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**Title**

Characteristics of participants who benefit most from personalised nutrition: findings from the pan-European Food4Me randomized controlled trial

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**Short running head:** Participants who benefits from personalisation

**Abbreviations:** Body mass index (BMI), Food frequency questionnaire (FFQ), Healthy eating index (HEI), Linear mixed model (LMM), Mediterranean diet (MD); Physical activity level (PAL), Personalised Nutrition (PN), Randomized controlled trial (RCT), Waist circumference (WC)

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## 1 **Abstract**

2 Little is known about who would benefit from internet-based personalised nutrition (PN)  
3 interventions. This study aimed to evaluate the characteristics of participants who achieved  
4 greatest improvements (i.e. benefit) in diet, adiposity and biomarkers following an internet-  
5 based PN intervention. Adults (n=1607) from seven European countries were recruited into a  
6 6-month, randomized controlled trial (Food4Me) and randomized to receive conventional  
7 dietary advice (control) or PN advice. Information on dietary intake, adiposity, physical  
8 activity, blood biomarkers and participant characteristics was collected at baseline and month  
9 6. Benefit from the intervention was defined as  $\geq 5\%$  change in the primary outcome (Healthy  
10 Eating Index) and secondary outcomes (waist circumference and BMI, physical activity,  
11 sedentary time and plasma concentrations of cholesterol, carotenoids and omega-3 index) at  
12 month 6. For our primary outcome, benefit from the intervention was greater in older  
13 participants and women. Benefit was greater for individuals reporting greater self-efficacy for  
14 “sticking to healthful foods” and who “felt weird if [they] didn’t eat healthily”. Participants  
15 benefited more if they reported wanting to improve their health and wellbeing. The  
16 characteristics of individuals benefiting did not differ by other demographic, health-related,  
17 anthropometric or genotypic characteristics. Findings were similar for secondary outcomes.  
18 Older individuals, women and individuals with less healthy diets at baseline benefitted more  
19 from PN advice. The odds of benefiting did not differ by weight status, genetic risk or socio-  
20 economic position. These findings have implications for the design of more effective future  
21 PN intervention studies and for tailored nutritional advice in public health and clinical  
22 settings.

23 **Key Words:** Food4Me; personalised nutrition; internet-based; intervention; European; adults

24

## 25 INTRODUCTION

26 Personalised nutrition (PN) approaches offer an alternative and potentially more effective  
27 strategy to improve dietary intake. <sup>(1; 2)</sup> PN interventions are tailored to key characteristics of  
28 the participant such as current diet, phenotype and genotype. <sup>(3)</sup> Although genotype-based  
29 personalised interventions designed to change risk behaviours (e.g. smoking and diet) have  
30 shown mixed results, <sup>(4)</sup> recent PN interventions have demonstrated encouraging  
31 improvements in dietary behaviours. <sup>(2; 5; 6; 7)</sup> Furthermore, internet-based interventions have  
32 the advantage of being scalable and more cost-effective than face-to-face interventions.  
33 Evidence from internet-based nutrition interventions suggests that participants who are most  
34 likely to benefit from a nutrition-related intervention are older, female and more highly  
35 educated. <sup>(8)</sup> These are also the characteristics of those who are interested in internet-based  
36 PN interventions. <sup>(9)</sup> These findings raise the possibility that other population groups may  
37 benefit less from internet-based PN interventions. However, this hypothesis is yet to be  
38 examined in a randomized controlled trial (RCT) and the characteristics of participants who  
39 benefit most from internet-based PN interventions are unknown. With the use of internet-  
40 based PN interventions increasing, <sup>(10; 11)</sup> understanding the characteristics of individuals who  
41 would benefit most from such interventions is an imperative for improving the design of PN  
42 interventions that are intended to improve diet and health outcomes across the population.

43 The Food4Me Study was a 6-month, internet-based, PN intervention conducted in seven  
44 European countries that showed that PN advice improved dietary intakes more than  
45 generalised dietary advice. <sup>(6; 10; 12; 13)</sup> The present paper examines the socio-demographic,  
46 anthropometric, physical activity-related, health-related, genotypic and behavioural  
47 characteristics of participants who benefited most from this PN intervention based on change  
48 in diet quality and adiposity following the intervention.

49

## 50 PARTICIPANTS AND METHODS

### 51 Study design

52 The Food4Me Study <sup>(14)</sup> was a 6-month, 4-arm, internet-based RCT conducted in seven  
53 European countries, designed to compare the effects of personalised dietary and physical  
54 activity advice with generalized advice in changing dietary and lifestyle behaviours. <sup>(7; 12; 15; 16;</sup>  
55 <sup>17)</sup> Recruitment included newspapers, radio advertisements and flyers and participants could

56 participate in the study by registering their details on the Food4Me website. <sup>(14)</sup> Participants  
57 and were asked via email to complete online questionnaires and to provide biological samples  
58 at baseline and after 3 and 6 months intervention. Participants could interact via email with the  
59 dietitians, nutritionists and researchers at each center during the 6-month intervention.  
60 Participants were randomized to one of four intervention arms and received either non-  
61 personalised, generalized dietary advice (Control; Level 0), or one of three levels of PN based  
62 on dietary, physical activity (PA), phenotypic and genotypic data (see below). Behaviour  
63 change techniques were included in the study protocol. <sup>(12; 18)</sup> Participants were asked to  
64 complete an online food frequency questionnaire (FFQ), the Baecke PA questionnaire, <sup>(19)</sup> to  
65 wear accelerometers and to provide self-measured anthropometric information, buccal swabs  
66 and dry blood spot cards.

67

### 68 **Ethics approval and participant consent**

69 Participants (n=1607) were recruited between August 2012 and August 2013. The Research  
70 Ethics Committees at each university or research centre delivering the intervention granted  
71 ethics approval for the study. The Food4Me trial was registered as a RCT (NCT01530139) at  
72 Clinicaltrials.gov. Participants signed online consent forms. <sup>(12)</sup>

73

### 74 **Eligibility criteria**

75 Participants aged  $\geq 18$  years were included in the study. The following exclusion criteria were  
76 applied: (i) pregnant or lactating; (ii) no or limited access to the Internet; (iii) following a  
77 prescribed diet for any reason, including weight loss, in the last 3 months; (iv) diabetes,  
78 coeliac disease, Crohn's disease, or any metabolic disease or condition altering nutritional  
79 requirements.

80

### 81 **Randomization and masking**

82 An urn randomization scheme was used to allocate individuals to each treatment arm.  
83 Participants randomized to Level 1 (L1) received personalized dietary advice based on  
84 current diet and physical activity (PA) alone, Level 2 (L2) received personalized dietary  
85 advice based on dietary, PA and phenotypic data and Level 3 (L3) received personalized  
86 dietary advice based on dietary, PA, phenotypic and genotypic data. Personalized dietary  
87 feedback was based on how intakes of specific nutrients compared with recommended

88 intakes, which was then translated into advice on changing intakes of food groups (fruits and  
89 vegetables, whole grain products, fish, dairy products and meat). Personalized phenotypic  
90 feedback utilized anthropometric measurements and nutrient- and metabolic-related  
91 biomarkers to derive personalized feedback and specific variants in five nutrient-responsive  
92 genes were used to provide personalized genotypic feedback. Personalized advice on PA was  
93 based on responses to the Baecke Questionnaire and accelerometer data.

94 Participants randomized to the control group (L0) received dietary advice based on  
95 population-level healthy eating guidelines. This non-personalized dietary advice was derived  
96 from national dietary recommendations in each of the seven European countries and included  
97 generalized advice on the food groups listed above. In addition, these recommendations  
98 included a generic PA recommendation. Further details of the Food4Me PoP study are  
99 provided elsewhere <sup>(12)</sup>.

100

### 101 **Personalised feedback report**

102 Participants randomized to L1, L2 and L3 received personalised feedback reports via email at  
103 baseline and at months 3 and 6 of the intervention. For those randomized to L1, L2 and L3,  
104 algorithms were used to provide participants with three specific top priority food-based  
105 dietary goals according to the individual's intakes of foods and nutrients. <sup>(20)</sup> For participants  
106 randomized to L2 and L3, the dietary advice was also based on phenotypic data (L2) and  
107 phenotypic plus genotypic data (L3). <sup>(12)</sup>

108

### 109 **Dietary and anthropometric measures**

110 Participants completed an online FFQ to estimate usual dietary intake at baseline and at  
111 months 3 and 6 of the intervention. This FFQ was developed and validated for the Food4Me  
112 Study <sup>(21; 22)</sup> and included 157 food items consumed frequently in each of the seven  
113 recruitment countries. Intakes of foods and nutrients were computed in real time using a food  
114 composition database. <sup>(23)</sup>

115 The Healthy Eating Index (HEI) 2010 was used to assess diet quality according to the 2010  
116 Dietary Guidelines for Americans. <sup>(24)</sup> The HEI included 12 food groups, 9 of which assessed  
117 adequacy of the diet: 1) total fruit; 2) whole fruit; 3) total vegetables; 4) greens and beans; 5)  
118 whole grains; 6) dairy; 7) total protein foods; 8) seafood and plant proteins; and 9) fatty acids.  
119 The remaining 3 groups, refined grains, sodium, and "empty calories" (i.e. energy from solid

120 fats, alcohol, and added sugars), included dietary components that should be consumed in  
121 moderation. Less beneficial food groups were scored such that lower intakes receive higher  
122 scores. For all components, higher scores reflected better diet quality. The scores of the 12  
123 components were summed to yield a total score with a maximum value of 100. <sup>(24)</sup> For use in  
124 sensitivity analyses, adherence to the Mediterranean diet (MD) was estimated based on a 14-  
125 point criteria. Participants scored 1 point for each of the 14 criteria they met and 0 for each  
126 they did not meet; points were summed to create an overall MD score, ranging from 0-14.  
127 More details are provided elsewhere. <sup>(25; 26)</sup>

128 Body weight (kg), height (m) and waist circumference (WC; cm) were self-measured and  
129 self-reported. Body mass index (BMI; kg/m<sup>2</sup>) was estimated from body weight and height.  
130 Self-reported measurements were validated in a sub-sample of the participants (n=140) and  
131 showed a high degree of reliability. <sup>(27)</sup>

132

### 133 **Study measures**

134 Participants self-reported smoking habits and occupations. Country of residence was treated  
135 as dummy variables, such that the odds of benefiting for participants from one country were  
136 compared to all other countries. PA level (PAL), the percentage of individuals meeting PA  
137 recommendations (>150 min moderate PA or >75 min vigorous PA or an equivalent  
138 combination of moderate and vigorous PA per week <sup>(28)</sup>) and sedentary time were estimated  
139 from triaxial accelerometers (TracmorD, Philips Consumer Lifestyle, The Netherlands) and  
140 the Baecke PA questionnaire. An online screening questionnaire collected information on  
141 meal habits, healthy eating perceptions, self-efficacy for sticking to healthy foods and  
142 motivation for participation in the study (Supplemental Table 1).

143 Participants collected buccal cell samples at baseline using Isohelix SK-1 DNA buccal swabs  
144 and Isohelix dried-capsules. LGC Genomics (Hertfordshire, United Kingdom) extracted  
145 DNA and genotyped specific loci using TaqMan genotyping assays to provide bi-allelic  
146 scoring of single nucleotide polymorphisms: *FTO* (rs9939609), *MTHFR* (rs1801133),  
147 *TCF7L2* (rs7903146), *APOE(e4)* (rs429358 and rs7412) and *FADS1* (rs174546). Dried blood  
148 spots were collected for measurements of total cholesterol, carotenoids, n-3 fatty acid index,  
149 32 individual fatty acids and vitamin D (25-OH D2 and 25-OH D3). <sup>(29; 30; 31)</sup>

150

### 151 **Statistical analysis**

152 All statistical analyses were performed using Stata (version 15; StataCorp, College Station,  
153 TX, USA). Data were analyzed based on intention-to-treat (ITT) of all individuals  
154 randomized into the intervention. Multiple imputation by chained equations and fully  
155 conditional specification methods, including augmentation, were used to address missing data  
156 for all outcomes. A total of 20 imputed datasets were used based on recent literature and the  
157 percent of missing data. Given that adjustment for multiple comparisons may increase the  
158 risk of type 2 error,<sup>(32)</sup> no adjustment for multiple comparisons was included.

159 The sample size was estimated a priori using Minitab® (version 16.1.0) based on data for n-3  
160 fatty acids and glucose concentrations in European adults. To address the primary aim of the  
161 Food4Me intervention, a sample size of n=326 was planned for each of the four intervention  
162 arms. This would enable detection of 0.22 SD differences in the main outcomes with 80 %  
163 power and alpha=0.05. Assuming that the population standard deviation for n-3 fatty acid  
164 index was 1.5 units and for glucose was 1.05 mmol l<sup>-1</sup>, a total sample of n=1,280 was  
165 estimated as sufficient to detect a difference of 0.33 units for n-3 PUFA and 0.23 mmol/L  
166 glucose post-intervention. Allowing for a potential 20% drop out, recruitment was targeted at  
167 1,540 participants (220 participants per centre).<sup>(7)</sup>

168 For our primary objective, participants randomized to L1, L2 or L3 of the intervention were  
169 identified as benefiting from the intervention if their HEI at month 6 was  $\geq 5\%$  better than at  
170 baseline. For our secondary outcomes, details for each definition of benefit are summarised in  
171 Supplemental Table 2. Briefly, benefit was defined as: i)  $\geq 5\%$  reduction in body weight  
172 and/or WC, ii)  $\geq 5\%$  increase in omega-3 index, iii)  $\geq 5\%$  increase in carotenoids, iv)  $\geq 5\%$   
173 reduction in cholesterol, v)  $\geq 5\%$  reduction in sedentary time and vi)  $\geq 5\%$  increase in PA at  
174 month 6. Cut points of 5% were based on recent literature, where a change of  $\geq 5\%$  in body  
175 weight was identified as clinically significant.<sup>(16; 33)</sup> Logistic regression analyses, using  
176 multiple imputation estimation commands, were employed to examine associations between  
177 benefiting from the intervention (independent variable) and participant characteristics  
178 (dependent variables). Logistic regression analyses were also used to examine associations  
179 between benefiting from the intervention (independent variable) and participant  
180 characteristics (dependent variable) among participants randomized to L0 of the intervention  
181 only. An interaction effect between the characteristic and study arm (Control vs PN) was  
182 included in the model to determine whether characteristics of benefit differed between the  
183 Control and intervention groups. Analyses were adjusted for baseline age (continuous), sex,  
184 country (categorical), intervention arm (categorical) and baseline values of the outcome (i.e.

185 HEI, WC and body weight). PA outcomes were further adjusted for accelerometer wear time  
186 at baseline (continuous) and season (categorical). Correlations between behavioural  
187 characteristics were explored using Pearson's correlation coefficients.

188 As a sensitivity analysis, any impact of regression towards the mean in our estimate of  
189 change in HEI was evaluated by including a correction factor in our models according to the  
190 following equation  $x_{adj} = \bar{x} + p(x - \bar{x})$ .<sup>(34)</sup> Benefit from the intervention (i.e. change in HEI  
191 and body weight/WC at month 6) was also treated as a continuous variable. To determine  
192 whether findings were robust for different measures of diet quality, benefit was defined  
193 according to change in MD score (continuous). To account for multiple comparisons, results  
194 were deemed significant at a conservative  $P < 0.02$ .

195

## 196 **RESULTS**

197 A total of 1607 participants were randomized into the intervention and 1270 of these  
198 completed the intervention (Figure 1). For the purposes of this analysis, only individuals who  
199 were randomized into L1 (n=414), L2 (n=404) and L3 (n=402) were included in the main  
200 analyses (n=1220). Data were imputed for individuals who dropped out between baseline and  
201 month 6 (Supplemental Table 3 and Supplemental Table 4).

202 The distributions of change in HEI, body weight and WC are shown in Figure 2, with the  
203 proportion of participants benefiting from the intervention by country shown in Table 1. The  
204 country with the highest proportion of participants benefiting based on the primary outcome  
205 (HEI) was Spain, whereas Greece and the Netherlands had the greatest proportion of  
206 participants with improvements in secondary outcomes (body weight and WC; Table 1).

207

208 (Table 1 here)

209

210 Baseline socio-demographic, anthropometric, health behaviour and biological characteristics  
211 of participants according to whether they benefited more from the PN intervention are shown  
212 in Table 2. The odds of benefiting were higher in women than in men. Older participants and  
213 participants with lower baseline HEI scores had higher odds of benefiting. The characteristics

214 of individuals benefiting did not differ by other health-related, anthropometric or genotypic  
215 characteristics (Table 2).

216

217 (Table 2 here)

218

219 Behavioural characteristics of participants benefiting from the PN intervention are shown in  
220 Table 3. The odds of a participant benefiting more from the intervention at month 6 were  
221 higher among those who reported greater self-efficacy for “sticking to healthful foods” and  
222 who “felt weird if [they] didn’t eat healthily” (HEI only), which were correlated ( $r$  0.25,  
223  $P < 0.0001$ ). Participants had a higher odds of benefiting if they were interested in improving  
224 their health and improving their wellbeing (HEI only), which were highly correlated ( $r$  0.40,  
225  $P < 0.0001$ ). The characteristics of individuals who benefited more from the intervention did  
226 not differ by other healthy eating habits or perceptions (Table 3). Baseline socio-  
227 demographic, anthropometric, health-related and behavioural characteristics of participants  
228 randomized to L1, L2 and L3 of the intervention associated with benefiting from the PN  
229 intervention at month 6 according to each definition of benefit (HEI, weight loss/WC  
230 reduction, physical activity, sedentary time, cholesterol, carotenoids, omega-3 index) are  
231 shown Supplemental Table 5 and Table 6. Few participant characteristics were comparable  
232 across definitions.

233 When stratified by PN intervention arm, odds of benefitting were higher with higher age in  
234 L2 (OR 1.05, CI: 1.01-1.08) and L3 (1.02, 1.00-1.06), with being female in L2 (3.75, 1.57-  
235 8.96), with being a participant in the Netherland in L3 (3.19, 1.41-7.22). Odds were higher in  
236 participants who reported with being able to stick to healthy foods even if they had to re-think  
237 their way of nutrition (4.96, 1.55-15.81) in L1 and even if they had to try several times until it  
238 worked in L1 (22.69, 1.64-313.2) and L2 (4.96, 1.55-15.81). Odds of benefiting were also  
239 higher in participants who wanted to know what foods are best for them in L2 (5.46, 1.88-  
240 15.90) and in those who reported frequently eating healthily (3.04, 1.30-7.11) in L3. Odds of  
241 benefitting were lower in participants in Germany (0.32, 0.12-0.88) in L3. No other  
242 significant differences by PN arm were observed.

243 When the analyses were restricted to participants randomized to generalized (non-  
244 personalised) dietary advice (L0), the odds of benefiting from the intervention were lower in  
245 *APOE* (rs429358) risk carriers (OR 0.53 [0.32, 0.91],  $P = 0.020$ ) but higher among individuals

246 reporting being in control of their own health (OR 1.71 [1.01, 2.91], P=0.047) and wanting to  
247 gain weight (OR 0.17 [0.03, 0.99], P=0.049). All other characteristics were consistent with  
248 those of participants randomized to PN. There was no interaction between participant  
249 characteristic and study arm (Control vs PN) on extent of benefit (change in HEI), with the  
250 exception of the *MTHFR* risk allele and participants who wanted to improve their health. HEI  
251 improved in participants randomised to PN advice who were carriers of the MTHFR risk  
252 allele (coeff 0.08, SE 0.39, P=0.043) and who wanted to improve their health (coeff 0.08, SE  
253 0.38, P=0.038) compared to those in the control arm who were not carriers of the MTHFR  
254 risk allele and did not want to improve their health, respectively.

255

256 (Table 3 here)

257

### 258 **Sensitivity analyses**

259 The pattern of results was similar when change in HEI and body weight/WC at month 6 was  
260 treated as a continuous outcome (data not shown). The characteristics of participants  
261 benefiting most from the PN intervention were similar when benefit was defined using MD  
262 (data not shown) and when results for benefit (defined by HEI) were adjusted for regression  
263 towards the mean (data not shown). Comparison of benefit from the PN intervention as  
264 defined based on HEI, adiposity, omega-3 index, carotenoids, cholesterol, sedentary time and  
265 physical activity are summarised in Table 4 and Table 5.

266

267 (Table 4 here)

268 (Table 5 here)

269

## 270 **DISCUSSION**

271 This study aimed to characterize the participants benefiting most from a 6-month, internet-  
272 based PN intervention. Our main findings are that older participants, women and those with  
273 less healthy diets at baseline benefited most from PN advice. The odds of benefiting did not  
274 differ by weight status, genetic risk or socio-economic position. These findings confirm the  
275 need to enhance the effectiveness of PN interventions in certain groups e.g. young men and  
276 those with unhealthier eating perceptions/motivations. These individuals may require

277 additional tailoring of PN advice using individual characteristics that were not investigated in  
278 this study. Nonetheless, since many participant characteristics did not affect the extent of  
279 benefit, our findings suggest that most population groups would benefit from PN advice.

280 To the best of our knowledge, no previous studies have investigated the characteristics of  
281 individuals benefiting most from an internet-based PN intervention. Studies have shown that  
282 women, older individuals, and generally healthier individuals are more likely to participate in  
283 nutrition interventions,<sup>(35)</sup> including internet-based interventions.<sup>(36)</sup> This may be due to a  
284 greater desire to lose weight among women and older adults being more time-rich than  
285 younger adults. In addition, individuals with greater motivation to be healthy and to  
286 participate in nutrition interventions may be more knowledgeable about the benefits of  
287 healthy eating.<sup>(37)</sup> Similarly, of the 5662 individuals who expressed an interest in  
288 participating in the Food4Me Study, 65% were women.<sup>(38)</sup> Nonetheless, these individuals  
289 were broadly representative of the wider European population in terms of need to improve  
290 dietary and PA behaviours,<sup>(38)</sup> and were not skewed towards individuals who were already  
291 healthy (i.e. the worried well). In addition, in the Food4Me Study, individuals who met fewer  
292 recommendations at baseline<sup>(39)</sup> and who had lower self-perception of healthy eating habits  
293<sup>(40)</sup> showed greatest improvement in diet following the intervention. In the present analysis,  
294 despite the odds of benefiting being higher in participants with better self-reported healthy  
295 eating perceptions and motivations, the odds of benefitting from PN advice were lower in  
296 those with higher HEI at baseline. The proportion of participants benefiting most appeared to  
297 differ by country, which suggests that there may be opportunities to tailor PN advice to  
298 different cultural norms.

299 To a large extent, the characteristics of participants benefiting from the Control intervention  
300 were similar to those of participants benefiting most from the PN intervention. If this is a true  
301 effect, it implies that participants who benefit from PN advice are comparable to those who  
302 received general dietary advice. Moreover, it suggests that benefit extends beyond those  
303 receiving the intervention. This confirms our observed effect of the intervention on  
304 improvements in diet, where participants in the control group showed modest improvements  
305 in their diet as a result of participating in the intervention.<sup>(7)</sup> Where there were differences  
306 between treatment arms, reduced power in the Control arm could have influenced these  
307 findings.

308 The effects of the intervention on adiposity markers (benefit from the intervention was  
309 defined as  $\geq 5\%$  weight loss or WC reduction), showed a somewhat different range of

310 participant characteristics compared with those benefiting more in respect of HEI. This may  
311 be that those who needed to lose weight were different from the general population.  
312 Moreover, the study has shown large individual variation in changes in health behaviours  
313 following a PN intervention. Such inter-individual variation is common in (dietary)  
314 intervention studies. For example, in the DIETFITS weight loss intervention study, individual  
315 body mass changes ranged over approximately 40 kg within each treatment group with some  
316 participants losing 30 kg over 12 months and others gaining 10 kg body weight.<sup>(41)</sup> Such  
317 inter-individual variation is one of the major challenges that personalised nutrition  
318 approaches aim to address. With better understanding of the participant characteristics that  
319 lead to no (or adverse) responses to interventions, there is scope to refine the personalization  
320 process and to develop intervention features that improve the target behaviours.

321 This study had a number of strengths. The Food4Me study is the largest RCT on the  
322 effectiveness of PN advice in European adults to date, it used a rigorous design and it  
323 investigated change in health-related outcomes sustained to 6 months. We applied multiple  
324 imputation to our analyses, thus limiting bias associated with missing data and the robustness  
325 of our findings was confirmed through extensive sensitivity analyses. The pattern of results  
326 remained consistent regardless of whether benefit was defined as binary or continuous change  
327 in HEI or any of the secondary definitions and following adjustment for regression towards  
328 the mean in HEI.

329 A limitation of our study is that data were self-measured and self-reported via the internet.  
330 Nonetheless, the accuracy of internet-based, self-reported anthropometric data have been  
331 confirmed in the Food4Me Study.<sup>(27)</sup> Dietary intakes may be subject to misreporting error,  
332 which was minimized by validation of the FFQ against a 4-day weighed food record.<sup>(22)</sup>  
333 Since 97% of our study participants were Caucasians, research in wider ethnicity groups is  
334 required to generalize our findings to other populations. Our sample is a self-selected group  
335 of individuals who may be more health-conscious than the general population. However,  
336 participants interested in joining the study were similar to the wider population of European  
337 adults, who would benefit from improved diet and PA.<sup>(42)</sup> In addition, although the cut-off  
338 points for defining benefit were based on previous research,<sup>(33)</sup> the clinical relevance of a 5%  
339 in outcome measures warrants further investigation. The present analyses requires replication  
340 in a larger study, which would provide more statistical power, particularly for testing  
341 subgroup differences in benefit. Moreover, while analyses were adjusted for appropriate  
342 confounders, we cannot discount the possibility of residual confounding. Given that analyses

343 were not adjusted for multiple testing, the risk of type 1 error is higher and so results should  
344 be interpreted with this in mind. Finally, although we included outcomes for 7 different  
345 health-related biomarkers, future PN interventions may wish to consider the impact of PN on  
346 the gut microbiota and on other markers of health. <sup>(43)</sup>

347 These findings have implications for the design of more effective future PN intervention  
348 studies and tailored nutritional advice in the public health or clinical settings. Future studies  
349 should consider ways of tailoring PN advice to improve efficacy in certain population groups  
350 such as young men. Nonetheless, with many characteristics, such as weight status and  
351 occupation, being unrelated to extent of benefit in the Food4Me Study, our findings suggest  
352 that most population groups will benefit from PN advice. Further improvements in the  
353 design, delivery and efficacy of PN interventions will support integration of PN strategies  
354 into public health policies.

355 In conclusion, older individuals, women and those with less healthy diets at baseline were  
356 likely to benefit most (i.e. improve their diet and achieve weight loss, where appropriate)  
357 from PN advice. Our findings confirm the need to enhance the effectiveness of PN  
358 interventions in certain groups e.g. young men. The odds of benefiting did not differ by  
359 weight status, genotype or socio-economic position. Since few characteristics affected the  
360 degree of benefit from the PN intervention, our findings suggest that PN approaches may be  
361 widely applicable.

362

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366

### 367 **Conflict of interest**

368 TEG is the CEO of Vitas Ltd. TEG and CAD have shares in Vitas Ltd, and CAD is a board  
369 member and consultant in Vitas Ltd; no other conflict of interests. KML is a consultant for  
370 HeadUpLabs. WHMS has received research support from several food companies such as  
371 Nestle, DSM, Unilever, Nutrition et Sante and Danone as well as pharmaceutical companies  
372 such as GSK, Novartis and Novo Nordisk. He is medical consultant for N&S and is an unpaid  
373 scientific adviser for the International Life Science Institute, ILSI Europe. MG reports that he  
374 is a non-remunerated member of the Google Food Innovation Lab Community of Practice on

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387 Nutrition (SACN) and a member of SACNs Carbohydrate Working Group and Saturated Fats  
388 Working Group during and after the study.

389

#### 390 **Author contributions**

391 CCM, KML and JCM had full access to all of the data in the study and take responsibility for  
392 the integrity of the data and the accuracy of the data analysis. The corresponding author had  
393 full access to all the data in the study and had final responsibility for the decision to submit  
394 for publication. Study concept and design: KML, CCM and JCM. Acquisition, analysis or  
395 interpretation of data: YM, IT, MJ, TEG, CAD, ERG, LB, JAL, JAM, WHS, HD, MG and  
396 JCM. Drafting of the manuscript: CCM, KML and JCM. Statistical analysis: KML, CCM,  
397 and JCM. Critical revision and final approval of the manuscript: All authors contributed to a  
398 critical review of the manuscript during the writing process. All authors approved the final  
399 version to be published.

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**Table 1.** Proportion of participants (%) randomized to a PN intervention arm (L1, L2 or L3) benefiting from the intervention by country<sup>1</sup>

	<b>Total (n=493)</b>	<b>Germany (n=63)</b>	<b>Greece (n=47)</b>	<b>Ireland (n=64)</b>	<b>NL (n=121)</b>	<b>Poland (n=62)</b>	<b>Spain (n=69)</b>	<b>UK (n=67)</b>
HEI	56.8	57.1	48.9	57.8	61.2	58.1	60.9	47.8
BW and/or WC	27.0	20.6	36.1	21.9	31.4	19.4	30.4	26.9
Physical activity	21.5	19.1	19.2	20.3	22.3	17.7	30.4	19.4
Sedentary time	38.5	42.9	34.0	32.8	40.5	45.2	43.5	28.4
Cholesterol	46.7	50.8	29.8	46.9	52.1	35.5	34.8	67.2
Carotenoids	42.2	30.2	34.0	39.1	52.9	53.2	31.9	43.3
Omega-3 index	51.9	42.9	53.2	59.4	63.6	41.9	47.8	44.8

NL, The Netherlands; BW, Body weight (kg); WC, waist circumference (cm). 1, Benefit was defined as a  $\geq 5\%$  improvement in the outcomes from baseline to month 6.

**Table 2.** Baseline socio-demographic, anthropometric, health-related and genotypic characteristics of participants randomized to L1, L2 and L3 of the intervention, and multivariable adjusted odds ratio (95% CI) of benefiting from the PN intervention at month 6 as defined by extent of improvement in HEI (n=493)<sup>1</sup>

	Total	No Benefit	Benefit	Odds of benefiting <sup>2</sup> OR, 95% CI	P value
HEI score	50.0 (9.54)	54.6 (8.07)	46.5 (9.11)	0.89 (0.86, 0.91)	<0.001
<b>Demographics</b>					
Age, years	43.9 (13.0)	43.0 (13.3)	44.6 (12.7)	1.03 (1.01, 1.04)	<0.002
Female, %	55.6	54.5	56.4	1.64 (1.07, 2.50)	0.023
Occupation, %					
Professional and managerial	43.6	42.3	42.9	1.09 (0.73, 1.64)	0.67
Intermediate occupations	25.2	23.5	26.4	1.06 (0.66, 1.69)	0.82
Routine and manual	8.32	7.98	8.57	1.04 (0.50, 2.16)	0.91
Country, %					
Germany	12.8	12.7	12.9	0.67 (0.37, 1.21)	0.19
Greece	9.53	11.3	8.21	0.72 (0.36, 1.42)	0.33
Ireland	13.0	12.7	13.2	1.08 (0.59, 1.97)	0.80
Netherlands	24.5	22.1	<b>26.4</b>	1.62 (1.01, 2.60)	0.044
Poland	12.6	12.2	12.9	0.59 (0.30, 1.15)	0.12
Spain	14.0	12.7	15.0	1.39 (0.78, 2.48)	0.26
UK	13.6	16.4	11.4	0.85 (0.48, 1.53)	0.60
<b>Anthropometrics</b>					
Body weight, kg	75.0 (14.8)	74.6 (14.3)	75.3 (15.1)	1.00 (0.98, 1.01)	0.81
BMI, kg/m <sup>2</sup>	25.5 (4.45)	25.1 (3.89)	25.8 (4.83)	1.02 (0.97, 1.07)	0.16
Waist circumference, cm	86.4 (12.8)	85.6 (12.4)	87.0 (13.0)	1.00 (0.98, 1.02)	0.66
<b>Health behaviours</b>					
PAL	1.75 (0.18)	1.75 (0.17)	1.76 (0.18)	1.60 (0.48, 5.35)	0.45
MVPA	45.8 (30.5)	47.1 (31.4)	44.8 (29.8)	1.00 (0.99, 1.01)	0.99
Sedentary behaviour, min/d	758 (70.6)	756.6 (71.7)	758.8 (69.9)	1.00 (0.99, 1.01)	0.95
Current smoker, %	8.11	7.04	8.93	1.03 (0.46, 2.31)	0.84
Medication use, %	33.5	31.9	34.6	0.96 (0.62, 1.47)	0.84
<b>Genotype<sup>3</sup></b>					
<i>FTO</i> (rs9939609)	70.4	72.3	68.9	0.91 (0.59, 1.41)	0.67
<i>FADS1</i> (rs174546)	42.8	42.3	43.2	0.91 (0.60, 1.36)	0.63
<i>TCF7L2</i> (rs7903146)	48.9	49.8	48.2	0.96 (0.64, 1.44)	0.85
<i>APOE</i> (rs429358)	27.4	30.1	25.4	0.95 (0.61, 1.48)	0.81
<i>APOE</i> (rs7412)	12.6	13.6	11.8	0.72 (0.39, 1.32)	0.29
<i>MTHFR</i> (rs1801133)	55.6	57.3	54.3	1.01 (0.67, 1.52)	0.96

Values represent means (SD) or percentages, L=Level; L1, Participants received personalised nutrition advice based on their current diet; L2, Participants received personalised nutrition advice based on their current diet and phenotype; L3, Participants received personalised nutrition advice based on their current diet, phenotype and genotype; MVPA, Moderate to vigorous physical activity

1, Multiple logistic regression was used to test for differences in characteristics between individuals who benefited most and the remaining participants, respectively. Analyses were adjusted for age, sex, country, intervention arm (except when used as the dependent variable) and baseline values of the outcome (i.e. HEI). PAL, MVPA and sedentary behaviour were additionally adjusted for time wearing the accelerometer and season.

2, More benefit:  $\geq 5\%$  increase in HEI from baseline to month 6; Less benefit:  $< 5\%$  increase in HEI from baseline to month 6.

3, probability carrier of minor allele

**Table 3.** Baseline behavioural characteristics of participants randomized to L1, L2 and L3 of the intervention and multivariable adjusted odds ratio (95% CI) of benefiting from the PN intervention at month 6 as defined by improvement in HEI (n=493)<sup>1</sup>

	Total	No Benefit	Benefit	Odds ratio of benefiting <sup>2</sup> (OR, 95% CI)	P value
<b>Meal habits</b>					
Often eat main meal away from home	34.3	32.9	35.4	1.08 (0.69, 1.66)	0.55
Often skip meals and replace them with snacks	6.09	4.69	7.14	0.78 (0.33, 1.93)	0.62
Often prepare a meal "from scratch"	30.8	28.2	32.9	0.93 (0.59, 1.45)	0.74
Often eat hot or cooked meals	28.4	29.6	27.5	1.12 (0.71, 1.75)	0.63
Spend a lot of time preparing a main meal	43.8	45.5	42.5	1.08 (0.72, 1.62)	0.72
<b>Heathy eating perceptions</b>					
Believe I am in control of my health	71.6	70.9	72.1	1.16 (0.74, 1.82)	0.51
Can stay healthy by taking care of myself	86.6	85.5	87.5	1.17 (0.65, 2.10)	0.61
Efforts to improve health are a waste of time	2.43	2.35	2.50	0.71 (0.18, 2.83)	0.63
Bored by attention paid to health and disease	1.42	0.94	1.79	1.29 (0.19, 8.87)	0.79
There's no use of being concerned about health	5.27	3.29	6.79	1.45 (0.53, 3.83)	0.46
Frequently eating healthily	76.3	77.9	75.0	1.74 (1.05, 2.89)	0.033
Eat healthily without thinking about it	44.6	47.0	42.9	1.01 (0.67, 1.51)	0.97
Feel weird if don't eat healthily	47.7	47.4	47.9	1.67 (1.10, 2.55)	0.017
<b>Self-efficacy for sticking to healthful foods</b>					
Even if I need time to develop the routines	93.1	92.0	93.9	2.35 (1.33, 4.14)	0.006
Even if I have to try several times until it works	96.4	94.4	97.9	2.45 (1.25, 4.78)	0.009
Even if I have to rethink my way of nutrition	85.8	83.6	87.5	1.74 (1.14, 2.46)	0.010
Even if I do not receive support from others	87.2	87.8	86.8	1.22 (0.80, 1.87)	0.36
Even if I have to make a detailed plan	88.4	86.9	89.6	1.30 (0.83, 2.04)	0.27
<b>Motivation for participating in the study</b>					
Interested in personalised nutrition	75.7	78.4	73.6	1.19 (0.74, 1.92)	0.47
Want to know what foods are best for him/her	79.3	76.5	81.4	1.83 (1.11, 3.02)	0.018
Want to lose weight	43.4	39.0	46.8	1.38 (0.91, 2.10)	0.13
Want to improve my family's health	27.6	25.8	28.9	0.98 (0.63, 1.54)	0.93
Want to improve my health	55.8	50.7	59.6	1.52 (1.06, 2.28)	0.047
Want to improve my wellbeing	54.8	52.6	56.4	1.31 (1.87, 1.97)	0.19
Want to improve my sports performance	35.7	36.2	35.4	1.40 (0.90, 2.16)	0.14
Want to prevent a future illness	60.0	56.8	62.5	1.37 (0.91, 2.07)	0.13
Have a family history of diet-related illness	8.92	7.98	9.64	1.35 (0.67, 2.75)	0.41
Think it is important to help academic studies	69.6	68.1	70.7	1.36 (0.88, 2.12)	0.17
Curious to find out what happens in PN studies	47.1	45.1	48.6	1.24 (0.83, 1.86)	0.30

Values represent percentages. L=Level; L1, Participants received personalised nutrition advice based on their current diet; L2, Participants received personalised nutrition advice based on their current diet and phenotype; L3, Participants received personalised nutrition advice based on their current diet, phenotype and genotype;

1, Multiple logistic regression was used to test for differences in characteristics between individuals who benefited most and the remaining participants, respectively. Analyses were adjusted for age, sex, country, intervention arm (except when used as the dependent variable) and baseline values of the outcome (i.e. HEI). PAL, MVPA and sedentary behaviour were additionally adjusted for time wearing the accelerometer and season. For the purposes of this table, phrasing of characteristics has been paraphrased from the original questionnaire (see Supplemental Table 1)

2, Benefit:  $\geq 5\%$  increase in HEI from baseline to month 6; No benefit:  $< 5\%$  increase in HEI from baseline to month 6.

Figure 1. Consort diagram of participants included in the Food4Me study

Figure 2. Distribution of change among Food4Me participants in a) Healthy Eating Index (HEI); b) waist circumference (WC); and c) body weight (BW). Participants achieving a greater than 5% improvement in HEI and BW/WC at month 6 are in light grey.

Supplemental Table 1. Screening questionnaire on dietary habits and reasons for interest in the study

Supplemental Table 2. Definitions for benefit from the intervention for secondary outcomes

Supplemental Table 3. Summary of missing data for variables at baseline

Supplemental Table 4. Baseline socio-demographic, anthropometric, health behaviour-related and genotypic characteristics of all participants randomized to L1, L2 and L3 of the intervention in imputed dataset and complete case analysis

Supplemental Table 5. Baseline socio-demographic, anthropometric, health-related and genotypic characteristics of participants randomized to L1, L2 and L3 of the intervention associated with benefiting from the PN intervention at month 6 according to each definition of benefit 1 ✓=significant benefit, X=significant non-benefit

Supplemental Table 6. Baseline behavioural characteristics of participants randomized to L1, L2 and L3 of the intervention benefiting from the PN intervention at month 6 according to each definition of benefit 1 ✓=significant benefit, X=significant non-benefit

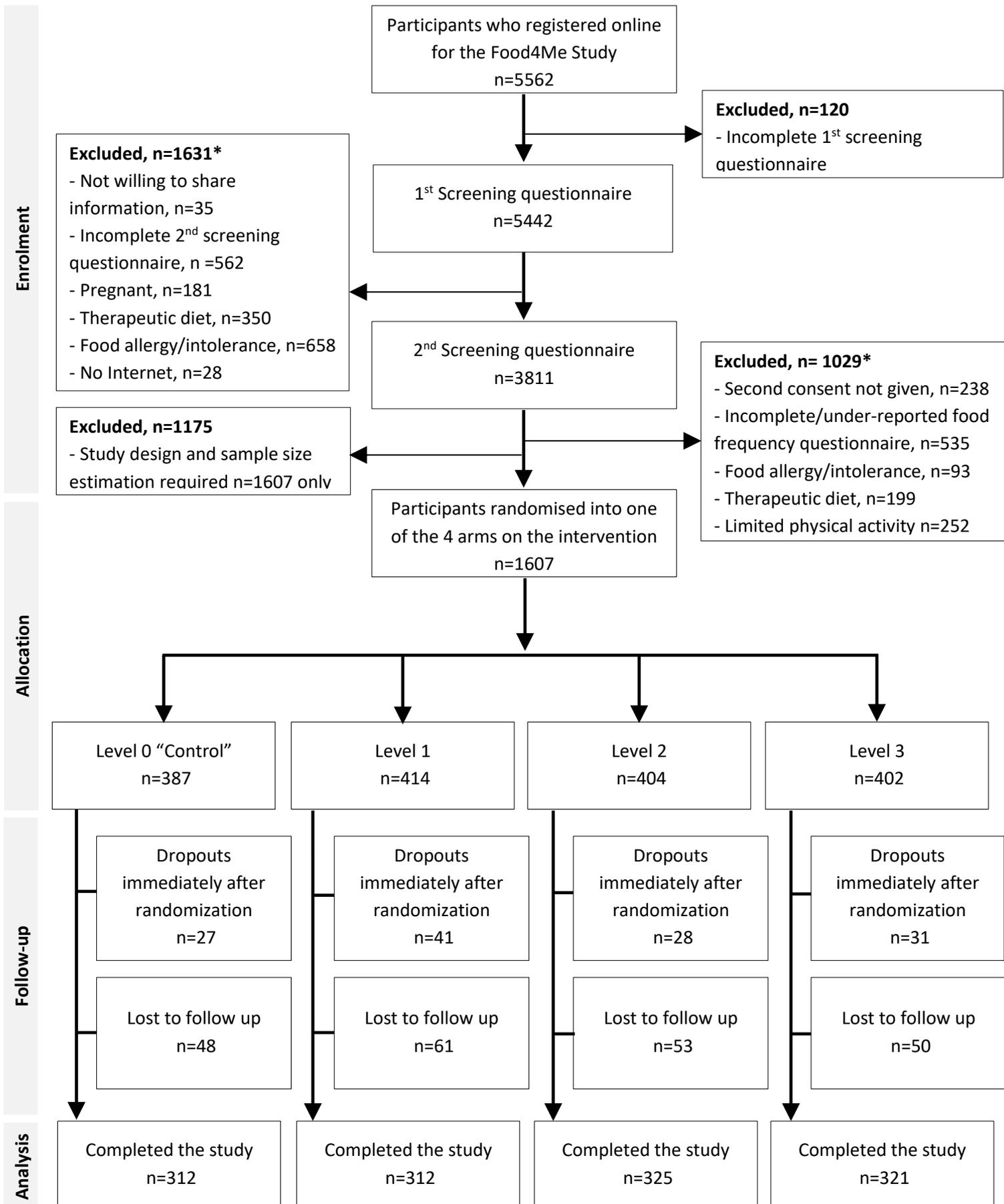


Figure 1

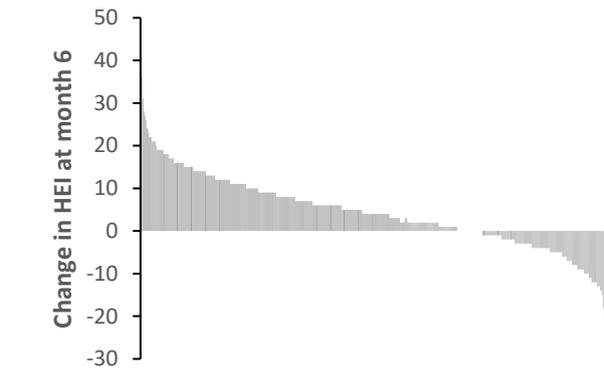
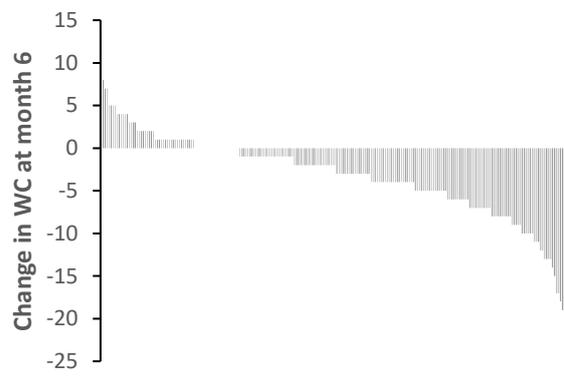
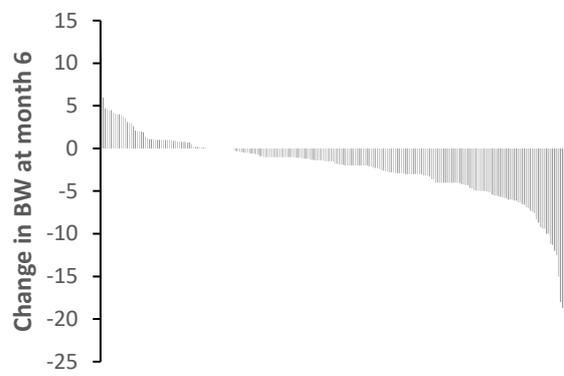
**A****B****C**

Figure 2

**Supplemental Table 1.** Screening questionnaire on dietary habits and reasons for interest in the study

<b>Question</b>	<b>Response options</b>	<b>Aggregated response</b>
How often do you eat your main meal away from home?	Never or up to once/ month	Rarely Often
How many hot or cooked meals do you normally eat per day?	Two to three times/ month Once per week Twice or more/ week	
How often do you prepare a meal "from scratch"?	Every day 4-6 times per week 1-3 times per week	Often Rarely
Do you skip meals and replace them with snacks?	(Almost) never	Often Rarely
How much time on average do you spend preparing a main meal?	Less than 10 min 10-20 min 20-30 min Up to an hour Over an hour	Less than 30 min More than 30 min
I can be as healthy as I want to be	Completely disagree	Disagree
I am in control of my health	Disagree	Neither disagree nor agree
I can pretty much stay healthy by taking care of myself	Neither disagree nor agree	Agree
Efforts to improve your health are a waste of time	Agree	Note that the option 'Neither disagree nor agree' was excluded in the data analysis
I am bored by all the attention that is paid to health and disease prevention	Completely agree	
What's the use of concerning yourself about your health - you'll only worry yourself to death		
Eating healthily is something I do frequently		
I eat healthily without having to consciously think about it		
I feel weird if I don't eat healthily		
Eating healthily is something he/she does without having to think about doing		
I'm interested in personalised nutrition	No	No
I want to know what foods are best for me	Yes	Yes
I want to lose weight		
I want to gain weight		
I want to improve my family's health		
I want to improve my health		
I want to improve my wellbeing		
I want to improve my sports performance		
I want to prevent a future illness		
I have a family history of diet-related illness		
I think it is important to help academic studies		
I am curious to find out what happens in these studies		
I can manage to stick to healthful foods: even if I need a long time to develop the necessary routines	Very uncertain Rather uncertain	Not certain Certain
I can manage to stick to healthful foods: even if I have to try several times until it works	Rather certain Very certain	
I can manage to stick to healthful foods: even if I have to rethink my entire way of nutrition		
I can manage to stick to healthful foods: even if I do not receive a great deal of support from others when making my first attempts		
I can manage to stick to healthful foods: even if I have to make a detailed plan		

**Supplemental Table 2.** Definitions for benefit from the intervention for secondary outcomes

Outcome	Definition
Body weight and/or WC	$\geq 5\%$ reduction in body weight and/or WC among individuals were advised to lose weight (i.e. if they had a BMI $>25$ kg/m <sup>2</sup> or a WC $>88$ cm in women and $>102$ in men)
Omega-3 index	$\geq 5\%$ increase in omega-3 index among individuals who were advised to increase their omega-3 intake (i.e. who had a blood cholesterol concentration $<4\%$ and/or dietary intake $<0.2\%$ of total energy and for whom omega-3 was a top 3 priority target)
Carotenoids	$\geq 5\%$ increase in carotenoids among individuals who were advised to increase their carotenoid intake (i.e. who had a blood carotenoid concentration $<1.3\mu\text{M}$ and for whom carotenoids was a top 3 priority target)
Cholesterol	$\geq 5\%$ reduction in cholesterol among individuals who were advised to improve their cholesterol concentrations (i.e. who had a blood cholesterol concentration $>8$ mmol/L and for whom cholesterol was a top 3 priority target)
Sedentary time	$\geq 5\%$ reduction in sedentary time among individuals who were advised to increase their PA (i.e. who had a PAL $<1.5$ or a total activity index $<5.5$ )
Physical Activity (PA)	$\geq 5\%$ increase in PA among individuals who were advised to increase their PA (i.e. who had a PAL $<1.5$ or a total activity index $<5.5$ )

**Supplemental Table 3.** Summary of missing data for variables at baseline<sup>1</sup>

Variable	Number of participants imputed	Percentage of imputed relative to baseline
Delta HEI at month 6	337	21·0
Delta MD at month 6	337	21·0
HEI	127	7·90
MD	127	7·90
PAL	320	19·9
Sedentary time	320	19·9
Moderate to vigorous physical activity	320	19·9
Wear time of accelerometer	320	19·9
Season accelerometer worn	23	1·43
Professional occupation	129	8·03
Intermediate occupation	129	8·03
Manual occupation	129	8·03
Body weight	127	7·90
Waist circumference	131	8·15
BMI	127	7·90
<i>FTO</i> (rs9939609)	125	7·78
<i>FADS1</i> (rs174546)	125	7·78
<i>TCF7L2</i> (rs7903146)	128	7·97
<i>APOE</i> (rs429358)	125	7·78
<i>APOE</i> (rs7412)	131	8·15
<i>MTHFR</i> (rs1801133)	125	7·78
Self-efficacy for sticking to healthful foods:		
Even if I need time to develop the routines	44	2·74
Even if I have to try several times until it works	44	2·74
Even if I have to rethink my entire way of nutrition	44	2·74
Even if I do not receive support from others	44	2·74
Even if I have to make a detailed plan	44	2·74

BMI, Body Mass Index, HEI, Healthy Eating Index, MD, Mediterranean Diet score, PAL, Physical Activity Level

1, All data refer to baseline with the exception of “Delta HEI at month 6” and “Delta MD at month 6”

**Supplemental Table 4.** Baseline socio-demographic, anthropometric, health behaviour-related and genotypic characteristics of all participants randomized to L1, L2 and L3 of the intervention in imputed dataset and complete case analysis

	<b>Imputed dataset<sup>1</sup></b> <b>(n=1220)</b>	<b>Complete case<sup>2</sup></b> <b>(n=930)</b>
HEI score	49.1 (0.30)	49.3 (9.77)
<b>Demographics</b>		
Age, years	39.7 (0.37)	41.1 (12.9)
Female, %	59.3 (1.41)	56.7
Occupation, probability		
Professional and managerial	39.3 (1.46)	40.3
Intermediate occupations	26.6 (1.33)	27.0
Routine and manual	9.89 (0.89)	9.25
Country, %		
Germany	13.8 (0.99)	14.3
Greece	14.5 (1.01)	14.6
Ireland	13.8 (1.00)	12.6
Netherlands	13.8 (1.00)	17.4
Poland	13.8 (1.00)	13.1
Spain	13.9 (1.00)	14.7
The UK	14.6 (1.01)	13.2
<b>Anthropometrics</b>		
Body weight, kg	74.6 (0.48)	75.0 (15.8)
BMI, kg/m <sup>2</sup>	25.5 (0.15)	25.5 (4.84)
Waist circumference, cm	85.5 (0.40)	86.1 (13.7)
<b>Health behaviours</b>		
PAL	1.74 (0.57)	1.74 (0.17)
MVPA	46.2 (0.99)	45.5 (29.7)
Sedentary behaviour, min/d	744 (2.47)	747 (74.6)
Current smoker, %	11.6 (0.92)	11.1
Medication use, %	29.5 (1.31)	30.3
<b>Genotype, % carrier of minor allele</b>		
<i>FTO</i> (rs9939609)	67.7 (1.41)	68.0
<i>FADS1</i> (rs174546)	42.9 (1.48)	43.9
<i>TCF7L2</i> (rs7903146)	47.5 (1.49)	47.4
<i>APOE</i> (rs429358)	25.6 (1.29)	26.3
<i>APOE</i> (rs7412)	12.6 (0.99)	12.4
<i>MTHFR</i> (rs1801133)	54.4 (1.47)	55.3

L=Level; L1, Participants received personalised nutrition advice based on their current diet; L2, Participants received personalised nutrition advice based on their current diet and phenotype; L3, Participants received personalised nutrition advice based on their current diet, phenotype and genotype; MVPA, Moderate to vigorous physical activity

1, Values have been imputed using multiple imputation. Values represent means (SE) or probabilities (SE)

2, Values represent means (SD) or percentage

**Supplemental Table 5.** Baseline socio-demographic, anthropometric, health-related and genotypic characteristics of participants randomized to L1, L2 and L3 of the intervention associated with benefiting from the PN intervention at month 6 according to each definition of benefit <sup>1</sup> ✓=significant benefit, X=significant non-benefit

	HEI (n=493)	Weight loss/ WC reduction (n=231)	Physical activity (n=333)	Sedentary time (n=333)	Cholesterol (n=36)	Carotenoids (n=140)	Omega- 3 index (n=88)
HEI score							
<b>Demographics</b>			X				
Age, years	✓						
Female, probability	✓			✓			
<b>Occupation, probability</b>							
Professional and managerial				X			
Intermediate occupations			✓				
Routine and manual							
<b>Country, probability</b>							
Germany							
Greece						X	
Ireland							
Netherlands	✓						
Poland							
Spain			✓				
UK							
<b>Anthropometrics</b>							
Body weight, kg							
BMI, kg/m <sup>2</sup>							
Waist circumference, cm		✓			X		
<b>Health behaviours</b>							
PAL							✓
MVPA							✓
Sedentary behaviour, min/d							X
Current smoker, probability							
Medication use, probability							
<b>Genotype, probability carrier of minor allele</b>							
<i>FTO</i> (rs9939609)							
<i>FADS1</i> (rs174546)							
<i>TCF7L2</i> (rs7903146)							
<i>APOE</i> (rs429358)							✓
<i>APOE</i> (rs7412)		✓				X	
<i>MTHFR</i> (rs1801133)							

**Supplemental Table 6.** Baseline behavioural characteristics of participants randomized to L1, L2 and L3 of the intervention benefiting from the PN intervention at month 6 according to each definition of benefit <sup>1</sup> ✓=significant benefit, X=significant non-benefit<sup>1</sup>

	HEI (n=493)	Physical activity (n=333)	Sedentary time (n=333)	Carotenoids (n=140)	Omega-3 index (n=88)
<b>Meal habits</b>					
Often eat main meal away from home					
Often skip meals and replace them with snacks			X		X
Often prepare a meal "from scratch"		✓			
Often eat hot or cooked meals		✓			
Spend a lot of time preparing a main meal					
<b>Heathy eating perceptions</b>					
Believe I am in control of my health					
Can stay healthy by taking care of myself		✓	✓		
Efforts to improve health are a waste of time					
Bored by attention paid to health and disease					
There's no use of being concerned about health					
Frequently eating healthily	✓				
Eat healthily without thinking about it					X
Feel weird if don't eat healthily	✓				
<b>Self-efficacy for sticking to healthful foods</b>					
Even if I need time to develop the routines	✓				
Even if I have to try several times until it works	✓				
Even if I have to rethink my way of nutrition	✓				
Even if I do not receive support from others					
Even if I have to make a detailed plan					
<b>Motivation for participating in the study</b>					
Interested in personalised nutrition					
Want to know what foods are best for him/her	✓				
Want to lose weight					X
Want to improve my family's health					
Want to improve my health	✓				
Want to improve my wellbeing					
Want to improve my sports performance					
Want to prevent a future illness					
Have a family history of diet-related illness					
Think it is important to help academic studies				✓	

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Curious to find out what  
happens in PN studies

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1, Columns for Weight loss/ WC reduction (n=231) and Cholesterol (n=36) were removed due to a lack of significant result



## CONSORT 2010 checklist of information to include when reporting a randomised trial\*

Section/Topic	Item No	Checklist item	Reported on page No
<b>Title and abstract</b>	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	4-5
<b>Introduction</b> Background and objectives	2a	Scientific background and explanation of rationale	6
	2b	Specific objectives or hypotheses	6
<b>Methods</b> Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	7
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	NA
Participants	4a	Eligibility criteria for participants	8
	4b	Settings and locations where the data were collected	7-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	8-10
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	11-12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	NA
Sample size	7a	How sample size was determined	NA
	7b	When applicable, explanation of any interim analyses and stopping guidelines	NA

## Randomisation:

Sequence generation	8a	Method used to generate the random allocation sequence	8
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	8
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	NA
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	8
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	NA
	11b	If relevant, description of the similarity of interventions	NA
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	11-12
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	11-12
<b>Results</b>			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Figure 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Figure 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	7-8
	14b	Why the trial ended or was stopped	NA
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	23-24
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	12

Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	25-27
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	NA
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	14
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	NA
<b>Discussion</b>			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	16-17
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	17
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	14-16
<b>Other information</b>			
Registration	23	Registration number and name of trial registry	3
Protocol	24	Where the full trial protocol can be accessed, if available	3
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	18

\*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming; for those and for up to date references relevant to this checklist, see [www.consort-statement.org](http://www.consort-statement.org).