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Nurse-led counselling programme on the adherence to eye patch application among children with amblyopia: a randomised control trial

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ABSTRACT

Objective To assess the impact of the nurse-led counselling programme on eye patch application for improvement of adherence to eye patch application and vision among children with amblyopia.

Material and methods A randomised control trial was done at the paediatric clinic in the eye outpatient department of a tertiary care institute in North India. A total of 70 children with amblyopia were enrolled in the study by using total enumeration sampling techniques and randomised into experimental and control groups with 35 children in each group. Data were collected by interviewing the children with amblyopia and their parents as per the interview schedule. A protocol for nurse-led counselling on the adherence to eye patch application was developed. The intervention included counselling sessions, demonstrations and booklets for the experimental group. A performa for maintaining daily records of the time and duration of eye patch application was given to parents of the experimental group. Eight telephonic follow-ups were done with the experimental group of patients to motivate parents to adhere. Standard care was given to the children of the control group. Both groups were finally evaluated at third month on adherence to eye patch application and visual acuity.

Result The adherence to eye patch application, vision (as per logMAR chart) knowledge and practices of eye patch application was significantly better in the experimental group as compared with the control group ($p<0.01$).

Conclusion The nurse-led counselling programme demonstrated improvement in visual outcomes and adherence to eye patch application.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Occluding the 'better eye' with an 'eye patch' can improve the vision of the 'amblyopic eye' in children having amblyopia.

WHAT THIS STUDY ADDS

⇒ 'Nurse-led counselling programme' for the adherence to eye patch application is a new concept that is, if nurses are appointed to counselling the parents and children with amblyopia it will help improve adherence to eye patch application and ultimately improvement in vision.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ In clinical practice, nurses can be posted in ophthalmology outpatient department (OPD) for counselling parents or nurse-led clinics can be started in ophthalmology OPD for counselling parents of children having amblyopia. This will also save the time of ophthalmologists, especially in developing countries with a shortage of ophthalmologists.

INTRODUCTION

Amblyopia is one of the common causes of visual impairment in early childhood affecting nearly 1%–2% of the population. It can be bilateral, but it is mostly unilateral which is caused by abnormal visual inputs to the brain during a critical period of visual development. In simple terms, the brain focuses only on the good eye and ignores the image of the other eye which becomes the 'lazy' eye. The nerve cells do not respond normally until the lazy eye is not stimulated properly.[1] During the first few years of life, abnormal visual inputs can result in amblyopia. Many factors can cause amblyopia, including muscle imbalance or refractive errors. Permanent visual loss can occur, if treatment is not taken in time. It is no organic problem in the eye itself but a developmental problem in the nerve supply from the eye to the brain.[2]

It can be cured with early detection, by correcting the abnormal visual inputs usually by occluding the good or normal eye for some periods of time during the early years of visual development.[3] To improve the working of the lazy eye patch therapy over the non-amblyopic eye is considered an effective treatment. The length of treatment of amblyopia depends on the age of the child, the severity of the problem and adherence to the treatment according to instructions given by a specialist. The patch is usually applied for

2–6 hours every day by the amblyopic patient. Children with amblyopia should be encouraged to do close work while wearing the patch, such as reading, colouring or doing school work. The studies from the paediatric eye disease investigator group give us evidence that eye patch application is effective in the treatment of amblyopia in children, if there is good compliance to eye patch application for the prescribed amount of time.[4]

The literature review shows that most of the patients are not compliant with the patching regimen. The reason for not adhering to the eye patch application is that it is difficult to convince the child to wear the patch. Many studies support the data of difficulty in adhering to full treatment sessions.[5] Due to the overload of patients in outpatient departments (OPDs) doctors do not have much time to spend on one patient. So, nurses can take the lead in counselling children with amblyopia because they can play a better role as counsellors, educators and advocates. Nurses can counsel the children with amblyopia and their parents regarding the adherence of eye patch application by educating them about how it is used, and how it helps the children to improve their vision. Hence, the need was felt to develop and implement nurse-led counselling on eye patch application and asses the adherence to eye patch application to improve the vision of amblyopia patients. The present study was done to assess the impact of the nurse-led counselling programme on eye patch application for improvement of adherence to eye patch application and vision among children with amblyopia.

MATERIAL AND METHODS

Study design

A quantitative randomised control trial to assess the effectiveness of a nurse-led counselling programme for adherence to eye patch application for the management of amblyopia among children was carried out. The primary outcome was the compliance with eye patch application. The secondary outcome was an improvement in vision.

Subjects

Newly diagnosed 70 patients with amblyopia attending the paediatric clinic in eye OPD of a tertiary care institute in North India between the ages of 1 and 15 years from July 2019 to August 2019 were enrolled by using total enumeration sampling techniques. For enrolment, amblyopia was defined as best-corrected visual acuity (BCVA) <6/12 or the difference of BCVA of 2 or more lines of acuity between the two eyes without any structural abnormality in the eye.[6] The enrolled participants were randomised into experimental and control groups by using a randomisation sequence created by Microsoft Excel. The sequence was generated by a research team member independently and prepared sequentially numbered, opaque, sealed and stapled envelopes to conceal the sequence from the researcher responsible for data collection. These sealed envelopes were handed over to the researcher responsible for data collection. The sample size was calculated using the non-inferiority method for a continuous outcome. Type 1 error was at 5% and power of study was at 80%. The ratio of cases to control was 1, as an equal ratio of participants was recruited. The prevalence of amblyopia was used as 5% for the Northern India population and the clinically meaningful difference was set at 3.5. A 15% drop-out rate was set for this study. It was set higher than the usual 10% as the population under study is a vulnerable one. A sample size of 60 was calculated, that is, 30 for the treatment group and 30 for the control group.[7]

Tools and protocol on nurse-led counselling programme

A protocol on 'nurse-led counselling programme on the adherence of eye patch application' was developed in the form of counselling sessions and demonstration of using an eye patch over the eye and a booklet on 'care of child with amblyopia'. The content validity of the tools and protocols was ascertained with the help of experts from the fields of ophthalmology, nursing and community medicine. The overall Content Validity Index of the tool was 0.9 and the protocol was 0.85. Data collection at the time of enrolment includes (a) sociodemographic profile of the parents and children; (b) knowledge and practice regarding adherence to eye patch application, (c) data retrieval sheet for clinical profile and (d) performa for recording time and duration of eye patch application.

Method of data collection

Children were enrolled as were first time diagnosed with amblyopia in the OPD. Written informed assent from children and consent from parents was obtained. Parents of children with amblyopia were interviewed as per the interview schedule. A data retrieval sheet was used to record baseline assessment of the clinical profile of children from their files. It consisted of visual acuity of children and prescription of eye patch application hours. After collecting baseline, they were allocated into experimental or control groups by opening sequentially numbered, opaque, sealed and stapled envelopes.

Intervention

Participants from the experimental group were counselled about the importance of eye patch application, the procedure for eye patch application, good time and time limits for using eye patch, and the importance of doing close work. Demonstration was given on preparing eye patches at home and applying them over the good eye of the child. Redemonstrations were taken from the parents till the parents learnt to prepare the eye patch and place it over the eye. At the end of the teaching a booklet on 'care of child with amblyopia' was given to parents for ready reference. A performa for recording daily details of eye patch application was given to patients to record the time and duration of applying the patch daily. The control group was asked to follow the advice given by the doctor.

Follow-up

In the experimental group, eight telephonic follow-ups for positive reinforcements were done for 3 months after the intervention. Initially close follow-ups, that is, two calls for the first 4 weeks after the intervention were done to motivate, and reinforce children with amblyopia and their parents regarding eye patch application. Then follow-ups were tapered and done with longer gaps that is, once in two weeks for the next 8 weeks. At the end of each call, the parents were asked to share a photo of the daily record performa with a detailed record of the time and duration eye patch application on the study WhatsApp number.

Postintervention

Final evaluation was done in third month of both the experimental and control group by the same interview schedule postintervention, to assess the knowledge and practice regarding the adherence to eye patch application. Postintervention visual acuity of both eyes was retrieved from the patient's files of both groups. Performa for recording daily details of eye patch application were collected from the experimental group. The control group was interviewed about the adherence to eye patch application during the last 3 months. There is no loss to follow-up. Data analysis and interpretation were used by descriptive and interferential statistics. χ^2, Fisher's exact test and paired and unpaired t-test have been used in the analysis.

RESULTS

We recruited 70 newly diagnosed children with amblyopia for the study. The age of the children with amblyopia was in the range of 1–15 years with a mean age of 7.02±3.69 years, in the experimental and 6.62±3.93 years in the control group. Half of the children in the experimental group (45.7%) and control (54.3%) group were males. All the children were living in their own houses. One-third of the children were studying in the 1st–5th standard in the experimental (40%) and control group (37.1%). The majority of the children with amblyopia in the experimental group (77.1%) and 68.6% in the control group were from joint families. Half of the children in the experimental group (51.4%) and 34.3% in the control group were from Punjab state. Both the groups were found to be homogeneous and comparable in terms of age, gender, type of house and type of family members (p>0.05 as per χ^2).

Sociodemographic profile of the parents of children with amblyopia in the experimental and control group revealed that nearly half of the accompanying parents in the experimental group (54%) and 37.1% in the control group were in the age group of 31–35 years with mean age 33.80±5.08 years in the experimental group and 33.02±7.38 years in the control group. The majority of the accompanying parents were mothers (80%) in the experimental group and 65.7% in the control group. The per capita monthly income of the experimental group ranged from INR625 to INR125 000 and INR833 to INR33 333.0 in the control group. Only 31.5% of parents in the experimental group and 25.7% for the control group were from the upper class as per the modified BG Prasad scale 2019.[6] Educational status of the parents, half of the mothers (51.4%) in both the experimental group and control group were graduated and above. Education status of the father half of the fathers (57.1%) in the experimental group and 31.4% in the control group were graduates and above. The majority of the mothers (80%) in both groups were housewives. Most of the fathers in the experiment group (60%) and 28% in the control group were having their own business. Both groups were homogeneous and comparable concerning the age of accompanying parents' education, occupation and per capita income (p≥0.01).

Table 1 Clinical profile of children with amblyopia

Variables	Experimental group n_1=35 n(%)	Control group n_2=35 n(%)	χ2 (df), p value
Affected eye			0.95
Right eye	14 (40.0)	15 (42.9)	(2)
Left eye	19 (54.3)	16 (45.7)	0.61
Both eyes	2 (5.7)	4 (11.4)	
occluded eye			0.95
Right eye	19 (54.3)	16 (45.7)	(2)
Left eye	14 (40.0)	15 (42.7)	0.61
Both eye	2 (5.7)	4 (11.4)	

The clinical profile of both groups describes that in the experimental group, 14 (40%) children had amblyopia in the right eye and more than half (54.3%) had a left eye affected with amblyopia while both eyes of 2 (5.7%) children were affected. In the control group, 15 (42.9%) were having problems with amblyopia in the right eye, 16 (45.7%) had it in the left eye and both eyes of 4 (11.4%) children were affected. Both groups were homogeneous and comparable in terms of the affected eye with amblyopia (p≥0.05) (table 1).

The adherence to eye patch time duration was observed weekly for 3 months. In first week, 94.3% of children with amblyopia were applying the patch according to the prescribed time, 2.9% used it less than the prescribed hours and 2.9% applied it more than the prescribed hours. In the 12th week, all children applied the patch according to the prescribed time which shows the improvement in the duration of applying the eye patch. Duration of close work in first week, 17.1% of children were doing the close work for 61–90 min, 42.9% were doing it for 91–120 min and 40.0% were doing it for more than 120 min. Most of the parents (88.6%) said that they did not face any difficulty while patching on eyes. The majority of the parents did the patching (82.9%) at home compared with 17.1% during both home and school time. All the parents maintained the daily performa of patching and daily recording time

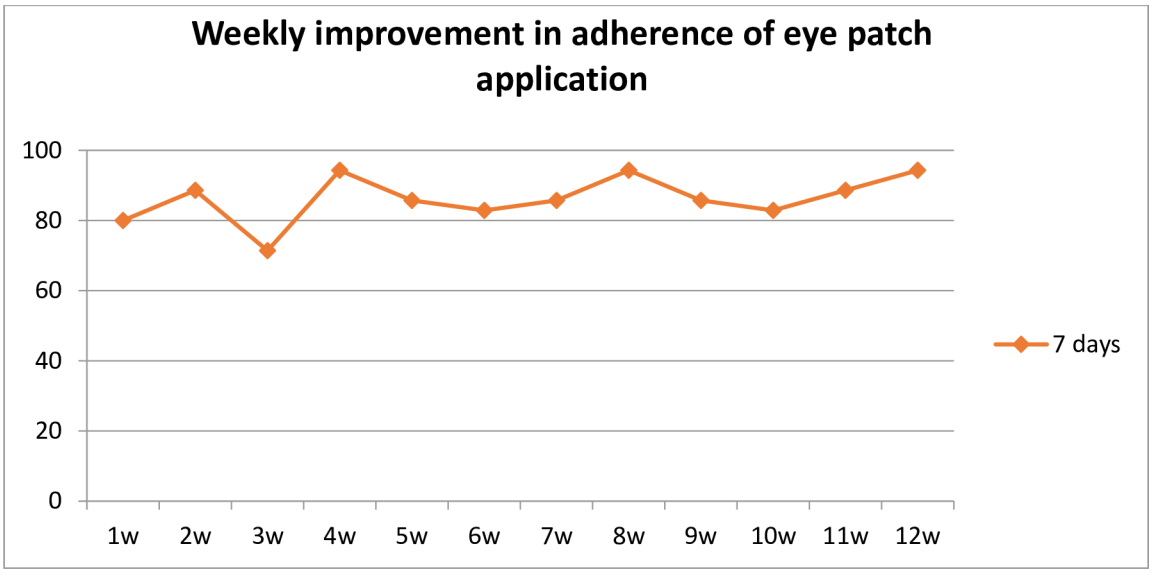

Figure 1 Weekly improvement in adherence of eye patch application.

and duration in the diary. The weekly improvement in adherence to eye patch application increased from 80% (1st week) to 96% (12th week) as shown in figure 1 and online supplemental table 1 while in the control group, only 4 (11.4%) children used eye patch application regularly rest of them (88.6%) used it irregularly. We could not document the control group's baseline adherence to patching as all the children were newly diagnosed and did not have any previous experience with patching.

Table 2 describes the practice patterns and awareness regarding eye patch application among children with amblyopia. All (100%) of the parents in the experimental group and 77.1% in the control group knew the reasons for applying eye patch application. Most of the (88.6%) parents in the experimental group and 2.9% in the control group knew the importance of regular use of eye patch application. In practice, all the (100%) children in the experimental group and 11.4% of children in the control group were doing the patching. Most of the children with amblyopia (94.3%) in the experimental group and (85.7%) in the control group were using the ready-made patch. All the (100%) parents in the experimental group and 82.9% of parents in the control group were using the patch over the normal eye but still 17.1% of parents in the control group were confused. Most of the children (88.7%) were cooperative in the experimental group and 5.7% in the control group. All the (100%) children in the experimental group and 5.7% in the control group were doing the patching regularly. All the (100%) children in the experimental group and 5.7% in the control group were doing close work with patching regularly. It shows a significant improvement in adherence in the experimental as compared with control group the ($p<0.05$).

Table 3 depicts an intergroup and intragroup comparison of vision (as per logMAR chart) of children in the experimental and control group applying eye patch application for amblyopia before and after the intervention. There was a significant increase in vision (as per the logMAR chart) in both the eyes (affected and occluded eye) in the experimental group after the intervention ($p<0.01$). In the control group, there was no significant difference in vision in the affected eye ($p=0.13$) and occluded eye ($p=0.196$). Hence, vision improvement observed in the experimental group was significantly higher than in the control group. Intergroup comparison in both groups revealed that during preintervention assessment there was no significant difference between the experimental and control group in the vision of the affected eye ($p=0.1$) and occluded eye ($p=0.57$). During postintervention, there was a significant difference in the vision of the affected eye in the experimental and control groups ($p=0.001$). No significant difference was observed in the experimental group as compared with the control group in the vision of the occluded eye ($p=0.784$). This has indicated that the intervention was effective in improving the vision in the affected as well as the occluded eye.

Table 4 depicts that the vision of the affected eye as per the logMAR chart in the experimental group ranged from 0.00 to 1.1. Before intervention, 10 (25.6%) children of the experimental group had 0.5 vision as per logMAR chart while after intervention 11 (28.2%) children had vision 0.2 (logMAR chart). In the control group, before intervention, nine (24.3%) children of the experimental group had 0.2 vision as per logMAR chart while after intervention only five (13.5%) children had vision 0.2 (as per logMAR chart).

The vision of the occluded eye as per logMAR chart in the experimental group ranges from 0.00 to 1.1. Before intervention, three (15.4%) children of the experimental group had 0.2 vision as per the logMAR chart while after intervention eight (25.8%) children had vision 0.2 (logMAR chart). In the control group,

Table 2 Practice patterns, awareness and compliance of eye patch application among children with amblyopia as per questionnaires

S.No	Variables	Experimental group f (%) n=35	Control group f (%) n=35	χ^2 (df) p value
Knowledge				
1	Reason for eye patch application			
	It improves the vision	35 (100)	27 (77.1)	9.032
	It improves misalignment eye		6 (17.1)	(2)
	No idea		2 (5.7)	<0.01
2	Why should eye patches used regularly			
	Improve vision	31 (88.6)	1 (2.9)	51.903
	Better for child	4 (11.4)	32 (91.4)	(2)
	No idea		2 (5.7)	<0.01
Practice				
3	Regular use of eye patch application			55.641
	No	–	31 (88.6)	(2)
	yes	35(100)	4 (11.4)	<0.01
4	Type of patch used for the patching			1.439
	Ready-made patch	33 (94.3)	30 (85.7)	(1)
	Self-made patch	2 (5.7)	5 (14.3)	0.232
5	Eye patch used on which eye			70.000
	Normal eye	35 (100.0)	29 (82.9)	(2)
	Confused	–	6 (17.1)	<0.01
6	Regular close work after applying the patch			62.432
	Yes regularly	35 (100.0)	2 (5.7)	(1)
	Not regularly	–	33 (94.3)	<0.01
7	Cooperation of child			
	Yes	31 (88.6)	2 (5.7)	51.056
	No	–	23 (65.7)	(2)
	Some time he resists	4 (11.4)	10 (28.6)	<0.01

N=70.

before intervention, 11 (33.3%) children had 0.2 vision as per the logMAR chart while after intervention only 10 (30.3%) children had vision 0.2 (as per logMAR chart). It indicates that some improvement has been observed after intervention in both eyes in the experimental group though this difference was not significant. Similarly, no significant difference was observed in logMAR chart values in affected and occluded eyes.

DISCUSSION

Amblyopia is becoming the leading cause of childhood visual impairment. Early detection and early start of occlusion therapy of the better eye results in excellent outcomes. The main problem with eye patch applications is the compliance of children with eye patch applications. Children must adhere to eye patch application as per required prescription hours. Although the treatment for amblyopia is very effective, compliance issues lead to a failure of the treatment.[4]

There is a need for a programme that can help the children to adhere to the eye patch. The present study included 'nurse-led counselling of children with amblyopia and their parents' regarding eye patch application and its importance as well as stressing compliance. Many studies have proved that 'nurse-led counselling' can improve adherence in the management of different diseases but such an approach has not been tried in ophthalmology.

In the present study, children with amblyopia aged 1–15 years were chosen because eye patching is recommended and effective in this age group. A previous study done on amblyopia showed that early identification of amblyopia is essential to obtain the best outcome of treatment. In the first few years of life, that is, the critical period of visual development the amblyopia responds best to treatment.[8]

Numerous studies done by the paediatric eye disease investigator group have proven that both atropine and

Table 3 Intergroup and intragroup comparison of vision as per logMAR chart among children with amblyopia receiving eye patch application

Vision (logMAR chart)	Group		Independent t-test t (df), p value
	Experimental n=35*	Control n=35*	
Affected eye			
Preintervention Vision	0.47±0.31	0.59±0.34	−1.66 (74), 0.1
Postintervention Vision	0.38±0.29	0.62±0.35	−3.365 (74), 0.001
Paired t-test			
Mean difference	0.089±0.13	−0.024±0.095	
SE	0.021	0.0157	
(CI) lower–upper	0.047–0.132	−0.56–0.007	
t (df), p value	4.2 (38), <0.001	−1.55 (36), 0.13	
Occluded eye			
Preintervention vision	0.54±0.36	0.38±0.32	1.94 (62), 0.57
Postintervention vision	0.39±0.31	0.42±0.31	−0.275 (62), 0.784
Paired t-test			
Mean difference	0.155±0.213	−0.03±0.15	
SE	0.038	0.145	
(CI) lower–upper	0.077–0.23	−0.084–0.018	
t (df), p value	4.054 (30), <0.001	−1.32 (32), 0.196	

N=70.
*Four children from experimental and 2 from the control group had both eyes affected so 39 affected eyes in exp and 37 in the control group.

patching therapy improve the vision of an amblyopic patient but recovery is faster with patching.[9] Hence, patching is the gold-standard therapy for amblyopia. However, this therapy fails or shows suboptimal results in about 25% of cases, the main reason being poor compliance with patching.

The present study along with teaching regarding eye patching demonstrations and return demonstrations was chosen as part of a counselling programme for preparing and applying eye patches at home. As it was reported from the previous study, only giving education regarding treatment is not sufficient for improving compliance. More efforts should be taken in the direction of understanding the true sense of the problem and its impact.[10]

As part of the intervention booklet on 'Care of Children with Amblyopia' was prepared and distributed to parents so that they could refer when needed. As teaching may not be retained, the availability of a booklet for ready reference helps in clearing doubts and improving adherence to eye patch application. A previous study was conducted to assess the usefulness of educating patients to increase the long-term value of compliance by persistence. It was concluded that giving education and support to these patients was needed to improve adherence to osteoporosis therapy.[11]

To achieve the desired outcome of treatment, children with amblyopia need to adhere to prescribed treatment. The desired result of treatment is not achieved because of poor adherence to the treatment.[12] Many methods have been employed to improve adherence in the literature. Diary writing is one of the best methods used to improve adherence. Another study suggested that there is a positive correlation between the completion of a daily diary and patient compliance with treatment. It was concluded that for the improvement in compliance, diaries can be used.[13] Hence, in the present study, the daily diary recording about the time and duration of eye patch application was used.

Many studies have proved that telephonic follow-ups can improve adherence. A study was conducted on nurse-led telephonic follow-ups on adherence to medication and diet after myocardial infarction. The telenursing intervention could positively affect the patients' adherence to the medication regimen. The medication adherence level increased from poor in the pretest to high in the post-test in the intervention group after receiving telenursing intervention. However, no significant difference was found between the medication adherence level in the pretest and post-test phases in the control group.[14] Similarly in the present study, telephonic follow-ups were done to motivate and reinforce children with amblyopia and their parents for eye patch application for prescribed hours a day and with a minimum 1-hour close work. Initial follow-ups were done very frequently because parents and children need more support at the beginning of treatment. Weekly follow-ups in the first 4 weeks and later the next 8 weeks the follow-up were done after 2 weeks gap as parents and children started getting accustomed to the therapy. It can be further taper down in the next weeks of therapy in future studies.

Table 4 Comparison of vision as per logMAR chart before and after intervention in experimental and control group

Vision as per logMAR chart	Experimental group n_1=35 n (%)			Control group n_2=35 n(%)		Fisher exact (df) p value
	Preintervention	Postintervention	χ2 (df) p value	Preintervention	Postintervention	
Affected eye			6.98			6.22
0.00	5 (12.8)	6 (15.4)	(9)	1 (2.7)	1 (2.7)	(9)
0.10	–	–	0.63	–	–	0.7
0.20	6 (15.4)	11 (28.2)		9 (24.3)	5 (13.5)	
0.30	4 (10.3)	5 (12.8)		1 (2.7)	3 (8.1)	
0.40	1 (2.6)	1 (2.6)		–	2 (5.4)	
0.50	10 (25.6)	5 (12.8)		10 (27.0)	8 (21.6)	
0.60	4 (10.3)	5 (12.8)		1 (2.7)	3 (8.1)	
0.70	2 (5.1)	1 (2.6)		1 (2.7)	1 (2.7)	
0.80	2 (5.1)	3 (7.7)		5 (13.5)	4 (10.8)	
1.0	3 (7.7)	–		2 (5.4)	4 (10.8)	
1.1	2 (5.1)	2 (5.1)		7 (18.9)	6 (16.2)	
Occluded eye						6.58
0.00	5 (16.1)	6 (19.4)	12.59	6 (18.2)	5 (15.2)	(7)
0.10	–	–	(9)	–	–	0.47
0.20	3 (9.7)	8 (25.8)	0.18	11 (33.3)	10 (30.3)	
0.30	3 (9.7)	3 (9.7)		1 (3.0)	1 (3.0)	
0.40	–	1 (3.2)		2 (6.1)	2 (6.1)	
0.50	5 (16.1)	2 (6.5)		6 (18.2)	3 (9.1)	
0.60	2 (6.5)	5 (16.1)		–	5 (15.2)	
0.70	2 (6.5)	–		–	–	
0.80	4 (12.9)	4 (12.9)		4 (12.1)	5 (15.2)	
1.0	5 (16.1)	1 (3.2)		2 (6.1)	1 (3.0)	
1.1	2 (6.5)	1 (3.2)		1 (3.0)	1 (3.0)	

N=70.
*Four children from experimental and 2 from the control group had both eyes affected so 39 affected eyes in experimental and 37 in control group.

Improvement in vision assessed through LogMAR chart is significantly higher after intervention in the experimental group as compared with control (p<0.01) in both affected and occluded eyes. It shows the direct relationship between adherence to eye patch and vision. Similar findings were also reported in another study by Sana Al-Zuhaibi, on compliance of patients with amblyopia with occlusion therapy. The improvement in vision was reported associated with better compliance with patching.[15] In another study, the intervention arm received an educational/motivational intervention before patching including information booklets, video, a cartoon storybook, sticker charts and a dedicated session with a researcher. The results reported an increased adherence success rate from 45.2% in the control group to 80.6% in the intervention group (p=0.0027). However, the visual outcome was not significantly better in the intervention group (p=0.190).[16]

The results of the present study revealed that the 'nurse-led counselling programme' on the adherence to eye patch application in children with amblyopia was feasible. It was effective in improving the adherence of eye patch applications. More than 90% adherence to eye patch application was reported by participants of the experiment group. Every week better adherence was observed in the experimental group. The adherence to eye patch application was significantly higher in the experimental group as compared with the control group. Another study to improve compliance with occlusion therapy for amblyopia by the use of different educational programmes. The compliance was reported as 55% in the control group whereas in three interventional groups, it improved to 89% in a cartoon story for amblyopic children group that explained without words why they should patch, 67% in a group with a calendar with reward stickers, and 73% in the group with an information leaflet for parents.[17] Another study reported that by use of educational cartoons for amblyopic children the compliance in patching improved from 52.0% preimplementation vs 62.3% postimplementation.[18] A systematic

review and meta-analysis reported that five intervention studies including an educational element significantly increased patching compliance.[19]

In a developing country where the doctor population ratio is less and a large number of patients may decrease the attending doctor's time, it is recommended to have 'nurse-led counselling clinics in the ophthalmic outpatient department. This will help to improve compliance among children with amblyopia and their parents regarding eye patch application which can in turn improve the visual acuity of these children.

Limitations

Our study has certain limitations. First, we need to be certain to what extent parental self-report about adherence to patching is certain as parents can overestimate levels of patching and are subject to correct recollection. Second, as this was a pilot study the follow-up period was limited to 12 weeks. Although the number was small, postintervention results were encouraging as there was improved visual acuity, nurse-led counselling programme on the adherence to eye patch application among children with amblyopia in addition to the use of written material in the form of a booklet on 'care of child with amblyopia' explaining the importance of patching, is a highly promising intervention. There is a need to do a study for a longer duration on a bigger sample to study the efficacy and cost-effectiveness of the intervention and investigate the influence of various variables on patch therapy in amblyopia.

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Contributors The manuscript is prepared and reviewed by all the authors.

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Competing interests The adherence to eye patching for amblyopic children is very challenging for their parents. Helping them to be adherent to eye patching is the main interest of the researchers.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Consent obtained from parent(s)/guardian(s).

Ethics approval Ethical clearance was taken from the institute ethical committee, PGIMER, Chandigarh as per letter no. INT/IEC/2019/00705, dated 2 April 2019, reference number NK/5155/MSc/10. The trial was registered in CTRI. The register no. of the trial is CTRI/2019/06/019641, dated 12 June 2019.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data are available on reasonable request.

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Supplementary table: Weekly data for eye patch application adherence of the Experimental group according to the prescribed pattern as per daily diary recording

N = 35

S. No.		1st Week	2nd Week	3rd Week	4th Week	5th Week	6th Week	7th Week	8th Week	9th Week	10th Week	11th Week	12th Week
1	**Time of Patching** According to the prescribe hours Less than prescribe hours More than prescribe hour	33(94.3) 1(2.9) 1(2.9)	35(100)	35(100)	29(82.9) 6(17.1)	33(94.3) 2(5.7)	34(97.1) 1(2.9)	33(94.3) 2(5.7)	34(97.1) 1(2.9)	33(94.3) 2(5.7)	33(94.3) 2(5.7)	35(100)	35(100)
2	**Duration of the close work** Less the 30 min 31-60 min 61-90 min 91-120min More than 120 min	 6(17.1) 15(42.9) 14(40.0)	 8(22.9) 15(42.9) 12(34.3)	 13(37.1) 18(51.4) 4(11.4)	 16(45.7) 13(37.1) 6(17.1)	2(5.7) - 6(17.1) 21(60.0) 6(17.1)	2(5.7) - 6(17.1) 21(60.0) 6(17.1)	2(5.7) - 6(17.1) 21(60.0) 6(17.1)	2(5.7) - 6(17.1) 21(60.0) 6(17.1)	2(5.7) - 5(14.3) 22(62.9) 6(17.1)	2(5.7) - 5(14.3) 22(62.9) 6(17.1)	2(5.7) 5(14.3) 22(62.9) 6(17.1)	2(5.7) 5(14.3) 22(62.9) 6(17.1)
4	**Difficulty in doing patching** No Yes	35(100)	31(88.6) 4(11.4)	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)	34(97.1) 1(2.9)	34(97.1) 1(2.9)	35(100)	35(100)
5	**Patching done at school time** No Yes	29(82.9) 6(17.1)	29(82.9) 6(17.1)	30(85.7) 5(14.3)	31(88.6) 4(11.4)	30(85.7) 5(14.3)	30(85.7) 5(14.3)	30(85.7) 5(14.3)	30(85.7) 5(14.3)	30(85.7) 5(14.3)	30(85.7) 5(14.3)	30(85.7) 5(14.3)	30(85.7) 5(14.3)
6	**Performa for recording daily details of patching**	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)	35(100)

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1,2
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2,3
	2b	Specific objectives or hypotheses	3
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	4
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	4
Participants	4a	Eligibility criteria for participants	4
	4b	Settings and locations where the data were collected	3,4
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	5
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	3
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	4
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	4
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	4
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	4,5
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	4
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	NA

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	5
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	NA
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	5
	13b	For each group, losses and exclusions after randomisation, together with reasons	5
Recruitment	14a	Dates defining the periods of recruitment and follow-up	4,5
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	7
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	7
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	8
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	8
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	8,9
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	14
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	13
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	13
Other information			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	4
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	14

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up-to-date references relevant to this checklist, see www.consort-statement.org.