Psychological causes of noncompliance with electronically monitored occlusion therapy for amblyopia

Sjoukje Loudon, Jan Passchier, Layal Chaker, Sander de Vos, Maria Fronius, Richard Harrad, Caspar Looman, Brigitte Simonsz-Toth, Huibert Simonsz

► To cite this version:

Sjoukje Loudon, Jan Passchier, Layal Chaker, Sander de Vos, Maria Fronius, et al.. Psychological causes of noncompliance with electronically monitored occlusion therapy for amblyopia. *British Journal of Ophthalmology*, 2009, 93 (11), pp.1499-n/a. 10.1136/bjo.2008.149815 . hal-00477824

HAL Id: hal-00477824

<https://hal.science/hal-00477824>

Submitted on 30 Apr 2010

HAL is a multi-disciplinary open access archive for the deposit and dissemination of scientific research documents, whether they are published or not. The documents may come from teaching and research institutions in France or abroad, or from public or private research centers.

L'archive ouverte pluridisciplinaire **HAL**, est destinée au dépôt et à la diffusion de documents scientifiques de niveau recherche, publiés ou non, émanant des établissements d'enseignement et de recherche français ou étrangers, des laboratoires publics ou privés.

Psychological causes of noncompliance with electronically monitored occlusion therapy for amblyopia

S E Loudon, J Passchier, L Chaker, S de Vos, M Fronius, R A Harrad, C W N Looman,
B Simonsz, H J Simonsz

Authors' affiliations:

S E Loudon, L Chaker, S de Vos, B Simonsz, H J Simonsz, Department of Ophthalmology, Erasmus
MC, University Medical Center Rotterdam, Rotterdam, the Netherlands

J Passchier, Department of Medical Psychology, Erasmus MC, University Medical Center Rotterdam,
Rotterdam, the Netherlands

M Fronius, Department of Ophthalmology, J.W.Goethe University, Frankfurt am Main, Germany

R A Harrad, Bristol Eye Hospital, Bristol, United Kingdom;

C W N Looman, B Simonsz, Department of Public Health, Erasmus MC, University Medical Center
Rotterdam, Rotterdam, the Netherlands

Trial Registration: clinicaltrials.gov Identifier: NCT 00131729

Controlled-trial.com: ISRCTN54685764

Correspondence to:

Prof.Dr. H.J. Simonsz, Dept. of Ophthalmology, Room Ee 1607

ErasmusMC University Medical Center Rotterdam, P.O. Box 2040, 3000 CA Rotterdam,

the Netherlands; simonsz@compuserve.com

Word count: 2541

Figures: 2; Tables: 2

Keywords: amblyopia, occlusion therapy, compliance, electronic monitoring, Protection Motivation Theory

Abstract

Aim: To analyze psychological causes for low compliance with occlusion therapy for amblyopia.

Method: In a randomized trial, the effect of an educational programme on electronically measured compliance had been assessed. 149 families who participated in this trial completed a questionnaire based on the Protection Motivation Theory after 8 months of treatment. Families with compliance less than 20% of prescribed occlusion hours were interviewed to better understand their cause for noncompliance.

Results: Poor compliance was most strongly associated with a high degree of distress ($p<0.001$), followed by low perception of vulnerability ($p=0.014$), increased stigma ($p=0.017$) and logistical problems with treatment ($p=0.044$). Of 44 families with electronically measured compliance less than 20%, 28 could be interviewed. The interviews confirmed that lack of knowledge, distress and logistical problems resulted in noncompliance.

Conclusion: Poor parental knowledge, distress and difficulties implementing treatment seemed to be associated with noncompliance. For the same domains, the scores were more favourable for families who had received the educational programme than for those who had not.

Introduction

Amblyopia (lazy eye) is the most frequent cause of visual deficit in childhood and is usually treated with occlusion of the fellow eye, preferably before the age of six years. The degree of compliance is the factor most frequently suggested to influence treatment outcome.[1-4] The development of the Occlusion Dose Monitor (ODM)[4-10] enabled objective monitoring of compliance with occlusion therapy. It was found that compliance averaged 50-60%.[3,11] Since studies have shown that occlusion treatment is effective,[2,3,10] efforts are underway to identify determinants of poor compliance, as well as ways to improve compliance.[9,11,12] The emotional impact[12-14] and poor parental understanding[11] seem to be important factors affecting the implementation of therapy. In a randomized clinical trial we showed that an educational programme, consisting of a cartoon story explaining to the child, without text, the rationale for treatment, together with a calendar and reward stickers, and an information sheet for parents, was effective in improving compliance and reducing the number of children who received no patching.[9] As part of the same trial, this study focuses on the association of psychological factors with compliance. For this purpose a questionnaire was developed, which was adapted from a Protection Motivation Theory (PMT) based questionnaire, [15,16] created and validated by Searle et al. and Norman et al.[17-19] In short, PMT is based on two behavioural adaptations (appraisal of threat and coping appraisal) that occur when an individual faces a health threat. It has been applied to predict a range of health protective behaviour (e.g. threat of HIV infection).[21,21] We used the PMT questionnaire and added questions using the most frequently expressed complaints from both practicing orthoptists and parents of children receiving occlusion therapy. Compliance was measured electronically using the ODM. In addition, reasons for total non-compliance were investigated.

Methods

The study population was a subset of the large prospective randomized clinical trial (n=310), reported previously.[9] In short, all newly diagnosed amblyopic children treated with occlusion therapy were registered. In addition to standard orthoptic care, included children were randomized: the intervention group received the educational programme, and the reference group did not. Compliance was measured electronically with the ODM, one week, every three months. The ODM was attached to the outside of the patch using double sided adhesive tape. It records the temperature difference between the front and backside every two minutes. The ODM and educational programme were distributed during home visits. During the third one-week ODM measurement, after approximately eight months of therapy, the questionnaire was distributed. The study design was prospective, so children recruited at a later stage in the study did not reach the third ODM measurement and consequently did not receive the questionnaire (figure 1). The Ethical Committee of Erasmus University Rotterdam and the boards of the participating clinics approved the protocol and informed consent forms. Written informed consent by the parents or guardian was a prerequisite for participation. The research adhered to the tenets of the Declaration of Helsinki.

Patching Success Questionnaire

The questionnaire consisted of ten domains ('Patching Success Questionnaire' – PSQ).[Supplemental File] Eight domains were based on components of the PMT.[17-19] All the PMT items were measured on a 5-point response scale (strongly disagree/strongly agree), scale range from 1 to 5. Measures of the variables were constructed by averaging responses to individual items such that high scores indicated high degrees on the variable of interest. The PMT contained the following domains: *Protection Motivation*, (3 items, e.g. 'I expect to patch my child as recommended'); perceived *severity* of the disease (6 items; e.g. 'I am concerned about my child's visual impairment'); perceived *vulnerability* (6 items; e.g. 'If left untreated, what are the chances that your child's visual impairment will restrict his/her future choice of occupation');

response efficacy (5 items; e.g. ‘My child’s vision will improve in the future if patched regularly’); *self-efficacy* (4 items; e.g. ‘I feel confident in my ability to patch’); perceived *distress* (8 items; e.g. ‘Patching causes distress for my child’); the extent to which patching may interfere or *prohibit* the child from engaging in every day activities (5 items; e.g. ‘Wearing a patch prohibits my child from reading’); and the *stigma* attached to wearing a patch was assessed using five items (e.g. ‘Negative comments from others about the patch upset me’).

Two domains were added and elaborated on in the study group. Firstly, an inventory was made of the most frequently expressed complaints from the parents, children and practicing orthoptist, which had not been addressed in the questionnaire by Norman et al.[19] Complaints included: not being able to implement the patching treatment into their daily routine: they were unaware as to where to buy the patches; they were unaware of the duration of treatment, etc. Afterwards, during discussions in the study group, these complaints were categorized into two domains: knowledge of disease and knowledge of treatment. A pre-test group (n=11) was asked to complete the questionnaire and comment on the relevance of the questions and whether they understood the questions. Parental knowledge of amblyopia was assessed using 3 items scored on a 5-point scale (response scale: strongly disagree/strongly agree)). Parental knowledge of treatment was assessed using 1 item scored on a 4-point scale. For the analysis, these values were rescaled to an equal range of a 5-point scale (i.e. ‘1’ equals ‘1’, ‘2’ equals ‘2.33’; ‘3’ equals ‘3.67’; and ‘4’ equals ‘5’); again, a high score indicated a high degree on the variable of interest. In addition to these two domains, nine general questions regarding the child’s health and logistics of treatment (e.g. ‘I find it difficult fitting patching into my daily routine’) were asked. The PSQ was completed by the parents and collected one week later. If the parents had difficulty completing the questionnaire, they were assisted by a researcher.

In-depth analysis of the noncompliers by semi-structured interview

Development of the semi-structured interview. In the overall study population (n=310) it was found that 14% had not been occluded.[9] Therefore, a more in-depth analysis was performed to explore families' experience with occlusion therapy and the causes for noncompliance. First, the group of noncompliers was defined using data from the first one-week ODM measurement. Mean compliance had a bi-modal distribution: the first peak was caused by children who were not occluded, and the second peak represented children who occluded approximately 80% of the hours prescribed (figure 2). The lowest point was found at the 20% compliance level, which separated the children who had not been occluded or had been occluded infrequently, from the children who occluded regularly. This was consequently chosen as the cut-off point: 44 (14%) children occluded less than 20% of the prescribed occlusion hours. Second, the noncompliant and more compliant groups were compared concerning the demographic factors and the PSQ scores. The following significant differences, in favour of the compliant group, were found: logistics of treatment ($F=15.1$; $p=0.001$), perceived distress ($F=12.5$; $p=0.001$), Protection Motivation ($F=12.1$; $p=.001$), parental knowledge ($F=8.13$; $p=.005$), self-efficacy ($F=9.32$; $p=0.003$), working knowledge of the Dutch language ($F=6.64$; $p=0.01$) and country of origin ($F=3.85$; $p=0.047$). These differences were used to develop a semi-structured interview with 33 questions, including 6 questions specifically for the child. The interview was open framed allowing a focused, conversational, two-way communication. Since compliance was related to fluency in the national language,[9] questions regarding communication and relationship with the treating orthoptist were also included.

Application of the semi-structured interview. Parents were interviewed by two researchers (LC and SdV) at their home, to overcome the problem of dropouts who no longer visited the clinic. An interpreter was present if the family did not speak Dutch.

Statistical analysis

The means, standard deviations, inter-correlations and Cronbach's alpha values of each of the domains were calculated. Cronbach's alpha values higher than 0.60 were considered sufficient for the purpose of group comparison. Test for Normality was performed to determine the distribution of the scores of each domain.

Multiple linear regression analysis was used to predict compliance (entered as dependent, continuous variable). The independent variables were: Protection Motivation, severity, vulnerability, response efficacy, distress, prohibition, stigma, self-efficacy, knowledge of disease, knowledge of treatment and logistics of treatment (all entered as continuous variables). F-values and β -values were calculated. The F-value is a test statistic that tests for differences in the variance between two groups; typically one with and one without a certain predicting variable. F=1 indicates no difference in variance between the two groups, indicating that no predicting value for the variable could be demonstrated. The percentage of the variation in compliance that could be ascribed to the different factors involved was defined as the ratio of the percentage of the variance explained by the model with, and the model without the factor in question. As potential confounding factors, gender, age, cause of amblyopia, initial visual acuity, fluency in the Dutch language and country of origin were analyzed. Analysis was both univariate and multivariate. Descriptive statistics were applied to analyze the completed semi-structured interviews. $p < 0.05$ was considered statistically significant.

Results

The PSQ was completed for 149 families (99%). The clinical and demographic characteristics were similar to those reported for the full study cohort ($n=310$).[9] Mean age of the included children was 4.6 yrs (SD 2.0 yrs); 56% were boys. Mean acuity in the amblyopic eye (logMAR) at start of therapy was 0.35 (SD 0.32; minimum 1.40; maximum -0.08).

Patching Success Questionnaire

Mean scores for each domain are shown in table 1. Mean scores for this study were slightly lower than the scores found by Norman et al.,[19] for the domains protection motivation, severity, vulnerability, degree of distress and stigma barrier. The inter-correlations between the domains were comparable to those reported by Norman et al.[19]

Univariate analysis of the variance demonstrated that a high degree of distress caused by occlusion therapy was negatively associated with compliance ($\beta=-17$; $p<0.001$; table 1). Compliance also decreased when the child was prohibited in his or her activities by the patch ($\beta=-8.4$; $p=0.01$). Compliance increased when parents found it easier to implement occlusion therapy into their daily routine ($\beta=11.1$; $p<0.001$), when parents were highly motivated to patch their child ($\beta=16.4$; $p<0.001$), when parents were able to adhere to the prescription given by the orthoptist ($\beta=12.8$; $p<0.001$) and when they thought their child's eye sight would get worse if left untreated ($\beta=10.9$; $p=0.009$).

Table 1.

Domains PSQ	Alpha values	Mean scores $\pm$ SD	β	F	P-value [†]
1. Protection Motivation ~	0.86	4.25 $\pm$ 0.68	16.4	14.1	*<0.001
2. Severity ~	0.89	3.02 $\pm$ 0.93	-3.1	0.8	0.358
3. Vulnerability ~	0.86	3.2 $\pm$ 0.74	10.9	6.9	*0.009
4. Response efficacy ~	0.83	4.36 $\pm$ 0.5	5.7	0.6	0.364
5. Distress barrier ~	0.9	2.19 $\pm$ 0.84	-17	24.2	*<0.001
6. Prohibit barrier ~	0.62	2.07 $\pm$ 0.95	-8.4	6.8	*0.01
7. Stigma barrier ~	0.78	2.48 $\pm$ 0.83	-5.9	2.5	0.116
8. Self-efficacy ~	0.88	4.04 $\pm$ 0.86	12.8	13.4	*<0.001
9. Knowledge disease §	0.65	4.23 $\pm$ 0.65	0	0	0.998
10. Knowledge treatment §		4.04 $\pm$ 1.02	2	0.4	0.546
11. Logistics of treatment §		2.83 $\pm$ 0.99	11.1	13.9	*<0.001

Stepwise backward selection showed that compliance increased when parents were capable of implementing the occlusion therapy into their daily routine ($\beta=6.1$; $p=0.044$) and when they replied that their child's eye sight would get worse if left untreated ($\beta=9.3$; $p=0.014$). Compliance decreased when distress and stigma increased ($\beta=-22$; $p<0.001$ and $\beta=-6.0$; $p=0.017$, respectively). The four domains explained 22% of the variation in compliance (adj. R^2).

In-depth analysis of the noncompliers by semi-structured interview

Of the 44 families, 28 (64%) were interviewed at their home, 11 (25%) could not be contacted due to wrong address or telephone numbers and 5 (11%) would no longer cooperate. Approximately 30 minutes (range 20-45 min) was spent per home visit. Mean age of the children was 5.7 years (range 4.9 – 7.2 years).

First, answers were categorized by the three main parties involved in the occlusion therapy i.e. caregiver, child and therapist, allowing for a systematic overview and analysis of the interviews.[22] Second, 12 items were drawn up, 4 for each party involved (table 2). The items refer to reasons for non-compliance as found in our study population. The analysis of the interviews was then conducted a second time by both researchers scoring each report of the interview on the above-mentioned 12 items. This was done on a scale from 1 (not present) to 5 (dominantly present or behaviour defining). The two independent scores were analyzed with the weighed kappa-test to test if the two scores differed significantly.

210 **Table 2.**

	Mean score ± SD
Caregiver related	
Lack of knowledge of amblyopia	3.54 ± 1.20
Perceived distress when patched	2.75 ± 1.08
Logistical problems	2.46 ± 1.26
Confidence in effectiveness of therapy	1.75 ± 1.24
Child related	
Teased by peers	2.29 ± 1.38
Lower self esteem when patched	2.25 ± 1.56
Poor visual acuity when patched	1.82 ± 1.10
Perceived discomfort when patched	1.96 ± 1.14
Therapist related	
Addressing problems encountered during patching	2.25 ± 1.38
Information about disease and treatment	2.25 ± 1.32
Time for questions about disease and treatment	1.89 ± 1.28
Child oriented instructions	1.75 ± 1.11

211

212

213 The results of the interview showed that only 14% of the parents had sufficient
 214 knowledge about amblyopia. 57% reported a high degree of distress and 46% had difficulties
 215 implementing occlusion therapy into their daily routine. Interviewed children replied they were
 216 often teased by their peers whilst wearing the patch (43%, of whom 29% suffered severe teasing),
 217 which decreased their self-esteem. A third of the parents answered they had received incomplete
 218 information from the treating orthoptist and that there was little time during the visit to discuss
 219 their problems. 18% of the parents thought that the orthoptist did not sufficiently address the child
 220 when explaining the eye condition and its treatment.

221

222

Conclusion & Discussion

This is the first study to analyze the association between psychological factors and compliance with occlusion therapy in concurrence with the electronic monitoring of compliance. A high degree of distress, a low perception of vulnerability, increased stigma and logistical problems with treatment were associated with poor compliance with prescribed occlusion hours.

In concordance with Searle et al.[17,18] and Norman et al.[19] the degrees of response efficacy and protection motivation were high, indicating that most parents thought eye patching to be an effective treatment for their child's amblyopic eye and were motivated to patch their child as prescribed by the orthoptist. This was also found in other studies that applied PMT in relation to compliance with treatment.[18-21,23] For several domains our study population had slightly lower scores than Norman's study population in Bristol. This could be explained by the difference in population, the timing of questionnaire completion and small changes in meaning of translated items.

In this study, the questionnaire was given after eight months of treatment. It would have been interesting to have also distributed the questionnaire immediately after the first visit to the orthoptist in order to predict and compare outcomes and assess any changes in opinions during treatment and their influence on compliance. A possible limitation of the study design was that the study ended before all participants had reached the third home visit during which the questionnaire was given. However, baseline characteristics were comparable between the group who had received and completed the questionnaire and the group who had not received it.

Compliance, as measured with the ODM, decreased most drastically when parents reported a high degree of distress. This was also found in other studies.[12-14,18,19]

Our study population was a subset of the large prospective randomized clinical trial studying whether compliance could be improved using an educational programme.[9] Even though this study was not designed to determine the effect of the programme on the scores of the

questionnaire domains, it would be interesting to observe any effect of the educational programme (using the Mann-Whitney test). This showed that the programme had a positive effect on the level of distress, the ability to implement treatment into the daily routine and parental knowledge about the treatment.

When further analyzing the group who did not occlude, it became apparent that only 14% of the parents had sufficient knowledge of amblyopia. Many parents were unaware of their lack of knowledge, and therefore, were less likely to pose questions to the orthoptist. A number of parents indicated that they would prefer the orthoptic visits to be more child-focused. Currently, children are poorly involved in the communication between parent and orthoptist and may therefore not be fully aware of the reason for patching.

These findings emphasize that occlusion therapy for amblyopia is difficult to implement, is accompanied by a high degree of distress and is hampered by poor knowledge and understanding. As the more confrontational and argumentative approach towards non-compliance is unsuccessful, a more empathic and supportive style that is less prone to moral judgment, should be used.[24] Various behavioural models (e.g. health belief model), which include both the physician and the patient, have been developed for the purpose of optimal clinical outcome. A useful technique for orthoptists and pediatric ophthalmologists could be the “Shared Decision Making”.[25] This is a process by which patient and health care provider consider the outcome probabilities (e.g. equal visual acuity after 6 months of occluding 4 hrs/day) and the patient preference (e.g. both full-time working parents who can accomplish 1 hr/day) and reach a health care decision based on a mutual agreement (e.g. 2 hrs/day, but treatment will continue for approximately one year). The current trend among orthoptists and ophthalmologists is that in individual cases where compliance is faltering, prescribing less hours of occlusion may result in better compliance.

Orthoptist’s and clinician’s knowledge regarding the obstacles which families encounter when they implement occlusion therapy should be improved. This would enhance the orthoptist’s

274 and clinician's confidence in their ability to address the issues and would ultimately improve
275 clinical outcomes. In addition, the educational programme would help clinicians, orthoptists and
276 parents to explain the reason for occlusion therapy to the child and offer guidelines to the parent
277 for carrying out the treatment.

278 **Acknowledgments**

279 The authors thank Bregje van Dijk, Ellen van Minderhout, Marleen Vermeulen, Roberta Delle
 280 Site, Janine van Zon, Eline Deelstra, Jorrien Bouma, Maurits Joosse, Hans Büller, Larisa Pepler,
 281 Yaroslava Chopovska, Iris Bachert, Angelika Cordey, Regine Neukam, Heike Bartz, Birgit
 282 Herrmann, Marlies Murtro, Dr. Marc Luchtenberg, Prof. Alina Zubcov and Dr. Claudia Kuhli for
 283 their advice, help with data collection and efforts in recruiting the children.

284 The Occlusion Dose Monitor was developed at the department for Medical Technical
 285 Development at the Academical Medical Center, Amsterdam, the Netherlands in 1996-1997 as a
 286 public domain project.

287

288 **This research was supported by:** Health Research and Development Council of the
 289 Netherlands; M. Fronius: Albert von Metzler Foundation, Augensterm Association, Research
 290 Award of the German Society of Ophthalmology (DOG), Germany.

291 **Financial Disclosure:** None

292 **Authors' contributions:** Dr. Loudon and Prof.dr. Simonsz had full access to all the data in the
 293 study and take responsibility for the integrity of the data and the accuracy of the data analysis.

294 The independent statistician was Ir. C W N Looman, Department of Public Health and
 295 Biostatistics, ErasmusMC University Medical Center Rotterdam, the Netherlands.

296 **Licence for Publication:** The Corresponding Author has the right to grant on behalf of all
 297 authors and does grant on behalf of all authors, an exclusive licence (or non exclusive for
 298 government employees) on a worldwide basis to the BMJ Publishing Group Ltd to permit this
 299 article (if accepted) to be published in BJO and any other BMJ PGL products and sublicences such
 300 use and exploit all subsidiary rights, as set out in our licence

301 (<http://bjournal.bmj.com/fora/licence.pdf>).

302 **Competing interests:** None declared.

References

1. **Simons K**, Preslan M. Natural history of amblyopia untreated owing to lack of compliance. *Br J Ophthalmol.* 1999;**83**:582-87.
2. **Dorey SE**, Adams GGW, Lee JP, Sloper JJ. Intensive occlusion therapy for amblyopia. *Br J Ophthalmol.* 2001;**85**:310-3.
3. **Stewart CE**, Fielder AR, Stephens DA, Moseley MJ. Treatment of unilateral amblyopia: factors influencing visual outcome. *Invest Ophthalmol Vis Sci.* 2005;**46**:3152-60.
4. **Loudon SE**, Polling JR, Simonsz HJ. Electronically measured compliance with occlusion therapy for amblyopia is related to visual acuity increase. *Graefes Arch Clin Exp Ophthalmol.* 2003;**241**:176-80.
5. **Fielder AR**, Irwin M, Auld R, Cocker KD, Jones HS, Moseley MJ. Compliance monitoring in amblyopia therapy. *The Lancet.* 1994;**343**:547.
6. **Simonsz HJ**, Polling JR, Voorn R, et al. Electronic monitoring of treatment compliance in patching for amblyopia. *Strabismus.* 1999;**7**:123-33.
7. **Chopovska Y**, Loudon SE, Cirina L, et al. Electronic recording of occlusion treatment for amblyopia: potential of the new technology. *Graefes Arch Clin Exp Ophthalmol.* 2005;**243**:539-44.
8. **Fronius M**, Chopovska Y, Nolden J, et al. Occlusion treatment for amblyopia: assessing the performance of the electronic occlusion dose monitor. *Strabismus.* 2006;**14**:65-70.
9. **Loudon SE**, Fronius M, Looman CWN, Awan M, Simonsz B, van der Maas PJ, Simonsz HJ. Predictors and a remedy for non-compliance with amblyopia therapy in children measured with the Occlusion Dose Monitor. *Invest Ophthalmol Vis Sci.* 2006;**47**:4393-400.
10. **Stewart CE**, Stephens DA, Fielder AR, Moseley MJ; for the ROTAS Cooperative. Objectively monitored patching regimens for treatment of amblyopia: randomised trial. *BMJ* 2007;**335**:707-13.
11. **Newsham D**. A randomised controlled trial of written information: the effect on parental non-concordance with occlusion therapy. *Br J Ophthalmol* 2002;**86**:0-4.
12. **Dixon-Woods M**, Awan M, Gottlob I. Why is compliance with occlusion therapy for amblyopia so hard? A qualitative study. *Arch Dis Child* 2006;**91**:491-4.
13. **Hrisos S**, Clarke MP, Wright CM. The emotional impact of amblyopia treatment in preschool children. *Ophthalmol.* 2004;**111**:1550-6.

14. **The Pediatric Eye Disease Investigator Group**. Impact of patching and atropine treatment on the child and family in the Amblyopia Treatment Study. *Arch Ophthalmol*. 2003;**121**:1625-32.
15. **Rogers RW**. A protection motivation theory of fear appeals and attitude change. *J of Psychology* 1975;**91**:93-114.
16. **Rogers RW**. Cognitive and psychological processes in fear appeals and attitude change: A revised theory of protection motivation. In B.L. Cacioppo, L.L. Petty & D. Shapiro (Eds), *Social Psychophysiology: A Sourcebook*. London: Guilford Press.
17. **Searle A**, Vedhara K, Norman P, Frost A, Harrad RA. Compliance with eye patching in children and its psychosocial effects: A quantitative application of protection motivation theory. *Psychology, Health and Medicine* 2000;43-54.
18. **Searle A**, Norman P, Harrad RA, Vedhara K. Psychosocial and clinical determinants of compliance with occlusion therapy for amblyopic children. *Eye*. 2002;**16**:155-5.
19. **Norman P**, Searle A, Harrad RA, Vedhara K. Predicting adherence to eye patching in children with amblyopia: An application of protection motivation theory. *Br J Health Psychology*. 2003;**8**:67-82.
20. **Abraham CS**, Sheeran P, Abrams D, Spears R. Exploring teenagers adaptive and maladaptive thinking in relation to the threat of HIV infection. *Psychology and Health*. 1994;**9**:253-72.
21. **Rippertoe PA**, Rogers RW. Effects of components of protection motivation theory on adaptive and maladaptive coping with a health threat. *J of Personality and Social Psychology*. 1987;**52**:596-604.
22. **DiMatteo RM**. Review. The role of effective communication with children and their families in fostering adherence to pediatric regimens. *Patient Educ Couns* 2004;**55**:339-44.
23. **Rudman LA**, Gonzales MH, Borgida E. Mishandling the gift of life: Non-compliance in renal transplant patients. *J of Soc and Appl Psychol*. 1999;**29**:834-51.
24. **Sutten S**. Health Behavior: Psychosocial Theories. International Encyclopedia of the Social & Behavioral Sciences. 2001:6499-506.
25. **Frosch DL**, Kaplan RM. Shared Decision Making in Clinical Medicine: Past research and future directions. *Am J Prev Med* 1999;**17**:285-94.

Legends

Figure 1. Flowchart illustrating the study design. After the first one-week measurement, children who patched less than 20% of the prescribed occlusion time were identified as noncompliant. Between November 2004 and March 2005, the noncompliant group received a separate semi-structured interview with more in-depth questions that was based on differences in answers from the Patching Success Questionnaire between the more compliant and the noncompliant group.

Figure 2. Bar chart presents compliance with prescribed occlusion hours during the first one-week ODM measurement, with 10% intervals.

Table 1. Cronbach's alpha, overall mean scores on a 5-point scale ($\pm$ SD) per domain, scale from 1 to 5 with a higher score indicating a high level of interest

~ The PMT items of the Patching Success Questionnaire;

§ Added items by our study group;

† The association between compliance and mean scores; *P-value indicates a significant influence of the domain on compliance using linear regression analysis;

Table 2. Mean scores ($\pm$ SD) for the 12 items derived from the semi-structured interview, which refer to reasons for total noncompliance. They are subdivided into the caregiver, the child and the therapist.

July 2001-June 2004

Nov 2004-
March 2005