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## Psychological causes of noncompliance with electronically monitored occlusion therapy for amblyopia

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1 **Psychological causes of noncompliance with electronically monitored**  
2 **occlusion therapy for amblyopia**

3

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20

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26

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30

31 **Abstract**

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

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

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

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

46

## 47 **Introduction**

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

70

## 71 **Methods**

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

87

### 88 **Patching Success Questionnaire**

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

98 *response efficacy* (5 items; e.g. ‘My child’s vision will improve in the future if patched  
99 regularly’); *self-efficacy* (4 items; e.g. ‘I feel confident in my ability to patch’); perceived *distress*  
100 (8 items; e.g. ‘Patching causes distress for my child’); the extent to which patching may interfere  
101 or *prohibit* the child from engaging in every day activities (5 items; e.g. ‘Wearing a patch  
102 prohibits my child from reading’); and the *stigma* attached to wearing a patch was assessed using  
103 five items (e.g. ‘Negative comments from others about the patch upset me’).

104 Two domains were added and elaborated on in the study group. Firstly, an inventory was  
105 made of the most frequently expressed complaints from the parents, children and practicing  
106 orthoptist, which had not been addressed in the questionnaire by Norman et al.[19] Complaints  
107 included: not being able to implement the patching treatment into their daily routine: they were  
108 unaware as to where to buy the patches; they were unaware of the duration of treatment, etc.  
109 Afterwards, during discussions in the study group, these complaints were categorized into two  
110 domains: knowledge of disease and knowledge of treatment. A pre-test group (n=11) was asked  
111 to complete the questionnaire and comment on the relevance of the questions and whether they  
112 understood the questions. Parental knowledge of amblyopia was assessed using 3 items scored on  
113 a 5-point scale (response scale: strongly disagree/strongly agree)). Parental knowledge of  
114 treatment was assessed using 1 item scored on a 4-point scale. For the analysis, these values were  
115 rescaled to an equal range of a 5-point scale (i.e. ‘1’ equals ‘1’, ‘2’ equals ‘2.33’; ‘3’ equals  
116 ‘3.67’; and ‘4’ equals ‘5’); again, a high score indicated a high degree on the variable of interest.  
117 In addition to these two domains, nine general questions regarding the child’s health and logistics  
118 of treatment (e.g. ‘I find it difficult fitting patching into my daily routine’) were asked.  
119 The PSQ was completed by the parents and collected one week later. If the parents had difficulty  
120 completing the questionnaire, they were assisted by a researcher.

121

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

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

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

146

147 **Statistical analysis**

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

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

166

## 167 **Results**

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

172

173 **Patching Success Questionnaire**

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

178 Univariate analysis of the variance demonstrated that a high degree of distress caused by  
179 occlusion therapy was negatively associated with compliance ( $\beta=-17$ ;  $p<0.001$ ; table 1).  
180 Compliance also decreased when the child was prohibited in his or her activities by the patch ( $\beta=-$   
181  $8.4$ ;  $p=0.01$ ). Compliance increased when parents found it easier to implement occlusion therapy  
182 into their daily routine ( $\beta=11.1$ ;  $p<0.001$ ), when parents were highly motivated to patch their  
183 child ( $\beta=16.4$ ;  $p<0.001$ ), when parents were able to adhere to the prescription given by the  
184 orthoptist ( $\beta=12.8$ ;  $p<0.001$ ) and when they thought their child's eye sight would get worse if left  
185 untreated ( $\beta=10.9$ ;  $p=0.009$ ).

186

187 **Table 1.**

188

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

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

195

### 196 **In-depth analysis of the noncompliers by semi-structured interview**

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

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

209

210 **Table 2.**

	<b>Mean score ± SD</b>
<b>Caregiver related</b>	
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
<b>Child related</b>	
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
<b>Therapist related</b>	
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

## 223 **Conclusion & Discussion**

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

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

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

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

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

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

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

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

272         Orthoptist’s and clinician’s knowledge regarding the obstacles which families encounter  
273 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.

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## 358 **Legends**

359

360 **Figure 1.** Flowchart illustrating the study design. After the first one-week measurement, children  
361 who patched less than 20% of the prescribed occlusion time were identified as noncompliant.

362 Between November 2004 and March 2005, the noncompliant group received a separate semi-  
363 structured interview with more in-depth questions that was based on differences in answers from  
364 the Patching Success Questionnaire between the more compliant and the noncompliant group.

365

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

368

369 **Table 1.** Cronbach's alpha, overall mean scores on a 5-point scale ( $\pm$  SD) per domain, scale from  
370 1 to 5 with a higher score indicating a high level of interest

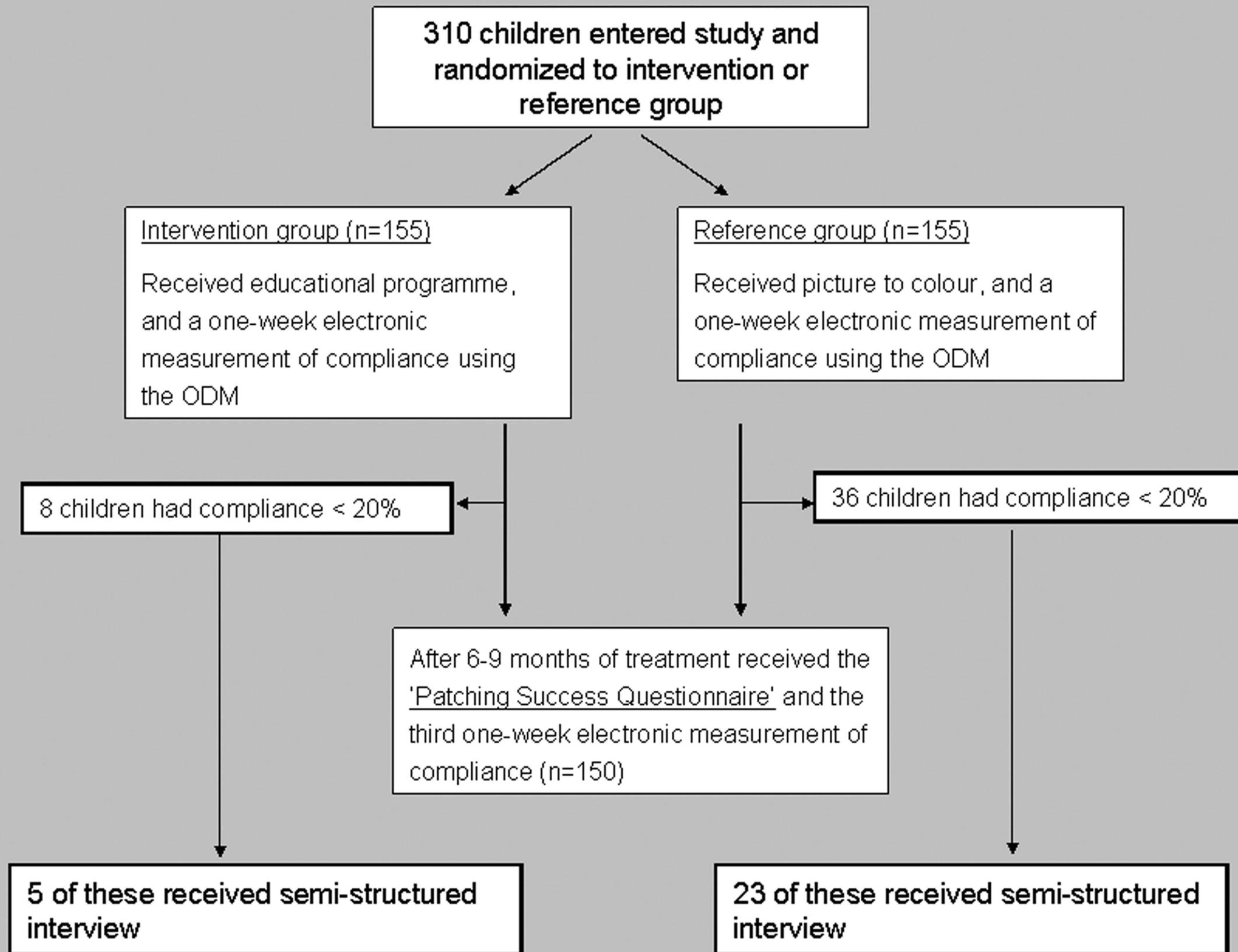
371 ~ The PMT items of the Patching Success Questionnaire;

372 § Added items by our study group;

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

375

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



July 2001-June 2004

Nov 2004-  
March 2005

