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The authors declare that the data presented are original material and have not been previously published, accepted or considered for publication elsewhere; that the manuscript has been approved by all the authors, who have met the requirements for authorship.

**1ST PRIZE PIDSP RESEARCH
CONTEST 2015**

ORIGINAL ARTICLE

COMPARISON OF SCHOOL-BASED AND HOME-BASED APPLICATION OF PERMETHRIN SHAMPOO FOR THE TREATMENT OF *PEDICULOSIS CAPITIS* – A PRAGMATIC CLUSTER-RANDOMIZED TRIAL

ABSTRACT

Background: Pediculosis continues to be a common yet neglected public health problem especially in children. Trials to test for effectiveness for head lice interventions are heterogeneous, and a recent systematic review recommended the use of cluster randomization and centralized administration (e.g. school) of permethrin for pediculosis trials.

Objective: To compare the effectiveness of a school-based to a home-based intervention using permethrin 1% shampoo in treating *pediculosis capitis*.

Methods: We conducted a pragmatic, cluster-randomized trial at the Makati Elementary School. All Grade Four students ($n = 211$), belonging to a total of five class sections, were invited to participate in the study. Students with a known allergic reaction to permethrin 1% shampoo, with open wounds on the scalp, or were absent on Days 1 or 10 of the intervention period were excluded. The five class sections were randomized to receive permethrin 1% shampoo to be applied either in school, or at home. The students were classified as having none, light, medium, or heavy infestation prior to Day 1 and after Day 10 treatment. Prevalence, incidence, and treatment outcomes were measured.

Results: The baseline prevalence of pediculosis capitis was 58.4%. General characteristics of students were similar between groups. No significant clustering in pediculosis classification was observed. The school-based group had the same prevalence in pediculosis at Days 1 and 10, had no incident cases, and were limited to light infestation by Day 10, but had no treatment success outcomes. The home-based group had increased prevalence by Day 10, poor compliance with Day 1 and 10 shampoo, incident cases, although it registered a higher treatment success rate.

Conclusion: Compared to standard home based intervention, a school-based strategy resulted in less incident cases (0% vs. 37%), reduction in pediculosis severity ($p = 0.007$), and higher compliance (100% vs. 58.3%). Control of pediculosis in this specific community is largely warranted because of its high prevalence rate of 59.7%.

KEYWORDS:

Pediculosis, head lice, permethrin, Pediculus humanus capitis, pediculosis capitis

INTRODUCTION

Pediculosis capitis infestation is a common but neglected problem in pediatric practice,¹ especially in schoolchildren.² It is caused by *Pediculus humanus capitis*, a species-specific and strictly obligatory ectoparasite that completes the entire life cycle on the scalp of humans. It can cause considerable distress to children and their families and may lead to bullying, social stigmatization, and poor school performance.¹ All socioeconomic groups are affected, and head lice infestations are common in many parts of the world.³ Despite the efficacy of permethrin for pediculosis on the level of the individual, no consensus based guidelines have been universally accepted due to the heterogeneity of trials.

The prevalence rate of pediculosis varies in different countries, ranging from 2% in the United Kingdom to 52% in Ukraine in various school based surveys.⁴ A local study in Muntinlupa City to determine the prevalence of pediculosis among school children showed that 45.9% had evidence of head lice infestation. The highest rate was noted among Grade Four students and least among Grade One students, particularly in females.⁵ A school-based study in Iranian primary school for girls found that shampoo treatment using permethrin resulted to 54.29% treatment success rate. Different factors such as parasite load, type of school, school location, level of education, level of awareness, and socio cultural factors influenced the efficacy level of the shampoos.⁶

Treatment failure from home-based intervention has been reported. Ozkan et al of Turkey identified social factors for treatment failure in the home such as lack of support, difficulties in the manual extraction of the nits and inability to purchase pediculicides.⁷

In a recent systematic review, 48 panel experts agreed that trials for pediculosis are appropriately carried out using cluster randomization, centralized

administration of permethrin, and blinding of outcome assessors. We hypothesized that the centralized administration of permethrin shampoo would be more effective for pediculosis control. Thus, we aimed to compare the effectiveness of school based versus home based interventions with permethrin 1% shampoo among schoolchildren at the Makati Elementary School, using the current recommendations for pediculosis trials.⁸

METHODOLOGY

We conducted a pragmatic cluster randomized trial was among Grade Four schoolchildren at the Makati Elementary School in October 1 to 15, 2014 after obtaining ethics approval and informed consent from the parents of the subjects. All Grade Four students (n = 211), belonging to a total of five class sections, were invited to participate in the study. Students with a known allergic reaction to permethrin 1% shampoo, with open wounds on the scalp, or were absent on Days 1 or 10 of the intervention period were excluded. Cluster randomization was employed in this study in order to minimize contamination between the two groups, in view of pediculosis being transmitted by direct head to head contact.⁹ A pragmatic approach was adopted to optimize applicability to usual school settings, and to measure effectiveness on a community level.¹⁰

Each of the subjects' hair was partitioned into quadrants, and lice combing was done on the right lower quadrant. Pediculosis classification was based on lice yield of three nit comb strokes (Box 1). Each subject was provided his or her own comb. Combing was stopped at the first sight of lice or nymph or nit. After each stroke, the comb was wiped on a paper towel to detect lice in between the teeth of the comb. All subjects were then classified under the category none, light, medium and heavy infestation.¹¹

Box 1. Classification of pediculosis capitis infestation*

Classification of pediculosis infestation	Criteria
Heavy infestation	More than one louse found with a single stroke of the comb
Medium infestation	One louse found with the first stroke of the comb
Light infestation	One louse is found after several strokes of the comb Presence of nits if no louse was found after several strokes
None	No presence of any form of infestation is present

*Adapted from pediculosis classification by Burgess et al⁶

Home-based intervention protocol

On Day 1 of the trial, the home-based intervention group sections were provided with a pediculosis treatment kit, which consisted of a nit comb, a sachet of permethrin 1% shampoo for single use, cotton towel and written instructions for the shampoo and nit combing for the parents or legal guardians. The students were likewise verbally instructed to apply the shampoo on Day 1 and Day 10 of the study. Both written and verbal instructions emphasized that the shampoo was to be applied onto the hair for 10 minutes and rinsed thoroughly using water, and to do daily nit combing. For students who were negative for pediculosis upon entry, a similar treatment kit was given, consisting only of a nit comb, cotton towel, and written instructions for daily nit combing. On Day 9 of the trial, we distributed a second sachet of permethrin 1% shampoo and a written reminder for use of shampoo for Day 10.

School-based intervention protocol

After screening for pediculosis on Day 1, we proceeded to shampoo the students with at least light infestation of pediculosis. The shampoo was applied on the scalp for 10 minutes and was rinsed

thoroughly with water and towel-dried. All students in the school-based intervention arm received a pediculosis treatment kit consisting of a nit comb, cotton towel, and written instructions for daily nit combing. On Day 10 of the trial, we performed a second round of treatment with permethrin 1% shampoo at the school clinic. On Day 10 of the trial, after application of permethrin of either home or school-based group, all students were re-classified according to infestation (none, light, medium, or heavy). Grade Four students who were previously classified as “none” were also re-classified, to inspect whether they remained pediculosis-free.

Measurement of outcomes

The following are the definitions of the outcomes of the interventions:

Treatment success- A subject who had either light, medium, or heavy infestation on Day 1 of the trial was classified as negative for pediculosis or ‘none’ on Day 10

Treatment failure- A subject who had light, medium, or heavy infestation on Day 1 was classified with the same degree of severity of infestation, or with increased severity

Improvement- A subject who had either medium or heavy infestation on Day 1, who was re-classified on Day 10 with decreased severity of infestation but not negative; i.e. medium to light, or heavy to medium, or heavy to light

Prevalence- The proportion of subjects with light, medium, or heavy infestation in among Grade Four students who were enrolled in the trial

Incidence- The proportion of subjects with light, medium, or heavy infestation on Day 10 of the trial who were negative for pediculosis at baseline

Statistical Analysis

A minimum total of 192 students were required in the study to estimate prevalence at desired precision and reliability of $\pm 5\%$ and 95% based on 45.9% prevalence of *pediculosis capitis* infestation and probability proportional to size sampling.⁴ Standard descriptive statistics were used to summarize general characteristics and pediculosis prevalence and classification. Baseline prevalence as well as incidence rates of pediculosis were computed. Intra-cluster and inter-cluster coefficients for ordinal variables were calculated to check for the effect of clustering on pediculosis levels. Chi-square test and chi-square test for trend were used to test for differences between pediculosis levels on Day 1 and 10, and treatment outcomes. Intention-to-treat analysis was applied. Conclusions were based on a 5% level of significance. STATA 12 was used in data processing and analysis. This study was approved by the Makati Medical Center Institutional Review Board (IRB).

RESULTS

Pediculosis prevalence

We enrolled a total of 181 students in this trial. Initially, 211 Grade Four students were recruited. Excluded from analyses were 19 students who did not submit consent and assent forms, and six who were absent on Days 1, and five students who were absent on Day 10 of the trial.

Pediculosis was found in 108 out of 181 students (baseline prevalence of 59.7%). Table 1 shows the age, gender composition, infestation profile, and reports of a household contact positive for pediculosis of the home-based and school-based groups.

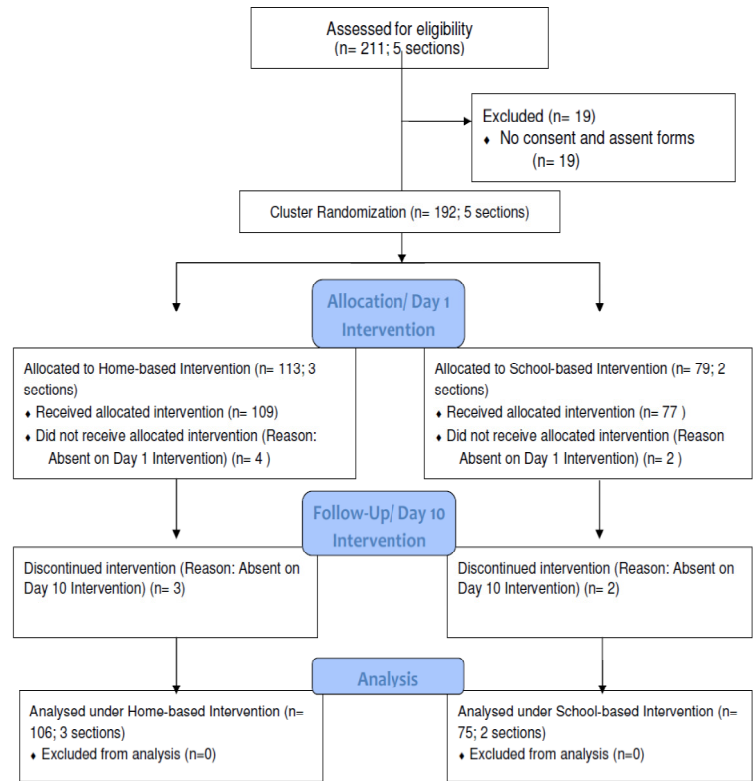


Figure 1. Flow Diagram of the Study

Table 1. Baseline characteristics of 181 grade four schoolchildren

	Home-based group N= 106	School-based group N = 75	P value
	Mean \pm SD, Frequency (%)		
Age, years	9.5 \pm 0.8	9.6 \pm 0.9	0.69
Male	46 (43)	41 (55)	0.17
Pediculosis prevalence	60 (57)	48 (64)	0.20
Infestation status			
None	46 (43)	27 (36)	0.49
Light	45 (43)	31 (41)	
Moderate	7 (7)	8 (11)	
Heavy	8 (7)	9 (12)	
Household contact/s with pediculosis	41 (9)	17 (23)	0.53

Effect of Clustering

We computed for the intra-cluster correlation coefficients (ICC) per cluster in each intervention. One class assigned to school-based intervention had an ICC of 0.1304 ($P = 0.03$), indicating a low degree of association in pediculosis outcomes of its members. The ICCs of the other classes were not statistically significant, indicating that the changes in pediculosis status of its members were not related to each other (Suppl Table 1).

Suppl Table 1. Intra-cluster and inter-cluster correlation coefficients

	Cluster	Intra-cluster correlation coefficient*	P value	Inter-cluster correlation coefficient†	P value
Home-based N = 106	A	0.0117	.51	0.063	.45
	B	0.0204	.40		
	C	0.0400	.24		
School-based N = 75	D	0.1304	.03	0.102	.31
	E	0.0657	.11		

Treatment Outcomes

We assessed levels of head lice infestation before permethrin treatment on Day 1 and after prevalence was unchanged at end of treatment (64.0%), significant improvements in infestation intensities were achieved ($P=0.007$). School children initially with moderate and heavy infestations changed to light status upon reclassification, while those with light infestation in the beginning remained unchanged. In contrast, distributions of pediculosis intensities in the home-based group were not significantly altered after the treatment period. There were no incident cases of pediculosis for the school-based group, while the home-based group had 12 new cases of head lice infestation (Figure 2; Suppl Table 2).

Table 2. Classification of Pediculosis capitis infestation after Day 10

	Home-based group N = 106 (%)			School-based group N = 75 (%)		
	Day 1	Day 10	P value*	Day 1	Day 10	P value*
None	46 (43)	41 (39)	0.319	27 (36)	27 (36)	0.007
Light	45 (42)	54 (57)		31 (41)	48 (64)	
Moderate	7 (7)	9 (3)		8 (11)	0 (0)	
Heavy	8 (8)	2 (2)		9 (12)	0 (0)	

Suppl Table 2. Matrix showing conversions in pediculosis capitis intensities

Day 1	Day 10				
	None	Light	Moderate	Heavy	Total
Home-based group					
None	34	11	1	0	46
Light	7	35	2	1	45
Moderate	0	0	6	1	7
Heavy	0	8	0	0	8
Total	41	54	9	2	106
School-based group					
None	27	0	0	0	27
Light	0	31	0	0	31
Moderate	0	8	0	0	8
Heavy	0	9	0	0	9
Total	27	48	0	0	75

Italics, improved; regular font, unchanged; boldfaced, worsened

Treatment success rates were 0% and 11.7% in the home-based and school-based intervention groups, respectively. Both recorded improvements and treatment failure did not differ significantly between groups (Table 3).

Table 3. Treatment outcomes of home-based and school-based groups

	Home-based group (n = 60)	School-based group (n = 48)	P value
Treatment success	7 (11.7)	0 (0.0)	0.040
Improvement	14 (23.3)	17 (35.4)	0.244
Treatment failure	39 (65.0)	31 (64.6)	1.00

Home-Based Compliance

Compliance rates to home-based permethrin shampooing based on student self-report were 60.0% (36 of 60) in Day 1 and 58.3% (35 of 60) in Day 10, in spite of written reminders and the complimentary shampoo which were provided to students.

Safety Analysis

There were five students who reported mild and tolerable stinging of the eyes while using permethrin shampoo. These were immediately relieved by rinsing with water. No other adverse effects were reported.

DISCUSSION

Prevalence and incidence of pediculosis

Head lice infestation varies greatly between and within countries. Baseline prevalence in our school-based trial was 59.7%, higher than the 45.9% found in another local study,² and considerably more so than rates noted in Turkey, Belgium, Australia, Brazil, Korea, China, United Kingdom and Iran.^{3,4,7} The range of prevalence rates may also differ depending on the grade level.³ Published literature consistently reports the increased propensity of primary schoolchildren for harboring *P. capitis* compared to other age groups.⁸

Demographic and infestation profiles of subjects did not differ significantly between treatment groups. Intra- and interclustering in pediculosis

statuses was minimal, allowing for analyses according to intervention arms instead of per individual classes. Pediculosis studies in Norway and Australia have examined the role of clustering for pediculosis, with equivocal results.^{8,12}

Post-treatment prevalence of pediculosis for the school-based group remained at 64%, with no incident cases. The rate increased from 57% to 61% in the home-based group, and there were twelve incident cases, all of which came from previously non-affected subjects.

Treatment success, failure, and improvement rates

An interesting finding in this study was that the home-based group posted a significantly higher treatment success rate (11.7% vs. 0%, $P = .040$) than the school-based group did. However, it also had more members with worsened pediculosis status, compared to none in the latter. Therefore, it would be misleading to assume that the home-based intervention is superior based on treatment success rates alone. We propose that these treatment outcomes must be reported alongside overall prevalence and incident cases of pediculosis, especially if community control of pediculosis is a program objective.

The technical criteria of treatment success or treatment failure did not fit for all subjects, particularly for those who had improved pediculosis intensity but not complete clearance. For this reason, we proposed the 'improvement' category to account for these subjects. The school-based group, albeit posting no treatment success, no longer had any subjects in the medium and heavy infestation categories after the ten day intervention period. A caveat in interpreting treatment failure in this case is that our reported rate merely pertained to failure to improve on a group or cluster level. It must not be misconstrued as indicating resistance to permethrin, as some

guidelines stipulate.¹³ Another caveat in interpreting treatment success in this case was that subjects who had no lice yield on nit combing but had visible nits were still classified as having light infestation, which may have led to an artefactual increase in prevalence on Day 10.

Compliance to permethrin treatment

Taking on a pragmatic perspective, we obtained self-reported compliance to home shampooing with permethrin on Days 1 and 10. The rates were approximately 60% for both days, despite provision of written reminders and the complimentary provision of medicated shampoo. Lack of adherence to treatment is one cause for pediculosis persistence, along with misdiagnosis, inadequate treatment, re-infestation, lack of ovicidal or residual killing properties of the product, and resistance to pediculicide.¹⁴ In Turkey social factors such as lack of support, difficulties in the manual extraction of the nits, and inability to purchase pediculicides were identified as contributory to the treatment failure from home-based intervention.⁹ On the other hand, factors such as parasite load, type of school, school location, level of education, level of awareness, and socio-cultural factors influenced the effectiveness of a school-based strategy in a study made in Iran.¹⁰ These are especially important to note because home-based treatment is the standard of care for permethrin shampooing.

Limitations

Our trial period was limited to ten days, preventing us from making inferences on the longer term differences between school- and home-based treatments. We also looked at only one aspect of pediculosis control, which was intervention with permethrin and nit combing. Other strategies, such as based on health behavior

theory or on prevention, were not within the scope of this study. Measurement of outcomes was largely ordinal in nature, and assessor bias may have been a factor in evaluation. Cross-contamination with students of other classes or grade levels was not taken into account.

CONCLUSION

Compared to standard home based intervention, a school-based strategy resulted in less incident cases (0% vs. 37%), reduction in pediculosis severity ($p = 0.007$), and higher compliance (100% vs. 58.3%). Control of pediculosis in this specific community is largely warranted because of its high prevalence rate of 59.7%.

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