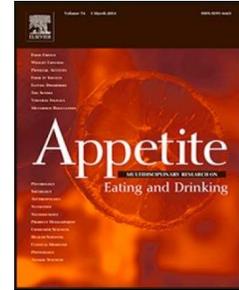


Accepted Manuscript

Title: Acceptability of new formulations of Corn-Soy Blends and Lipid-based Nutrient Supplements in Province du Passoré, Burkina Faso

Author: Ann-Sophie Iuel-Brockdorf, Tania Aase Dræbel, Christian Fabiansen, Bernardette Cichon, Vibeke Brix Christensen, Charles Yameogo, Christian Ritz, Mette Frahm Olsen, Henrik Friis



PII: S0195-6663(15)00204-4
DOI: <http://dx.doi.org/doi:10.1016/j.appet.2015.04.058>
Reference: APPET 2537

To appear in: *Appetite*

Received date: 20-11-2014
Revised date: 15-4-2015
Accepted date: 19-4-2015

Please cite this article as: Ann-Sophie Iuel-Brockdorf, Tania Aase Dræbel, Christian Fabiansen, Bernardette Cichon, Vibeke Brix Christensen, Charles Yameogo, Christian Ritz, Mette Frahm Olsen, Henrik Friis, Acceptability of new formulations of Corn-Soy Blends and Lipid-based Nutrient Supplements in Province du Passoré, Burkina Faso, *Appetite* (2015), <http://dx.doi.org/doi:10.1016/j.appet.2015.04.058>.

This is a PDF file of an unedited manuscript that has been accepted for publication. As a service to our customers we are providing this early version of the manuscript. The manuscript will undergo copyediting, typesetting, and review of the resulting proof before it is published in its final form. Please note that during the production process errors may be discovered which could affect the content, and all legal disclaimers that apply to the journal pertain.

1 **Acceptability of new formulations of Corn-Soy Blends and Lipid-based Nutrient Supplements in**
2 **Province du Passoré, Burkina Faso**
3

4 Ann-Sophie Iuel-Brockdorf^{1,2}, Tania Aase Dræbel³, Christian Fabiansen², Bernardette Cichon^{1,2}, Vibeke Brix
5 Christensen^{2,4}, Charles Yameogo^{2,5}, Christian Ritz¹, Mette Frahm Olsen⁶, Henrik Friis²
6

7 ¹Médecins Sans Frontières – Denmark, Dronningensgade 68, 3. 1420 Copenhagen, Denmark (A Iuel-Brockdorf MIH,
8 ai@msf.dk; B Cichon, MSc, Bernardette.Cichon@london.msf.org; V Christensen DMSc, vb@msf.dk)

9 ²Department of Nutrition, Exercise and Sports, University of Copenhagen, Rolighedsvej 30, DK-1958 Frederiksberg C,
10 Denmark (A Iuel-Brockdorf MIH, ai@msf.dk; C Fabiansen MD, chfr@nexs.ku.dk; B Cichon, MSc,
11 Bernardette.Cichon@london.msf.org; C Ritz PhD, ritz@nexs.ku.dk; Prof H Friis PhD, hfr@nexs.ku.dk)

12 ³ Department of International Health, Faculty of Health and Medical Sciences, University of Copenhagen, Blegdamsvej
13 3, 2200 Copenhagen, Denmark (T. A Dræbel PhD, Lecturer, taniadraebel@gmail.com)

14 ⁴ Department of Paediatrics, Rigshospitalet, Blegdamsvej 9, 2100, Copenhagen, Denmark (V Christensen DMSc,
15 vb@msf.dk)

16 ⁵ Research Center in Biological, Food and Nutritional Sciences UFR-SVT/University of Ouagadougou, 03 BP 7131
17 Ouagadougou, Burkina Faso (C Yameogo MSc, yamway@yahoo.fr)

18 ⁶ The Nordic Cochrane Centre, Rigshospitalet dept. 7811, Blegdamsvej 9, 2100 Copenhagen, Denmark (M. Frahm
19 Olsen, PhD, meosmail@gmail.com)
20

21 **Address for correspondence:**

22 Ann-Sophie Iuel-Brockdorff
23 Department of Nutrition, Sports and Exercise
24 University of Copenhagen,
25 Rolighedsvej 30,
26 1958 Frederiksberg C, Denmark
27 Telephone: +45 41 77 74 23
28 Email: ai@msf.dk
29
30

31 Highlights

- 32 • *LNS and CSB products with different milk-quantity and soy-quality are equally well accepted on*
- 33 *organoleptic parameters*
- 34 • *CSB was not consumed as readily as LNS*
- 35 • *Both CSB and LNS products were perceived as easy to administer*
- 36 • *Similar CSB and LNS products used in the study location were perceived as beneficial to child health*
- 37 • *LNS were to a higher degree associated with medicine or foods with medicinal properties*
- 38

39
40

41 Abstract

42 *The objective of this study was to evaluate the acceptability of new formulations of six corn-soy blended*

43 *flours (CSB) and six lipid-based nutrient supplements (LNS) with different quantities of milk and qualities of*

44 *soy to be used for the treatment of moderate acute malnutrition (MAM). Furthermore, we wanted to*

45 *explore the acceptability of foods currently used for the prevention and treatment of malnutrition in Burkina*

46 *Faso to identify possible barriers that could affect the acceptability of the new formulations of*

47 *supplementary foods. The study was carried out prior to a randomized controlled trial evaluating the*

48 *effectiveness of these new formulations.*

49

50 *The study involved an observed test-meal and a three-day take-home ration of the experimental food*

51 *supplements to 6-30-months-old healthy children, followed by questionnaire-based interviews about the*

52 *acceptability of these supplements. Interviews and focus group discussions were carried out to explore the*

53 *acceptability of foods currently used for the prevention and treatment of malnutrition.*

54

55 *The results suggest that both LNS and CSB products with different quantities of milk and qualities of soy are*

56 *equally well accepted among healthy children in rural Burkina Faso based on general appreciation of the*

57 *supplements and organoleptic properties. All experimental foods received good ratings and there was no*

58 *significant difference between the foods. However, after the take-home ration, 58% of participants receiving*

59 *CSB reported having left-overs at the end of the day compared to 37% (n=33) of the participants receiving*

60 *LNS (p=0.004), suggesting that CSB was not as readily consumed as LNS. Yet, both CSB and LNS products*

61 *were perceived as easy to administer and the frequency of feeding was estimated to be adequate. The study*

62 *also found that similar foods, used for the prevention and treatment of malnutrition, were well appreciated*

63 *in the study location. LNS were to a higher degree associated with medicine or foods with medicinal*

64 *properties, but both LNS and CSB were perceived as beneficial to child health.*

65

66 **Keywords**

67 Acceptability, supplementary food, Lipid-based Nutrient Supplement, Corn Soy Blend, malnutrition,
68 moderate acute malnutrition

69 **Introduction¹**

70 Moderate acute malnutrition (MAM) affects 33 million children worldwide and is a major global health
71 problem as it results in increased morbidity and mortality and delayed cognitive development (M. M. Black
72 et al., 2008; Black et al., 2013; R. E. Black et al., 2008). Yet, there is presently no consensus on
73 supplementary foods for the management of MAM. According to the World Health Organization, (WHO),
74 who are currently reviewing their guidelines, more evidence is needed before clear guidelines can be
75 developed (World Health Organization, 2012).

76 In recent years different approaches have been introduced for the management of MAM using fortified
77 blended flours, such as enhanced versions of corn-soy blend (CSB) or lipid-based nutrient supplements
78 (LNS) (Lazzerini et al., 2013). These supplementary foods vary in terms of cost, taste, texture, shelf life, how
79 they are used as well as in nutritional composition. These are all factors that may affect the acceptability
80 and thereby the beneficial effect of a nutritional intervention. Acceptability refers to how foods are
81 perceived and acknowledged in terms of recommended quantity consumed, the perceived benefits and/or
82 undesirable effects, ease of use as well as organoleptic qualities of the foods based on test meals and/or
83 take-home rations for a minimum of seven days as described in previous studies (Adu-Afarwuah et al., 2008;
84 Bahwere et al., 2009; Rowe et al., 2008).

85 Soy and milk are key ingredients in existing supplementary foods for children with MAM. Soy is used to
86 obtain high levels of protein. Yet unrefined soy contains anti-nutrients and may produce flatulence and
87 abdominal discomfort due to the fermentation of indigestible oligosaccharides. Consequently this may
88 affect the acceptability (Suarez et al., 1999). As an alternative, soy isolate can be used. It has an increased
89 protein content and an enhanced protein digestibility as well as less anti-nutrients and indigestible
90 oligosaccharides (Björck et al., 1983). Milk may have a beneficial impact on growth (Grillenberger et al.,
91 2003; Hoppe et al., 2008), it contains high quality protein and may furthermore influence the acceptability,

¹ Abbreviations:

MAM, moderate acute malnutrition; CSB, corn-soy blend; LNS, lipid-based nutrient supplement; WHO, World Health Organization;
DS, dehulled soy; SI, soy isolate; DSM, dry-skimmed milk; MUAC, mid-upper arm circumference

92 as it provides a more sweet and creamy taste (Hoppe et al., 2008). However, both soy isolate and milk are
93 more expensive ingredients.

94 Only a few studies have compared the acceptability of CSB vs LNS products and found them equally well
95 accepted. However, LNS were less likely to be left-over (Flax et al., 2010) and CSB was more likely to be
96 shared (Flax et al., 2010; Wang et al., 2013). Acceptability of soy vs. milk-based foods have so far also only
97 been compared in a few studies, and only in LNS products, where both types of foods were reported to be
98 well-accepted by the target population (Kuusipalo et al., 2006; Matilsky et al., 2009). One study compared
99 and assessed the acceptability of LNS products with and without milk and found that milk did not affect
100 acceptability (Owino et al., 2014). This was also the case for a study on soy- and rice-based complementary
101 foods with and without milk powder (Paul et al., 2008). However, to our knowledge, no studies have
102 assessed and compared the acceptability of CSB vs LNS products with different quantities of milk and
103 different qualities of soy for the treatment of MAM.

104 Prior to a randomized controlled trial evaluating the cost-effectiveness of 12 different new formulations of
105 CSB and LNS with different quantities of milk and soy qualities for the management of MAM
106 (ISRCTN42569496 at <http://www.controlled-trials.com>), we conducted a study to evaluate the acceptability
107 of these new formulations. Furthermore, we wanted to explore the acceptability of foods currently used in
108 the study location for the prevention and treatment of malnutrition, to identify possible barriers that could
109 affect the acceptability of the new formulations of supplementary foods.

110

111 **Methodology**

112 The study took place in the department of Gonponsom, Yako health district, Province du Passoré in
113 northern Burkina Faso in January-February 2013. The prevalence of MAM and SAM in the area were 9% and
114 1.4%, respectively ("Ministere de la Santé, Burkina Faso, Direction de la Nutrition. Rapport Enquete
115 Nutritionnelle Nationale," 2013). Regular preventive food distributions by WFP for children 6-36 months-
116 old, with either CSB or ready-to-use foods, depending on availability, were carried out at the local health
117 centres in relation to routine mother-child healthcare activities. A combination of quantitative and
118 qualitative methods was applied to evaluate and compare the extent of acceptability of the new products
119 (part I) and to capture the multitude of views on supplementary foods currently used for the prevention
120 and treatment of malnutrition in the study location(part II).

121 **Methodology Part I: Acceptability of the new supplementary foods**

122 **1.1 Participants**

123 A convenience sample of 180 children aged 6-30 months who had initiated complementary feeding, and
124 with mid-upper arm circumference (MUAC) >125 mm were identified by local community health workers.
125 Exclusion criteria were children with moderate or severe acute malnutrition by MUAC, oedema, history of
126 peanut allergy, or who had severe illness requiring hospitalisation or who were registered in a nutritional
127 program. An informed consent form was signed or thumb printed by caretakers prior to participation.

128 **1.2 Design**

129 Children were randomised to one of the 12 different supplements, i.e. 15 children/group, according to a
130 blocked randomisation list with varying block sizes using <http://www.randomization.com>. Each of the 12
131 supplementary foods was masked with a one-letter code and participants and all members of the research
132 team were blinded to the soy and milk content of the supplementary foods, but not to the main type of
133 food (CSB or LNS).

134 The study included an observed test meal (visit 1) and a three-day take-home test (visit 2) with one of the
135 12 experimental supplementary foods per participant. Both visits included questionnaires evaluating the
136 acceptability of the new foods in terms of organoleptic qualities and perceived ease of use as well as
137 adherence to recommendations. The take-home ration was included, because it was assumed that
138 acceptability could increase over time. Other studies have provided a take-home ration for minimum a
139 week (Hess et al., 2011, Wang et al., 2013). However, in this study, children were not malnourished and a
140 supplement high in calories, fat and protein for a longer period of time could potentially have adverse
141 effects. Therefore, it was decided to limit the take-home ration to three days.

142 **1.3 Intervention**

143 The 12 supplementary foods included six CSB and six LNS products, with either dehulled soy (DS) or soy
144 isolate (SI) and with 0%, 20% or 50% of total protein as dry skimmed milk (DSM). All products were
145 manufactured by GC Rieber Compact A/S (Bergen, Norway) and had similar micronutrient content provided
146 by a pre-mix of vitamins and minerals according to a WHO Technical Note on supplementary foods for the
147 management of MAM (World Health Organization, 2012) (**Table 1**). A daily ration of LNS (92 g) and CSB
148 (120 g) provided 500 kcal per child. LNS products were packed in 92 grams foil sachets containing a daily
149 ration and did not require any preparation prior to consumption. CSB products were packed in foil bags and
150 required cooking to become an edible porridge. The home ration of three daily rations of 120 gram CSB per
151 day was dosed and provided in neutral local plastic bags. Mothers were instructed to prepare the porridge
152 with a CSB-water volume ratio of either 1:3 or 1:4, depending on the desired viscosity. It was advised to

153 serve the porridge in three meals per day, giving 40 gram of CSB (167 kcal) per meal. Individual dose cups
154 (per meal) were provided to all participants receiving the CSB products.

155

Accepted Manuscript

156 *Observed test meal (visit 1)*

157 Participants were offered either 40 g of one of the CSB products corresponding to 1/3 of the daily ration or
158 1 sachet of the LNS products corresponding to a full daily ration. The ration was served by two health
159 workers between 8 am and 12 pm. Caretakers and children were divided into groups, placed in a quiet
160 area, and served one group at a time with a maximum of four children per group at a time. Children in the
161 CSB groups were served first and caretakers were showed how to prepare the porridge hygienically.
162 Caretakers were also instructed to wash their hands before feeding the child. All children were offered
163 water during the meal and there were no restrictions on breastfeeding prior to or during the test.
164 Breastfeeding 30 minutes prior to serving was registered.

165 After 30 minutes of observed consumption, caretakers were asked to evaluate the supplementary foods in
166 terms of child appreciation, general perception, taste, colour, odour and texture according to their child's
167 reaction and own perception, based on a 5-point hedonic scale, where 1=dislike very much, 2=dislike,
168 3=neither like nor dislike, 4=like and 5=like very much. The scale was illustrated in a series of human face
169 symbols with varying degrees of smile or discontent. This is a method previously used to measure food
170 acceptability in illiterate populations (Cohuet et al., 2012; Hess et al., 2011). If children were not able to
171 finish the ration within the 30 minutes, caretakers were asked to estimate the quantity of left-overs.

172 *Three day take-home test (visit2)*

173 After the observed test, participants were given a three-day ration to take home and asked to come back
174 the following week to complete the final questionnaire, which included the same questions as in the
175 observed test. Additionally questions related to acceptability and management of the supplementary foods
176 were included. These questionnaires were developed together with an experienced local research assistant
177 fluent in the local language, Mooré, and familiar with the local culture. She also assisted in training and
178 supervision of the two health workers carrying out the serving and the questionnaires on all participants.

179

180 **Methodology Part II: Perceptions of foods currently used in the study location**

181 Individual interviews and focus group discussions (FGD) were carried out with caretakers of young children
182 to explore the acceptability of foods currently used for the prevention and treatment of malnutrition in the
183 study location.

184 **2.1 Participants**

185 Participants for this part of the study included both caretakers from the quantitative part of the study and
186 other caretakers of young children. The majority of the participants had personal experience with foods

187 used for the prevention and treatment of malnutrition, having young children that had either been treated
188 for malnutrition or had benefitted from the regular food distributions at the health centres.

189 **2.2 Design**

190 Purposive sampling was used to ensure that data was as diverse as possible in terms of age and number of
191 children of the caretakers. The number of interviews/FGDs was based on the principle of data saturation,
192 including new participants as long as new themes emerged. The aim was to achieve analytical
193 generalization, so that the emerging information would be comprehensive, complete, saturated and would
194 account for deviant cases. The interviews and FGDs were carried out in Mooré by two research assistants
195 trained for the purpose by the first author and a phenomenological approach was applied as described by
196 Kvale (Kvale, 1996). The interviews and FGDs took place at the health centre or in the village of the
197 participants in a secluded area, and lasted between 20-45 minutes. All interviews and FGDs were carried
198 out following a semi-structured interview guide using open-ended questions within topics related to the
199 perception of treatment of malnutrition in the study location. The interview guide was carefully discussed
200 and developed with the two research assistants prior to the study, to ensure semantic coherence and
201 relevance to the context. All interviews and FGDs were recorded, transcribed and translated from Mooré to
202 French by the two research assistants and from French to English by the first author.

203 **Data analysis**

204 Quantitative data were doubly entered into Epidata 3.1 Software (Epidata Association, Odense, Denmark)
205 and analyzed using Stata 12 (StataCorp, College Station TX, USA). Baseline characteristics, performance and
206 management results of questionnaires from the observed and take-home tests were analyzed using chi-
207 square tests, initially considering contingency tables including all 12 supplementary foods. In addition,
208 pairwise comparisons for 2-by-2 tables were carried out separately within the CSB and LNS groups,
209 respectively. In case comparisons within these two groups were non-significant, an overall comparison was
210 made between CSB and LNS. Differences in frequency of feeding between CSB and LNS were analyzed using
211 analysis of variance. Differences in ratings of the organoleptic acceptability between supplementary foods
212 and visits were analyzed using linear mixed models including product-visit interactions as fixed effects and
213 participant-specific random effects. Additionally, all models were adjusted for age and sex. Likelihood ratio
214 tests were used to evaluate product-visit interactions and, if these were non-significant, separate product
215 and visit effects were estimated. Bonferroni adjustment was applied whenever multiple p-values were
216 considered in an analysis. A significance level of 0.05 was used.

217 Interviews and FGD were analyzed applying qualitative content analysis as outlined by Graneheim and
218 Lundman (2004). First, each interview and FGD was kept intact and read through several times to obtain a

219 general sense of the content, searching for common themes and identifying manifest and latent content.
220 From the text, condensed meaning units or portions of the text that were connected to a central meaning
221 were formed and coded for that specific meaning. For example, if caretakers were talking about the
222 abilities of supplementary foods, the specific ability would be coded (i.e; *foods provide health*). These codes
223 were then assimilated into categories (i.e; *abilities of supplementary foods*) and from these, themes
224 emerged (i.e; *perceptions of supplementary foods*). In line with Graneheim and Lundman, meaning units,
225 codes and categories could fit into more than one theme. Finally, findings from each of the interviews/FGDs
226 were compared with the aim of exploring similarities, differences and patterns. The analysis was carried out
227 with a focus on the subject and the context and an emphasis on differences and similarities found in the
228 data, which is characteristic for the direction of qualitative content analysis described by Graneheim and
229 Lundman. This approach rests on the underlying assumption that "*reality can be interpreted in many*
230 *different ways and the understanding is dependent on subjective interpretation*". Consequently, a certain
231 degree of interpretation is involved in the analysis of data (Graneheim and Lundman, 2004).

232 Ethical approval

233 As part of a larger study, this study was approved by the Ethical Committee for Health Research in Burkina
234 Faso (2012-8-059) and consultative approval was obtained from the Danish National Committee on
235 Biomedical Research Ethics (1208204).

236 Results

237 Participants characteristics

238 180 children and their caretakers were included in the study during a period of four weeks. Randomization
239 resulted in baseline equivalence. The mean age of the children were 14 months (SD ± 5), 62% (n=112) were
240 males and 95% (n=171) (95%CI: 92-98%) were breastfed at inclusion. 82% (n=146) were reported healthy at
241 inclusion (95%CI: 76-87%), while 15% (n= 27) and 3% (n=6) reported having light or moderate illness
242 respectively (95%CI: 10-20% and 0.7-6% respectively). All children except one completed both visits of the
243 study (**Table 2**).

244 For the qualitative part of the study, four FGDs and 11 individual interviews were carried out with a total of
245 38 caretakers, who were all biological mothers of the children. The mean (SD \pm) age of the caretakers was
246 29.1 years (SD ± 8.3), the mean quantity of children per caretaker was 3.6 (SD ± 1.9) and number of
247 household members was 12.8 (SD ± 6.5). 84% (n=32) of the caretakers had no education, 11% (n=4) had
248 attended primary school and 5% (n=2) had attended secondary school.

249 **General appreciation and organoleptic qualities of the new formulations**

250 In **Table 3** organoleptic ratings of all products are listed. In terms of caretaker's general perception and the
251 organoleptic attributes related to odor and color of the supplementary foods, results show mean ratings
252 between 3.8 and 4.1. There was no difference between the supplements, neither in ratings, nor how they
253 were rated from visit 1 to visit 2. Similarly, no difference was found between the supplements in terms of
254 rating of taste. However, there was an increase in this rating from visit 1 to visit 2 (0.23, 95% CI: 0.11-0.35,
255 $p < 0.001$), which was also seen in the mean rating of the child's perceived appreciation of the supplements
256 (0.18, 95% CI: 0.04-0.31, $p = 0.012$). Ratings of texture changed from visit 1 to visit 2 ($p = 0.01$), however only
257 for some of the products: For CSB DS 0% (1) ratings increased from visit 1 to visit 2, from 3.5 to 4.0 (95%
258 CI: 3.2-3.69 and 95% CI: 3.7-4.22, respectively, $p = 0.012$). For LNS SI 0% (10), the rating decreased from visit
259 1 to visit 2. However this difference was not significant after Bonferroni adjustment ($P = 0.12$).

260

261 **Observed test meal – consumption and leftovers**

262 After 30 minutes of consumption of the supplementary foods, 78% ($n = 137$) of participants had leftovers,
263 with no marked differences between the 12 groups ($p = 0.21$). The total mean of participants breastfeeding
264 their children prior to the test meal were 55% ($n = 92$), and presented no clear difference between the
265 products ($p = 0.58$)

266 52% ($n = 73$) of participants estimated to have half of the ration left, while 32% ($n = 45$) estimated having half
267 of the meal left. No clear differences between the 12 supplementary foods were found ($p = 0.12$), despite
268 the fact that the ration of CSB (40 g/167 kcal) corresponded to 1/3 of a daily ration, while the ration of LNS
269 (92 g/500 kcal) corresponded to a full daily ration. Regardless of the large proportion of children having
270 left-overs, 74% ($n = 133$) of caretakers said that the quantity to consume was adequate, with no clear
271 difference between the products ($p = 0.47$).

272

273 **Take home test – consumption and leftovers**

274 The number of caretakers reporting left-overs during the take home test was different between the 12
275 supplementary foods ($p = 0.037$) and between the CSB and LNS products ($p = 0.004$) (**Table 4**). In the LNS
276 group, 37% ($n = 33$) reported having left-overs at the end of the day, compared to 58% ($n = 52$) of caretakers
277 receiving CSB. In the CSB groups, 46% ($n = 23$) and 44% ($n = 22$) of caretakers reported having less than half
278 or half of the daily ration left, respectively vs 53% ($n = 17$) and 34% ($n = 11$) of caretakers in the LNS groups,

279 respectively. 10% (n=5) of caretakers in the CSB groups reported having more than half of the daily ration
280 left at the end of the day vs 13% (n=4) in the LNS groups.

281 Out of the 85 caretakers reporting left-overs, 51% (n=42) stated that another under 5-year-old child ate
282 what was left. 27% (n=22) said that the remains were eaten by the mothers, 15% (n=12) said that it was
283 eaten by an older child (> 5 years), while 7% (n=6) said that it was either thrown out or other.

284

285 **Administration of the supplementary foods**

286 The reported mean frequency of feeding during the take home test was higher for CSB, than for LNS (**Table**
287 **5**). When asked how they perceived the number of times they had been feeding their children with the
288 supplement per day, 83% (n=150) of caretakers said that it had been adequate, while 14% (n=25) thought
289 that it had not been frequent enough. Only 2% (n=4) thought that it had been too much. There was no
290 difference between the 12 supplementary foods ($P=0.23$). The majority of the caretakers (96%) said that
291 the administration of the products was easy, and there was no difference in the perception of
292 administration neither between each of the products nor between the CSB and LNS groups. In the CSB
293 groups, 85% (n=74) of caretakers reported that they preferred a less viscous porridge with a CSB:water-
294 ratio of 1:4, compared to 15% (n=13) who said they preferred a CSB:water-ratio of 1:3.

295

296 **Symptoms of illness after consumption**

297 When asked if the child had been ill following consumption of the supplementary foods, 8% of all
298 caretakers (n=15) reported illness, with no significant difference between the 12 supplementary foods
299 ($P=0.71$). Of the reported illnesses 47% (n=7) was diarrhea, while 13% (n=2) and 7% (n=1) were vomiting
300 and rash respectively. The remaining 33% (n=5) were reported as other symptoms.

301 **Foods used for the treatment and prevention of malnutrition in view**

302 Foods used for the prevention and treatment of malnutrition in the study location included both LNS and
 303 CSB products depending on availability. LNS were used for the treatment of severe acute malnutrition,
 304 while both LNS and CSB were used for the treatment of MAM and regularly distributed during routine
 305 maternal and child healthcare services for the prevention of malnutrition. Both types of foods were
 306 perceived as different from traditional/local foods and referred to as “Yombdo” in Mooré which means
 307 “wrinkled skin”. This is also a word used to describe malnutrition; the largest ethnic group in the study
 308 setting, the Mossi people, is known to have a metaphoric and metonymic style of reasoning when defining
 309 and categorizing an illness. This way, cause, effect and cure are often grouped together in concrete images,
 310 which is used as a way of conceptualizing an illness (Sjaak van der Geest and Meulenbroek, Adèle, 1993).

311 There were different perceptions of CSB and LNS in terms of the origin of the foods and their respective
 312 abilities. Although the ingredients were recognizable and to a large extent familiar in the study location,
 313 interviewees emphasized that LNS products were different from local foods. Many believed that it came
 314 from the Western part of the world and this was associated with high effectiveness.

315

316 *“If it is this food [LNS], even only with two sachets, the child will be revitalized very fast, but*
 317 *with our local foods, even if you make” Tô” [local dish of staples] of millet for the child, you*
 318 *will not see the same results. So you cannot say that it is the same thing, it is not at all the*
 319 *same thing”*

320

(20-year-old mother of one)

321

322 *“We think it [LNS] is peanut butter mixed with oil, but we still think it is the food of the white*
 323 *people”*

324

(FGD village of Ounon)

325 CSB products appeared to be more familiar to the caretakers, as the ingredients and the composition of the
 326 foods were perceived as similar to local foods and many caretakers thought that CSB could be produced
 327 locally. Nevertheless, they believed that the preparation was different and that external aid had been used
 328 to refine the foods so that they could be beneficial to the health of the children.

329

330 *“The appearance is a mix of cereals, so this mix must be a combination that tries to improve*
 331 *the health of children..... I don't know how they make it but I think that it [CSB] is based on*

332 *our local foods. I think that the composition of the foods includes some of our local crops, and*
 333 *then they have improved it so that it is good for children”*

334
 335 (48-year-old mother of six)

336
 337 *“You can find healthy foods here but it depends on how you combine it. The white people can*
 338 *transform millet to other things which we cannot. Perhaps the basic building blocks are here,*
 339 *but they have their way of preparing it [CSB]. Based on our crops, they are able to make*
 340 *beans, peanut, with lots of vitamins, but we do not know how to do that. Only they know*
 341 *what they are doing and then they send it to us”*

342 (40-year-old mother of seven)
 343

344 *“Yes it is possible [that CSB can be produced here], the flour used looks like maize flour”*
 345 (FGD village of Ounon)

346
 347 The perceived abilities of the products also differed. While the LNS products were strongly associated with
 348 medicine or perceived as having medicinal properties, no such associations were made for CSB at any point.
 349 Some caretakers perceived LNS as being medicine while others perceived them as being foods to improve
 350 the child’s condition during illness. Finally, some caretakers perceived LNS as being both foods and
 351 medicine.

352
 353 *“... we believe that it [LNS] is a drug, a drug that helps children very much.... This is the drug*
 354 *that saved my child when he was sick”*

355 (40-year-old mother of six)

356
 357 *“It [LNS] ensures an improvement of his [the child’s] condition... this is because it is food”*
 358 (30-year-old mother of four)

359
 360 *“I believe that it [LNS] is both, a drug and food to treat children with malnutrition”*
 361 (18-year-old mother of one)

362

363 Overall there was a perception that foods used for the prevention and treatment of malnutrition were
 364 something that ensured the health of children.

365 *We admire this food that treats our children..... it provides health*
 366 (38-year-old mother of five)

367
 368 *These foods are foods for the health*

369 (48-year-old mother of six)
370

371 Furthermore, there was a very strong confidence in the foods in terms of their abilities to provide health.

372 *The foods are powerful..... because when eating these foods, the child becomes healthy and*
373 *strong in no time*

374 (FGD Ounon)
375

376 This confidence seemed to be very fundamental. A mother whose child was having diarrhea after
377 consuming LNS products replied the following after being asked if she continued to give the child the foods;

378 *“How can I do differently? This is what will make him recover”*

379 (18-year-old mother of one)

380
381

382 Discussion

383 The primary objective of this study was to evaluate the acceptability of 12 new formulations of
384 supplementary foods for the treatment of MAM with different milk quantity and soy quality. Moreover, we
385 wanted to explore the acceptability of foods currently used for the prevention and treatment of
386 malnutrition in the study location to identify possible barriers for acceptability of new supplementary
387 foods.

388 All the new supplementary foods received high ratings in terms of caretakers' appreciation, the perceived
389 appreciation by the children and on organoleptic properties. There was no indication that the level of milk
390 or the quality of soy had an impact on these parameters and overall there was little variability in the
391 hedonic ratings. However, this result may not necessarily be conclusive as participants may have been
392 reluctant to give poor ratings, as suggested in other studies (Adu-Afarwuah et al., 2011; Young et al., 2010).
393 Yet, interestingly, ratings increased on certain parameters after the supplementary foods had been tested
394 at home. Children's food preferences are shaped by their early experience, and repeated exposure to foods
395 in a safe and supportive environment increases food preference and acceptance (Birch and Marlin, 1982;
396 Ventura and Worobey, 2013). The fact that the children were exposed to the supplementary foods more
397 than once and that they were fed in their home environment may have increased the acceptability of the
398 foods after the first visit, although the duration of home-feeding was shorter compared to other studies.

399 Acceptability of foods in terms of organoleptic preferences is difficult to assess in small children: study
400 findings often reflects the taste and food preferences of the caretakers, which may be different from those
401 of the child and which may not even reflect the real opinion, if participants engage in socially desirable
402 responding. Therefore looking at the quantity of left-over may be a useful indicator of acceptability (Adu-
403 Afarwuah et al., 2011; Flax et al., 2010; Owino et al., 2014).

404 In this study, the majority of caretakers estimated to have half or less of the ration served left following the
405 observed test meal in all groups. In other studies, it has been suggested that acceptability is reached if 50-
406 75% of the meal is consumed (Adu-Afarwuah et al., 2011; Owino et al., 2014). However, as leftovers in this
407 study were based on caretakers' estimation, it may be difficult to compare these findings with other
408 studies, where leftovers have been weighed and calculated by observers (Adu-Afarwuah et al., 2011, Hess et
409 al., 2011). Yet, it is unexpected that the proportion of participants having leftovers was similar in all groups
410 due to the difference in ration served: In the LNS groups a full daily ration of LNS was served (92 g), while in
411 the CSB groups, the meal was rationed into single meals (40 g). It would therefore have been more likely
412 that participants in the LNS groups had leftovers, as they were served a full day's ration in a single meal as
413 oppose to participants in the CSB groups who were served 1/3 of a full days ration. Additionally, more
414 participants in the CSB groups reported left-overs, after having tested the supplementary foods for three
415 days at home, compared to participants in the LNS groups. These findings suggest that the proposed single
416 meal portion size and the recommended daily ration of CSB were difficult for small children to consume
417 and therefore, that the CSB was not consumed as readily as the LNS. This is in line with a previous study
418 (Nackers et al., 2010) comparing the effectiveness of traditional CSB with a therapeutic LNS product
419 (Plumpy'Nut®, Nutriset). It should be noted that no restrictions on breastfeeding were given prior to eating
420 the supplementary foods, which may have influenced the appetite of the children and their ability to
421 consume the ration served. However, these foods are only supplements to the diet and in order not to
422 interfere with current breastfeeding practices, normal breastfeeding practices were encouraged and no
423 restrictions were made at any point during the study.

424 The difference in leftovers between CSB and LNS is likely due to the fact, that CSB products are less energy-
425 dense and have high bulkiness and volume compared to the high energy dense and low volume LNS
426 products (de Pee and Bloem, 2009). This means that children receiving CSB have to eat several times the
427 mass of food as children treated with LNS (LaGrone et al., 2012). For this reason, smaller and more frequent
428 meals are recommended for less energy-dense diets, in order not to exceed the gastric capacity of the
429 children (Brown et al., 1995). In our study, the mean frequency of feeding for the CSB products was 2.8
430 meals/day, providing 40 g of CSB per meal and an increase of recommended feeding frequency could be

431 considered. However, recommending higher frequency of feeding with CSB may be problematic since
432 preparation of the porridge is time-consuming and requires material for cooking in contrast to LNS which
433 can be eaten directly out of the package. Increasing the frequency of feeding for a longer period of time
434 with meals that require a long preparation may not be sustainable and could influence the acceptability in a
435 context where the working day of the caretaker of children is already overloaded and resources are sparse.
436 Surprisingly, the majority of caretakers reported the administration of the supplementary foods to be easy,
437 regardless of the type of product (> 98%) and despite the fact that the frequency of feeding was higher for
438 CSB than for LNS. In addition the frequency of feeding was perceived as adequate (83%) and only 2% of
439 caretakers said that it was too high. Yet, the duration of the take-home test was short compared to other
440 studies and to the average treatment duration of MAM. Consequently, the administration of the
441 supplementary foods may have been perceived less burdensome than if supplementation had continued
442 for a longer period of time.

443 The qualitative data suggests that similar foods used for the prevention and treatment of malnutrition were
444 well appreciated in the study location, although especially LNS were considered different from local foods.
445 LNS were associated with both medicine or with foods with medicinal properties while no such reference
446 were made for CSB, although it was considered to have been refined and to be beneficial to child health.

447 Other studies have shown that in Niger, LNS were mainly considered as medicine (Cohuet et al., 2012),
448 while in Malawi both CSB and LNS were considered as foods (Flax et al., 2009) as well as medical
449 treatments (Matilsky et al., 2009). The perception of foods used for the prevention and treatment of
450 malnutrition as having medicinal properties is likely to have an impact on the acceptability. It may confirm
451 the condition of the child as being ill, which enhances the care and adherence to the treatment and can
452 promote the good intentions of the mother to ensure the health of her child (Whyte et al., 2002). These are
453 important factors that could contribute to the acceptability of the supplementary foods, but would need to
454 be explored further.

455 Both types of products were perceived as beneficial to child health and there was a high degree of
456 confidence in the abilities of the foods, as they were referred to as “powerful” while others said that they
457 made children “strong in no time”. Whyte et al has suggested that the efficacy of medical treatments is
458 much related to the provenance of the product (Whyte et al., 2002). The fact that the foods were perceived
459 to be developed or refined by “white people”, could have enhanced their perceived efficacy in this context,
460 where there seemed to be a high confidence in western medicine. This may not be applicable to other
461 contexts.

462 We believe that the findings from the qualitative part of the study supports and qualifies the findings from
463 the quantitative part: The fact that similar foods currently used in the study location for the prevention and
464 treatment of malnutrition were well appreciated and perceived as beneficial to child health, whether they
465 were considered as medicine, foods with medicinal properties or just refined foods, could explain the high
466 level of acceptability of the new formulations.

467 **Limitations**

468 Still, we also acknowledge the limitations of the study. The relatively small sample size could be a limitation
469 inasmuch as only few differences were found to be significant. Thus, the study lacked power to produce but
470 few claims for individual acceptability outcomes. A larger sample size may have enabled us to find more
471 significant differences between products. Yet, it was sufficient to demonstrate an overall proof of concept.
472 Another limitation is that the quantity of left-overs was estimated by the caretakers and not weighed and
473 calculated by observers as has been done in other studies. For the qualitative part of the study, the
474 duration of the interviews and FGDs were relatively short and time to create trust between participants and
475 the interviewers was therefore limited. Furthermore, community-sensitisation and communication
476 regarding the project had been on-going prior to the interviews/FGDs and the non-local research team had
477 been introduced to the local community. This may have influenced participants to respond more positively.
478 Also, the analysis of qualitative data usually involves some degree of interpretation, while the translation
479 from Mooré to French to English may have involved some loss of meaning. Finally, the acceptability was
480 evaluated in healthy children, although the supplementary foods are designed for the treatment of children
481 with MAM. The appetite of malnourished children is often compromised, which influences consumption
482 and thus the acceptability of foods.

483

484 **Conclusion**

485 Knowing that foods used for the treatment and prevention of malnutrition are nutritionally and
486 scientifically correct is not enough. The way that they are perceived and accepted by beneficiary
487 populations are important factors determining the beneficial effect of a nutritional intervention. The results
488 from this study showed that LNS and CSB products with different quantities of milk and qualities of soy
489 were equally well accepted among healthy children in rural Burkina Faso on organoleptic parameters.
490 However, participants in the CSB groups were less likely to consume the proposed single meal portion size
491 or finish their daily ration. This may be due to the nature of the products, being high bulkiness foods, but it
492 suggests that CSB is not consumed as readily as LNS. Although home testing of the products was shorter

493 compared to other studies, both CSB and LNS products were perceived as easy to administer and the
494 frequency of feeding was estimated to be adequate. The study also found that foods, similar to the
495 introduced new formulations, currently used for the prevention and treatment of malnutrition in the study
496 location were well appreciated. LNS were to a higher degree associated with medicine or foods with
497 medicinal properties, but both LNS and CSB were perceived as beneficial to child health. Further research is
498 needed to explore the acceptability of new formulations of supplementary foods among children with
499 MAM and to assess how the perception of foods used for the prevention and treatment of malnutrition as
500 having medicinal qualities may affect acceptability.

501

502 **Acknowledgements**

503 *We are grateful to the study participants and their families, our research assistants Ms Albertine Ouédraogo*
504 *and Mrs Adja Belem and the rest of the staff of the Alliance for International Medical Action (ALIMA) for*
505 *their valuable contribution to this study. We thank the Ministry of Health in Burkina Faso, the health*
506 *authorities in Province du Passoré, the village authorities and the staff at the healthcenter in Gonponsom*
507 *for their support to this study. We furthermore thank GC Rieber Compact A/S for their contribution to the*
508 *development and production of the experimental supplementary foods. Finally, we thank Médecins Sans*
509 *Frontières in Norway and Denmark and the Danish International Development Assistance (09-097 LIFE) for*
510 *funding this study as part of the TreatFOOD project.*

511

512 **Conflict of interest**

513 *None declared. Neither the funders nor the manufacturer of the experimental food supplements had any*
514 *role in the design, implementation, analysis or reporting of the results from this study.*

515

516

517

518

519 **References**

- 520 Adu-Afarwuah, S., Lartey, A., Brown, K.H., Zlotkin, S., Briend, A., Dewey, K.G., 2008. Home fortification of
 521 complementary foods with micronutrient supplements is well accepted and has positive effects on
 522 infant iron status in Ghana. *Am. J. Clin. Nutr.* 87, 929–938.
- 523 Adu-Afarwuah, S., Lartey, A., Zeilani, M., Dewey, K.G., 2011. Acceptability of lipid-based nutrient
 524 supplements (LNS) among Ghanaian infants and pregnant or lactating women. *Matern. Child. Nutr.*
 525 7, 344–356. doi:10.1111/j.1740-8709.2010.00286.x
- 526 Bahwere, P., Sadler, K., Collins, S., 2009. Acceptability and effectiveness of chickpea sesame-based ready-
 527 to-use therapeutic food in malnourished HIV-positive adults. *Patient Prefer. Adherence* 3, 67–75.
- 528 Birch, L.L., Marlin, D.W., 1982. I don't like it; I never tried it: effects of exposure on two-year-old children's
 529 food preferences. *Appetite* 3, 353–360. doi:10.1016/S0195-6663(82)80053-6
- 530 Björck, I., Noguchi, A., Asp, N.G., Cheftel, J.C., Dahlqvist, A., 1983. Protein nutritional value of a biscuit
 531 processed by extrusion cooking: effects on available lysine. *J. Agric. Food Chem.* 31, 488–492.
 532 doi:10.1021/jf00117a006
- 533 Black, M.M., Walker, S.P., Wachs, T.D., Ulkuer, N., Gardner, J.M., Grantham-McGregor, S., Lozoff, B., Engle,
 534 P.L., 2008. Policies to reduce undernutrition include child development. *Psychol. Child Dev.* 1.
- 535 Black, R.E., Allen, L.H., Bhutta, Z.A., Caulfield, L.E., de Onis, M., Ezzati, M., Mathers, C., Rivera, J., Maternal
 536 and Child Undernutrition Study Group, 2008. Maternal and child undernutrition: global and
 537 regional exposures and health consequences. *Lancet* 371, 243–260. doi:10.1016/S0140-
 538 6736(07)61690-0
- 539 Black, R.E., Victora, C.G., Walker, S.P., Bhutta, Z.A., Christian, P., de Onis, M., Ezzati, M., Grantham-
 540 McGregor, S., Katz, J., Martorell, R., Uauy, R., Maternal and Child Nutrition Study Group, 2013.
 541 Maternal and child undernutrition and overweight in low-income and middle-income countries.
 542 *Lancet* 382, 427–451. doi:10.1016/S0140-6736(13)60937-X
- 543 Brown, K.H., Sanchez-Griñan, M., Perez, F., Peerson, J.M., Ganoza, L., Stern, J.S., 1995. Effects of dietary
 544 energy density and feeding frequency on total daily energy intakes of recovering malnourished
 545 children. *Am. J. Clin. Nutr.* 62, 13–18.
- 546 Cohuet, S., Marquer, C., Shepherd, S., Captier, V., Langendorf, C., Ale, F., Phelan, K., Manzo, M.L., Grais,
 547 R.F., 2012. Intra-household use and acceptability of Ready-to-Use-Supplementary-Foods distributed
 548 in Niger between July and December 2010. *Appetite* 59, 698–705. doi:10.1016/j.appet.2012.07.019
- 549 De Pee, S., Bloem, M.W., 2009. Current and potential role of specially formulated foods and food
 550 supplements for preventing malnutrition among 6- to 23-month-old children and for treating
 551 moderate malnutrition among 6- to 59-month-old children. *Food Nutr. Bull.* 30, S434–463.
- 552 Flax, V.L., Phuka, J., Cheung, Y.B., Ashorn, U., Maleta, K., Ashorn, P., 2010. Feeding patterns and behaviors
 553 during home supplementation of underweight Malawian children with lipid-based nutrient
 554 supplements or corn-soy blend. *Appetite* 54, 504–511. doi:10.1016/j.appet.2010.02.003
- 555 Flax, V.L., Thakwalakwa, C., Phuka, J., Ashorn, U., Cheung, Y.B., Maleta, K., Ashorn, P., 2009. Malawian
 556 mothers' attitudes towards the use of two supplementary foods for moderately malnourished
 557 children. *Appetite* 53, 195–202. doi:10.1016/j.appet.2009.06.008
- 558 Graneheim, U.H., Lundman, B., 2004. Qualitative content analysis in nursing research: concepts, procedures
 559 and measures to achieve trustworthiness. *Nurse Educ. Today* 24, 105–112.
 560 doi:10.1016/j.nedt.2003.10.001
- 561 Grillenberger, M., Neumann, C.G., Murphy, S.P., Bwibo, N.O., van't Veer, P., Hautvast, J.G.A.J., West, C.E.,
 562 2003. Food supplements have a positive impact on weight gain and the addition of animal source
 563 foods increases lean body mass of Kenyan schoolchildren. *J. Nutr.* 133, 3957S–3964S.
- 564 Hess, S.Y., Bado, L., Aaron, G.J., Ouédraogo, J.-B., Zeilani, M., Brown, K.H., 2011. Acceptability of zinc-
 565 fortified, lipid-based nutrient supplements (LNS) prepared for young children in Burkina Faso.
 566 *Matern. Child. Nutr.* 7, 357–367. doi:10.1111/j.1740-8709.2010.00287.x

- 567 Hoppe, C., Andersen, G.S., Jacobsen, S., Mølgaard, C., Friis, H., Sangild, P.T., Michaelsen, K.F., 2008. The use
568 of whey or skimmed milk powder in fortified blended foods for vulnerable groups. *J. Nutr.* 138,
569 145S–161S.
- 570 Kuusipalo, H., Maleta, K., Briend, A., Manary, M., Ashorn, P., 2006. Growth and change in blood
571 haemoglobin concentration among underweight Malawian infants receiving fortified spreads for 12
572 weeks: a preliminary trial. *J. Pediatr. Gastroenterol. Nutr.* 43, 525–532.
- 573 Kvale, S., 1996. Interviews. An Introduction to Qualitative Research Interviews. SAGE Publications,
574 Thousand Oaks.
- 575 LaGrone, L.N., Trehan, I., Meuli, G.J., Wang, R.J., Thakwalakwa, C., Maleta, K., Manary, M.J., 2012. A novel
576 fortified blended flour, corn-soy blend “plus-plus,” is not inferior to lipid-based ready-to-use
577 supplementary foods for the treatment of moderate acute malnutrition in Malawian children. *Am.*
578 *J. Clin. Nutr.* 95, 212–219. doi:10.3945/ajcn.111.022525
- 579 Lazzerini, M., Rubert, L., Pani, P., 2013. Specially formulated foods for treating children with moderate
580 acute malnutrition in low- and middle-income countries. *Cochrane Database Syst. Rev.* 6,
581 CD009584. doi:10.1002/14651858.CD009584.pub2
- 582 Matilsky, D., Maleta, K., Castleman, T., Manary, M., 2009. Supplementary Feeding with Fortified Spreads
583 Results in Higher Recovery Rates Than with a Corn/Soy Blend in Moderately Wasted Children. *J.*
584 *Nutr.* 139, 773–778.
- 585 Ministère de la Santé, Burkina Faso, Direction de la Nutrition. Rapport Enquete Nutritionnelle Nationale,
586 2013.
- 587 Nackers, F., Broillet, F., Oumarou, D., Djibo, A., Gaboulaud, V., Guerin, P.J., Rusch, B., Grais, R.F., Captier, V.,
588 2010. Effectiveness of ready-to-use therapeutic food compared to a corn/soy-blend-based pre-mix
589 for the treatment of childhood moderate acute malnutrition in Niger. *J. Trop. Pediatr.* 56, 407–413.
590 doi:10.1093/tropej/fmq019
- 591 Owino, V.O., Irena, A.H., Dibari, F., Collins, S., 2014. Development and acceptability of a novel milk-free
592 soybean-maize-sorghum ready-to-use therapeutic food (SMS-RUTF) based on industrial extrusion
593 cooking process. *Matern. Child. Nutr.* 10, 126–134. doi:10.1111/j.1740-8709.2012.00400.x
- 594 Paul, K.H., Dickin, K.L., Ali, N.S., Monterrosa, E.C., Stoltzfus, R.J., 2008. Soy-and rice-based processed
595 complementary food increases nutrient intakes in infants and is equally acceptable with or without
596 added milk powder. *J. Nutr.* 138, 1963–1968.
- 597 Rowe, J.P., Brodegard, W.C., Pike, O.A., Steele, F.M., Dunn, M.L., 2008. Storage, preparation, and usage of
598 fortified food aid among Guatemalan, Ugandan, and Malawian beneficiaries: a field study report.
599 *Food Nutr. Bull.* 29, 213–220.
- 600 Sjaak van der Geest, Meulenbroek, Adèle, 1993. Metaphors, Metonyms and Homeopathy: Terms of Illness
601 and Therapy among Mossi People in Burkina Faso. *Congrès Eur. Kolloqu. Ethnopharmakologie* 285–
602 290.
- 603 Suarez, F.L., Springfield, J., Furne, J.K., Lohrmann, T.T., Kerr, P.S., Levitt, M.D., 1999. Gas production in
604 human ingesting a soybean flour derived from beans naturally low in oligosaccharides. *Am. J. Clin.*
605 *Nutr.* 69, 135–139.
- 606 Ventura, A.K., Worobey, J., 2013. Early influences on the development of food preferences. *Curr. Biol.* CB
607 23, R401–408. doi:10.1016/j.cub.2013.02.037
- 608 Wang, R.J., Trehan, I., Lagrone, L.N., Weisz, A.J., Thakwalakwa, C.M., Maleta, K.M., Manary, M.J., 2013.
609 Investigation of Food Acceptability and Feeding Practices for Lipid Nutrient Supplements and
610 Blended Flours Used to Treat Moderate Malnutrition. *J. Nutr. Educ. Behav.* 45, 258–263.
611 doi:10.1016/j.jneb.2012.08.001
- 612 Whyte, S.R., Geest, S. van der, Hardon, A., 2002. *Social Lives of Medicines*. Cambridge University Press.
- 613 World Health Organization, 2012. World Health Organization. Technical note: supplementary foods for the
614 management of moderate acute malnutrition in infants and children 6-59 months of age.

615 Young, S.L., Blanco, I., Hernandez-Cordero, S., Pelto, G.H., Neufeld, L.M., 2010. Organoleptic properties,
 616 ease of use, and perceived health effects are determinants of acceptability of micronutrient
 617 supplements among poor Mexican women. *J. Nutr.* 140, 605–611. doi:10.3945/jn.109.113498
 618
 619

620 Tables

Table 1. Food composition table of the 12 experimental supplementary foods

| Product | Unit | WHO Technical Note | CSB per 120 g ⁴ | | | | | | LNS per 92 g | | | | | |
|--------------------------|------|---------------------------------|----------------------------|-------|-------|---------|---------|---------|--------------|-------|-------|---------|---------|---------|
| | | 2012 ²³ | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Energy | Kcal | 500 | 500 kcal | | | | | | 500 kcal | | | | | |
| Fat | g | 12.5-32.5 | 11,4 | 11,7 | 11,4 | 11,4 | 11,4 | 11,4 | 31,6 | 31,5 | 32,1 | 31,4 | 31,5 | 31,4 |
| Protein | g | 10-21.5 | 16,8 | 16,5 | 16,5 | 15,9 | 16,2 | 16,5 | 13,5 | 13,5 | 13,1 | 12,5 | 12,8 | 13,1 |
| Soy quality ⁵ | | | Flour | Flour | Flour | Isolate | Isolate | Isolate | Flour | Flour | Flour | Isolate | Isolate | Isolate |
| DSM ⁶ | % | | 0 | 8 | 20 | 0 | 8 | 20 | 0 | 8 | 20 | 0 | 8 | 20 |
| Calcium | mg | 500-700 | 600 | | | | | | 600 | | | | | |
| Iron | mg | 9 ⁷ -15 ⁸ | 12 | | | | | | 12 | | | | | |
| Magnesium | mg | 140-210 | 175 | | | | | | 175 | | | | | |
| Phosphorus ⁹ | mg | 425-700 | 563 | | | | | | 563 | | | | | |
| Potassium | mg | 750-1100 | 925 | | | | | | 925 | | | | | |
| Sodium | mg | max 250 | <250 | | | | | | <250 | | | | | |
| Zinc | mg | 10-17.5 | 14 | | | | | | 14 | | | | | |
| Copper | mg | 0.5-1.8 | 1.15 | | | | | | 1.15 | | | | | |
| Manganese | mg | 0.5-1.0 | 0.75 | | | | | | 0.75 | | | | | |
| Selenium | µg | 17.5-45 | 31.5 | | | | | | 31.5 | | | | | |
| Iodine | µg | 75-175 | 125 | | | | | | 125 | | | | | |
| Vitamin C | mg | > 75 | 188 | | | | | | 94 | | | | | |
| Thiamin B1 | mg | > 0.5 | 1.0 | | | | | | 0.65 | | | | | |
| Riboflavin B2 | mg | > 2.0 | 3.0 | | | | | | 2.5 | | | | | |
| Niacin | mg | > 12.5 | 20.2 | | | | | | 15.5 | | | | | |
| Pantothenic acid | mg | > 2.5 | 4.5 | | | | | | 3.2 | | | | | |
| Vitamin B6 | mg | > | 1.8 | | | | | | 1.25 | | | | | |
| Folic acid | µg | > 200 | 300 | | | | | | 250 | | | | | |
| Biotin | µg | > 10 | 13.8 | | | | | | 12.5 | | | | | |

² The specifications are calculated as an example when food supplements provide 70% of energy. Note. This is not a recommendation that food supplements should constitute 70% energy intake of MM children. The formulation is such that it would be safe and effective if the quantity taken by MM children represented 100% energy needs and it would also provide benefit, though of a lesser order of magnitude, if taken in lower quantities (World Health Organization, 2012)

³ The energy density of food supplements when they are ready to be consumed (i.e. cooked foods ready for consumption or ready-to-use foods) should be not less than 0.8 kcal/g (World Health Organization, 2012)

⁴ Some of the water soluble vitamins have been overdosed, in order to compensate for the degraded vitamins during preparation of CSB (GC Rieber Compact A/S)

⁵ Flour = Dehulled soya flour; Isolate = Soy protein isolate

⁶ Percentage of total weight

⁷ assuming a 10 % bioavailability (World Health Organization, 2012)

⁸ assuming a 5% bioavailability (World Health Organization, 2012)

⁹ excluding Phosphorus from phytate because it is not bioavailable (World Health Organization, 2012)

| | | | | |
|--------------|----|-------------|------|------|
| Vitamin B 12 | µg | 2.5 | 4.1 | 3.15 |
| Retinol | µg | 1000 - 1500 | 1375 | 1250 |
| Vitamin E | mg | > 15 | 22.8 | 19 |
| Vitamin D | µg | 10-30 | 22.0 | 20 |
| Vitamin K | µg | 25 | 34.7 | 31.5 |

Accepted Manuscript

621

622

Table 2. Baseline characteristics among 180 children

| Product | CSB | | | | | | LNS | | | | | |
|--|--------------|------------|------------|-------------|------------|------------|--------------|------------|------------|-------------|-------------|-------------|
| | Dehulled Soy | | | Soy Isolate | | | Dehulled Soy | | | Soy Isolate | | |
| DSM % | 0% (1) | 20% (2) | 50% (3) | 0% (4) | 20% (5) | 50% (6) | 0% (7) | 20% (8) | 50% (9) | 0% (10) | 20% (11) | 50% (12) |
| Participants | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 | 15 |
| Age (months) mean (\pmSD) | 13 \pm 5 | 15 \pm 5 | 12 \pm 6 | 14 \pm 6 | 15 \pm 7 | 15 \pm 5 | 15 \pm 5 | 14 \pm 5 | 13 \pm 5 | 15 \pm 6 | 16 \pm 5 | 12 \pm 5 |
| Males % (n) | 73(11) | 53(8) | 40(6) | 67(10) | 73(11) | 80(12) | 67(10) | 60(9) | 40(6) | 80 (12) | 47(7) | 67(10) |
| Breastfeeding % (n) | 100(15) | 100(15) | 100(15) | 93(14) | 93(14) | 100(15) | 93(14) | 87 (13) | 93(14) | 100(15) | 80(12) | 100(15) |
| <u>Health status at inclusion¹⁰</u> | | | | | | | | | | | | |
| Healthy % (n) | 86(13) | 86(13) | 87(13) | 79(11) | 66(10) | 93(14) | 80(12) | 73(11) | 73(11) | 80(12) | 93(14) | 80(12) |
| Light illness, no medication % (n) | 7(1) | 7(1) | 13(2) | 7(1) | 27(4) | 7(1) | 20(3) | 27(4) | 20(3) | 20(3) | 7(1) | 20(3) |
| Moderate illness, medication but no hospitalization % (n) | 7(1) | 7(1) | 0 | 14(2) | 7(1) | 0 | 0 | 0 | 7(1) | 0 | 0 | 0 |

¹⁰ Missing data on one participant in the CSB SI 0%-group

Table 3. Estimated mean perception (scale from 1 to 5¹¹) of the 12 experimental foods at two visits

| Product | Soy quality DSM (%) | CSB | | | | | | LNS | | | | | | Mean per visit | 95% CI | P-values | | |
|-------------------------|------------------------|--------------|------------|------------|-------------|------------|------------|--------------|------------|------------|-------------|-------------|-------------|----------------------|-----------|---|-------------------------------------|-----------------------------------|
| | | Dehulled Soy | | | Soy Isolate | | | Dehulled Soy | | | Soy Isolate | | | | | product-visit interaction [†] | product main effect [‡] | visit main effect [‡] |
| | | 0% (1) | 20% (2) | 50% (3) | 0% (4) | 20% (5) | 50% (6) | 0% (7) | 20% (8) | 50% (9) | 0% (10) | 20% (11) | 50% (12) | | | | | |
| Child's appreciation | Visit 1 | 3.7 | 3.8 | 3.7 | 4.1 | 4.0 | 4.1 | 3.6 | 4.1 | 4.1 | 4.3 | 4.1 | 4.1 | 4.0 | [3.9-4.1] | 0.63 | 0.24 | <i>0.012</i> |
| | Visit 2 | 4.1 | 4.3 | 4.1 | 4.1 | 4.2 | 4.3 | 4.0 | 3.9 | 4.3 | 4.1 | 4.3 | 4.2 | 4.2 | [3.9-4.4] | | | |
| General perception | Visit 1 | 4.1 | 3.9 | 4.1 | 4.2 | 4.1 | 4.0 | 4.0 | 4.1 | 4.3 | 4.1 | 4.1 | 4.1 | 4.1 | [3.9-4.2] | 0.4 | 0.11 | 0.66 |
| | Visit 2 | 4.1 | 4.1 | 4.1 | 3.9 | 4.0 | 4.1 | 4.0 | 4.0 | 4.3 | 4.0 | 4.1 | 4.1 | 4.1 | [4.0-4.1] | | | |
| Taste | Visit 1 | 3.8 | 3.5 | 3.8 | 3.9 | 3.5 | 3.8 | 3.8 | 3.9 | 4.1 | 3.8 | 3.9 | 4.0 | 3.8 | [3.7-3.9] | 0.48 | 0.23 | <i><0.001</i> |
| | Visit 2 | 4.1 | 4.1 | 4.0 | 4.2 | 4.0 | 3.8 | 3.9 | 3.9 | 4.1 | 4.0 | 4.3 | 4.1 | 4.0 | [3.8-4.3] | | | |
| Odor | Visit 1 | 4.0 | 3.7 | 3.9 | 3.7 | 4.0 | 4.1 | 3.9 | 3.9 | 3.9 | 3.9 | 4.0 | 4.0 | 3.9 | [3.9-4.0] | 0.68 | 0.86 | 0.8 |
| | Visit 2 | 4.0 | 4.0 | 3.9 | 3.9 | 3.9 | 3.9 | 4.0 | 3.9 | 3.9 | 3.8 | 3.8 | 3.9 | 3.9 | [3.8-4.1] | | | |
| Colour | Visit 1 | 4.2 | 4.1 | 4.1 | 4.1 | 3.8 | 4.1 | 3.9 | 4.0 | 4.2 | 4.0 | 4.1 | 3.9 | 4.0 | [4.0-4.1] | 0.66 | 0.27 | 0.09 |
| | Visit 2 | 4.0 | 4.0 | 4.0 | 4.0 | 4.0 | 4.0 | 4.0 | 3.9 | 4.0 | 3.9 | 4.0 | 3.8 | 4.0 | [3.9-4.1] | | | |
| Texture | Visit 1 | 3.5 | 3.6 | 3.9 | 3.9 | 3.9 | 3.7 | 3.7 | 3.7 | 3.9 | 4.1 | 3.8 | 3.6 | 3.8 | [3.7-3.8] | <i>0.01</i> | - | - |
| | Visit 2 | 4 | 4 | 3.9 | 4 | 4 | 4 | 3.9 | 3.7 | 3.9 | 3.7 | 4 | 3.8 | 3.9 | [3.8-4.1] | | | |

623

¹¹ Organoleptic ratings on a 5 point hedonic scale where 1=dislike very much, 2= dislike, 3=neither like or dislike, 4 =like, 5= like very much

[†] Evaluation of differences between combinations of product and visit effects by means of linear mixed models with adjustment for age and sex and differences between children (random effects) .

[‡] In case product-visit interaction is non-significant, evaluation of differences between products (also using linear mixed models)

[‡] In case product-visit interaction is non-significant, evaluation of differences between the two visits (also using linear mixed models).

Table 4. Leftovers during take home test on 179 children

| Product | Soy quality | DSM % | CSB | | | | | | LNS | | | | | | Total | P-value |
|---------------------------------|-------------|-------|--------------|----------|--------|-------------|--------|--------|--------------|--------|--------|-------------|---------|--------|---------|---------|
| | | | Dehulled Soy | | | Soy Isolate | | | Dehulled Soy | | | Soy Isolate | | | | |
| | | | 0% | 20% | 50% | 0% | 20% | 50% | 0% | 20% | 50% | 0% | 20% | 50% | | |
| | | | (1) | (2) | (3) | (4) | (5) | (6) | (7) | (8) | (9) | (10) | (11) | (12) | | |
| Left-over at the end of the day | % (n) | | 67 (10) | 53 (8) | 64 (9) | 60 (9) | 47 (7) | 60 (9) | 67 (10) | 27 (4) | 47 (7) | 40 (6) | 13 (2) | 27 (4) | 48 (85) | 0.037 |
| | CSB vs LNS | | 58 (52) | | | | | | 37 (33) | | | | | | | 0.004 |
| Quantity of left-over | < than half | | 40 (4) | 37.5 (3) | 45 (4) | 62.5 (5) | 43 (3) | 50 (4) | 40 (4) | 75 (3) | 50 (3) | 50 (3) | 100 (2) | 50 (2) | 49 (40) | 0.84 |
| | half | | 50 (5) | 37.5 (3) | 33 (3) | 37.5 (3) | 57 (4) | 50 (4) | 30 (3) | 25 (1) | 50 (3) | 33 (2) | 0 | 50 (2) | 40 (33) | |
| | > than half | | 10 (1) | 25 (2) | 22 (2) | 0 | 0 | 0 | 30 (3) | 0 | 0 | 17 (1) | 0 | 0 | 11 (9) | |

Table 5. Administration of products during take-home test on 179 children

| Product | | CSB | LNS | |
|---|-----------------|------------|------------|-------------|
| Frequency of feeding/day, | Mean (Std. Err) | 2.8 (0.08) | 2.3 (0.07) | 0.000 |
| Administration of the products % (n) | difficult | 1 (1) | 0 | 0.6 (1) |
| | indifferent | 1 (1) | 0 | 0.6 (1) |
| | easy | 96 (84) | 97 (85) | 96 (169) |
| | very easy | 2 (2) | 3 (3) | 2.8 (5) 0.5 |

Accepted Manuscript

Accepted Manuscript