1 Cow's milk allergy in children: adherence to a therapeutic elimination diet and

# 2 reintroduction of milk into the diet

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50 ADSTRACT	50	Abstract
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Background/Objectives: The basic treatment of cow's milk allergy (CMA) is the 51 52 elimination of all cow's milk proteins (CMP) from the diet. The present study aimed at 53 characterising the diet of children with a diagnosis of CMA, to assess the degree of adherence 54 to the elimination diet and to evaluate factors associated with the adherence and age of 55 recovery. Subjects/Methods: From a birth cohort study, food records of 267 children with diagnosed 56 57 CMA were studied to define how strictly the elimination diet was adhered to. Subsequent food records were studied to assess the age at reintroduction of milk products in the child's 58 59 diet. 60 **Results**: The families adhered to the elimination diet of the child with extreme accuracy in 85% of the cases. Older and monosensitised children had more often small amounts of CMP 61 in their diet, possibly due the absence of nutritional information by a dietitian/nutritionist. 62 Adherence to the diet was not related to any other sociodemographic factor studied nor to the 63 age at reintroduction of milk products into the diet. 64 Conclusions: The therapeutic elimination diet of children with a diagnosed CMA was well 65 66 adhered to. Low intakes of vitamin D, calcium and riboflavin are of concern in children who follow or have followed a cow's milk-free diet. 67 Key words 68 69 adherence; child, preschool; cow's milk allergy; elimination diet; infant

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# 71 INTRODUCTION

72	Special infant formulas are used instead of cow's milk -based formulas in the diet of milk-	
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allergic infants if the infant is not fully breastfed. If cow's milk allergy (CMA) is diagnosed

- by a physician, children up to the age of 2 years receive reimbursement for their costs from
- the Finnish Social Insurance Institution, offering a great opportunity to study CMA. The costs
- of the special infant formulas are substantial to the society, but management will not be fully
- <sup>77</sup> effective if the cow's milk free diet is not followed properly.
- 78 The risks of a cow's milk-free diet are well documented (Hidvegi *et al.* 2003, Jensen *et al.*
- 79 2004, Rockell *et al.* 2005). The diet should be balanced, providing adequate amounts of
- 80 calcium and vitamin D, either by using the correct substitute foods or by supplementation
- 81 (Grimshaw 2006, Vandenplas *et al.* 2007).
- 82 By asking parents about the level of the elimination, adherence to a therapeutic elimination
- diet in children has been assessed in three previous studies (Vlieg-Boerstra *et al.* 2006,
- Eggesbo *et al.* 2001, Allen *et al.* 2009). These studies suggest problems in adhering to an
- 85 elimination diet, whether warranted or not.
- 86 So far no study has objectively assessed the adherence to a therapeutic elimination diet in
- children with food allergy, such as in the form of food records. The aims of the present study
- were to analyse the diet of children following a cow's milk protein (CMP) -free diet, to study
- 89 the reintroduction of milk products into children's diets, and to evaluate factors associated
- <sup>90</sup> with the adherence and age of development of tolerance.

#### 92 SUBJECTS AND METHODS

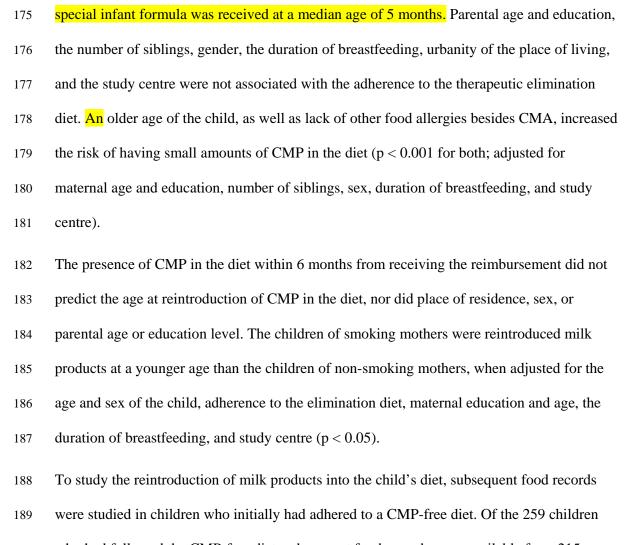
93 The Finnish Type 1 Diabetes Prediction and Prevention (DIPP) Study is a multidisciplinary prospective population-based cohort study (Kupila et al. 2001). All newborns from the 94 95 catchment areas of three university hospitals in Finland (Turku, Oulu, and Tampere) are screened for HLA-conferred susceptibility to type 1 diabetes from cord blood samples after 96 97 parental informed consent. Infants with high and moderate risk for type 1 diabetes (15% of 98 those screened) are invited to participate in the study, excluding children with severe 99 congenital abnormalities or diseases, or whose parents are of non-Caucasian origin or do not understand Finnish, Swedish or English. The DIPP Nutrition study is performed in the Oulu 100 101 and Tampere University hospitals among children born since October 1996. The local Ethical 102 Committees have approved the study. All families have given their written informed consent 103 to participate in the DIPP study. 104 The presence of special infant formula reimbursement was checked from the Finnish Social 105 Insurance Institution for children in the DIPP Nutrition Study for whom a personal 106 identification code was known to the study (n = 6412). According to clinical practice 107 guidelines, the diagnosis is based on improvement of symptoms on an elimination diet, followed by a positive food challenge outcome or, in rare cases, on a high IgE level and 108 109 improvement of symptoms on an elimination diet (Finnish Paediatric Association 2004). For 110 those 398 (6.2%) children who received the reimbursement, information on the month and 111 year of the beginning of the reimbursement (in other words a diagnosed CMA) was obtained. 112 Three-day food records, completed blindly to the purpose of the present study, were collected 113 at the ages of 3 and 6 months, and 1, 2 and 3 years (Kyttälä *et al.* 2010). Parents were given 114 written and oral instructions on how to record everything the child ate and drank during the 115 recording period. Separate food record forms, which also comprised questions e.g. about the

116 origin of the food, were provided for the day care. Three consecutive food record dates were 117 assigned to the family in advance and contained two week and one week end day. Examples 118 were given on how to report food consumption with household or weighed measures. 119 Vitamin and mineral supplement usage was also recorded. Food picture booklets were used to help the estimation of portion sizes (Paturi *et al.* 2006, Ovaskainen *et al.* 2008). 120 121 Trained research nurses checked the food records with the families, and nutrition researchers 122 entered all the food consumption data using an in-house software into the Finnish national food composition databank Fineli (National Institute for Health and Welfare, Nutrition Unit 123 124 2009). Food consumption and nutrient intakes, as well as the amount of CMP were calculated 125 as average daily intake using the database. When calculating the amount of CMP, its quantity 126 in all foods was taken into account, except for sausages, fat spreads and commercial biscuits. 127 However, these were taken into account when classifying adherence. The recording of food records was checked for food consumption and nutrient intakes, and for sources of CMP, to 128 129 ensure valid recording and the validity of the databank used. 130 Information on special diets was collected at the ages of 3 and 6 months, and at 1 and 2 years 131 by open questions and at the age of 3 years by a structured, validated questionnaire (Tuokkola 132 et al. 2008). Parental reports of food allergies were double-entered to ensure valid recording. 133 To study the adherence to the cow's milk elimination diet, the next food record within 6 134 months from receiving the special reimbursement was analysed for the level of the 135 elimination. Food records were classified as containing milk products, containing hidden or 136 small amounts of CMP, containing no CMP, and containing no obvious sources of CMP but 137 having recipes for which there is some uncertainty on whether they contain CMP or not. The 138 latter consists of food items from small local bakeries and meat product manufacturers for 139 which the detailed composition could not be traced, and if a commercial product name was 140 not identified in the food record. To study the reintroduction of milk products into the diet,

- subsequent food records either up to a food record containing milk products, up to the latest
- 142 food record or up to 3 years of age were further analysed.
- 143 Background information (parental age and education, the number of siblings) was collected at
- the time of recruitment. Information on parental smoking, former childbirths of the mother,
- and place of residence were obtained from the Finnish Medical Birth Registry.
- 146 SPSS software package 15.0 (SPSS Inc, Chicago, IL, 2006) and R 2.7.0 (R Development
- 147 Core Team, 2008) were used for statistical analyses. Multinomial logistic regression was
- applied to study the associations of adherence to the therapeutic elimination diet with
- 149 background factors. Cox proportional hazards model with an accommodation to interval
- 150 censored data was used to identify the factors associated with the age of recovery.

## 151 **RESULTS**

The adherence to the cow's milk elimination diet was studied in 267 children (67% of those 152 153 with the reimbursement), from whom a food record within 6 months from receiving the 154 reimbursement was available. Of these 267 families, 226 had followed the therapeutic 155 elimination diet extremely accurately (Table 1). Small amounts of CMP were seen in the diet 156 of 14 children, but only eight had used actual milk products. In addition, in 19 children there 157 were no obvious sources of CMP, but food records included some recipes or foodstuffs for which there is uncertainty of them containing CMP. The parents of three children reported 158 being in a process of an oral challenge test with milk and these children were classified 159 adherent. 160 161 Those eight children whose parents reported consumption of milk products had a mean intake 162 of 350 g (range 76 g - 1136 g) of milk products during the 3 days. The amount of CMP 163 ranged from 2.0 g to 36.5 g, with a mean intake of 8.5 g and median intake of 4.0 g of CMP. 164 Those 14 children whose parents reported consumption of foodstuffs classified as containing 165 small amounts of CMP had a mean intake of 6.8 g (range 0.0 g - 42.7 g) of milk products 166 during the 3 days. The amount of CMP from these foods ranged from 0.0 g to 9.1 g, with a 167 mean intake of 1.0 g and median intake of 0.02 g. 168 Four of the eight children who had used milk products had also used special infant formulas 169 (Table 2). Mean intakes of calcium were below recommendations, but due to 170 supplementation, mean intakes of vitamin D were sufficient (Table 3). In addition, the intakes 171 of riboflavin and calcium were especially low in food records containing neither milk 172 products nor a special infant formula (n = 89, data not shown). 173 Of the children with CMA, 59% were boys. The median duration of overall breastfeeding was 6 months and that of exclusive breastfeeding 2 months, and the reimbursement for the 174



190 who had followed the CMP-free diet, subsequent food records were available from 215

191 children, who were observed further. Altogether 120 children had begun to use milk products

during follow-up (Fig 1). At the age of 3 years, 55 children were still avoiding milk; 40

193 children had left the study before the age of 3 years and had not begun to use milk products

194 up to the last available study point.

195 The main milk products used after the period of milk elimination were milk (87% of

196 children), cheese (67% of children), and yoghurt (45% of children). However, amounts of

milk products used were small, and only 17% of children consumed three glasses of milk,

198 23% used at least two slices of cheese and 15% used at least 1 dl of yoghurt daily.

## 199 **DISCUSSION**

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The therapeutic elimination diet in children with a diagnosed CMA was very well adhered to. 200 201 As many as 85% of the families followed the diet extremely accurately, and an additional 7% 202 had no obvious sources of CMP, but food records contained some foodstuffs with an 203 unknown recipe. Small amounts of CMP were observed in the diet of 5% of the children, and 204 only 3% had used milk products. Those who had consumed small amounts of CMP were 205 older and more often monosensitised, but otherwise sociodemographic factors were not 206 associated with the adherence. By the age of 3 years about a half of the children had begun to 207 use milk products and a quarter of the children were still avoiding CMP. Initial adherence to the elimination diet was not associated with the age of ending the CMP-free diet. 208 209 Major strengths of the study are the large population studied, and that food records were 210 collected for purposes other than to study the adherence to a CMP elimination diet, 211 diminishing embellishment. On the other hand, there were some inexact elements in some 212 food records: imprecise recording of food items consumed, or not having information 213 detailed enough on products such as from small bakeries and meat product manufacturers 214 dating years back. However, for 93% of the children consumption of foods containing even 215 the smallest amounts of CMP could be accurately evaluated. 216 The limitations of the study lie within possible problems in diagnostics, in not knowing the 217 children's' symptoms, in the cumbrousness of the database used for the purpose of the 218 present study, and in the rather long intervals in which the diets of the children could be studied. Relying on registry data for the diagnosis of CMA may, in part, explain the rather 219 220 high percentage (6.2%) of children with a diagnosed CMA, despite the national guidelines for 221 the diagnosis (Finnish Paediatric Association 2004). In our previous validation study, we 222 found that not all children underwent an oral challenge test before receiving the diagnosis, so

overdiagnosis is possible (Tuokkola et al. 2008). In addition, the strong research in the field

- <sup>224</sup> of food allergies in both university hospitals where the cohort was gathered may increase
- awareness of the disease and the tendency to seek for a diagnosis.

226 Two of the eight children with milk products in their diet had reportedly used a special infant

- formula only for 2 weeks, and these children had likely received the reimbursement on false
- 228 grounds. There were four children, who consumed both a special infant formula, and some
- 229 milk products. The costs of the use of special infant formulas to society are considerable, and
- unnecessary use should be avoided. Why eight children had consumed CMP-containing
- 231 porridges, gruels and other ready-to-use baby foods, is not known.
- 232 Compared with previous studies addressing the adherence to a therapeutic elimination diet in
- children with food hypersensitivities, in which approximately one to two thirds of the
- 234 populations were fully adherent, our study subjects show a much higher adherence (Vlieg-
- Boerstra *et al.* 2006, Eggesbo *et al.* 2001, Allen *et al.* 2009). The reasons for this are most
- 236 likely due to methodological differences (questionnaires vs. food records), as well as
- <sup>237</sup> differences in the populations studied (age groups, the basis for diagnosis, and food allergies).
- Adherence to dietary treatment of celiac disease shows variation between 30% to 95%,
- 239 depending on the methods used and the age of the children; no studies report adherence in an
- age group comparable to the present cohort of children under the age of 3 years (Hommel *et*
- 241 *al.* 2008). Our results are based on 3-day food records, and we have no knowledge on the
- <sup>242</sup> diets beyond those days, which is a limitation compared with the studies using questionnaires
- in defining the level of adherence. However, food records collected blindly to the purpose of
- the present study are presumed to give an otherwise reliable answer. The total number of days
- examined in our study amounts to 781. One particular reason for the high level of adherence
- in our study population could be the requirement for the food industry to mention CMP on
- food labels, making it easier to follow the elimination diet. Being aware of an increased
- 248 genetic risk for type 1 diabetes may also increase the adherence to a dietary treatment.

249 In Finland those children who are allergic only to CMP do not often see a nutritionist, which 250 may explain the association between monosensitisation and consuming CMP hidden in 251 foodstuffs. The ingestion of these foods may be considered as accidents or as ignorance, and 252 could be counteracted by dietary counselling, if necessary. Unfortunately, information on 253 visits to a nutritionist was not available to us. On the other hand, monosensitised children 254 may have a milder form of the disease, and actually tolerate small amounts of CMP. As in the 255 study by Eggesbo et al. (2001), maternal age and education were not associated with 256 adherence to the elimination diet.

257 When studying the introduction of milk into the child's diet, our main hypothesis was that 258 consuming small amounts of CMP would lead to a quicker recovery from CMA and 259 reintroduction of milk products into the child's diet. However, in this group of children this 260 was not the case; initial adherence was not associated with the age at reintroduction of milk products. Vlieg-Boerstra et al. (2006) reported similar findings: in their study unintentional 261 262 consumption of an allergenic food did not predict the outcome of an oral challenge. Likewise, 263 in the study by Allen *et al.* (2009), adherence to an egg elimination diet did not predict the 264 outcome of a challenge. In our study, the only background factor associated with an earlier 265 introduction of milk products was maternal smoking during pregnancy. We assume that this 266 association does not truly reflect a quicker recovery from CMA, but rather the motivation for 267 following the prescribed diet. The question of whether ingesting small amounts of CMP in a 268 home setting would induce tolerance should be addressed with more frequent follow-up. We 269 could not find any such associations, but this could be due to the lengthy intervals of studying 270 the inclusion of CMP into the diet. The age at recovery from CMA is earlier in the present study than that previously reported by Skripak et al. (2007), who studied children with an 271 272 IgE-mediated CMA. The recovery rate in the present study follows more closely that

273 presented by Vanto et al. (2004), who also included both IgE-mediated and non-IgE-

- 274 mediated CMA in his study. The recovery rate may also be affected by the fact that the
- 275 diagnosis is done in clinical practice and not by the researchers in the present study.
- 276 Children following a CMP-free diet require attention to fulfil their needs for calcium, vitamin
- 277 D and riboflavin. In addition, children recovered from CMA consume less milk products than
- children on average do (Kyttälä et al. 2010); the concern of receiving enough calcium and
- 279 vitamin D is still present after the inclusion of milk into the diet.
- 280 In summary, adherence to a therapeutic elimination diet of children with diagnosed CMA was
- extremely good. Monosensitisation and older age are associated with sloppier adherence,
- 282 possibly due the absence of nutritional information by a dietitian/nutritionist. Intakes of
- calcium, riboflavin and vitamin D are of concern in children who follow or have followed a
- 284 CMP-free diet. This study does not show evidence that small amounts of CMP would lead to
- a quicker recovery from CMA in a real-life setting.

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- 299 Conflict of interest statement
- 300 The authors declare no conflict of interest.

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Table 1. Adherence to cow's milk protein (CMP) elimination diet within 6 months after the

diagnosis of cow's milk allergy, n = 267

Child has consumed	n	%
No CMP	226	85.0
Some uncertain food items without obvious sources of CMP <sup>1</sup>	19	7.1
Hidden or small amounts of CMP <sup>2</sup>	14	4.9
Milk or milk products <sup>3</sup>	8	3.0

<sup>1</sup>Meat and bakery products for which a recipe was not known, or if a commercial name of a

352 meat or bakery product or a ready-to-use baby food was not specified

<sup>2</sup>CMP in food items such as industrial baby-foods, bakery and meat products, or fat spreads

354 containing CMP as an ingredient, cookies with milk chocolate, or a few cheese puffs.

<sup>3</sup>Milk products used were cheese, ice cream, infant formulas, as well as milk-containing

infant porridges, and gruels.

Table 2. Adherence to the cow's milk elimination diet: milks and special infant formulas that were used during the 3 study days<sup>1</sup> within 6 months from receiving a diagnosis of cow's milk allergy by age (each child may be accounted for more than once if having consumed more than one type of milk or drink; number of children = 264).

	3 months $n = 48$	6  months n = 106	1 year n = 106	2 years n = 4
Breast milk	26	41	17	0
Amino-acid formula	6	26	25	0
Hydrolysed formula	22	48	47	1
Soy formula	3	7	24	2
Cow's milk formula <sup>2</sup>	1	6	1	0
Cow's milk <sup>2</sup>	0	0	1	0
Soydrink	0	0	6	0
Oatdrink	0	0	2	1
Ricedrink	0	0	2	1

<sup>363</sup> <sup>1</sup>Those who had reported an ongoing challenge test with cow's milk are not included.

<sup>364</sup> <sup>2</sup>The reason for the consumption of cow's milk formula and cow's milk is not known.

Table 3. Adherence to the cow's milk elimination diet: mean (SD) intakes of energy and

366 certain nutrients, intake from foods and supplements together, of non-breastfed children by

 $367 ext{ age}^1$ 

		3 months (n = 22)	6 months (n = 67)	1 year (n = 89)	2 years (n = 4)
Energy kJ <sup>2</sup>		2430 (277)	2800 (554)	3910 (760)	4370 (325)
Protein	% of energy	10.2 (0.8)	10.2 (1.6)	12.2 (2.7)	12.1 (2.9)
Carbohydrates	% of energy	40.7 (5.3)	50.8 (7.4)	55.0 (6.7)	56.1 (5.5)
Fat	% of energy	49.0 (5.1)	38.7 (7.0)	32.4 (7.2)	31.2 (7.7)
Calcium <sup>3</sup>	mg	467 (60)	430 (130)	473 (191)	780 (248)
Vitamin D <sup>4</sup>	μg	14.7 (4.2)	14.1 (4.0)	13.3 (4.2)	12.3 (10.7)
Riboflavin <sup>5</sup>	mg	0.84 (0.26)	0.74 (0.25)	0.81 (0.38)	1.14 (0.55)

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<sup>1</sup>within 6 months from receiving a reimbursement of the special infant formulas

<sup>2</sup>Estimated needs for energy at 3 months 2100 kJ for girls and 2200 kJ for boys, at 6 months

for 2600 kJ for girls and 2700 kJ for boys, at 1 year 3400 kJ for girls and 3700 kJ for boys,

and at the age of 2 years 4400 kJ for girls and 4700 kJ for boys.

<sup>3</sup>Recommended intake 540 mg for 6 - 11 months of age, 600 mg for 1-2 years of age

- <sup>4</sup>Recommended intake 10  $\mu$ g for 6 23 months of age, 7.5  $\mu$ g for 2 years of age
- $^{5}$ Recommended intake 0.5 mg for 6 11 months of age, 0.6 mg for 12-23 months of age, and
- 375 0.7 mg for 2 years of age

Figure 1. Number of children, in whom cow's milk was reintroduced into the diet for the first time after the diagnosis of cow's milk allergy. In addition, 40 children had dropped out from the study before the age of 3 years, and had not reintroduced milk products into the diet at the last available food record.

