

What hypothesis is being tested health and social care essay



Abstract:

Head lice infestation (*Pediculosis capitis*) is one of the most common infections occurring worldwide (Heukelbach et al., 2008). The point prevalence in the developed countries in children aged 6 to 12 years varies from 1% to 3%. The estimation of the incidence rate per 10 000 children is between 800 and 2400 new cases per year (Jahnke et al., 2009). Treatment choices are limited because of the increasing rate of the mechanisms of resistance to frequently used pediculicides (Heukelbach et al., 2008). Wet combing has been recommended by the health departments in Australia as a method of treating head lice infestation (Department of Health, 2005). This method consists of combing the wet conditioned hair with a nit comb (Greive et al., 2007). This process is repeated every two days for 10 consecutive days until no more head lice are found. A randomized controlled trial showed that wet combing achieved a cure rate of only 38% compared with 78% for two doses of 0.5% malathion (Roberts et al. 2000). Roberts et al. (2000) along with the Cochrane review concluded that wet combing is ineffective for head lice treatment (Dodd, 2003; Roberts et al., 2000). In this study, Hill (2005) compared the effectiveness of the Bug Buster (BB) Kit (1998) with over the counter pediculicides consisting of malathion or permethrin among representative populations from one country in Scotland and four countries in England (Hill et al., 2005).

What hypothesis is being tested?

Alternative Study Hypothesis (Research Study): Bug Buster Kit is more effective than a single treatment of over the counter pediculicides for head lice treatment. Null Hypothesis: Bug Buster Kit has the same effect as over the counter pediculicides.

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the counter pediculicides in eliminating head lice. In this study, Hill and his colleagues (2005) perform their study in order to reject the null hypothesis in favour to the alternative hypothesis.

What is the study design?

This study is an interventional randomised controlled trial. The type of the study design is mostly quantitative with a random sampling since quantitative usually use the sample to generalise. The study population (four counties from United Kingdom and one county from Scotland) in this research was considered in the paper as representative of the population in United Kingdom as a whole. Moreover, the internal validity was used in this paper to show the extent the study findings are representative of the study population while the external validity showed to which extent there is generalisation of the target population. Internal validity is a pre-requisite for external validity.

What type of study?

This is a single blind, multicentre, randomised, comparative clinical study comparing the BB Kit with a single treatment of over the counter pediculicides (Derbac-M, 0.5% aqueous malathion or Lyclear, 1% permethrin).

How was the population chosen?

This comparative study, the research was conducted among representative populations; 66 from Bedfordshire, 15 from Cornwall, 34 from Cumbria, 4 from Dumfries and Galloway, and 14 from Surrey. Young people with confirmed active cases of lice were recruited through general practitioner

practices and 56 of them were randomized to BB Kit and 70 to pediculicide treatment. No information was given to the family other than that provided on the product and carried out in their own home following manufacturer's instructions. Hill and his colleagues (2005) aimed to recruit infested young people with a live head louse from families who would normally buy a treatment from pharmacies or go a practitioner for advice. They chose the population with a lower age of 2 years for safety reasons and with no upper age limit; thus they recruited young people aged 2-15 years. The infested children should not been through any head lice treatment in the previous three weeks and their guardian should agree to not use other head louse treatment during the trial. The guardians should also provide a written informed consent and agree for immediate family lice examination, and if necessary give the same treatment as allocated for the family if any head louse was infested. The inclusion and exclusion criteria for population should be clearly defined. In fact, the research of Hill and his colleagues (2005) matched two of the three inclusion criteria in Cochrane review for randomised controlled trial (Dodd, 2001). Firstly, participants should have live lice; secondly, participants should not have used any other pediculicide in the month preceding enrolment (only three weeks in this study); and finally, lice and eggs should not be removed by combing following treatment with a pediculicide, except during detection combing.

What were the outcomes examined?

The main outcome was to measure the presence of head lice 2-4 days after end of treatment; day 5 for pediculicides and day 15 for the BB kit. They

aimed examine the presence or absence of live head lice in patients assessed.

How were these determined?

Randomization was done using Minitab 11. 0 for Windows by each general practitioner assigned to an individual randomization list at the start of the trial. Participants were visited at home and asked for follow-up . In fact, success (no live lice) or failure (one or more live live) was recorded by trained nurses using the wet combing method on conditioned hair from root to tip across the whole scalp for detection of head lice. Study nurses were unaware of treatment allocation after recording the presence, the number, and stage of lice. Lice were stored at -20°C for detection of the mechanisms of resistance. A simple questionnaire was advocated to participants and their guardians in order to obtain epidemiological information about age, sex, number of siblings, history of head lice treatment and infestation, and recent usage of antibiotics.

Were they valid measures of the outcomes?

The authors mentioned in the paper that choosing of these end points is to give treatments sufficient time and to offer similar chance for reinfestation to occur in both groups. However, the assessment of BB Kit participants was open to re-infestation ten days longer (on day 15) than those allocated to pediculicide on day 5. Thus, it is possible the cure rate may be affected for kit participants. Moreover, because it was proved in different studies that resistance mechanism exist against pediculicide used; additional studies should be assessed using BB Kit in comparison with other pediculicides

(Plastow et al., 2001). Furthermore, they did not evaluate the ovicidal
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activity which is important to make sure that re-infestation will not occur again.

What was the sample size?

In this epidemiological study, Hill and his colleagues (2005) recruited 133 young people aged 2-15 years; 66 from Bedfordshire, 15 from Cornwall, 34 from Cumbria, 4 from Dumfries and Galloway, and 14 from Surrey. 62 of the participants was assigned randomly to BB Kit and 71 of them to pediculicide treatment. After exclusion and lost to follow up, 126 participants completed the study; 56 were assigned to BB Kit and 70 to pediculicides (30 to malathion and 40 to permethrin).

Were any variables uncontrolled?

Uncontrolled variable may lead to false correlations and inappropriate analysis since it can affect the outcomes negatively. One of the uncontrolled variables in this study is exclusion and lost to follow up. For instance, one participant from Surrey allocated to BB Kit was excluded for his use of an insecticide and six others (three each from Cumbria and Surrey) were lost to follow up; one assigned to pediculicide (malathion) and five assigned to BB Kit. History of patients and their background is a factor that can affect the results also. The recruitment number of participants varied from region to region and the participants assigned to either of the two treatments were not equal in number. Also the percentage of girls was quite large (77% in BB Kit and 81% in pediculicide treatment). Participation of girls three times more than boys reflects a higher occurrence of head lice in girls (Downs et al., 1999). Type of Shampoo or conditioner used by families was uncontrolled also. Measurement variation can cause confusion in the experiment as the <https://assignbuster.com/what-hypothesis-is-being-tested-health-and-social-care-essay/>

questionnaires that can be remarkably inexact. Uncontrolled variables can be considered confounding variables.

Are there possible confounding problems and bias?

Although randomization reduces confounding, bias and errors, they still exist in this study. Confounding consists of: The type of hair; curly or straight, long or short, colored or not can significantly affect the results. Depending on the length and thickness of the hair, the duration of combing can change between 20 to 45 minutes (Plastow et al., 2001). Past infestation of head lice and also the sensitivity of the head scalp of patients. The time or the season at which the participants were chosen because the weather and seasons may affect the cure rate or the incidence rate. Non-examination of the head lice in all individuals of the family. Bias involves: Measurement bias that can be manifested by the wrong assessment and the misclassification bias because of the unequal grouping the participants. Selection Bias as the exclusion criteria Attrition Bias like the loss of follow up The non-evaluation of ovicidal activity; in fact an egg may be cemented to the hair craft close to the root so the comb cannot get them. Time period of each treatment should be considered and the time taken to comb out the hair of the participant should be provided (Plastow et al., 2001). Honesty, the proper use of the treatment as described, carrying out the treatment as recommended every 3rd day for a 2-week period so the immature louse will not be allowed to mature neither to reproduce (Plastow et al., 2001). The test used efficacy and the absence of certain statistical terms as the power. There was no subgrouping at different age intervals that may give more accurate results. Chance can happen since the studied cannot include entire populations and

cannot ever last. So the chance may arise since the outcomes do not represent of the definitive true values. However variations from the mean value can be reduced if confounding and bias are minimised.

What is the data presented?

A final number of 133 participants were recruited and assigned randomly to either BB Kit (62) or to pediculicide group (71). After exclusion of one participant and lost to follow-up of 5 participants, the trial was completed with a total of 56 patients completed the trial in BB Kit group. One participant of pediculicide group was lost to follow-up, so 70 participants remained (30 for malathion and 40 for permethrin). They observed a cure rate of 17% for malathion (5/30) and 10% (4/40) for permethrin. The cure rate of BB Kit was significantly greater than that for pediculicides (57% vs. 13%; relative risk 4.4, 95% confidence interval 2.3 to 8.5). 2.26 is the number needed to treat for BB Kit in comparison with the pediculicides. Assuming treatment failure for missing participants or their failure in BB Kit but success in pediculicide group, the cure rates are respectively 52%(32/62) and 14%(10/71) with a relative risk 3.7, 2.0 to 6.8CI. The percentage of females participants were significantly higher; 77% for BB Kit and 81% for pediculicide.

How is it presented?

The data was presented using diagram to indicate the flow of participants through the trial and two tables representing the descriptive characteristics and outcomes measure. The tables showed the numbers, the percentage, the mean and standard deviation, the p-value, the relative risk and finally

the 95% confidence interval results. Finally, a summary was presented of what is already known on the topic and what the study adds in table.

Is this a legitimate way of presenting it?

The data are presented in the usual way (diagram and tables). Nevertheless, this study missed a lot of important details especially concerning the descriptive characteristics of participants. Indeed, Burgess and his colleagues (2005) presented more detailed data which can affect the validity and reliability of results outcomes; they presented the groups assigned in detailed table containing age, sex, intensity of infestation, hair thickness, length, degree of curl, and dryness or greasiness (Burgess et al., 2005). Moreover the sample sizes in the study of Burgess and his colleagues are twice larger (253) than those of Hill's study (133 participants). The larger the sample size, the bigger the validity, and the more accurate and valid the outcomes will be. However, the major flaw was the lack of information on long term outcome. It is necessary to examine head lice recurrence over a period of at least 1 year in order to definitely discover which treatment is more effective. Furthermore, BB Kit is described as a four times course of wet combing over two weeks and includes day-by-day calendar which demonstrate exactly the days the combing is done. Hill and his colleagues did not mention this calendar and did not presenting it to the readers as an evidence of accuracy and validity.

What are the main conclusions?

The authors came to the conclusion that " the Bug Buster kit was significantly more effective(four times more effective) than current over the counter pediculicides for eliminating head lice" (Hill et al., 2005). Moreover, <https://assignbuster.com/what-hypothesis-is-being-tested-health-and-social-care-essay/>

the modern BB Kit appears to act as an alternative to over the counter pediculicides. They concluded also that popular over the counter pediculicides are poorly effective. They declared also that Kdr-type resistance to pyrethroids is widespread in head louse in the United Kingdom. Finally, they finished by mentioning that insecticide treatments potentially expose consumers to repeat the treatment with no important decrease in infestations, therefore these insecticide treatment need to be reassessed.

Are they justified?

Hill and his colleagues explained their conclusions accordingly. First, they mentioned that a previous study for Roberts and his colleagues (2000) showed that malathion treatment was twice more effective than BB Kit, which contradicted their results. The main reason declared is the updated BB Kit used in Hill's research rather than the use in Wales study of the earlier 1996 pilot kit. They believe that the fine comb was the crucial and active constituent of their current Kit. Indeed it improved the effectiveness of the BB Kit and increased the cure rate. In the other hand, Welsh trial also contradicted their findings by reporting the cure rates of pediculicides much higher than Hill's study data. Moreover, a previous trial in Bristol showed 36% cure rate for malathion and 13% for permethrin. They justified this discrepancy in different ways. First, they used single dose of pediculicide rather than the unlicensed use of two doses six days apart. Moreover, a double dose is likely to give better success in killing nymphs. Second, in contrast to the Welsh trial that took a follow-up time after seven days of treatment, they took five days only in this study in order to avoid the risk of infestation. Third, they used aqueous formulation instead of an alcohol one

to avoid allergies. The use of either formulation according to the allergic state of participants in Welsh trial did not show any variance in effectiveness between the two. Fourth, they recruited families reporting lice infestation in their child and seeking for a treatment rather than sending professionals into schools for screening with fine combs in order to find cases. Therefore, they consider their study representative of treated population as a whole. Finally, they ended their justification by mentioning the widespread Kdr- type mechanism of resistance which affected the permethrin action and the finding of L932F and T929I resistant genotype of the sodium channel gene in one of the lice from the failure treatment.

Are there alternative explanations?

In principle, the authors can only conclude that BB kit used is better than the two pediculicides studied and not better than the over present over the counter pediculicides in general. Hill and his colleagues claim that the main reason about the significant difference between their results and those of Roberts trial (2000) is due to the comb used. This statement is unverified. According to Community Hygiene Concern, there is no difference in effectiveness of the combs formed. In addition to that, the combs used in Wales trial were provided from CHC on 25 March 1999 (Robert et al., 2000). If authors cannot provide a proof for their claim, then this claim should be withdrawn. Their statement that the dose rate is recommended six days apart is also incorrect since the dose was given a week apart as recommended from the British National Formulary (mentioned in their report) (Roberts et al., 2000). The reasons affecting the high cure rate of BB Kit may be related to other factors. One of them may be associated with the

type of participants. There was no report about how many participants were asked to be a part in the study, neither their response rate nor how many refused or agreed. Since the number assessed was relatively low, the study cannot be judged as representative of the population as a whole. For instance, in Wales research 4037 children were screened randomly from 24 different schools with a participation rate of 84% (Roberts et al., 2000). According to CHC, BB Kit consists of four times wet combing spaced over two weeks and the period should be extended if any live lice is founded at the first session . Hill et al evaluated their outcome on day 15 with no exception and they did not consider the variance of assessment of the outcome depending on the treatment duration. There was no report of the duration of treatment also. In fact, in Wales trial only 16% of participant completed BB Kit treatment by day 14 (Roberts et al., 2000). Since also the assessment did not contain viable eggs, many of cured cases may be " false negatives". Therefore the cure rates of Bug Busting may be overestimated in Hill's paper (2000).

What are the recommendations?

The authors questioned if the cure rate of BB Kit of 57% is still undesirable and cannot provide an effective head lice treatment. They also mentioned in BMJ group while responding to the criticism that Hill and his colleagues look forward to see a future work on comparative efficacy srudy of different fine tooth combs especialy in the absence of pediculicide treatment.

Are they logical and justified?

This study recommendation was supported by a trial for Plastow and his colleagues who reported 53% cure rate of BB Kit at first use and 100%
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eradication of head lice by day 24. Because of Plastow's evidence, NHS prescription by general practitioners allowed then BB Kit for children (Plastow et al., 2001). However, the cure rate observed in this study was 17% for malathion and 10% for permethrin. However, there is no pediculicide that can kill 100% of the eggs for the first application (Mumcuoglu, 1999). Furthermore, In the United Kingdom as in different parts in the world, head lice become resistant to pediculicides mostly permethrin that became ineffective for treatment of head lice. Consequently, comparing a treatment to another that is considered as a bad treatment as permethrin with resistance mechanisms cannot make the study beneficial. In fact, a very recent study confirmed that wet combing is the optimal method only for diagnosis and detection of active head lice infestation but not for treatment (Feldmeier et al., 2012). the authors should mention any potential impact of limitations on the results found. Finally, Because of the lack of a proper validity and reliability and because the study did not extend the time to assure its results efficacy and since confounding and bias considerably exist and data were not properly detailed, and since this study did not reflect good clinical practice in terms of study design, this study is not well justified.