6-15-2020

Icon-based Digital Food Allergen Labels for Complementation of Text-based Declaration

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ICON-BASED DIGITAL FOOD ALLERGEN LABELS FOR COMPLEMENTATION OF TEXT-BASED DECLARATIONS

Research paper

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Abstract

Food allergen declarations on packaged products lack coherent regulation, standardisation and therefore manifest in a variety of terminology. This unfortunately leads to a magnitude of preventable allergy-related outbreaks and emergencies, as consumers rely on allergen declaration for self-management. Together with dieticians, we therefore developed a purchase-related barcode scanning mHealth application that utilises a standardised taxonomy of food allergens for the display of user-friendly digital food allergen labels. The application design allowed for an in-the-wild randomised controlled trial, randomly attributing users to two treatment groups that either received icon-based or text-based digital food allergen labels. 74 users met the eligibility criteria for our study. The findings suggest that users in both groups use the application similarly frequently, but users perceive icon-based allergen labels more recommendable and more useful than text-based labels. Especially, users with low fluency in the local language (German), and frequent travellers, both segments prone to food allergy related emergencies, prefer the icon-based label, indicating that standardised, icon-based digital food allergen declarations can complement current text-based declarations. Especially users who are travelling internationally or are non-fluent in their local language can benefit from language-agnostic icon-based digital food allergen labels.

Keywords: Food allergy, mHealth, visualisation, digital food allergy label, nutrition.

1 Motivation

The rate of population affected by food allergies is rising globally, constituting an increasing burden on health-care systems and patients alike. Today, the prevalence of food allergies affects an estimated 10% of population (Sicherer and Sampson, 2018, 2014). While the exact drivers of this development are still not fully understood, suspected factors include consumption of processed foods, surge in diet-related diseases, increased hygiene, as well as environmental and (epi-)genetic interactions (Sicherer and Sampson, 2018, 2014). Affected patients experience adversarial health responses mediated by their immune system, resulting in hypersensitive reactions to certain kinds of foods. Such post-exposure onsets depend very much on individual level of sensitivity and include rashes, hives, itching, swelling, diarrhoea, nausea, running or congested noses, vomiting, as well as more serious and potentially life-threatening consequences such as wheezing, cyanosis, fainting, anaphylactic shocks (Sicherer and Sampson, 2018, 2014; Umasunthar et al., 2015). Within the United States (US) alone, it is estimated that food allergies account for annual healthcare costs of over 25 billion USD (Gupta et al., 2013), and cause roughly 30'000) emergency room visits and 150 deaths per year (FDA, 2017).

In absence of a cure, effective management of food allergies usually requires strict avoidance of relevant allergens (Sicherer and Sampson, 2018), often hindered by non-standardized food labels (Versluis et al., 2015). Although future therapies might be able to mitigate or even reserve food allergies, current best practice today is patient compliance with strict avoidance of food items containing allergens (Sicherer and Sampson, 2018). Unfortunately, when making food choices, consumers are confronted with non-regulated allergen declaration on food packages (Sicherer and Sampson, 2018). While consumers believe that allergen declaration is regulated, it is in fact subject to far less regulation than expected (Sicherer and Sampson, 2018). Especially the precautionary allergen labelling (PAL) (Marchisotto et al., 2017) is voluntary and has lots of varying definitions, terminologies and no threshold amounts (Marchisotto et al., 2017; Sicherer and Sampson, 2018; Versluis et al., 2015), leaving customers confused and researchers calling for a global definition of food allergens (Allen et al., 2014). Nevertheless, geographic regions still differ in their mandates to declare allergen presence in food: For example, while the European Union (EU) (EU-1169/2011, 2014) requires the declaration of 14 different allergens, the US only requires declaration of eight allergens (FDA, 2017). The varying, non-standardized implementations of allergen declarations on packaged foods represent one of the largest drivers of food allergy related emergencies which are especially difficult to manage when happening during consumption of packaged foods at home (Versluis et al., 2015).

2 Related Work

2.1 Purchase-related mHealth

Mobile Health (mHealth) offers the opportunity for pervasive yet context adaptive health behavior interventions (Goldstein et al., 2017). Research on food allergy related mHealth primarily focusses on patients under ongoing medical supervision by a physician, e.g. in de-sensitization therapies. Such mHealth focus on the initial diagnosis and diagnostic refinement of food allergies (Waibel et al., 2019). However, with only few exception assessing products for a single food allergy (e.g. gluten) (Dunford and Neal, 2017), or limited technical prototypes (Frey et al., 2016), such purchase-related mHealth apps supporting allergy affected patients in food purchasing are not yet discussed in detail. This is counter-intuitive, as similar purchase-related mHealth aimed at improving purchase decisions based on the assessment of macro-nutrients have been already been discussed and adopted by consumers (Dunford et al., 2014; Mhurchu et al., 2019; Volkova et al., 2016). Front-of-package labels (FoPL), food labels in general, and in turn also standardized allergen labels are hard to regulate and implement for food producers, brands and retails (Dunford et al., 2014; Julia et al., 2017; Volkova et al., 2016). Food producers fear the costs, administrative burden, potential loss of revenue upon introduction of novel labelling standards. In addition, production processes, product lifetime cycles and potentially competing standards hinder the implementation of globally standardized allergen labels (Allen et al., 2014). Nonetheless, since most packaged products within a retail environment carry a product-specific barcode identifier (Brock, 2001) and most consumers carry a smartphone (Dunford et al., 2014), purchase-related mHealth applications are a promising channel for informing users on present allergens after scanning a barcode of a product. Such purchase-related mHealth for pre-consumption detection of present allergens offers advantages for consumers. First, mHealth is inclusive, since most packaged food products carry a product-specific barcode (Brock, 2001), and most consumers nowadays carry a smartphone (Dunford et al., 2014). Second, in contrast to existing allergy-related mHealth that usually focus on interpreting or treating symptoms of food allergies, such mHealth can provide relevant warnings prior to consumption, especially relevant to preventing anaphylactic shocks at home (Versluis et al., 2015). Third, mHealth can customize the language to the user, thereby overcoming current language barriers of travellers, remote workers or illiterate citizens towards interpretation. This is especially relevant, since food allergies also affect socio-demographics segments prone to illiteracy, who usually do not have access to diagnostics or treatment (Sicherer and Sampson, 2018). Fourth, mHealth can display food allergens in standardized forms, potentially even in accordance to a future, global standard framework (Allen et al., 2014). Fifth, mHealth can extend the scope and include allergens currently not mandated by regulators. This is especially relevant, given that at least 170 different food allergies and triggers exist (Boyce et al., 2010). Last but not least, mHealth can leverage tailoring (Brug et al., 2003) and produce user-specific warnings to reduce the impact of false or vague warnings of possible allergen contamination that are often unhelpful and can contribute to unintentional exposure (Allen et al., 2014; Turner et al., 2011).

Since current allergen declarations use varying terminology, non-standardized items, ill-defined precautionary statements and require above-average literacy to be understood, researchers and practitioners are calling for an easier-to-understand labels (Declaratio, 2019), and a global definition framework (Allen et al., 2014). Therefore, we designed and implemented an application by the name "AllergyScan" and conducted a randomized controlled trial (RCT) to assess design choices for such a system. Specifically, we demonstrate feasibility of mHealth to visualize food product allergen declarations in a novel, i.e. standardized nomenclature of icon-based digital food allergen labels. Further, this study aims to assess whether such language-agnostic icon-based digital food labels can lead to improve usage behavior and intention in comparison to current text-based declarations. We thus address the following research question in this study: do digital food allergen labels improve usage behaviour and intention to use over contemporary text-based allergen labels in mHealth applications?

3 System Design

Similar to many mHealth apps, we relied on a design science approach (Gregor and Hevner, 2013; Hevner et al., 2004; Peffers et al., 2008), which were also applied in similar mHealth research (Fuchs et al., 2016). We hence focus on describing the application design in detail.

3.1 Application Design

We built on previous purchase-related mHealth studies (Dunford et al., 2014; Mhurchu et al., 2019; Volkova et al., 2016) and hence designed and implemented a barcode-scanning mobile application to provide users with digital food allergen labels to collect data on usage behavior within the automated RCT. The application was developed specifically for release within Switzerland. We argue, that the focus on Switzerland does not compromise generalizability to other regions for multiple reasons. First, similar to other developed countries, also Switzerland shows increasing prevalence of diet-related diseases and food allergies which current empirical studies indicate to affect a population rate of 6% (Aha!, 2019). Second, the study team had access to the largest curated product database in Switzerland (GS1-CH, 2018) and extended the product coverage through crowdsourcing, automatic and manual data quality checks, thereby ensuring high data quality product data on nutrients, allergens and ingredients. Similarly, also other regions offer food composition databases as mandated the European regulation on public provision of food composition data (EU-1169/2011, 2014). In total, over 52,750 of the most-frequently purchased food products in Switzerland were available in the study's food product composition database. Third, the study was supported by the Swiss Society for Nutrition (SGE-SSN) with their dietary expertise, with similar national associations also existing in other countries, enabling the adoption of the mHealth intervention towards local customs and cultural aspects. Throughout several iterations with dietary experts from SGE-SSN and multiple rounds of user testing, the final design of the "AllergyScan" was achieved. The app was then published in the Swiss Apple and Android app stores. In the following, its most important functions as identified by users or experts are introduced.

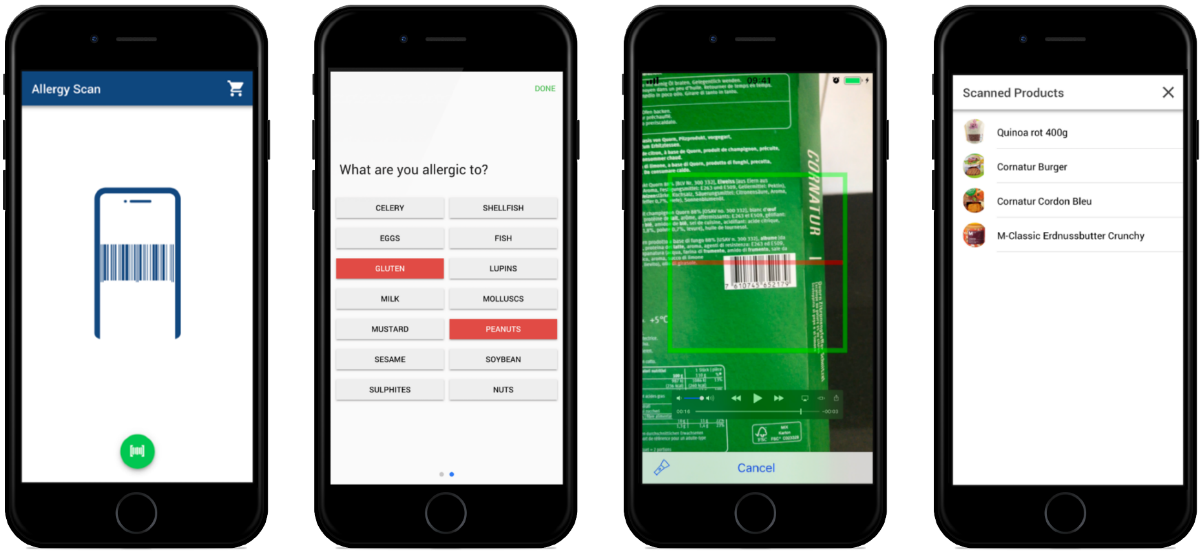

Figure 1. AllergyScan user flow (1.1 home screen, 1.2 user profile, 1.3 scanning, 1.4 scan log)

3.1.1 Barcode Scanning

The app allows barcode scanning by activating the smartphone-integrated camera to capture a product's barcode-encoded global trade item number (GTIN) (Figure 1.3). After having set up a personal profile (Figure 1.2), users can easily access the barcode scanning functionality from the application's home screen (Figure 1.1). After scanning and given that the product exists in the study database, users receive a digital food allergen label, according to their allocation in the RCT.

3.1.2 Display of Product Images

The app displays product details including a product image after scanning a product (Figure 2). This is important for visual confirmation, a key function in the search-phase of purchasing decisions, especially in supermarkets (Clement et al., 2013).

3.1.3 Inclusion of Weighted Products

Products that are weighed before purchasing (e.g. fruit, vegetables, meat, etc.) can carry price-specific barcodes. Conventional barcode-scanning mHealth apps do not correctly identify these products, due to their often uniquely generated barcode. We therefore programmed a reverse-mapping to identify the corresponding base product (2110085000005 = 'Le Gruyère Cheese') of any weighted product (e.g. barcode 2110085004959 identifies 4.95 Swiss Francs of 'Le Gruyère Cheese'). This feature appears important, since weighted products should not be neglected, e.g. cheeses, meat, fish, etc.

3.1.4 Tailoring

Through tailoring, mHealth can adapt interventions to the individual user (Nahum-shani et al., 2014). Especially given the plethora of potential food allergy triggers not captured by current labelling practice (Boyce et al., 2010), a filtering mechanism to not differentiate relevant from irrelevant warnings is needed. Therefore, we allowed users to select if they want to receive warnings for all allergens present in a food item or just relevant ones for their individual profile. Accordingly, users either see i) tailored, i.e. when a user's allergy profile and a food item's allergens conflict (Figure 2.1 and Figure 2.2) or ii) non-tailored warnings of all present allergens (Figure 2.3 and Figure 2.4). Respectively, the label's disclaimer statement differed: Tailored allergen labels stated 'This result is based on your allergy profile. People with a different allergy profile cannot rely on it.' The static labels stated, 'This information is provided by the manufacturer's food package and complies with the legal requirements'.

3.1.5 Usability & Learning

To support users in familiarizing themselves with the app, an introductory tutorial was included. Further, to foster nutritional literacy, the app included educative tips regarding a scanned product's category or nutrients. In total, 130 of such texts and icons were produced by the Swiss Society for Nutrition and shown while loading the list of product substitutes including images from the server.

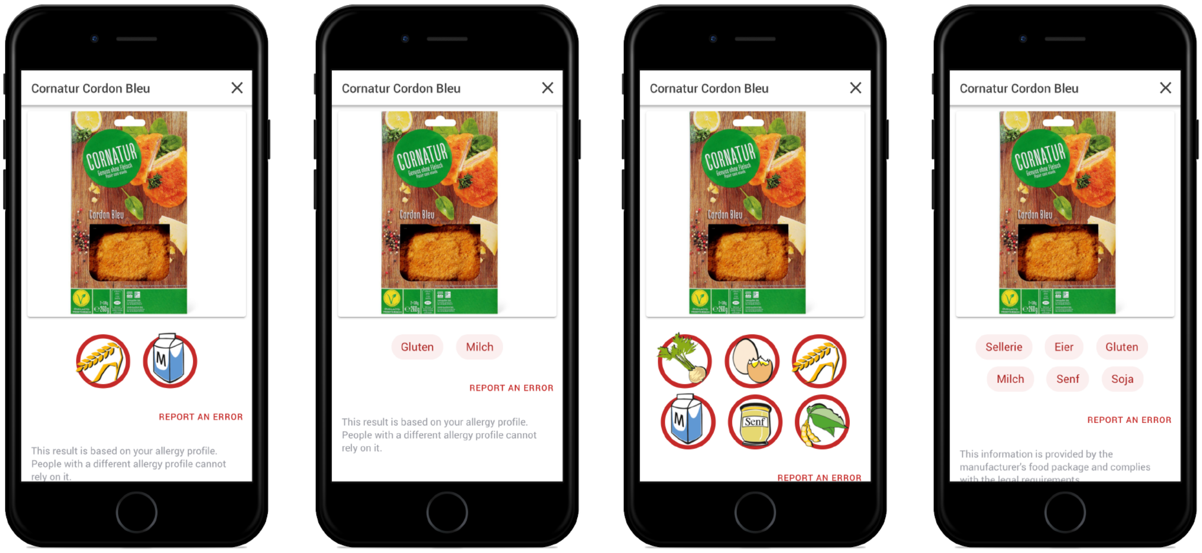

Figure 2. *Digital food allergen labels were icon-based or text-based. Users could select tailored or static warnings. 2.1 icon-tailored, 2.2 text-tailored, 2.3 icon-static, 2.4. text-static.*

3.1.6 Convenience

To support users in identifying healthier choices during shopping, the application allows storing discovered products within an easy-to-access scan log list. From there, a user can quickly access the product details of each stored product in order to check the digital food allergen label (Figure 1.4).

3.1.7 Error Reporting and Crowdsourcing

To continuously improve data quality, users of the 'AllergyScan' app were able to report erroneous data entries. Further, the application would also automatically collect errors, if a product data entry appears to contain errors by applying pre-configured checks (e.g. if an image is present, texts are well defined, ingredients and allergens seem compliant). Also, to collect information on products that were previously not yet in the study database, users were invited to add pictures of the front and back of each product, an established approach in purchase-related mHealth applications (Codecheck, 2016; Dunford et al., 2014; Gigandet, 2019). Research team members would then manually review the collected errors and crowdsourced pictures to implement the necessary changes in the database.

3.1.8 Blocking of Product Categories

To reduce processing of irrelevant items or because of lacking data quality, we blocked certain food categories (medicine, beauty and healthcare products, tobacco, alcohol) or special food categories that ideally require advice from health-care professionals (e.g. baby food, supplements).

4 Methodology

4.1 Icon versus Text-based Allergen Labels

In this study, we want demonstrate feasibility of mHealth to visualize food product allergen declarations in a novel, i.e. standardized nomenclature of icon-based digital food allergen labels and assess whether such language-agnostic icon-based labels can lead to improve usage behavior and intention in comparison to text-based declarations. mHealth can complement or even substitute the current printed, text-based allergen declarations on packaged products through display of alternative icons that follow intuitive, easy-to-understand, purpose-driven design. First, consumer confusion caused by varying terminology and precautionary allergen statements could be mitigated. Further, such icons are promising to be understood by users unable to understand a local language e.g. travellers, migrants, or less educated citizens. This is relevant, as food allergy related emergencies often affect socio-demographics segments prone to illiteracy with less access to treatment (Sicherer and Sampson, 2018).

4.2 Participant Recruitment

The application was made available to smartphone users aged 16 years or older in Switzerland via the iOS and Android app stores. Between November 2018 and March 2020, in total 1641 users installed the AllergyScan application. There was no monetary incentive for users to participate, nor were any promotions used for the study. To observe natural behavior among consumers, users did not receive a study protocol and were free and able to use the app as they wanted.

4.3 Randomized Controlled Trial

In intervention delivery mode, food allergen labels were displayed for products, if matched successfully with an existing product in the database (the rate of successful scans was approximately 72%). To explore the impact of icon-based labels on user behavior, performance expectation and usage intention, we therefore randomly assigned users with either i) language-agnostic, intuitive icon-based labels (‘icons’) (treatment group (TG)) or ii) text-based allergen labels in German (‘text’) (control group (CG)) (as required by local regulation in Switzerland, i.e. one of the official languages). Users were randomly assigned to receive either one of the two visualizations with a probability of 50%. Besides overcoming potential language barriers, the icons also replace the currently ill-defined PAL statements with a simple two stage color scheme. Via text mining, the current text fragments were transposed into either ‘orange’ labels (e.g. trays of allergens may be expected) and ‘red’ labels (explicitly declared presence). The icon-based labels follow a standardized nomenclature to mitigate varying terminology for the allergens (e.g. milk=lactose or wheat=gluten). After randomly allocating users to the two intervention types, the study protocol assessed the impact of icon-based labels on mHealth usage rates, performance expectancy and usage intention. All users’ assignment to their allocation group were static and could not be changed on a device. Generating the digital food allergen labels within the app relied on each product’s corresponding allergen composition in the food composition database, interpreted by the systematic generation of the food allergen labels (see System design).

4.4 Eligibility Checks and Data Collection

The system’s functionalities included automation of the RCT with randomized user segmentation, eligibility screening, intervention delivery, data collection facilitation. The app also included duplicate checks, automatic in-app logic checks, collection of informed consent, questionnaire administration, outcome data collection from usage behavior and survey completion. To gather meaningful results, only eligible users were invited to participate in the study. Therefore, eligible users were required to be affected by at least one food allergy (self-reported within the user profile in the application). Further, users were only invited to participate in the study after a minimum usage of eight product scans on at least four separate days. In addition, the minimum number of successful scans that were found on the study server was set to at least four products. Last but not least, the users that complied with the eligibility criteria were invited via notification in-app to opt into the non-mandatory survey to participate in the study. In total, 74 eligible users completed the survey and opted-in to share their usage statistics. The participation rate of 4% indicates an acceptable response rate for public, non-requested invites to surveys, such as e-mail marketing which often have response rates between 1-5%. In data collection mode, eligible users were invited to share their profile, usage statistics and survey data. The following ethical and security requirements were adhered to: (1) privacy-by-design: all collected data were anonymized on device. No locations or addresses were stored to avoid processing of personalizable data. (2) participant information statement was made available via app store and link.

5 Results

First, we included a descriptive analysis to describe the study sample. Second, we examined usage behavior across the two treatment groups (number of scans and therefore usage behavior of the digital allergen label). Third, we assessed the self-reported survey data. Specifically, self-reported intention-to-use (four items), as well as performance expectation (three items) and effort expectancy between the treatment groups via a one-way ANOVA. We performed a Tukey's honestly significant difference (HSD) post hoc test for items found significant. To prevent confounding of the comparisons, we split the data set into cross-sectional subsegments and compared socio-demographics prone to food allergy emergencies accordingly (i.e. users who are non-fluent in German, or who frequently travelling abroad to countries where they do not speak the language, or who suffer under multiple food allergies).

5.1 Sample Description

Variable	Type	N (%)	Variable	Type	N (%)
Gender	Male	16 (22%)	Age	16-29	32 (43%)
	Female	48 (65%)		30-39	14 (19%)
	Not stated	10 (14%)		40-49	10 (14%)
International travel	Frequent	30 (41%)		50+	8 (11%)
	Occasionally	33 (45%)		Not stated	10 (14%)
	Rarely	11 (15%)	Checking product ingredients	Frequently	61 (82%)
Number of food allergies	One	47 (64%)		Occasionally	13 (18%)
	Two	16 (22%)	Local language skills	Fluent	63 (85%)
	Three or more	11 (15%)		Non fluent	11 (15%)

Table 1. Baseline characteristics of study participants (N=74).

Between November 2018 and March 2020, 1641 users installed the 'AllergyScan' app, of which an acceptable 4.5% met the eligibility criteria and also responded to the non-mandatory study survey (N = 74). Participants in the study had a mean age of 29.97 (SD = 12.66) years. The relatively young age distribution is typical for mHealth studies and does not prevent generalizability. Also, this convenience sample included more females than males, which is a frequent self-selection phenomenon in diet-related studies (Mhurchu et al., 2019). Among the study participants, most frequent food allergies included gluten (N=56, 76%), followed by eggs (N=12, 16%) celery (N=8, 11%), crustaceans, milk and peanuts (each N=7, 9%). This distribution is also in line with publicly available reports on self-declared allergens and intolerances (Aha!, 2019). Most eligible users suffer under one food allergy (N=47, 64%), while roughly one third (N=27, 36%) suffer under at least two food allergies in combination. The majority (82%) states that they have to manually read food items' allergen declarations at least once a week during their purchasing decisions. Regarding international travel, most (N=33, 45%) spend between one and two weeks a year in a country whose language they do not speak. Contrary, similarly many users spend more time abroad internationally (N=30, 41%), and less users stay in

Switzerland for at least 51 weeks a year (N=11, 15%). Among the sample, most users (N=63, 85%) are either native or fluent in German, while a minority (N=11, 15%) only speaks basic or no German at all.

5.2 Usage Statistics

App usage	**All users** (N_{TG}=32, N_{CG}=42)	**Frequent travellers** (N_{TG}=12, N_{CG}=18)	**Not fluent in local language** (N_{TG}=5, N_{CG}=6)
All users	25.95 (21.66)	26.40 (20.02)	23.27 (20.09)
TG: Icon-based	**27.44** (18.84)	**26.83** (11.70)	**35.80** (25.23)
CG: Text-based	24.81 (23.75)	26.11 (21.92)	12.83 (3.13)
ΔTG-CG	2.63	0.72	22.97
P	.61	.92	0.052

Table 2. Usage behavior: Mean (Standard deviation) of usage events, i.e. barcode scans

Between installing the application, and over the course of the at least eight-day long study period during which users had to use the application on at least four different days, and until the time point completing the survey, participants scanned on average 26 products (Table 2). In total, 1920 scans were conducted. One user even scanned 108 products, indicating that such a system can have a high value during the food making process for an individual. This user was in the text-based group and has a high impact in the assessment of the overall, average usage statistics, but was not removed as he passed the survey including manipulation check. A paired t-test across the two treatment groups (CG: text-based, TG: icon-based) showed no significant differences in effect on scanning usage. However, it can be seen that on average, the users with the icon-based digital food label show the tendency to scan 11% more products than users with the text-based declaration. Similarly, there was no significant difference between frequent travellers in usage of icon-based or text-based labels. Still, again there was the tendency observable that icon-based digital food labels were used more than text-based declarations. Finally, albeit at a small sample size, there was a big difference in label usage between users with no or only basic levels of German. Concretely, users with a low proficiency in German scanned over 53% more products in the icon-based group, compared to low proficient users in the text-based control group. Given the small sample size of the hard-to-recruit citizens with a low proficiency who have at least one food allergy, the difference in usage can be considered significant (albeit only at a p-value of 5.2%).

5.3 Usage Antecedents

In the following table (Table 3), we compared the self-reported survey items across three usage antecedents between treatment group (icon-based label) and control group (text-based label), namely intention to use, effort expectancy and performance expectancy. We highlighted the respective group that was perceived superior on the five-item Likert scale in bold.

Overall, the icon-based treatment group was evaluated with relatively higher ratings for all nine out of nine dimensions, with all ratings being higher than neutral (i.e. three on the five-level Likert scale). A two-sided t-test reveals only few significances between the two groups. Significant differences were observable regarding the intention to use and some aspects of performance expectancies (albeit only at a *p*-value of below 10%). Specifically, the intention to use the app in the future is perceived significantly higher within the icon-based treatment group (p=0.025). Overall, the results indicate that icons labels seem to have a lot of non-significant and some significant positive impacts on intention to use and performance expectancy when compared to text-based labels. Similarly, albeit weaker, icon-based labels also seem to have a positive impact on at least some aspects of effort expectancy.

Usage antecedents	All users			Frequent travellers			Low fluency		
	TG (Icon) N=32	**CG (Text) N=42**	***P***	**TG (Icon) N=12**	**CG (Text) N=18**	***P***	**TG (Icon) N=5**	**CG (Text) N=6**	***P***
Intention to use [A]	**4.08** (0.91)	3.56 (1.03)	**0.025**	**4.28** (0.75)	3.70 (1.14)	.14	**4.33** (0.97)	3.33 (0.99)	.13
I would recommend the application to friends.	**4.16** (1.05)	3.62 (1.15)	**0.042**	**4.25** (0.97)	3.61 (1.20)	.13	**4.40** (1.34)	3.50 (1.22)	.27
I will keep using the app in future for regular purchases.	**4.25** (0.91)	3.79 (1.09)	0.057	**4.25** (0.62)	3.94 (1.11)	.39	**4.20** (0.83)	3.50 (0.83)	.20
I will keep using the app in future during travelling abroad.	**3.84** (1.22)	3.26 (1.34)	0.059	**4.33** (0.98)	3.56 (1.42)	.11	**4.40** (0.89)	3.00 (1.26)	0.068
Performance expectancy [A]	**3.93** (0.82)	3.57 (1.01)	0.09	**4.17** (0.63)	3.67 (1.10)	.17	**4.53** (0.51)	3.83 (0.72)	.10
The app supports me in identifying products that I am allergic to.	**4.00** (0.92)	3.62 (1.01)	0.099	**4.25** (0.62)	3.67 (1.12)	.13	**4.60** (0.55)	3.67 (0.82)	.058
The app saves time, as I do not need to check the list of ingredients for potential allergens myself.	**3.91** (1.06)	3.45 (1.19)	0.093	**4.25** (0.87)	3.50 (1.34)	0.098	**4.60** (0.55)	3.50 (1.05)	.065
I like the application and rate it highly.	**3.91** (0.77)	3.64 (1.28)	.31	**4.00** (0.74)	3.83 (1.29)	.69	**4.40** (0.55)	4.33 (1.03)	.90
Effort expectancy [A]	**3.85** (0.88)	3.68 (0.89)	.41	**3.92** (0.78)	3.68 (1.04)	.42	**3.73** (1.09)	3.67 (0.91)	.92
The app is convenient to use for detection of allergens in a product.	**3.75** (0.62)	3.45 (1.06)	.26	**3.83** (1.03)	3.44 (1.24)	.38	**3.80** (1.30)	3.67 (0.82)	.84
The app's visualization format makes it easy to notice allergens in a product.	**3.91** (1.02)	3.79 (1.05)	.62	**4.00** (0.95)	3.72 (1.18)	.50	**4.20** (1.30)	4.17 (0.98)	.96
Using the app is worth my time.	**3.91** (0.93)	3.81 (0.94)	.66	**4.08** (1.08)	3.89 (1.02)	.62	**4.20** (1.30)	3.67 (0.82)	.43

Table 2. Likert scale in survey: 1 (strongly disagree) to 5 (strongly agree)
[A]: equally weighted sums of all three sub-items below

Next, we compare the socio-demographic segments prone to food allergy related emergencies, i.e. travellers that frequently spend time in countries where they do not speak the local language, as well as users who are not fluent in the local language. Therefore, both groups are exposed to the risk of accidently purchasing food items that contain relevant allergens, as text-based declarations in a local language might not be helpful to them. To prevent confounding, only the relevant cross-sections among within the icon-based treatment group and text-based control group are selected, leading to small sample sizes. Concretely, frequent travellers (i.e. spending at least two weeks a year in a country of which the user does not speak the language of) do not show significant differences between icons and text-based labels. Still, the tendency to prefer icons is even stronger than in the overall group, as the absolute ratings as well as the differences between the groups are reported more favourable towards the icons. Similarly, users who only have no or only basic fluency in German rate, give very high intention to use ratings in comparison to the German text-based version (albeit not significant, due to the low sample size).

6 Discussion

In this paper we developed, implemented and assessed a novel icon-based digital food allergen labels to overcome the existing limitations of contemporary food allergy declaration printed on packaged products. First, the introduction of icon-based labels that follow a standardized nomenclature instead of text-based declarations with their varying terminology. Also, the application allowed for a novel tailoring approach of digital food allergen labels towards the individual consumer instead of declaring all allergens to all users at all times. This exploratory study was conducted as a fully automated RCT across 74 users who fulfilled the eligibility criteria, agreed to anonymously sharing their usage behavior and successfully completed the non-mandatory study survey.

Benefits of study protocol include the observable potential of icon-based digital food allergy labels on usage behavior and the intention to use, effort expectancy and performance expectancy items assessed in this study, all important usage antecedents towards adopting mHealth applications. Strengths of this study include its rigorous RCT design with strict user assignment to one of the two treatment groups and device-based, privacy-preserving duplicate checks, automatic in-app logic checks, collection of informed consent, questionnaire administration, and outcome data collection from usage behavior and survey completion. To our knowledge, this study was the first food allergy labelling RCT in a real-world setting on digital food allergen labels for packaged products in any store across an entire country. Moreover, the study was able to attract users from different socio-demographic segments, including users with multiple food allergies, low proficiency in the local language (i.e. German) as well as frequent travellers who are often in regions where they do not understand the local language. These segments are important to cater to, as they are especially prone towards suffering post-consumption emergencies such as anaphylactic shocks.

Although icon-based labels did not correlate with significantly, but only a tendency towards, higher application usage when compared to text-based labels, there were some significant in the usage antecedents between icon-based and text-based labels. Concretely, compared to the text-based control group, intention to use was perceived significantly among the overall group. Especially the self-reported future usage intention and recommendablility were significantly higher among the icon-based label group. Further, icon-based food allergy labels scored higher on every single dimension of intention to use when compared to their text-based counterparts. Also, the values for all dimension of intention to use, performance expectancy and effort expectancy were significantly higher than neutral (Likert scale for all items ranked from 1 to 5). Also, the icon-based label was always appreciated more than the text-based alternative, as the ratings were constantly higher than for the text-based declaration. This indicates that icon-based digital food allergen labels indeed have potential to positively impact intention-to-use. Regarding performance expectancy, the positive impact of icon-based labels is weaker, but still positive. More specifically, this study shows that especially in terms of supporting the purchase decision process, icon-based labels perform superior. Regarding effort expectancy, icon-based labels again perform better than text-based labels, especially in the aspect of convenience. Similarly, the mHealth system scores better for intention to use, effort expectancy and performance expectancy among frequent travellers (i.e. users that spend more than two weeks a year in a country of which they do not understand the language), as well as users with low proficiency in German (i.e. the local official language used to declare allergens in text form on packaged products). Albeit not significant due to the low sample sizes, as non-fluent users with at least one food allergy are very hard to recruit, these are promising tendencies that icon-based labels can be helpful for such segments that are prone to food allergy related emergencies.

In summary, the study demonstrated feasibility of mHealth systems to cater to users with food allergies through a standardized nomenclature, thereby overcoming existing barriers of current allergen declaration. In addition, there was a significant increase in the intention to recommend the application when receiving icon-based labels. In conclusion, even despite the fact that there was no observable significant difference in actual label usage, the findings suggest the hypothesized potential of improving at least some important aspects food allergy usage antecedents, especially for users prone to allergy related outbreaks.

The findings of this study ought to be considered with certain limitations. A first key limitation deals with the fact that we selected individual established concepts which we saw as especially relevant in the initial stage of a behavioral change intervention. Future study designs could assess users' compliance and intervention efficacy on actual food selection. The sufficient, yet low sample size (N = 74) may represent another limitation for external validity and may have played a role in limiting the significance of some of the statistical comparisons conducted. Also, the self-selection bias towards female users is limiting the generalization of the gathered insights towards the entire population. The study protocol was rather strict and excluded users who did not have at least one self-reported food allergy (given that only 6% of Swiss citizens suffer under food allergies, recruiting affected users can be rather cost- and effort-intense). It is also worth to mention the low retention rate in this context. As described earlier, only 4.5% of all users decided to participate in the optional, non-supervised study. To increase such figures future studies may thus opt for a more invasive study design, potentially requiring users to complete the survey or to recruit patients supervised by health-care professionals to ensure compliance with the study protocol. In any case, we recommend optimizing and testing the user conversion rate for future studies on purchase-related mHealth. Another important limitation deals with barcode identification. Approximately 72% of barcode scans were successfully identified in the server backend. Even though, data of 52,750 products were available for the study, there are still thousands of products missing in order to cover the product universe of the entire country of Switzerland. This problem is compounded when users frequently buy groceries abroad, as can be the case for users who live or work in border regions. Practitioners and researchers should be aware of the effort involved in preparing and maintaining such a country-wide product database. A statistical power analysis can then be performed to better ensure external validity.

In future works on this field, researchers should assess the concrete needs for users within socio-demographic segments that are more prone to food allergy related emergencies under the current food allergy declaration, e.g. illiterate, low-educated users or travellers. Naturally, research should try to increase the sample size of a future study in order to enable more robust cross-sectional or stratified sampling for the detection of further significant findings through increased statistical power. In addition, we suggest including assessment of the degree of nutritional quality and allergen composition of the scanned products and categories within a future study protocol, to see if icon-based and tailored labels lead to an increased uptake of healthy allergen-free food products. An interesting opportunity for future research on purchase-related mHealth also arises from head-mounted devices such as Microsoft HoloLens or Magic Leap One. Such mixed-reality headsets can enable automatic, passive triggering of icon-based, just-in-time delivered novel digital food allergen labels, as these devices have always-active front-facing cameras and do not require the active user command to scan for barcodes or recognize an item via computer vision, without the need of scanning a barcode (Krizhevsky et al., 2012; Pandey et al., 2017). Especially, since operating a mobile application can be cumbersome while carrying groceries within a fast-pace supermarket environment, such wearable camera devices represent a novel opportunity for passive, adaptive just-in-time interventions (Nahum-shani et al., 2015).

The present study adds to the body of research in meaningful ways. First, the icon-based food allergen labels show positive impact on intention to use and some areas of effort and performance expectancy when compared to text-based labels, suggesting that visual, easy-to-understand food allergen labels indeed have potential to improve constructs relevant for mitigation of food allergy related onsets. Counterintuitively, text-based labels are correlated with higher ratings for trust. This aspect could also be caused by the introduction of the optional tailoring framework for personalization of digital food allergen labels which had not been suggested before. But since tailoring is one of the key advantages of mHealth, researchers, regulators and practitioners should assess the potential negative impacts of tailoring digital food allergen labels on trust. Therefore, consequentially, future applications should include both, i.e. a language-agnostic icon as well as a text-based declaration in the language that the user can understand. Thereby, the text-based presentation that a user is used to, can be complemented by the intuitive icon in order to create awareness for relevant allergens present in a food product. Third, this study shows, that even in absence a global standardization of allergen declaration, mHealth can produce standardized digital food allergen labels after scanning a barcode. Thereby, as this study indicates, consumers, especially travellers, illiterate citizens, elderly with reduced eyesight, low-educated consumers can potentially benefit from improved visualization of mHealth-mediated allergen declaration in the future. Fourth, also the reverse-mapping of weight-encoded barcodes of this study represent a valuable extension to current purchase-related and diet-related mHealth. This is especially relevant, as the reverse-mapping enables barcode-scanning of weighted products, which previously was not possible due to the uniqueness of their price encoding. Especially since weighted products include processed products, their impact on diets cannot be ignored. Fifth, this study contributes to the development of standards on food composition databases such as EuroFIR or LanguaL, which aim to harmonize terminology on ingredients, nutrients and allergens. Besides the important work on standardizing databases, this study suggests that the visualization towards consumers can improve usage of food allergen labels. This study suggests that similar to Nutri-Score (Julia and Hercberg, 2017), intuitive icon-based food allergen labels, in digital or potentially also in printed forms, seem to improve intention to use (especially recommendablility and while travelling) and at least some aspects of performance expectancy. Last but not least, this study does not only yield results for prevention of food allergy related onsets and emergencies, but its insights are also relevant for researchers and practitioners working on mitigation of food intolerances which affect even more consumers (Acker et al., 2017).

As a final note, the introduction and increased usage of novel digital food allergen labels may also represent an approach to further increasing transparency between products' ingredients and consumers. There exists consistent evidence, that the introduction of transparency measures such as FoPL can lead to healthier product reformulation by manufacturers (Volkova et al., 2016). Therefore, novel icon-based digital food allergen labelling could have an additional, indirect health-beneficial effect besides individual improvement of food choices via food reformulation (Volkova et al., 2016), which could not be tested in the current study.

7 Conclusion

In conclusion, this study identified a promising context for mHealth research to expand to. Since mobile medical apps are changing the way the world and health consumers handle their personal health care. These applications allow health consumers to track their own health and make their adjustments according to their lifestyles. In the assessed context of food allergies, this study contributed to identifying a scalable method for the display of digital food allergen labels on users' mobile devices after scanning a barcode identifier. The usage statistics and usage antecedents indicate that especially users who suffer under a language barrier in the local language can benefit from icon-based digital food allergen labels. Further, there exists the tendency that also frequent travellers and all users in general prefer icon-based digital food labels over contemporary allergen declaration. It remains vital to continue researching the ways in which such applications must work to prevent food allergy related onsets and emergencies. Our study contributes to this effort, by examining the promising effect of digital allergen declarations that could complement or even substitute non-standardised text-based declarations.

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