey and DXT group.[6] This is comparable to the present study which showed significant reduction in the cough symptoms in the honey group when compared with the DPH group (with p-values of <0.001 in both groups). The caregivers of participants in the DPH group however reported that some of the children became sleepy while on the medication when compared with the honey group. This study showed a significant reduction, of the median post intervention score of cough effect on child's sleep p <0.001 when compared to the baseline (Tables 2 and 4). The overall effect on daytime child activities was also not significant, p 0.005. This study was comparable to the Parviz, *et al* study on sleep quality of 3.4±1.3 and 2.4±1.1 for pre intervention for the honey and DPH groups respectively, and a post intervention scores of 1.6±2.1 and 1.5±1.0 for honey and DPH groups respectively.[6] The findings in this study on the effect of intervention on the child's sleep pattern was also comparable to the Oduwole et al three-study review which showed a 0.55 reduction of this variable in the honey group and –1.64 mean difference in the DPH group.

Although the within group analysis showed a statistically significant outcome, p< 0.001 in the intervention and control groups, the difference in the median score (effect size) was more significant in the former than in the latter group (Table 5). This also demonstrated the superior effect of honey over DPH in managing cough symptoms in children. The pooled median cough symptoms

showed a significant effect size of −10.00, $p < 0.001$. These statistics therefore showed the superior effect of honey for alleviation of cough symptoms in children with URTI with significant effect on the secondary outcomes of child's sleep and his overall daily activities too. There were however no reported side effects in the honey group.

Most of the participants on the control group however reported somnolence as the only side effect. This probably influenced the statistically significant effect on child's sleep and relative reduction of cough symptoms for the DPH group.

In the present study, the pre intervention baseline parameters for the caregivers revealed a significant burden occasioned by the care of their children with cough from URTI especially from being trapped by the demand of care giving on their social life, and on their previous day's work schedules. However, the care for their children did not significantly affect their relationship with their children, p=0.960.

The baseline clinical parameters of the caregivers also showed the burden of care on them while taking care of their children with a significant pooled median caregiver burden, for intervention and control groups, respectively. Out of these clinical parameters, the only comparable one was the effect on the sleep quality of the caregivers in the Parviz, *et al* study where the present study was similar to that study with a pre intervention mean sleep score of 4.2±0.7 and 2.6±0.9 as compared to the present study finding of median score of 4.00 with IQR of 2.00, p=0.817 for both the honey and DPH groups respectively for both studies.

Post intervention, the present study showed a statistically significant difference in caregivers' sleep quality, effect on social life, previous day's work, and being trapped by the demand of caregiving. The Parviz, *et al* study, showed a superior effect of Honey over DPH similar to the present study. The difference in effect size in the Parviz study could be as earlier highlighted. The within group comparison of effect of care on caregivers also showed larger effect size in the intervention group than in the control group.

The post intervention within group comparison on the effect on the caregivers for all the parameters showed statistically significant differences, except for the relationship with the care recipients, meaning that the burden of care for their loved children did not affect their interaction with them.

The control drug DPH was compounded to look and taste like honey with the use of Astymin syrup as a base. Astymin is a multivitamin with some amino acids, Ascorbic acid, Vitamin A and has a caramel colour which makes it look like honey. DPH is an antihistamine and sedative drug. These components of Astymin and properties of DPH may have been responsible for some of the positive effects noticed in this study. Some of the caregivers of participants also reported somnolence which could have influenced the better sleep score for the participants, and therefore a limitation. The researcher could not monitor the administration of the intervention medications by the caregivers, but they were reminded by phone calls and SMS. The post intervention assessment was based on subjective reports from the caregivers which was another limitation.

In conclusion, the study showed a statistically significant effect of honey in the intervention group compared to DPH in the control group. There was significant post intervention reduction of cough frequency and severity as primary outcomes, as well as improvement in the sleep quality of both the participants and their caregivers, with a better effect size in the Honey group as secondary outcomes. There was also a significant post intervention improvement among the caregivers of other variables like effect on social life, conflict with previous day's work, daily function at workplace being trapped by the demand of caregiving to their children, etc. Table 6.

Duality of Interest

None to declare.

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