# Intake of dietary supplements in infants and (young) children in Germany

## Results of the KiESEL Study

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## Abstract

To improve the knowledge on the nutrition of infants and (young) children, the German Federal Institute for Risk Assessment (BfR) conducted the Children´s Nutrition Survey to Record Food Consumption (KiESEL). Data were collected from children aged 0.5 to 5 years (inclusive), selected to be representative for Germany, using a questionnaire (n = 1,104) and a 3 + 1-day weighing protocol (n = 1,008). In this paper, results regarding dietary supplements (DS) intake are reported. According to the questionnaire, based on the past 12 months, 42% of children, as well as 18% of children on the days logged in the food consumption protocols, take DS. Vitamin D represents the majority (78%) of these supplements. A negative age dependence of DS intake on vitamin D supplementation is observed, as well as a positive correlation with parental socioeconomic status. The main motivation is the recommendation by pediatricians.


**Key words:** Dietary supplements (DS), supplements, children, infants, child nutrition, vitamin D, dietary record


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## Introduction

Children are a particularly exposed and at the same time a vulnerable consumer group. Thus they must be considered separately in risk assessment. From 2014 to 2017, the German Federal Institute for Risk Assessment (BfR) conducted the Children's Nutrition Survey to Record Food Consumption („Kinder-Ernährungsstudie zur Erfassung des Lebensmittelverzehrs“, KiESEL) as a module of the Study on the Health of Children and Adolescents in Germany („Studie zur Gesundheit von Kindern und Jugendlichen in Deutschland“, KiGGS Wave 2) conducted by Robert Koch-Institute (RKI). KiESEL should update and expand the VELS study (Consumption study to determine the food intake of infants and young children for the estimation of an acute toxicity risk from pesticide residues, „Verzehrsstudie zur Ermittlung der Lebensmittelaufnahme von Säuglingen und Kleinkindern für die Abschätzung eines akuten Toxizitätsrisikos durch Rückstände von Pflanzenschutzmitteln“) which was conducted in 2001/2002 [1]. Few current data on the use of dietary supplements (DS) in infants and (young) children (definition: ◆ Overview 1) exist in Germany up to date. Also in the VELS study, no data were collected on the intake of DS in children aged 6 months to 4 years inclusive. Thus, the aim of the KiESEL study is to establish an up-to-date data basis for the risk assessment of both dietary habits and DS intake for children in the first years of life on the basis of recorded consumption data and a questionnaire.

Previous studies concerning dietary supplement use include all age groups in childhood and adolescence. Moreover, comparability is also limited due to different definitions and study designs. At the end of the 1990s, 110 DS existed on the German market which were directly or indirectly advertised for the target group of children

| Overview 1: **Definitions of the terms "infant," "toddler" and "child".** | |
|---|---|
| **term** | **age** |
| infant | 0 to < 12 months |
| toddler | 1 to < 3 years |
| child | from 3 years |
| The term "child" is also used in general statements in reference to the entire cohort. | |

[2]. The Dortmund Nutritional and Anthropometric Longitudinally Designed (DONALD) cohort study identified 133 DS by 2005 [3]. In contrast, for (young) adults, 2273 DS were recorded in the National Nutrition Survey II (NVS II) in 2008 [4]. According to a survey among pharmacists, the demand for DS is steadily increasing for both, children and adults [5]. In the German Representative Study of Toddler Alimentation (GRETA) of 10-month- to 3-year-old children, a 7-day estimation protocol was used in 2011 to determine that 42% of participating children were taking DSs (n = 530). With increasing age, the proportion of supplement users decreased from 75% in the 10–11 month age group to 24% in the 25–36 month age group. 74% of 10-11 month old infants were taking vitamin D [6]. In the DONALD study, food supplementation was observed in 7% and 6% of 2- to 3-year-olds and in 8% and 9% of 4- to 6-year-old boys and girls, respectively, using a 3-day weighing protocol in 2005 (n = 5,990) [3]. In the Nutrition Study as KiGGS Module (EsKiMo Study I), which includes participants aged 6–17 years, 7.5% of boys and 8.7% of girls took supplements, including vitamin D, among 6- to 11-year-olds in 2007. The prevalence among 12- to 17-year-olds was 18.5%. There was no age dependence of supplementation [7]. In the EsKiMo study II from 2015 to 2017, 16.4% of 12- to 17-year-olds took DS [8].

To account for changes in the food market and recommendations, the KiESEL study can update or complete this picture for the 0.5–5 year age group based on representative data. In this paper, the prevalences of the intake of DS in infants from 6 months, toddlers and children up to and including five years in Germany are described with a focus on vitamin D. We also present the relationship to the age of the children and the socioeconomic status of the parents. In addition, a supplement database was created and will be made available via the KiESEL homepage (→ www.bfr.bund.de/ de/kiesel-studie.html).

## Methods

According to the Food Supplement Regulation, dietary supplements are defined as foods that are taken to supplement the diet [9]. In this study, vitamin D, which is used for rickets prophylaxis, was explicitly included under the term dietary supplement. Dietary supplements containing vitamin D, either exclusively or in combination, were considered both separately and as a whole in the evaluation. The term "vitamin D" thus also includes single and combination preparations, unless otherwise stated. Fortified foods and homeopathic medicinal products, on the other hand, were not considered in this work. The evaluation refers to the data collected nationwide in the KiESEL study in 2014–2017, which comprises a subsample of KiGGS wave 2 [10]. Here, both a 3 + 1-day weighing protocol and a questionnaire were used to obtain the consumption data. In the protocol, the consumption of both food and dietary supplements was recorded, and the supplements taken on the respective day were queried as free text. All participants with at least three logged days were included in the study (sample 2, n = 1,008) [11]. In addition, the questionnaire (sample 1, n = 1,104) was used to inquire about longer-term use of vitamin D and other supplements.

Three separate questions were used to determine whether the child had taken vitamin D with or without fluoride in the last 12 months and, if so, over what period of time and how frequently. Similarly, questions asked about the use of other DSs in the last 12 months or since birth, including product name and manufacturer, duration of use and frequency, and asked about motivation for supplementation with the option of multiple responses. The two methods thus represent short-term (dietary record) and long-term (dietary record and questionnaire) consumption, respectively. The different sample sizes are due to the fact that not all participants in the interview completed and returned the dietary records or they had to be excluded after the quality check.

Both samples include infants and (young) children aged 6 months to 5 years inclusive. An equal distribution in relation to both sexes as well as all age groups was aimed for, but is slightly shifted towards older ages due to the time period between recruitment and the survey. Children who were 5 years old at recruitment but turned 6 years old during the course of the study were still included. The selection of the study population, survey methods and instruments, and study design were described by Golsong et al [1]. Sample 1 is weighted by age, sex, region, day of the week, and education of parents to improve the representativeness of the data for Germany via weighting factors [12]. For sample 2, weighting factors that could have been applied for the analysis were not yet available at the time of this analysis. The cohort is characterized in ◆ Table 1.

The evaluation was performed separately for defined drug groups as well as for the sum of DS, with the association to the age of the children and the socioeconomic status (SES)

| | sample 1 (n weighted [%]) | sample 2 (n unweighted [%]) |
|---|---|---|
| **method** | questionnaire | 3 + 1 day dietary record |
| **sample size (n)** | 1104 | 1008 |
| sex | | |
| male | 565 (51) | 510 (51) |
| female | 539 (49) | 498 (49) |
| socioeconomic status[a] | | |
| low | 173 (16) | 60 (6) |
| medium | 669 (61) | 596 (59) |
| high | 253 (23) | 351 (35) |

Tab. 1: **Description of the study population including sample 1 (questionnaire) and sample 2 (dietary record).**
Data as absolute numbers and percent of sample.
[a] Due to weighting or missing data in the total not equal to the respective sample size.
[b] 3 + 1-day weighing protocol

as an additive index of education, occupation, and income of the parents according to CASMIN classification (Comparative Analysis of Social Mobility in Industrial Nations) [21]. For group comparisons, the $\chi^2$-independence test was applied and $\alpha = 0.05$ was set. The analysis of the dietary records with respect to DS was performed with R version 3.3.2, and the questionnaire with IBM SPSS Statistics version 21.0. Based on both samples, a supplement database was created, the classification of which was made into the groups of single-nutrient and dual-nutrient supplements with specification, and multivitamin, mineral, multinutrient, and multifatty acid supplements, as well as probiotics and „others" without specification. Nutrient doses as well as product mass and dosage were recorded. In addition to the prevalences, the dosages of the DS were also determined, but these are not the subject of this work and will be taken into account when the Max Rubner Institute (MRI) considers nutrient exposure in the future.

## Results

90 dietary supplements were identified and included in the supplement database. Among others, 19 multinutrient preparations, 10 multivitamin preparations, 7 probiotics, 6 vitamin D3 preparations and 5 each of iron, magnesium, fluoride and vitamin D3 with fluoride preparations were named. Note: The supplements in the KiESEL study do not exclusively include dietary supplements specifically for children, but also products without age-specific usage information.

### Evaluation of supplementation in the consumption protocol

Sample 2 (unweighted) included 510 boys and 498 girls. A total of 184 children (18%) took DS. There are no significant sex differences (17% boys, 20% girls). Supplementation decreases significantly with increasing age ($p < 0.001$, ◆ Table 2). Here, the DSs are largely composed of vitamin D as a single-nutrient or combination supplement with fluoride (n = 144; 78% of all DS users), which also show a negative association with age ($p < 0.001$). 56% of 0.5- to < 1-year-olds take vitamin D. Among 1- to < 2-year-olds, consumption is 28%; at ages 2 to < 5 years, supplementation decreases to 4% to 6%, dropping to 1% at ages 5 years and older. Excluding vitamin D, only 52 participants (5%) take DS. This is independent of age ($p = 0.69$). The proportion of users of other dietary supplements is highest at the age of 4 years (7%) and ranges between 4% and 6% in all other age groups. These include mainly multivitamin preparations (n = 16), fluoride (n = 12) and multinutrient preparations (n = 12). ◆ Table 2 provides an overview across all age groups.

### Intake of dietary supplements according to questionnaire

In sample 1 (n = 1,104, weighted), information on the intake of DS is available for 565 male and 539 female participants. Regarding the question on vitamin D prophylaxis, parents of a total of 387 children (35%) reported supplementation. No gender differences were observed. This includes both claims of vitamin D with (14%) and vitamin D without fluoride (21%). Of these, 74% of parents gave vitamin D throughout the year and 10% exclusively in winter. Supplementation was done mostly daily (75%) or several times a week (18%). The number of children taking total DS was 461 (42%), of whom 259 were male and 202 were female. Relative supplementation decreases significantly with age from 95% in <1-year-olds to 16% in 5- to <7-year-olds ($p < 0.001$, Table 3). Vitamin D supplementation decreases significantly with age ($p < 0.001$). At age 0.5 to < 1 year, 95% and at age 1 to < 2 year, 81% of children take vitamin D. From 3 years of age, the proportion decreases to 42% and steadily decreases to 7% by 5 to < 7 years of age.

| Age (years) | 0,5 to < 1 | 1 to < 2 | 2 to < 3 | 3 to < 4 | 4 to < 5 | 5 to < 7 | total |
|---|---|---|---|---|---|---|---|
| SD total (%[a]) | 58 | 31 | 10 | 7 | 12 | 6 | 18 |
| Vitamin D (%[a]) | 56 | 28 | 5 | 4 | 6 | 1 | 14 |
| SD without vitamin D (%[a]) | 4 | 4 | 6 | 5 | 7 | 5 | 5 |
| **Total participants (n)** | **118** | **190** | **164** | **147** | **163** | **226** | **1008** |

Tab. 2: **Age dependency of the intake of dietary supplements (DS) in infants and (small) children in the dietary record**
[a] Percentage of age group

| Age (years) | 0,5 to < 1 | 1 to < 2 | 2 to < 3 | 3 to < 4 | 4 to < 5 | 5 to < 7 | total |
|---|---|---|---|---|---|---|---|
| SD total (%[a])[c] | 95 | 81 | 49 | 28 | 21 | 16 | 42 |
| Vitamin D without fluoride (%[a]) | 55 | 44 | 19 | 20 | 7 | 5 | 21 |
| Vitamin D with fluoride (%[a]) | 41 | 37 | 23 | 2 | 2 | 0 | 14 |
| Vitamin D - sum (%[a])[b] | 95 | 81 | 42 | 22 | 9 | 7 | 35 |
| SD without vitamin D (%[a]) | 6 | 5 | 13 | 14 | 14 | 12 | 11 |
| **Total participants (n)** | **88** | **186** | **181** | **187** | **191** | **272** | **1104** |

Tab. 3: **Age dependence of the intake of dietary supplements (SD) in infants and (small) children within the last 12 months or since birth in the questionnaire.**
The weighted figures are rounded in accordance with standard commercial practice. To form the totals, the exact numerical values were were first added and then rounded to whole numbers.
[a] Percentage of the age group
[b] Sum includes "Yes, with fluoride" and "Yes, without fluoride".
[c] excluding duplicates for "Vitamin D - sum" and "DS without vitamin D".

Other supplements were used by 122 children. Intake of DS excluding vitamin D increased significantly with participant age from 6% to 12–14% ($p = 0.0068$). ◆ Figure 1 provides an overview of supplementation and is based on both questionnaire and dietary record data.

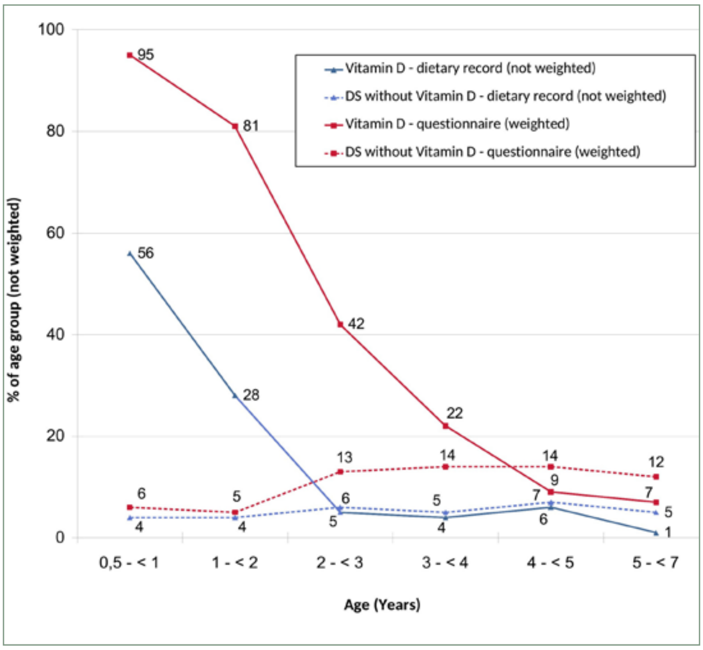


Fig. 1: **Overview of the relative supplementation within the age group in questionnaires and dietary record**

## DS intake dependent on parents' SES

The two samples were analyzed for dependencies on SES according to CASMIN classification and divided into "low", "medium" and "high" levels. The analysis shows that the proportion of participants consuming DS increases with SES (low 10% < medium 15% < high 25%, $p = 0.006$). Vitamin D supplementation also appears to be dependent on parental SES, increasing from 10% and 11% for low and medium SES, respectively, to 21% for high SES ($p < 0.001$). Moreover, even when vitamin D is excluded, a tendency for supplementation to increase with increasing SES can be observed (low 0% < medium 5% < high 6%, $p = 0.18$). Also in the questionnaire, both the proportion of total supplement users increases significantly from 41% to 52% at higher SES ($p = 0.0012$) and vitamin D intake increases from 38% to 43% ($p < 0.001$). However, supplement intakes at low and medium SES were not significantly different from each other. With regard to other non-vitamin D supplements, the proportion of those consuming them (low 7% < medium 10% < high 16%) also increases with increasing SES ($p = 0.0045$). An overview is provided in ◆ Table 4.

## Motivation

In the questionnaire we also asked about the motivation for taking dietary supplements, including vitamin D. The majority of respond-

| SES | | low | medium | high |
|---|---|---|---|---|
| dietary record | SD total (%[a])[c] | 10 | 15 | 25 |
| | Vitamin D (%[a]) | 10 | 11 | 21 |
| | SD without vitamin D (%[a]) | 0 | 5 | 6 |
| | Total participiants (n)[d] | 60 | 596 | 351 |
| questionnaire | SD total (%[a])[c] | 41 | 39 | 52 |
| | Vitamin D - sum (%[a])[b] | 38 | 32 | 43 |
| | SD without vitamin D (%[a]) | 7 | 10 | 16 |
| | Total participiants (n)[d] | 173 | 669 | 253 |

Tab. 4: **Supplement intake as a function of the socioeconomic status (SES) of parents in dietary record (sample 2) and questionnaire (sample 1)**
[a] percentage of the social status group
[b] sum includes "yes, with fluoride" and "yes, without fluoride"
[c] by excluding duplicates for "Vitamin D - sum" and "DS without vitamin D"
[d] due to weighting or missing data in the sum not equal to the respective sample size

ents used DS on the recommendation of their pediatricians (73%, n = 805). This is true for 83%, 87%, and 82% in the three youngest age groups. In the other age groups, the proportion was ≥ 60%. Parents' SES did not affect confidence in doctor´s recommendation. In addition, 19% of parents reported using DS "to improve the health" of their children. This reason was cited by 17% of parents with low SES and 18% and 26% for medium and high SES, respectively. Other motivations are summarized in ◆ Table 5.

## Discussion

The 90 different preparations recorded in the supplement database of KiESEL show a comparatively low variability of the dietary supplements for children compared to the range of supplements for adults and are in the order of > 100 preparations surveyed so far [2-4]. Despite the small number, the protocoled dietary supplements of KiESEL show a high heterogeneity with regard to their composition, the form of administration and the consumption recommendations.

### Supplementation by age

Taking into account the methodological and age-structural differences, the results of the KiESEL study fit into the previous overall picture of the situation in Germany [3, 6]. Regarding the similar age dependence of vitamin D supplementation in the first months of life, the data are congruent with the GRETA study [6]. Consumption of DS excluding vitamin D increases significantly from 6 to 12 to 14% with increasing age in the KiESEL study questionnaire. Diary logging varies in the range of 4 to 7%. The prevalences are on the same level as in the DONALD and EsKiMo study I from 2 to < 3 years of age, taking into account methodological differences [3, 7].
In the KiESEL study, the age group considered results in a high proportion of vitamin D and fluoride supplements in relation to the total number of dietary supplements used. In particular, multivitamin, multinutrient and fluoride supplements were taken. In this respect, the GRETA study, which investigated vitamin D and fluoride supplementation in the first months of life, provides comparable results. A large proportion of infants and (young) children (3/4 of infants at the end of the 1st year of life) take vitamin D [6]. Due to the lower age limit of 2 years in the DONALD-cohort, the focus of this study is not on rickets prophylaxis, but on the administration of vitamins C, B1, B2, E and niacin [3]. The high prevalence of vitamin D and fluoride should be classified in the context of the recommended

| sorted by frequency of mention in the questionnaire | Motivation | n | % |
|---|---|---|---|
| 1 | recommendation of pediatricians | 805 | 73 |
| 2 | for the improvement of health | 215 | 19 |
| 3 | I do not give to my child in principle | 161 | 15 |
| 4 | because I have heard and read many good things about it | 46 | 4 |
| 5 | to compensate for a low fruit and vegetable consumption of my child | 20 | 2 |
| 6 | recommendation of pharmacists | 6 | 0,5 |
| 7 | to improve my child's performance | 2 | 0,2 |
| 8 | not specified | 4 | 0,4 |
| 9 | other | 102 | 9 |

Tab. 5: **Motivation for taking supplements sorted by frequency of mention in the questionnaire**

rickets and fluoride prophylaxis for infants. During the first year of life and the winter months of the second year of life, supplementation of 10 μg/day of vitamin D is recommended according to the German Nutrition Society (DGE). Vitamin D supplementation is often useful beyond the first year of life [13] and, although decreasing, is partly continued. The results of the questionnaire show that the recommendation for vitamin D prophylaxis is adhered to by the majority of respondents in the first and second years of life (95% and 81%, respectively) and continuously decreases in the subsequent years, as expected. The recommended fluoride supplementation depends on the age of the children and the fluoride content of the consumed drinking water and ranges in the KiESEL cohort between 0 mg fluoride at 0.3-0.7 mg/L drinking water fluoride in infancy and 0.5 mg at < 0.3 mg/L drinking water fluoride and the additional use of fluoridated table salt in 4- to < 7-year-old children [14]. Assessment of compliance with the recommendation of fluoride supplementation is not possible due to lack of information on the individual drinking water fluoride content of the families surveyed.

Striking is the discrepancy of > 50% of the prevalences in dietary records and questionnaires in the KiESEL study. This may be caused by the different reference period, which may lead to an underestimation of long-term use in the dietary record, e.g. seasonal use. The personal interview allows direct focus on the question. Furthermore, the aspect of possible social desirability of rickets prophylaxis has to be considered, so that the mention in the questionnaire is higher than in the dietary record.

### Influence of SES

It has already been shown that the health of children in Germany is associated with their social status [15], which influences diet quality [16]. Therefore, it is reasonable to assume that socioeconomic status may also have an effect on the use of DS (in children) [17, 18]. It is important to distinguish between the recommended prophylaxis and other dietary supplements, the use of which is not recommended without indication [19].

The evaluations of the KiESEL study confirm this assumption. However, it cannot be decided whether the significant differences in supplementation between social status groups are based on the intake of vitamin D, or whether the effect is due to the consumption of total DS. Unlike the GRETA study, which did not find a significant relationship of vitamin D and fluoride supplementation to social class [6], the KiESEL study questionnaires show significantly different intakes of the DS except vitamin D when SES is taken into account. The influence of SES on the intake of DS should also be discussed in relation to the motivation of intake. According to our survey, the recommendation of pediatricians is indicated as a motivation independent of SES, whereas the more prevalent administration of DS at higher SES can be justified by the desire of health optimization in children of parents with high SES. The conclusions regarding the association between the intake of DS, except vitamin D, and SES are limited in the dietary record by the sample size. Calculation of the $\chi^2$-test may be imprecise as a result, because the minimum size of the expected frequencies for comparison with a $\chi^2$-distribution is not given for the combination of DS except vitamin D/low SES (n = 0).

### Motivation to take dietary suplements

The majority of the children receive DS independently of the SES of the parents on the advice of the pediatricians. Since vitamin D was supplemented in particular and the medical advice was based on the health benefits of prophylaxis, both motives must be considered reciprocal. EsKiMo II shows the improvement of health as the main reason (59 %) for taking DS. 21% of the participants supplemented on the advice of a physician [8]. The NVS II [20] concluded that motivation depends on the subjectively perceived health status. Since in childhood parents decide on supplementation, the results of the KiESEL study are conclusive. Pediatricians are of great importance for decision-making in the age group considered. With regard to the influence of SES on the intake of vitamin D and other DS, other professional groups such as midwives or more target group-specific education could be helpful.

## Conclusion and outlook

The study situation on the use of DS in infants and (young) children in Germany is insufficient so far. This evaluation helps to assess the use of supplements in this age group more accurate and to be able to determine the proportion of nutrient supply by DS in this age group in the future. The observed differences in supplementation with respect to parents' SES indicate that social determinants have a significant impact on children's health in Germany, which should be overcome through public health interventions. In general, a balanced and varied diet for children should be aimed for.

**Conflict of Interest**
The authors declare that there is no conflict of interest.

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