1	Design and characterization of dietary assessment in the German National Cohort										
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68 Abstract

Background/objectives: The aim of the study was to describe a novel dietary assessment strategy based on two instruments complemented by information from an external population applied to estimate usual food intake in the large-scale multicenter German National Cohort (GNC). As proof of concept, we applied the assessment strategy to data from a pretest study (2012-2013) to assess the feasibility of the novel assessment strategy.

Subjects/methods: First, the consumption probability for each individual was modeled using three 24h food lists (24h-FL) and frequencies from one food frequency questionnaire (FFQ). Second, daily consumed food amounts were estimated from the representative German National Nutrition Survey II (NVS II) taking the characteristics of the participants into account. Usual food intake was estimated using the product of consumption probability and amounts.

81 **Results:** We estimated usual intake of 41 food groups in 318 men and 377 women. 82 The participation proportion was 100%, 84.4%, and 68.5% for the first, second, and third 24h-FL, respectively. We observed no associations between the probability of 83 84 participating and lifestyle factors. The estimated distributions of usual food intakes were plausible and total energy was estimated to be 2,707 kcal/day for men and 85 2,103 kcal/day for women. The estimated consumption frequencies did not differ 86 substantially between men and women with only few exceptions. The differences in 87 88 energy intake between men and women were mostly due to differences in estimated 89 daily amounts.

90 Conclusions: The combination of repeated 24h-FLs, a FFQ, and consumption-day 91 amounts from a reference population represents a user-friendly dietary assessment 92 approach having generated plausible, but not yet validated, food intake values in the 93 pretest study.

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94 Introduction

The desire to facilitate dietary measurements in large-scale epidemiologic studies is probably as old as the estimation of diet itself in such studies [1]. Dietary data from large-scale epidemiologic studies are used for investigations of the diet-diseaserelations that often form the basis for dietary recommendations. Thus, dietary assessment in such studies needs to provide estimates of an individual's usual food intake with a minimum burden to the participant and should also reflect the intake of the study population [2].

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103 Evidence suggests that self-reported dietary assessment instruments have imperfect 104 validity in estimating an individual's diet [3-5] and could therefore generate 105 underestimated and/or biased diet-disease relations [6-8]. Specifically, validation 106 studies using recovery biomarkers indicate that self-reported intakes of macro- and micronutrients such as total energy, protein, potassium, and sodium are 107 underreported and misspecified [7, 9]. Bias appears to be less severe when intake 108 estimates are derived from short-term dietary assessment instruments such as 24h 109 110 dietary recalls (24h-DRs) [4-7, 9-11]. Recent statistical developments suggest that the combination of short-term and long-term dietary assessment techniques - such 111 112 as repeated 24h-DRs and food frequency questionnaires (FFQs) – yield less biased estimates of usual food intake than stand-alone instruments [12-16]. Hence, we 113 combined the information from repeated applications of a recently developed short-114 115 term 24h-food list (24h-FL) [17] designed to represent a simplified web-based dietary 116 questionnaire, one FFQ, and information from an external source as reference 117 population to estimate usual food intake.

The aim of the current study was to present the methodological concept of usual food intake estimation based on the above mentioned combination of information and to apply this concept to food intake data collected in a pretest study for the large-scale multicenter German National Cohort (GNC) [18, 19].

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124 Methods

125 Study population

The main phase of the GNC began in 2014 and it comprises a random sample of the general population drawn from population registries in 18 study centers [18, 19]. In accordance with the guidelines and recommendations of the German Society for Epidemiology to assure Good Epidemiologic Practice [20], pretest studies were conducted between 2011 and 2013 to select appropriate methods and instruments, to develop standard operating procedures, and to test the exposure assessment program according to its feasibility, acceptability, and expected duration.

133

The pretest study II consisted of a basic program that was mandatory for all study centers. It also included an optional dietary assessment module, which was performed by 16 of 18 study centers. The ethics committees of each local study centers approved the study protocol of the pretest study including the optional modules and written informed consent was obtained from all study participants [18].

139

In the pretest study II, participants were asked to complete three 24h-FLs on nonconsecutive days over a period of 1.5 months after their visit to the study center, and one FFQ. Participants could complete the first 24h-FL at their visit to the study center and had to complete the FFQ within two weeks thereafter. Participants who were willing to fill in the questionnaires via the internet received an individual access code for a web-based internet-portal during the course of the study and were asked by email to fill in the 24h-FL on a specific day. These days were selected at random by a computer program. Participants without internet access received the questionnaires as paper version, and completion of the 24h-FL on a specific day was organized via phone calls. Completed paper versions of the 24h-FLs were returned by mail with pre-paid envelopes.

151

152 Data collection took place from August 2012 to April 2013. Since the repeated dietary 153 assessment would have exceeded the pretest study period, study centers terminated 154 all reminder activities by the end of April 2013, even though not all participants had 155 completed three 24h-FLs by that time. Of 1010 study participants who took part in the 156 dietary assessment, 999 provided at least one completed 24h-FL or one FFQ. After 157 exclusion of 2 participants with no 24h-FL, 301 participants with no FFQ, and 1 participant with missing anthropometric data, a data set including at least one 24h-FL 158 and one FFQ was available for 695 study participants (318 men and 377 women), 159 160 forming the basis for the present analysis.

161

162 **Dietary assessment approach**

163 Figure 1 shows the blended dietary assessment strategy in the GNC. Usual food 164 intake is assessed by estimating two components which are subsequently multiplied. 165 The first component consists of the estimated individual consumption probability from 166 repeatedly filled in 24h-FL and one FFQ – estimated by a mixed effects logistic 167 regression model in which the frequency information from the FFQ is used as 168 covariate. The second component consists of the specific consumption-day amount 169 provided from a reference population – estimated by a mixed effects linear 170 regression model.

The idea of subdividing the assessment process into such components was outlined by Tooze et al. (2006) [16]. Further, the EPIC-Potsdam study showed that selfreported potion sizes from FFQ adds little information to the variance of food intake [21] implying that consumption frequencies has a stronger influence on the variation in food and nutrient intake between persons than portion sizes. Hence, the novel aspect

177 of the current dietary assessment strategy is the probability component derived from 178 the 24h-FL.

179

The individual food intake probability is multiplied by the person-specific daily consumption amount to obtain an estimated usual (habitual) intake value for each food item. The consumption day amounts of food intake were derived from a reference population. For nutrient calculations, the food items were linked to the German Nutrient Database (Bundeslebensmittelschlüssel, BLS Version 3.02), the national food composition data base.

186

187 Dietary assessment instruments

188 The 24h-FL was designed for simple and quick application with low burden for study participants and is available as a web application and a print version with the option 189 190 of optical scanning. The 24h-FL generates binary information (consumption versus 191 no consumption) for pre-specified foods consumed during the previous day. The 192 feasibility of this food list was evaluated in GNC pretest study I (August 2011 to 193 February 2012). In that study, the instrument was found to be acceptable to 194 participants and appeared feasible for application in large multi-center cohort studies, 195 with an average completion time of 8 to 10 minutes [17].

The 24h-FL was designed to explain at least 75% of variation in nutrient intake of 197 198 each of the 27 selected nutrients and four major food groups (fruits, vegetables, meat 199 and meat products, and milk and dairy products) based on 24h dietary recall data from the representative German National Nutrition Survey II (NVS II) [17, 22]. In the 200 201 pretest study, two food items were identified as missing by study participants and were subsequently added to the 24h-FL. After further discussion with leading 202 203 nutritionists, 10 additional food items were incorporated in the 24h-FL. Thus, the final version of the 24h-FL comprises 258 food items. 204

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206 In addition, an FFQ was developed as a web application and as a print version with 207 the option of optical scanning. The FFQ is based on the German version of the multilingual European Food Propensity Questionnaire [13] and it was aligned with the 208 209 food item list of the 24h-FL. The FFQ inquired about the intake frequencies of 133 210 foods and beverages during the previous 12 months. Portion sizes for food items are graphically displayed with pictograms [13]. The frequency scales have a closed-211 ended format of discrete categories that range from "never", "one time per month" to 212 213 "11 times per day or more frequent", depending on the food item. Food item 214 frequencies from the FFQ were converted to mean frequencies per day; for example, 215 1 time/week was converted to one-seventh times per day.

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The specific consumption-day amounts of food intake were derived from the representative NVS II. Amongst others, dietary intake in the NVS II was assessed from 2005 to 2007 by telephone interviews on two non-consecutive days using the 24-hour dietary recall method EPIC-Soft [22, 23] (renamed GloboDiet in 2014). Dietary data of 12,502 NVS II study participants aged 20-80 years were used. A list of concordance was established that link each food consumed at the NVS II with thelist of food items of the 24h-FL.

224

225 Formation of food groups and nutrient/energy intake

In the pretest data set, the number of applied 24h-FLs and FFQs were low compared 226 227 to the expected numbers which will be provided within the GNC due to the lower 228 number of participants. In the present data set, statistical modeling of individual usual food intakes on the single food item level was often not possible due to high 229 230 proportion of nonconsumers in the 24h-FL. Thus, 39 food groups comprising food 231 items with a similar composition or nutrient content (e.g., bread or milk and dairy 232 products) were formed for the current analysis [24]. Two further food groups were 233 also formed that reflected either vegetarian (e.g., vegetarian casserole) or nonvegetarian (e.g., lasagne) mixed dishes (for listing of food groups please see Tables 234 235 **3** and **4**). Information on single food item consumption provided by the 24h-FL was 236 summarized by defining an occurrence variable for each food group with a value of 1, 237 if at least one single 24h-FL food item was covered by the corresponding food group and a value of zero if the corresponding 24h-FL food item was not consumed on that 238 239 day. FFQ information was also summed up into reported frequencies at the food group level using the same approach as was done with the data from the 24h-FL. 240 241 Likewise, the daily consumption amounts were summarized taking the 24h-FL food 242 item specific daily amounts, if eaten.

243

For each food item of the 24h-FL, nutrient values were also calculated, weighted by the amounts of the detailed corresponding food items eaten in the NVS II. The nutrient values for each food item of the 24h-FL were multiplied by the estimated usual food intakes of that food item, calculated for each individual. Energy intake was

11 (27)

calculated for all food groups. Total individual energy intake was calculated by summing the energy intake of the food groups. An additional food group was also formed that comprised foods not covered by the 24h-FL but reported in NVS II. The energy amount of this food group was added to the total energy as a constant.

252

253 Missing Data

254 The FFQs were considered complete if information was provided for at least 80% of 255 core food items. Fats used for food preparation (e.g., butter, plant oils) or additives to 256 hot beverages (e.g., cream, sugar, and sweeteners) were not considered as core 257 food items. Missing data on the FFQ were found for only 44 food items, with a 258 maximum of 12 missing values in one FFQ item. Most food items had only one 259 missing value. To retain all observations in the analyses, missing values on the FFQ were single imputed by applying linear regression models to food item frequencies 260 taking sex, age, body mass index (BMI), and study site into account. 261

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When a participant was unable to report which kind of fat was typically used for food preparation, information on discretionary fats was single imputed by modeling individual consumption probabilities (p_i) for all fats applying a mixed effects logistic regression, adjusted for sex, age, BMI, and study site. For each imputation, a random number u_j from a uniform distribution (0, 1) was drawn. If u_j was $\leq p_i$ we assumed that this fat item was consumed on the specific assessment day.

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270 Statistical analysis

271 Descriptive statistics of the study population are shown as frequencies and 272 proportions, or means with standard deviations (SD). Study participants completed 273 up to three 24h-FLs. Hence, nine different reporting scenarios existed for each food group. Study participants with one 24h-FL could report 0 or 1 consumption days for each food group on the available 24h-FL. Study participants with two 24h-FLs could report 0, 1 or 2 consumption days for each food group on the two available 24h-FLs. Study participants with three 24h-FLs could report 0, 1, 2, or 3 consumption days for each food group on the three available 24h-FLs. For simplification, **Table 3** summarizes these 9 possible reporting patterns in the simplified categories of 0, 1, 2, or 3 times of reported food intake.

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282 The mixed effects logistic regression model with random intercept was applied to 283 estimate individual probabilities of food consumption and used the occurrence 284 variable collected by 24h-FLs as outcome variable and the following regression 285 variables: age, sex, BMI, habitual frequency of food intake taken from the FFQ, and 286 study center. Age and BMI were coded as continuous variables, sex as binary 287 variable, habitual frequency as ranked variable from 0 to several times a day, and study center as indicator variable. Individual consumption probability was calculated 288 for all food groups including the different methods of preparation and fat content 289 290 (e.g., raw vs. cooked). The mixed effects linear regression model with random 291 intercept was applied to estimate individual daily amounts of food consumption and 292 used the daily amounts collected in the NVS II as outcome variable and age, sex, 293 and BMI as regression variables using the same coding as in the mixed effects 294 logistic regression model [25]. In the food group 'Miscellaneous', consumption-day 295 amounts of negative values were estimated for 9 participants. Those were replaced 296 by half of the lowest standard consumption-day amount with positive value estimated 297 in that food group.

Especially, BMI is used to estimate resting energy expenditure (REE). Correspondingly, we included BMI as predictor for energy intake. Furthermore, we found in a previous work that the intake of some food groups benefit of using BMI as predictor [25].

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Usual food group intakes, total energy intake, and estimated energy expenditure
distributions are shown as percentiles (5th–95th), means, and standard deviations.
Usual food intake was not calculated for the food group "offal" since only 15
participants consumed foods of that particular group on a single consumption day.

308

309 *Misreporting*

Energy intake (EI) was compared with estimated total energy expenditure (TEE). Estimated energy expenditure was calculated as the product of resting energy expenditure (REE) and physical activity level (PAL), which was assumed to be 1.6 for all study participants because information on individual PAL was unavailable for this study. The REE was estimated according the prediction equations given by Müller et al. [26] (Table 7) taking weight, age, sex, and BMI into account.

316

317 For classifying misreporters the Goldberg method [27] was adopted and the ratio 318 (EI:TEE) of reported energy intake and estimated total energy expenditure and the 319 corresponding standard deviation (SD) was calculated. Study participants who fell 320 below the cut-off of mean(EI:TEE)-1.5*SD were classified as under-reporters and 321 those who fell above the cut-off of mean(EI:TEE)+1.5*SD as over-reporters. All 322 others were classified as acceptable reporters. Mean bias (=(mean(EI)-323 mean(TEE))/mean(TEE)) was calculated. Spearman partial correlation φ between EI and TEE adjusted for age, BMI and education was calculated. 324

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All analyses were carried out using SAS, version 9.4, and SAS Enterprise Guide, version 6.1 (SAS Institute, Cary, NC).

328

329 Code availability

330 Computer code is not available.

331

332 **Results**

333 In phase II of the GNC pretest studies, the dietary assessment included 996 out of 334 1010 participants who completed at least one 24h-FL. Participants who did not 335 additionally complete an FFQ also tended to not complete a second or third 24h-FL. Of subjects who did not complete an FFQ, only 15.3% completed a second 24h-FL 336 337 and 6.0% completed a third 24h-FL. On the other hand, among participants who 338 completed an FFQ, 84.6% completed a second 24h-FL and 68.6% completed a third 24h-FL. However, completion status of an FFQ did not vary according to sex, age, 339 BMI, or school level (Table 1). In this context, we like to remind readers that a 340 341 common and frequently practiced system of reminding participants to fill in the questionnaires did not exist in the pretest study. The mean time period between 342 343 completion of the first and second 24h-FL was 26.3 days (median=21 days, P5=15 344 days, P95=56 days). A similar time span was noted between the second and third 345 24h-FL (mean=25.8 days, median=20.5 days, P5=15 days, P95=51 days). Because 346 estimation of usual food intake in the current study was based on the combination of 347 24h-FL data and FFQ, all further analyses were restricted to the 695 (69.8%) study 348 participants who completed at least one 24h-FL and one FFQ. The mean age of 349 those participants was 52 years (minimum=20 years, maximum=71 years), 54.2% were female, and the mean BMI was 26.3 kg/m^2 (**Table 1**). 350

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The study population of this pretest study well reflected educated adult population in Germany with respect to basic socioeconomic variables including BMI. **Table 2** shows that participants with different numbers of repeated 24h-FLs did not differ substantially regarding sex, age, BMI or school level.

356

Table 3 shows the observed frequencies of intake per food group for men and 357 women. In the first four columns, the distribution of the number of days with 358 359 consumption is shown as percentage across the number of repeated 24h-FL. There 360 are substantial differences between food groups, ranging from foods with a high 361 percentage of being eaten at all three 24h-FL such as bread, and rarely eaten foods 362 with a high percentage of zero consumption on all days such as offal. A further 363 column shows the proportion of 24h-FL with consumption, taking all days into 364 account. Among solid foods, the most frequently consumed food groups were bread, sugar and confectionary, processed meat, milk and dairy products, and fresh fruits, 365 and among beverages, coffee and non-alcoholic beverages. Spirits were only rarely 366 consumed. Overall, the observed proportions of consumption were similar in men 367 368 and women, with some exceptions. The largest differences in the proportions between sexes were seen for processed meat (75.0% in men vs. 60.8% in women 369 with 24h-FL of consumption), meat (35.9% in men vs. 26.0% in women), fruiting 370 371 vegetables (42.8% in men vs. 51.8% in women), and beer (28.1% in men vs. 6.9% in 372 women). We were further interested in whether our observed proportions of 24h-FL 373 with consumption fit with proportions found in the NVS II. When comparing the 374 proportions of 24h-FL with consumption in the current study with the proportions of 375 the 24h-DR in the NVS II, the proportions in the current study appeared to be slightly higher than in the NVS II. Differences of greater than 10% in absolute values were 376

found for certain food groups, including eggs, vegetable fats, fresh fruits, milk and dairy products, nuts, other vegetables, and root vegetables.

379

The results of the modeling of the individual probabilities multiplied by the consumption-day amounts for each food group are shown in **Table 4.** Overall, the approach generated mean energy intakes that amounted to 2,707 kcal/d in men and to 2,103 kcal/d in women. It seems as the food intake of the study population was estimated well if compared to the estimated energy expenditure as a surrogate for energy needs.

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The ratio of EI:TEE was 0.96 (95% CI: 0.95; 0.97), 0.95 (0.94; 0.97) and 0.96 (0,95; 0.98) for all, men and women, respectively. The mean bias was -4.0% (-5.2%; -2.8%), -4.6% (-6.1%; -3.1%) and -3.5% (95% CI: -5.3%; -1.8%) for all, men and women, respectively. The Spearman partial correlation was 0.70 (95% CI: 0.66; 0.74), 0.05 (-0.06; 0.16) and 0.10 (0.001; 0.20) for all, men and women, respectively.

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The Goldberg limits to classify misreporters were (0.75, 1.15) for men and (0.70, 1.22) for women as shown in **Figure 2**. 24 (7.6%) and 20 (6.3%) of men were classified as under-reporters and over-reporters, respectively. 21 (5.6%) and 16 (4.2%) of women were classified as under-reporters and over-reporters, respectively.

397

Mean daily usual intakes of beverages were higher in men than in women, including beer, wine, juice, and soft drinks. In contrast, the estimated consumption of tea and non-alcoholic drinks per day were higher for women than men. Usual intakes of coffee, spirits and other alcoholic drinks did not substantially differ between sexes. Similar to beverage consumption, usual intakes of solid food items were generally

higher in men than women. The most profound differences were observed for bread, 403 red meat, processed meat, milk and dairy products, non-vegetarian dishes, pasta 404 405 and rice, potatoes, and soup. Furthermore, the estimated consumption of fats such 406 as butter was higher for men than for women but it was equal for vegetable oils and other fats. Estimated consumption of cake and cookies and sugar and confectionary 407 408 were slightly higher in men than women. On the other hand, women tended to 409 consume slightly more fresh fruits, fruiting vegetables, root vegetables, and other 410 fruits than men. Differences in estimated usual food intakes between men and 411 women were mostly due to differences in estimated person-specific daily 412 consumption amounts (Supplemental Table 1).

413

The percentiles show a wide range of usual individual intakes across food groups, suggesting that the method was able to differentiate between individuals regarding their intakes.

417

418 **Discussion**

This article describes the concept and statistical background of a blended 419 420 assessment strategy to estimate usual food intake of individuals in population-based 421 studies that had been piloted for large scale application in the pretest study phase of 422 the GNC. The results of the pilot study indicate that the estimated dietary intake reflects plausible food intake. Further, individual usual intakes across food groups 423 424 showed wide variation, suggesting that the assessment strategy was able to 425 differentiate between individuals regarding their food intakes. The novelty of the 426 assessment strategy is based on the statistical approach of separating the probability 427 of intake from daily consumption amounts. Since the participant had to provide easy 428 to obtain information only for estimating the individual probability, participant burden

was reduced compared to traditional methods aimed at similar precision inquantifying dietary data.

431

432 The blended dietary assessment strategy was motivated by the need for rapid completion time and low participant burden in the GNC and it built on the previous 433 434 development of a 24h-FL dietary assessment instrument for assessing an individuals' 435 consumption probability. The average time needed to complete the 24h-FL was 9 436 minutes, with high acceptability by participants [17]. Although the instrument is easy 437 to complete, the participation proportion dropped with subsequent applications and it 438 reached a participation proportion of 68.5% when the 24h-FL was applied a third 439 time. This drop was also caused by the termination of all reminder activities before 440 the end of the pilot study phase. Furthermore, around 30% of FFQs were not completed. The non-completion of the questionnaires could not be explained by 441 442 socioeconomic variables. Recently, a reminder system was developed to maintain a 443 high participation proportion for both instruments, the 24h-FLs and the FFQ.

444

445 Recent statistical developments suggest that the combination of short-term and long-446 term dietary assessment techniques to estimate usual food intake reduces biases compared to stand-alone instruments [12, 13, 15]. Thus, further thoughts are needed 447 448 to define the minimum set of information needed to calculate usual intakes. Currently, we calculated intakes if one 24h-FL and one FFQ were available. The statistical 449 450 procedure cannot deal with the situation, if only a FFQ is available since the 451 information of the FFQ is considered covariate information. In addition, the FFQ 452 information is not directly comparable with information from a 24h-FL and the use of 453 only one FFQ would generate different types of information with different bias within 454 a study. Previous methodologic studies were able to show that FFQ information

improves the estimation from 24h information, resulting in greater precision of the estimated individuals' usual food intakes and of the parameter estimation in a diethealth outcome model compared to 24h information only [12, 15]. FFQ information can also help distinguish between usual consumers, never consumers, irregular consumers, and ever consumers. The number of repetitions of the 24h-FL affects the precision of the estimate of the consumption probability of an individual but not the population mean.

462

463 One challenge of our approach is the need for an adequate reference population for 464 estimating person-specific consumption-day amounts. The reference population can 465 be derived from an external source or by conducting a sub-study within the main 466 study. In our study, information on person-specific consumption-day amounts was obtained from 24h-DRs of the NVS II, a representative nutrition survey for Germany 467 468 [22]. The NVS II was conducted more than 10 years ago, but is the most 469 comprehensive source of nutritional data for the entire Germany. A third German 470 nutrition survey is currently being planned. These future data may be used to update 471 the derived individual usual food intakes to more present food intake in Germany.

472

The use of an appropriate dietary assessment instrument as reference and as a guide for the development of study specific dietary assessment instruments generates dietary intake estimates in a study that are close to intake values of the source population. Less biased dietary data in terms of absolute estimates ease their use for recommendations and dietary guidelines.

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An unbiased estimate of the variance of dietary intake in a study population is only attainable if both the individual probability of consumption and the individual day

amounts are estimated. The latter requires an estimate of the daily consumption for 481 each individual, which can be challenging and time consuming in view of the low 482 483 proportion of the variance that a portion size contributes to the overall variance of 484 food intake between subjects [21]. Thus, we chose a compromise in that expected values of daily amounts obtained by a statistical model were used instead of 485 486 individual values. This decision also affected our ability to establish the exact 487 distribution of the daily amounts between individuals and generated slightly lower variances due to the use of expected values instead of individual values. However, 488 489 the loss of variance may have been minimal since we use a mixed linear model that 490 considered covariates (sex, age, BMI). In future studies, the intake distributions will 491 be compared to those obtained in the NVS II and the loss of variance will be further 492 investigated.

493

Furthermore, the exact reproduction of the distributions of intake values within the source population may also depend on whether the estimation of intake probability is based on a 24h-FL or a full 24h-DR. However, the observed differences between GNC and NVS II in frequencies of consumption might not originate solely from the type of assessment instrument (24h-FL was repeated up to three times, the NVS II are based on two 24h-DRs) but by differences in time trends of consumption, characteristics of the study population, and local dietary practices.

501

The novel dietary assessment strategy showed low mean bias but weak Spearman partial correlations for energy intake compared to total energy expenditure. The mean bias is lower than for example in the pooled results from five validation studies [7] where the mean relative bias was -13% for men and -18% for women. The smaller mean bias in our study could be based on the fact that in the current study 507 higher consumption probabilities were estimated and thus the individuals' energy 508 intake was estimated to be higher. This could have led to lower mean bias compared 509 to the five validation studies [7]. On the other hand, the Spearman partial correlations 510 were smaller in comparison to five validation studies [7] where the correlation was 511 0.29 for men and 0.34 for women based on three 24h-DRs. This indicates that further 512 evaluation of the proposed dietary assessment strategy is needed. But the low 513 proportion of under- and over-reporter suggests that overall the estimated individuals' 514 energy intakes are in the acceptable range and therefore appears plausible.

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Biomarker data was not available for the present study; hence, the predicted energy expenditure was used as a rough proxy to evaluate the relative validity in terms of plausibility. Further studies are required to evaluate the (relative) validity of the proposed dietary assessment strategy using Biomarkers.

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521 Even with a large sample size as being expected in the GNC, convergence problems 522 in modeling-based probability calculations can occur. This could arise when the 523 number of study participants reporting non-consumption is high on all 24h-FLs or the 524 number of subjects with at least one consumption day is low. For example, in the 525 current study, we observed that only 15 of 1,760 24h-FLs included offal consumption. 526 Thus, in the future even with the availability of the full GNC data we may only be able to calculate the individual probabilities for foods that are eaten frequently or regularly. 527 528 Such foods usually form the basis of the diet in a study population. Foods that are 529 less regularly consumed will nevertheless provide valuable information on individual 530 diet because they increase the variation between subjects but they may be less 531 relevant for estimating overall consumption or overall nutrient intake in the 532 population.

22 (27)

534 Conclusion

We presented a novel concept of dietary assessment in the GNC and showed that the application of repeated 24h-FLs, a FFQ, and data from a reference population represents a promising dietary assessment strategy in large-scale studies. However, there is a need for further investigation with regard to the (relative) validity of the usual intake estimates.

540

541 **Contribution of the authors**

HBo, UN, and JL designed this project; SK, MC, and JC analyzed the data; SK, MC, and HBo drafted the first version of the manuscript, SG, KBM, ML, LK, TP, GK, WA, NE, KJ, AK, NO, RK, WL, SaS, and HBr were responsible for implementing the procedures and the acquisition of data in each study center including accuracy and integrity of the data; TH was responsible for the acquisition and preparation of the NVS II data; UH had responsibility for programming the web-based dietary questionnaires; All authors critically reviewed and revised the manuscript.

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- 560

561 **Conflict of interest**

562 The authors declare that they have no conflict of interest.

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- **Table 1:** Number of questionnaires and characteristics of participants with and without
- 672 completed FFQ in phase II of the GNC pretest studies (2012-2013)^a

673

- 674 Table 2: Number of completed 24h food lists of participants with completed FFQ (n=695) in
- phase II of the GNC pretest studies (2012-2013)

676

Table 3: Observed relative consumption frequencies in phase II of the GNC pretest studies
(2012-2013) and in NVS II (2005-2007)

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Table 4: Distribution of estimated individual usual food intakes (gram/day), total energy intakes (kcal), and total energy expenditure (kcal) in phase II of the GNC pretest studies (2012-2013)

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Figure 1: Dietary assessment strategy of the novel blended approach applied in the GermanNational Cohort (GNC).

688

689 Figure 2: Ratio of EI to TEE by participants stratified by sex and ranked by ratio within each

690 strata. Gray lines represents mean bias and Goldberg limits of mean +/-1.5*SD.





Table 1: Number of questionnaires and characteristics of participants with and without

	with FFQ	no FFQ
Number of participants, n	695	301
Number of 24h-FL completed, n (%)	1760	365
repeat 1	695 (100.0)	301 (100.0)
repeat 2	589 (84.6)	46 (15.3)
repeat 3	476 (68.5)	18 (6.0)
Women, n (%)	377 (54.2)	161 (53.5)
Age (years), mean (SD)	51.5 (11.8)	50.8 (12.4)
Body mass index (kg/m²), mean (SD)	26.3 (4.6)	26.4 (4.3)
School level ^ь , n (%)		
Higher education entrance qualification	290 (47.7)	130 (44.2)
Secondary school qualification	310 (51.0)	160 (54.4)
None	8 (1.3)	4 (1.4)

completed FFQ in phase II of the GNC pretest studies (2012-2013)^a

^a A total of 1010 participants took part in the dietary assessment. ^b 94 values are missing.

Table 2: Number of completed 24h food lists of participants with completed FFQ (n=695) in

	Number of completed 24h-FLs					
	1	2	3			
Ν	106	113	476			
Sex, n (%)						
			213			
Men	54 (50.9)	51 (45.1)	(44.7)			
			263			
Women	52 (49.1)	62 (54.9)	(55.3)			
	50.2	49.5	52.3			
Age (years), mean (SD)	(12.3)	(11.7)	(11.6)			
Body mass index (kg/m2), mean						
(SD)	25.9 (4.0)	26.7 (5.0)	26.2 (4.7)			
School levelª. n (%)						
Higher education and university			185			
entrance qualification	51 (49.5)	54 (50.0)	(46.6)			
•	, , , , , , , , , , , , , , , , , , ,	, , , , , , , , , , , , , , , , , , ,	205			
Secondary school qualification	51 (49.5)	54 (50.0)	(51.6)			
None of the two above	1 (1.0)	0 (0)	7 (1.8)			

phase II of the GNC pretest studies (2012-2013)

^a 87 values are missing.

 Table 3: Observed relative consumption frequencies in phase II of the GNC pretest studies

 (2012-2013) and in NVS II (2005-2007)

	Man n - 219						Women n - 277					
	Percer	anet	of 24	nen, n h-Fl e	Total	Total Borcontago o		$_{\rm of 24b-El s}$ Total		Total	Total	
	with co	naye	nntior	1 - 1 - 5 1 - 1 - 5	nronortion	nronortion	with co	naye	ntion	$(\%)^{a}$	nroportion	nroportion
	with co	Jiiouii	iptioi	1 (/0)	of	of	with co	Jiisuii	iption	(/0)	of	of
	Numb	er of 2	24h-F	L = 1	24h-FL= 1	24h-DR>0	Numb	er of 2	24h-Fl	L = 1	24h-FL= 1	24h-DR>0
	(maxi	mum				(maxir	num			
	p	ercen	tage)				p	ercen	tage)			
Food group	0	1	2	3	GNC	NVS II	0	1	2	3	GNC	NVS II
	(100)	(100)	(83)	(67)			(100)	(100)	(86)	(70)		
Bread	2.8	18.2	19.5	59.4	94.2	94.3	2.7	15.1	21.2	61.0	94.0	93.9
Butter	33.0	24.5	17.0	25.5	54.0	46.8	28.4	25.2	21.8	24.7	55.8	45.1
Cabbage	57.6	31.5	8.8	2.2	22.3	12.6	54.1	35.3	8.5	2.1	22.9	12.9
Cake and cookies	32.7	28.0	21.7	17.6	49.7	39.9	21.8	35.0	27.6	15.7	53.6	44.9
Cheese	19.5	28.9	23.6	28.0	64.0	56.1	17.8	26.5	29.2	26.5	64.3	59.0
Eggs	50.9	32.7	12.9	3.5	27.6	13.7	48.5	37.4	10.1	4.0	27.2	14.3
Other fats	90.3	9.8	0.0	0.0	3.9	1.1	91.3	7.4	1.1	0.3	4.0	0.9
Vegetable fats	16.4	33.3	30.2	20.1	61.6	28.5	18.3	30.8	27.3	23.6	61.0	27.8
Fish	62.0	28.6	7.2	2.2	19.9	15.3	64.5	25.2	9.3	1.1	18.3	14.4
Fresh fruits	16.7	25.8	21.4	36.2	71.0	50.6	10.3	22.0	26.5	41.1	77.6	64.9
Other fruits	83.7	11.3	3.5	1.6	9.2	6.8	72.2	17.0	7.2	3.7	16.6	9.1
Legumes	89.0	9.8	1.3	0.0	4.9	5.6	86.5	10.3	3.2	0.0	6.5	6.0
Margarine	60.1	13.2	12.9	13.8	32.2	38.7	64.5	14.1	9.0	12.5	27.2	36.6
Meat	37.4	39.9	18.2	4.4	35.9	33.9	51.2	33.7	12.7	2.4	26.0	27.8
Processed meat	10.1	29.6	23.3	37.1	75.0	74.3	19.1	30.0	27.1	23.9	60.8	58.5
Milk and dairy products	15.7	26.4	28.6	29.3	68.6	46.2	9.3	25.7	28.1	36.9	75.2	55.2
Miscellaneous	67.0	19.5	7.6	6.0	21.0	19.6	67.1	16.2	10.6	6.1	21.8	21.0
Non-vegetarian dishes	70.8	23.3	5.0	0.9	14.5	11.3	78.3	17.5	4.0	0.3	10.3	9.3
Vegetarian dishes	88.1	10.4	0.9	0.6	5.7	1.9	84.4	11.4	2.9	1.3	8.3	2.6
Nuts	55.0	24.2	13.8	6.9	29.1	7.0	41.9	31.8	13.5	12.7	38.0	7.6
Offal	98.7	1.3	0.0	0.0	0.5	0.6	97.1	2.9	0.0	0.0	1.1	0.7
Other cereals	62.0	25.8	9.4	2.8	21.3	16.3	54.1	28.7	10.1	7.2	27.5	17.5
Pasta and rice	42.1	34.9	19.2	3.8	33.9	29.1	40.6	35.0	17.5	6.9	35.5	30.3
Potatoes	29.9	39.0	21.7	9.4	44.3	42.3	35.5	36.1	20.2	8.2	39.5	39.6
Poultry	70.8	24.8	4.4	0.0	13.5	11.4	71.1	22.8	5.8	0.3	13.8	11.0
Sauces	43.4	31.8	20.4	4.4	34.3	36.2	34.5	42.2	18.3	5.0	36.7	37.3
Soup	66.0	26.7	6.3	0.9	16.9	15.7	63.4	29.4	6.4	0.8	17.4	15.6
Sugar and confectionary	13.5	23.3	20.1	43.1	77.1	69.0	8.0	24.9	26.3	40.9	78.1	72.3
Fruiting vegetables	33.7	36.8	18.6	11.0	42.8	34.3	26.5	30.0	27.9	15.7	51.8	42.2
Leafy vegetables	58.2	29.9	7.9	4.1	23.1	27.0	51.5	33.2	11.7	3.7	26.4	31.2
Other vegetables	24.5	34.6	27.0	13.8	52.1	28.6	20.4	32.1	29.7	17.8	56.6	30.2
Root vegetables	57.9	28.3	10.7	3.1	23.7	7.4	50.9	30.8	12.2	6.1	28.7	9.7
Beer	56.3	24.8	11.3	7.6	28.1	33.1	88.1	7.7	2.9	1.3	6.9	7.1
Coffee	11.6	18.6	19.8	50.0	83.3	78.3	8.8	15.7	20.4	55.2	86.8	81.3
Juice	46.2	24.5	16.4	12.9	38.4	36.5	51.2	27.1	11.7	10.1	31.5	40.2
Other non-alcoholic	8.5	20.4	23.3	47.8	84.2	82.2	3.7	15.9	21.8	58.6	91.9	92.4
arinks		40.0	0.0	0.0		0.5	74.0	47.0		4.0	10.0	10.0
Other alcoholic drinks	81.1	16.0	2.2	0.6	8.9	9.5	/4.8	17.2	6.4	1.6	13.6	10.6
Sort arinks	54.4	27.0	10.1	8.5	29.1	22.5	54.4	27.3	12.7	5.6	27.2	13.6
Spirits	89.0	8.2	2.8	0.0	5.5	∠.b	93.1	6.1	0.8	0.0	3.0	1.2
i ea Wino	74.5	13.5	5.0	ю.9 Л	1/./	20.0	63.7	16.2	10.1	10.1	∠0.U	20.5
vvine	70.1	17.9	0.1	4.4	18.5	14.4	67.1	21.0	9.3	2.1	10.0	14.8

24h-FL 24h food list, GNC German National Cohort, NVS II German National Nutrition Survey II ^a The nine possible reporting patterns (see section statistical analysis) are summarized in the simplified categories of 0, 1, 2, or 3 times of reported food group intake.

Food group^a Men, n = 318Women, n = 377 Mean SD **P5** P50 P95 Mean **P5** P50 P95 SD Bread Butter Cabbage Cake and cookies Cheese Eggs Other fats 0.5 0.5 0.0 0.3 1.5 0.4 0.4 0.0 0.3 1.1 Vegetable fats Fish Fresh fruits Other fruits Legumes Margarine Meat Processed meat Milk and dairy products Miscellaneous Non-vegetarian dishes Vegetarian dishes Nuts Other cereals Pasta and rice Potatoes Poultry Sauces Soup Sugar and confectionary Fruiting vegetables Leafy vegetables Other vegetables Root vegetables Beer Coffee Juice Other non-alcoholic drinks Other alcoholic drinks Soft drinks Spirits Теа Wine Total energy intake 2092 2525 Total energy expenditure^b 2183 2665

Table 4: Distribution of estimated individual usual food intakes (gram/day), total energy intakes (kcal), and total energy expenditure (kcal) in phase II of the GNC pretest studies (2012-2013)

^a Usual food intake was not calculated for the food group offal.

^b Total energy expenditure = REE * PAL; estimation of resting energy expenditure (REE) according to Müller et al. (2004) and physical activity level (PAL) assumed to be equal to 1.6 for all study participants. Individual information about PAL was not available for our study.