Gregory M. P. O'Hare
Michael J. O'Grady
John O'Donoghue
Patrick Henn (Eds.)

LNICST 320

# Wireless Mobile Communication and Healthcare

8th EAI International Conference, MobiHealth 2019
Dublin, Ireland, November 14–15, 2019
Proceedings

EAI
Springer

# Lecture Notes of the Institute for Computer Sciences, Social Informatics and Telecommunications Engineering 320

More information about this series at http://www.springer.com/series/8197

Gregory M. P. O'Hare ·
Michael J. O'Grady · John O'Donoghue ·
Patrick Henn (Eds.)

# Wireless Mobile Communication and Healthcare

8th EAI International Conference, MobiHealth 2019
Dublin, Ireland, November 14–15, 2019
Proceedings

Springer

*Editors*
Gregory M. P. O'Hare
School of Computer Science and Informatics
University College Dublin
Dublin 4, Ireland

Michael J. O'Grady
School of Computer Science and Informatics
University College Dublin
Dublin, Dublin, Ireland

John O'Donoghue
Malawi eHealth Research Center
Cork, Ireland

Patrick Henn
University College Cork
Cork, Ireland

ISSN 1867-8211 ISSN 1867-822X (electronic)
Lecture Notes of the Institute for Computer Sciences, Social Informatics and Telecommunications Engineering
ISBN 978-3-030-49288-5 ISBN 978-3-030-49289-2 (eBook)
https://doi.org/10.1007/978-3-030-49289-2



This Springer imprint is published by the registered company Springer Nature Switzerland AG
The registered company address is: Gewerbestrasse 11, 6330 Cham, Switzerland

# Preface

MobiHealth 2019 was the 8th in a series of scientific conferences seeking to bring together transdisciplinary expertise from the technological, physiological, medical, and AI domains among others. The conference took place on the campus of University College Dublin (UCD), Ireland, during November 14–15, 2019. Many timely and pertinent mHealth topics covered included: activity recognition, wearable devices, Apps, and sensor platforms, among others. The conference compromised 6 sessions incorporating 26 papers and attracted over 40 attendees from all over the world.

The MobiHealth conference series has been in existence for almost a decade; its commencement closely aligned with the launch of the smartphone and it has continued to remain aligned with many vital developments during this time, in particular sensors and wearable computing. This current time juncture may be especially auspicious for future mobile healthcare paradigms; 5G networks are being launched and offer significant potential to successfully usher in a new era of innovative mobile health services. Such a profound development will undoubtedly give rise to new technical, ethical, legal, and social challenges. Looking forward, future meetings of MobiHealth must seek to keep abreast of these developments, as well as promote innovate pathways for the realization of impactful research and solutions in the mobile health space.

All accepted papers underwent a triple-blind review process, involving members of the Technical Program Committee (TPC) and other external experts. This highly selective review process increased the scientific level of all papers accepted for presentation and subsequent publication. This current volume includes all papers presented during the conference in Dublin.

The editors wish to express their gratitude to the European Alliance for Innovation for their sponsorship and to UCD for hosting the event. The efforts of the TPC in reviewing manuscripts in a timely and professional manner was indispensable to the quality of the conference, and these proceedings. The dedicated efforts of the Local Organizing Committee members for the efficient operation of the conference is acknowledged. We wish to thank all the participants for their efforts in preparing and revising their manuscripts and then making their way to Dublin to present and discuss their work. The editors are acutely aware of the effort expended by the authors, reviewers and Organizing Committee, and consider the publication of these proceedings the culmination of a creative but collaborative journey. It is our fervent hope that these proceedings will serve as an invaluable resource for community and society on the state of the art in mHealth technologies. Finally, we wish to thank the local UCD team on the ground – Eleanor, Nestor, and Karl – for their dedication and efforts to ensure the smooth operation of the conference on the day.

December 2019

Michael O'Grady
Gregory O'Hare
Patrick Henn
John O'Donoghue

# Organization

## Steering Committee

### Chair

| | |
|---|---|
| Imrich Chlamtac | University of Trento, Italy |

### Founding Chair

| | |
|---|---|
| James C. Lin | University of Illinois at Chicago, USA |

### Members

| | |
|---|---|
| Dimitrios Koutsouris | National Technical University of Athens, Greece |
| Janet Lin | University of Illinois at Chicago, USA |
| Arye Nehorai | Washington University in St. Louis, USA |
| Konstantina S. Nikita | National Technical University of Athens, Greece |
| George Papadopoulos | University of Cyprus, Cyprus |
| Oscar Mayora | CREATE-NET, Italy |

## Organizing Committee

### General Chairs

| | |
|---|---|
| Gregory O'Hare | University College Dublin, Ireland |
| Patrick Henn | University College Cork, Ireland |
| Simon Smith | University College Cork, Ireland |
| Michael O'Grady | University College Dublin, Ireland |

### Program Chair

| | |
|---|---|
| John O'Donoghue | University College Cork, Ireland |

### Workshops Chair

| | |
|---|---|
| David Power | University College Cork, Ireland |

### Sponsorship and Exhibits Chairs

| | |
|---|---|
| David Power | University College Cork, Ireland |
| John O'Donoghue | University College Cork, Ireland |

### Publications Chair

| | |
|---|---|
| John O'Donoghue | University College Cork, Ireland |

### Local Arrangement Chair

| | |
|---|---|
| Patrick Henn | University College Cork, Ireland |

### Web Chairs

| | |
|---|---|
| Kevin McGuire | University College Cork, Ireland |
| John O'Donoghue | University College Cork, Ireland |

### Conference Manager

| | |
|---|---|
| Dominika Belisova | EAI |

## Technical Program Committee

| | |
|---|---|
| Alessandro Tognetti | Università di Pisa, Italy |
| Angelo Basteris | Griffith University, Australia |
| Anja Exler | Karlsruhe Institute of Technology (KIT), Germany |
| Athanasios Kakarountas | University of Thessaly, Greece |
| Benard Bene | Imperial College London, UK |
| Bo Andersson | Lund University, Sweden |
| Carlo Emilio Standoli | Politecnico di Milano, Italy |
| Chipo Kanjo | Chancellor College of the University of Malawi, Malawi |
| Chris Watson | Queen's University Belfast, UK |
| Daniel Carter | University of Limerick, Ireland |
| Gregory O'Hare | University College Dublin, Ireland |
| Griphin Baxer | Mzuzu University, Malawi |
| Henry Potts | University College London, UK |
| Holger Kunz | University College London, UK |
| Jane Walsh | NUI Galway, Ireland |
| John O'Donoghue | University College Cork, Ireland |
| John Nelson | University of Limerick, Ireland |
| Kevin Balanda | University College Cork, Ireland |
| Liam Glynn | University of Limerick, Ireland |
| Mary Sibande | Livingstonia University, Malawi |
| Michael O'Grady | University College Dublin, Ireland |
| Nikolaos Papachristou | University of Surry, UK |
| Patrick Henn | University College Cork, Ireland |
| Peter Harrington Palms | GP Surgery, Ireland |
| Philip Fadahunsi | Imperial College London, UK |
| Salma Kammoun | Abdulaziz University Jeddah, Saudi Arabia |
| Simon Smith | University College Cork, Ireland |
| Siobhan O'Connor | University of Edinburgh, UK |
| Zuhal Hussein | Universiti Teknologi MARA, Malaysia |

# Contents

# Mobility and Real-Time Assessment

# Remote Testing of Usability in Medical Apps

Janina Sauer[1,2](✉), Alexander Muenzberg[1,2], Laura Siewert[1], Andreas Hein[2], and Norbert Roesch[1]

[1] University of Applied Sciences Kaiserslautern, Kaiserslautern, Germany
{janina.sauer,alexander.muenzberg,norbert.roesch}@hs-kl.de
[2] Carl von Ossietzky University of Oldenburg, Oldenburg, Germany
{janina.sauer,alexander.muenzberg,andreas.hein}@uni-oldenburg.de

**Abstract.** Usability tests play an important role in any kind of software, as they limit errors and misunderstandings. Especially in the growing market of medical applications it is indispensable, but time-consuming and expensive. In order to improve the quality of medical applications and remove obstacles for developers, a method has been developed that simplifies testing the usability of mobile medical applications and provides additional data on compliance and effectiveness. Because this test method is remote-controlled and asynchronous, finding examiners is simplified. It also allows more subjects to be found and more data to be collected. This increases user experience and achieves more natural results as study participants act in their natural environment. In order to decide whether the app developed is suitable for this remote testing method, a questionnaire was developed to assist in the decision-making process. The described method will be tested in a study.

**Keywords:** Medical app · Usability · Remote testing · App testing · Mobile health

## 1 Introduction

The market for mobile healthcare has grown steadily in recent years and continues to grow. In 2017, 325,000 health, fitness and medical apps are available in all major app stores. Last year, 78,000 new health apps were launched in the major app stores. Estimated 3.7 billion downloads of health apps in 2017 [1].

Within the European Union (EU), medical apps have to be considered as medical device and are entitled under the European Medical Device Regulation (93/42/EEC) if the intended use is linked with medical purposes. But even in other cases, comprehensive tests are mandatory to improves product quality, reduce user errors, increase customer loyalty and satisfaction. It's also reduces support costs and increases the recommendation rate [2].

Regarding the United States (US) market and according to the US Food and Drug Administration, most errors are only discovered at the end of development, so special attention should be paid to formative testing during development. Regardless of when the tests are performed, the type of test is crucial.


G. M. P. O'Hare et al. (Eds.): MobiHealth 2019, LNICST 320, pp. 3–17, 2020.
https://doi.org/10.1007/978-3-030-49289-2_1

Therefore, usability planning should be considered from the beginning. There are different guidelines for this, also special ones for apps in the health sector. After comparing several existing guidelines, the following aspects occur frequently:

- "Representation of Elements" (I, II, III, IV, VI, IX)
  Information should be presented effectively and clearly formulated. In some cases, images and icons are more appropriate than words, as long as they are unambiguous.
- "Learning facilitation and support" (I, II, III, IV, V, VII)
  The app should be intuitive to use and contain a logic in the process.
- "Consistency and predictability" (I, II, III, V, X)
  All parts of the app should look and feel the same. The action of different buttons should be predictable.
- "Giving feedback" (I, II, V, VII)
  The user should always be informed of what is happening and should always be given the opportunity to correct possible errors.
- "Clarity and Functionality" (I, II, III, IV, VI)
  The app should be as simple as possible and make all important functionalities clearly visible to the user.
- "Metaphors" (I, II, III)
  Virtual objects and actions should be represented as metaphors from the real world.
- "Self-description" (I, III, X)
  The user should always know where he or she is. The navigation of the app should be uniform and comprehensible.
- "Effective Use of Language" (I, III, IX)
  Developers should use short phrases with simple words.
- "Fastest way" (I, V, IX)
  The user should always be clearly offered the fastest way to the desired destination and clearly represented.
- "Direct manipulation" (II, III, X)
  Direct manipulation of onscreen content engages people and facilities understanding. Icons from the real world are helpful.
- "Give the user control" (II, III, V)
  Users have control without receiving unwanted outcome.
- "Use platform specific functions" (III, IX, X)
  The developers must be aware of the platform or platforms for which they are developing.

The following guidelines and principles were taken into consideration:

I. HIMSS Guidelines [3]
II. iOS Design Principles [4]
III. Android Principles [5]
IV. MARS [6]
V. Sheiderman's Eight Golden Rules of Interface Design [7]
VI. UX Planet Principles [8]
VII. The Startup Principles [9]

VIII. Principles in the Design of Mobile Medical Apps [10]
IX. Mobile Health Consumer App Design Aspects [11]
X. Ergonomics of human-system interaction - Part 110: Principles of dialogue design (ISO 9241-110:2006)

Furthermore, the Food and Drug Administration declares: "Usability is often confused with design, human factors engineering is a better term. Usability is not just chic color and trendy design elements."

Strict and often complex regulations are a major constraint on the digital healthcare market. Regulation is often cited as one of the main reasons for the slow development of digital healthcare solutions. A survey conducted by mHealth App Economics in 2017 showed that 18% of digital healthcare players are reluctant to develop apps due to uncertain regulatory frameworks [1].

The healthcare sector is subject to intensive regulation. Both digital and non-digital healthcare solutions that could pose a risk to patient safety must be approved by an official regulatory body such as the Food and Drug Administration in the United States. Currently, many medical apps are of poor quality and sometimes potentially dangerous [12]. Also, the great potential is not used.

In July 2017, the Food and Drug Administration announced a new approach to the approval of digital healthcare solutions, the Digital Health Innovation Plan. Instead of approving individual digital products, entire companies could be approved, and digital products approved by these pre-selected companies would not have to go through a regulatory process for each of their product approvals. This development is still new, but the Food and Drug Administration appears to be initiating a paradigm shift in the regulation of digital healthcare solutions. This could serve as a blueprint for other countries to follow [1].

At present, however, a medical app still has to undergo comprehensive, time-consuming and cost-intensive certification processes. One factor that must be extensively tested in this context is usability. In the European Union, the standard IEC 62366 Medical devices - Application of usability engineering to medical devices is to serve as support. This standard is closely linked to ISO 14971 Medical Devices - Application of Risk Management to Medical Devices. It follows that usability is primarily seen as a risk factor. According to the Food and Drug Administration, more damage is caused by incorrect operation than by technical errors. In the IEC 62366-1:2007 standard, usability is described as a characteristic of the user product interface that encompasses effectiveness, efficiency, as well as the user's ability to learn and satisfaction. Also, here a usability file is promoted, which covers the following points: Extended purpose including user specification and usage context, core tasks and pre and post conditions and subtasks, usage requirements, user product interface specification including main functions, verification results, validation plan and validation results. Since the new version of the 2015 standard, the standard compliance requirements are very similar to the Food and Drug Administration requirements.

The standard requires that usability be extensively tested and documented. However, the user experience is not considered.

The standard requires the testing of usability. This means that the medical device must perform various tasks in an environment of representative selected test persons from the user group under observation without help, but with a test leader. As Jakob Nielsen points out, testing with potential users is the most effective way to identify usability problems [13]. These tests are documented and evaluated.

IEC 62366-2 assumes that with six testers approx. 80% of the errors are found (recommended for formative tests), with 15 test subjects approx. 90% of the errors (recommended for summative tests). Both the IEC 62366-2 and the Food and Drug Administration agree that the figures can only be read per target group.

The good usability of the products enables users to perform tasks quickly and correctly. The usability measures are effectiveness, efficiency and user satisfaction.

## 2 Methods

With remote testing, testers can use the application asynchronously in their natural environment according to their needs and the requirements of the app. These activities can be stored by little additional programming effort and sent to the developers without affecting the test subjects.

Depending on the functionality of the app, timestamps can be set at important points in the app. A flowchart is helpful for this, because so it is possible to see the whole procedure of the app. If these are then set in a predefined flow context, it is easy to see where the user's handling problems were. So, the whole activity can be tracked by simple button events and an analysis of the runtime behavior can be created. Each timestamp needs a unique name so that the evaluator knows exactly which button belongs to which timestamp and can place it in the correct sequence [14].

In addition, it is possible to record the entire screen in order to be able to reproduce the behavior in even more detail. Audio recordings can also be documented, if the test persons are animated to think aloud, i.e. to pronounce all thoughts, positive as well as negative, questions, etc., the developers can give the best insight. However, this data must also be evaluated manually, which is difficult to achieve with a large group of testers and requires more time and money due to the additional effort.

Remote testing has the advantage that the testers do not only have to fulfill the given task, but mostly all areas of the application have to be tested automatically including the main and secondary functions, as well as to be defined for certification.

Since the testing is carried out in the everyday life of the users, many testers do not notice any more that they are testing a medical app because the test environment is not present.

In the case of a large group of testers, it is advisable to determine the optimal way to complete a task, the so-called happy path. For this purpose, the buttons that are required for this have to be defined so that they can be automatically compared later with the timestamps or their sequence. In addition, it is possible to define the time range between two buttons. This not only makes it possible to evaluate whether the effective way was found, but also whether it was found quickly.

Further functionalities of the smartphone can also be used, for example to determine the location of use.

Furthermore, no professional trainer is required, as the test persons use and test the app asynchronously according to their needs in their familiar environment. A test leader is only required when the test results are evaluated. However, he or she can also act asynchronously.

However, it can be an advantage that the test persons fill out questionnaires after the test phase has been completed, depending on the requirements of the app and its developers. These can be standardized, such as the System Usability Scale [15] and the User Experience Questionnaire [16], or individually adapted to the requirements of the app and its developers.

The advantages and disadvantages of the usability laboratory and the remote variant are listed in Table 1.

Some of the disadvantages of remote testing can be eliminated with regular online meetings. Here the test coordinator and the respondent have the opportunity to exchange

**Table 1.** Usability laboratory with remote tests in comparison

| Usability laboratory | Remote usability tests |
|---|---|
| Advantages: | |
| • Certainty that the test person will carry out the task conscientiously<br>• Direct observation of the entire test situation<br>• More details can be observed | • Size of the tester group can be extended<br>• Larger selection of test subjects<br>• Tester is located in its natural environment, so it feels more comfortable and a more natural result is created<br>• Lower expenses<br>• More usability problems can be detected as more cases and applications are tested with the app<br>• Less strenuous for the test persons, as the test environment is less present<br>• Possibility of automated evaluation of results<br>• Test persons can test the app more freely, according to their needs. This results in much more diversified results<br>• Less costs (resources, space, travel expenses …)<br>• Comfort, better in everyday working life<br>• It is easier to find test persons because they are often more likely to take part in a test in which they do not have to travel<br>• Simplified finding of test persons through recruitment via the Internet<br>• Suitable if the target group is difficult to reach (at different locations)<br>• Not fixed location<br>• Not time-bound<br>• Simplified recruitment of usability experts |

(*continued*)

**Table 1.** (*continued*)

| Disadvantages: | |
|---|---|
| • Complex recruitment of test persons<br>• Uncomfortable for test persons, as they are in a test situation and in an unfamiliar environment<br>• It is time-consuming to plan the recruitment and the execution of the tests<br>• Expensive (recruitment, provision of usability laboratory and resources), depending on the budget not many users can be checked and developers only meet the required minimum requirements | • No direct observation, one does not directly see the reactions of the user, some problems may remain undiscovered because gestures and facial expressions of the user are missing and therefore the entire emotional reaction is missing<br>• Code of the test app must be slightly adjusted<br>• It is unknown whether the test persons really test the app carefully and seriously<br>• It is more difficult to interact, interview, train and observe the participants<br>• If hardware is to be provided, some logistics are required to distribute it to the participants and collect it again. In the case of pure software applications, regular installation support is required<br>• Confidentiality during screen sharing; it must be ensured that no confidential data of the test person is displayed<br>• Technical problems can occur more frequently. Under certain circumstances help can only be offered after some time |

ideas, the test coordinator can ask specific questions to the satisfaction and draw first results and the respondent can convey his or her first impressions and get possible questions about handling answered. This also provides the respondent with an opportunity to perform certain tasks set by the test leader so that the test leader can directly perceive the facial expressions and gestures of the proband. However, there are disadvantages that cannot be avoided in the usability laboratory. The respondent is taken out of his natural environment and thus becomes aware of the test situation. He or she no longer acts as usual. Therefore, the execution of synchronous tasks is only recommended in exceptional cases.

It is also important to mention that various studies have already shown that the results of remote usability are at least comparably good with the results of classic usability tests, such as a usability laboratory [17–19].

The study by Tullis et al. [20] has shown that test subjects are more willing to participate in a remote test than in a laboratory test. In this study 108 people agreed to participate in a remote test, while only eight people could be found for a test in the usability lab. One reason for this is the lower effort a remote test entails compared to a laboratory test for the test subjects [21].

Studies comparing a laboratory test with a remote test show that both synchronous and asynchronous remote usability tests produce quantitative and qualitative comparable results. The number and severity of the found usability problems could not be determined significantly either [17]. Often even more usability problems were detected by a remote test [16]. The impression of the test persons is also of great importance. The remote test situation is usually positively received. In the study by Brush et al. [17], seven out of eight participants found the remote tests more pleasant than the situation in the usability laboratory. Of these eight test persons, four preferred the remote test, but no test person preferred the test in the laboratory.

In order to decide which type of testing is appropriate, a questionnaire was developed:

1. Doesn't the app fall under the MDD or MDR according to its purpose? If so, is the app already certified?
2. Has the app been developed for long-term use?
3. Does the app have more than five main and secondary functions?
4. Are the users people without medical qualifications?
5. Is the app used by private individuals in their private environment?
6. Is there a wide range of users?
7. Are the test persons at different locations, widely distributed?
8. Can the test persons use their own smartphones, or is the use of a private smartphone advantageous?
9. Can the testing be carried out without additional hardware?
10. Isn't the respondent's facial expressions and gestures of decisive importance in the evaluation?

If most of the above questions are answered with "YES", remote testing is recommended. The financial factor is not to be despised, but it is strongly dependent on individual framework factors. In the same way, time can still influence the selection of the test, but here this point has to be considered very individually, too.

With the presented method not only, the usability and the user experience can be tested, the entire compliance can be evaluated. Measurement parameters such as frequency of use, duration of use, completeness, continuity and regularity can be easily collected. In this case the developer can quantify these metrics with a range in order to compare the results of the tests, too. Or he or she does not give a range and interprets the evaluation freely in order to draw his conclusions. This depends strongly on the requirements of the application and developer and the group size of the testers.

It can be assumed that an increase in usability quality will also increase compliance.

## 3 Results

In order to find weak points and difficulties regarding usability in the mobile app, it was decided to assign timestamps to different buttons. The following questions were defined in advance:

"How long does the user spend in our app?"
"How long does a user need to complete a certain process (e.g. adding food)?"
"When does the user abort a process or delete his entries?"

"Where does the user call up the help function?"

In accordance with these questions, the buttons in the app are provided with timestamps to measure the time intervals between and during the various processes. After the evaluation, the measured time can be used to identify the processes in which the user needs longer, or deletes or aborts them more frequently, and to identify where further usability problems exist and analyze them. An alpha test is then performed to determine standard times and optimum values for comparison with the users and to detect deviations. Furthermore, by measuring the total time the user has spent in the app, compliance can be tested to determine whether the users are all using the app regularly, as prescribed, and conscientiously.

To see where to set timestamps, it is helpful to create a simplified flowchart which shows all main and secondary functions as shown in Fig. 1. In this way, the best points for time stamps can be found easily and individually, so that the best possible evaluation is available.

The diagram should provide a precise overview of what is relevant for processes and what happens in them. The red dashes are actions like add, fill in text fields, select or save settings and so on. The trash can always indicate the point in time at which individual elements are to be deleted in the process. The red X indicates the period in which the process can be aborted and the green question mark indicates the period in which the user has the possibility to call up the help function.

Note that an individual minimum number of timestamps is required for comprehensive results, but too many measurement points can complicate interpretation and possibly even falsify it. This figure is based on the developer's own alpha test to control the process, as shown in the appendix.

The app developed in the DiDiER project (Digitization of Services in the Nutritional Counselling Process) funded by the German Federal Ministry of Education and Research (grant 02K14A150) is used here as an illustrative example. The purpose of this mobile app is to make it easier for the patient to keep a diary by documenting all distorted foods and their symptoms, from which the diagnosis of possible food intolerances and allergies can be made by professional nutritionists [22]. As part of this study, 25 test persons will receive a smartphone including the DiDiER App over the period of their diagnosis (two to six weeks), on which they must record all nutrition-relevant data, such as distorted foods, symptoms, including strength and possible cofactors. For this purpose, the study participants are provided with various smart services, such as a Food Information Service, which also enables the scanning of food barcodes so that all ingredients can be stored directly. The Food Information Service is a collection of existing food databases that are enhanced by various quality optimization algorithms [23]. It is also possible to photograph symptoms and foods, as well as search by text input in the Food Information Service. The developed standards are expected to lead to a significant increase in the quality of nutritional advice for patients and nutritionists.

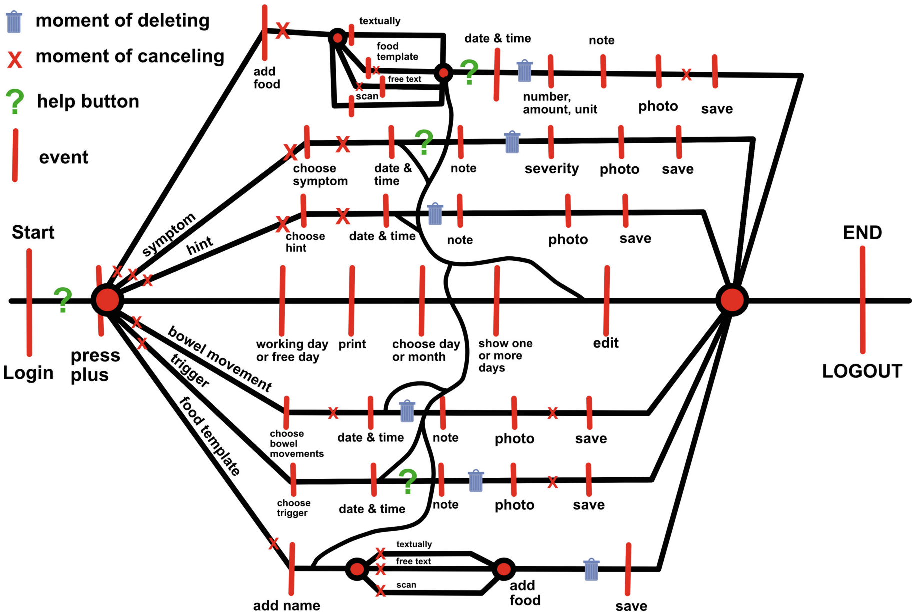



**Fig. 1.** Sequence diagram to find the appropriate buttons for timestamps (Color figure online)

Currently, the entire system, consisting of patient app and consultant platform, is being tested in a study. The study protocol was reviewed and approved by the Ethics Committee of the Carl von Ossietzky University Oldenburg, Germany.

The questions already presented, as to decide whether remote testing would be appropriate, were answered as follows (Table 2):

**Table 2.** Answering the questionnaire to decide if remote tests are suitable for the DiDiER App

| No. | Question: | Answer: |
|---|---|---|
| 1. | Doesn't the app fall under the MDD or MDR according to its purpose? If so, is the app already certified? | Yes, the app does not fall under MDD/ MDR because of its purpose, so far, the app itself is a pure tool for documentation, therefore no certification is necessary |
| 2. | Has the app been developed for long-term use? | Yes, at the moment the app should be used for a period between two and six weeks. Later the app will be used even longer |
| 3. | Does the app have more than five main and secondary functions? | Yes, the mobile app has several main and secondary functions |
| 4. | Are the users people without medical qualifications? | Yes, the users of the app come from many different backgrounds and do not need medical training |

(*continued*)

**Table 2.** (*continued*)

| No. | Question: | Answer: |
|---|---|---|
| 5. | Is the app used by private individuals in their private environment? | Yes, it is used by private individuals in everyday life |
| 6. | Is there a wide range of users? | Yes, the users, both during and after the study, should use the app by various users |
| 7. | Are the test persons at different locations, widely distributed? | Yes, the app can be used from anywhere and is not location-bound. However, the test persons are in the vicinity of their nutritionists during the study |
| 8. | Can the test persons use their own smartphones, or is the use of a private smartphone advantageous? | Yes, the app can be used from any smartphone. But during the study, the subjects receive a smartphone |
| 9. | Can the testing be carried out without additional hardware? | Yes, no additional hardware is required |
| 10. | Isn't the respondent's facial expressions and gestures of decisive importance in the evaluation? | Yes, facial expressions and gestures do not play an important role in the evaluation |

A timestamp on the login and logout button can be used to determine how long the respective user has been using the application. Since a button event is also saved on the different view options, for example on the calendar views, a statement can then be made as to which view is preferred. Furthermore, a start point and one or two end points (saving the entered data and canceling the entry) have been defined for each sequence. So, it can be tracked exactly how long the tester needs for a sequence, if he or she confirms it or when this task is aborted. Each help button is provided with a tracker so that it is clear where the user needs special help and is unsure how to use it.

The collection of button tracks makes it possible to track the entire usage without any gaps.

At the end of each test phase, the entire data is displayed pseudonymized in tables for evaluation. Different events are grouped so that the evaluation is simplified.

No audio or screen recordings are made during the study. This is not required here.

## 4 Conclusion and Outlook

In many countries within Europe, the population is accustomed to insurance paying for most health-related matters. It is therefore difficult to get users to pay for a health app. So, developers need to use other ways to cover the costs of development and certification and make a profit. At the moment there is a trend for developers to contact different insurance companies, so that these insurance companies include the app in their offer [1].

This has to be considered for distributors, because they either have to get in contact with many different health insurance companies or convince the user directly. In both cases, more than just certification is often expected. Usability is one of the most important factors, and even more so is the overall user experience. Because if the app is not easy to use, it is not popular to use and the potential increase in quality of life remains unused.

With the presented concept apps can be tested completely and comprehensively regarding their usability. With this easier way, they can identify and reduce possibly risk factors. The test persons can be easily found in remote testing, since no effort and costs are incurred for the journey. Earlier studies have already shown that the results of remote tests and in the usability laboratory are comparable or even more errors are found in remote tests.

Timestamp can be used to collect all relevant information on specific buttons without influencing the test persons. Additional information can be obtained through further possibilities, such as screen- and audio monitoring and consultation hours with experts. The evaluation of the collected data can take place time-independently and can be automated by previously defined happy path.

The test method is currently used in the study for testing the DiDiER App. The developed questionnaire demonstrates that the DiDiER App is suitable for this purpose. Usability results are expected by the end of 2019. The data to be evaluated will then also be examined for compliance and compared with the previously defined compliance area. The creation of the automated evaluation with the help of the happy path is one of the next steps.

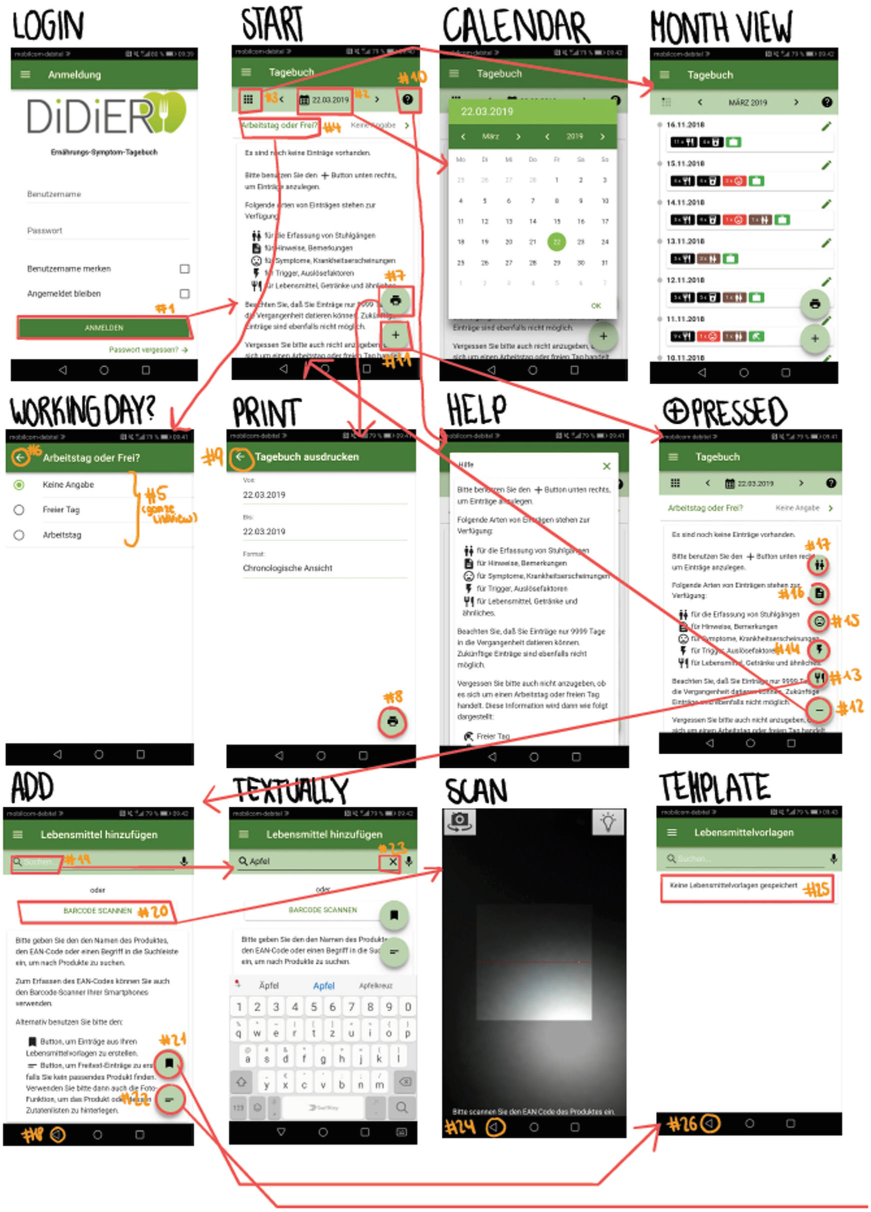
If the results are as positive as currently expected, the presented concept will be adapted to further apps in the health sector and further investigated, for example with regard to the effectiveness of the smartphone application.

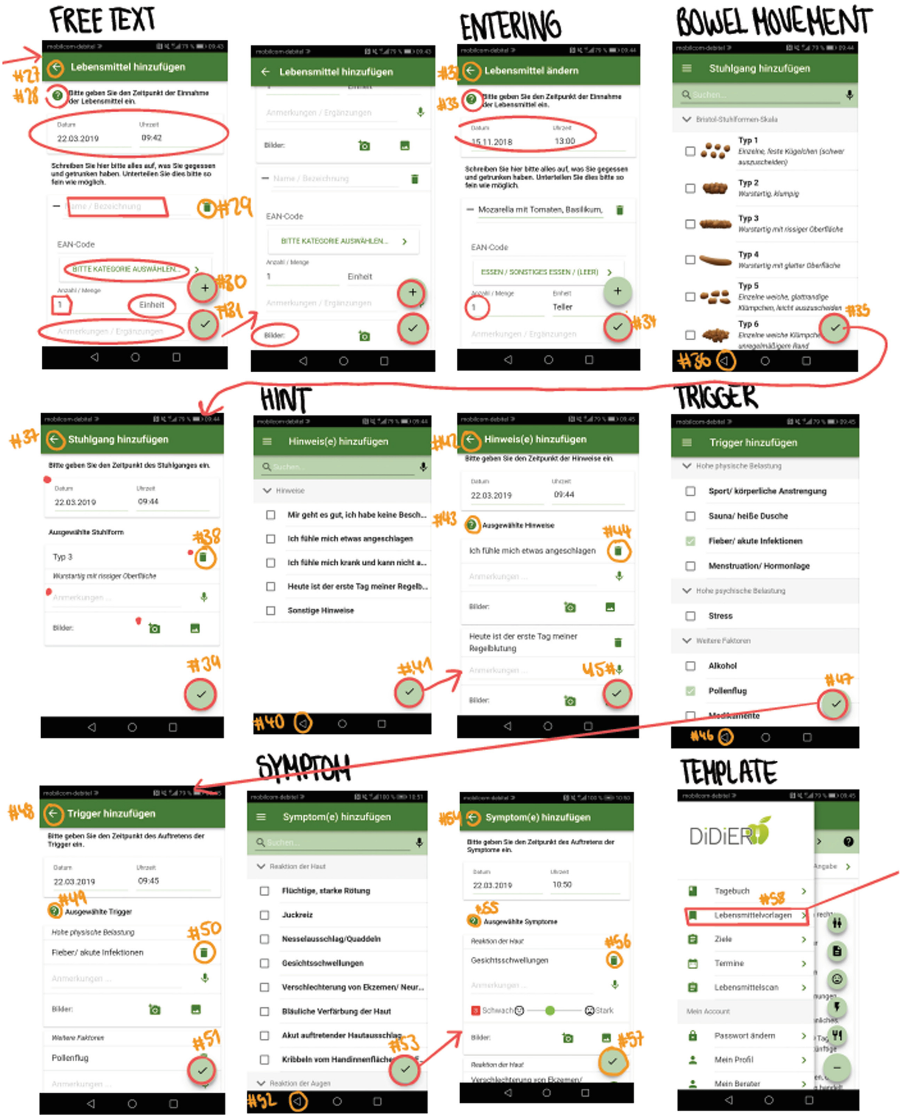
It is expected that the new remote tests will lead to an enormous increase in quality and a decrease in risk, even though the medical app has already been certified according to the EU directive. The IEC 62304 Medical device software - Software life-cycle processes (IEC 62304:2006 + A1:2015) also requires permanent validation.

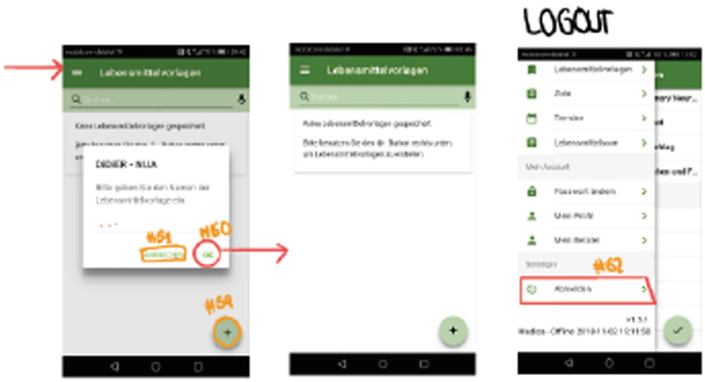
**Acknowledgment.** This research was done within the framework of the DiDiER project, which is funded by the German Federal Ministry of Education and Research (grant 02K14A150). Different institutes are working together on this joint project. Particularly the German Allergy and Asthma Association (DAAB) as application partner and executor of the study and EUROKEY GmbH Saarbrücken, which took over many parts of the development of the app, are to be mentioned here.

The cooperation between the University of Applied Sciences Kaiserslautern and Carl von Ossietzky University was extremely positive and beneficial.

## Appendix


LOGIN
Anmeldung
DiDiER
Ernährungs-Symptom-Tagebuch
Benutzername
Passwort
Benutzername merken
Angemeldet bleiben
ANMELDEN
START
Tagebuch
22.03.2019
Arbeitstag oder Frei?
CALENDAR
22.03.2019
MONTH VIEW
MÄRZ 2019
WORKING DAY?
Arbeitstag oder Frei?
Keine Angabe
Freier Tag
Arbeitstag
PRINT
Tagebuch ausdrucken
Chronologische Ansicht
HELP
Hilfe
⊕PRESSED
ADD
Lebensmittel hinzufügen
BARCODE SCANNEN
TEXTUALLY
Apfel
SCAN
Bitte scannen Sie den EAN Code des Produktes ein.
TEMPLATE
Lebensmittelvorlagen
Keine Lebensmittelvorlagen gespeichert


FREE TEXT
ENTERING
BOWEL MOVEMENT
HINT
TRIGGER
SYMPTOM
TEMPLATE
Lebensmittel hinzufügen
Lebensmittel ändern
Stuhlgang hinzufügen
Hinweis(e) hinzufügen
Trigger hinzufügen
Symptom(e) hinzufügen
DiDiER




## References

1. Research 2 Guidance mHealth App Economics 2017/2018
2. Healthcare Information and Management Systems Society Promoting Usability in Healthcare Organizations: Initial Steps and Progress Towards a Healthcare Usability Maturity Model
3. Healthcare Information and Management Systems Usability Evaluation Guide for Clinicians Practice: https://www.himss.org/himss-emr-usability-evaluation-guide-clinicians-practices-9-essential-principles-software-usability. Accessed 14 May 2019
4. IOS Design Principles. https://developer.apple.com/design/human-interface-guidelines/ios/overview/themes/. Accessed 14 May 2019
5. Android Design Principles. https://www.designprinciplesftw.com/collections/android-design-principles. Accessed 14 May 2019
6. Stoyan, S.R., Hides, L., Kavanagh, D.J., Zelenko, O., Tjondronegoro, D., Mani, M.: Mobile app rating scale: a new tool for assessing the quality of health mobile apps. JMIR Mhealth Uhealth 2015 Jan-Mar, **3**(1), E 27, p. 1
7. Ben Sheiderman's Eight Golden Rules of Interface Design https://faculty.washington.edu/jtenenbg/courses/360/f04/sessions/schneidermanGoldenRules.html. Accessed 14 May 2019
8. UX Planet: Mobile UX Design: Key Principles https://uxplanet.org/mobile-ux-design-key-principles-dee1a632f9e6. Accessed 14 May 2019
9. The Startup, Mobile App Design Principles: 13 Rules for Creating Apps that Stick https://medium.com/swlh/infographics-mobile-app-design-principles-13-rules-for-creating-apps-that-stick-f607959692be. Accessed 14 May 2019
10. Lienhard, K.R., Legner C.: Principles in Design of Mobile Medical Apps: Guidance for Those who Care. University of Lausanne, Switzerland
11. MLSDev: Healthcare Mobile App Development: Types, Trends, & Features https://mlsdev.com/blog/healthcare-mobile-app-development. Accessed 14 May 2019
12. Albrecht, U.V.: Chances and Risks of Mobile Health (Chancen und Risiken von Gesundheits-Apps) (2016) Hannover, Germany (2016)
13. Nielsen, J.: Usability Engineering. Academic Press, Boston (1995)
14. Brooke, J.: SUS - a quick and dirty usability scale. United Kingdom (1986)
15. Sauer, J., Muenzberg, A., Hein, A., Roesch, N.: Simplify testing of mobile medical applications by using timestamps for remote, automated evaluation. In: 2019 15th International Conference on Wireless and Mobile Computing, Networking and Communications (WI Mob) (2019)

16. Laugwirtz, B., Held, T., Schrepp, M.: Construction and evaluation of a user experience questionnaire. In: HCI Usability Education, Work, pp. 63–76 (2008)
17. Brush, B.A.J., Ames, M., Davis, J.: A comparison of remote and local usability studies for an expert interface. In: CHI Vienna, Austria, pp. 1179–1182 (2004)
18. Thompson, K.E., Rozanski, E.P., Haake, A.R.: Here, there, anywhere: remote usability-testing that works. In: SIGITE 2004, pp. 132–137. ACM, USA (2004)
19. Hartson, H.R., Castillo, J.C., Kelson, J., Neale, W.C.: Remote evaluations: the network as an extension of the usability laboratory. In: CHI 1996, pp. 228–235 (1996)
20. Tullis, T., Fleischman, S., McNulity, M., Cinanchette, C., Bergel, M.: An empirical comparison of lab and remote usability-testing on web sites. In: Usability Professionals Association Conference (2002)
21. Dumas, J.C.: Usability evaluation from your desktop. In: Association for Information Systems (AIS) SIGCHI Newsletter, November 2003, pp. 6–8 (2003)
22. Elfert, P., Eichelberg, M., Tröger, J., Britz, J., Alexandersson, J., et al.: DiDiER digitized services in dietry counselling for people with increased health risk related to malnutrition and food allergies. In: IEEE Symposium on Computers and Communications (ISCC), pp. 100–104. IEEE (2017)
23. Muenzberg, A., Sauer, J., Hein, A., Roesch, N.: The use of ETL and data profiling to integrate data and improve quality in food databases. In: 2018 14th International Conference on Wireless and Mobile Computing, Networking and Communications (WI Mob), pp. 231–238 (2018). https://doi.org/10.1109/wimob.2018.8589081

# Mobile Application for Celiac Disease Patients' Wellness and Support

Sara Altamirano(✉), Gudrun Thorsteinsdottir, and Verónica Burriel

Utrecht University, Heidelberglaan 8, 3584 CS Utrecht, The Netherlands
{s.e.altamiranoortega,g.thorsteinsdottir}@students.uu.nl, v.burriel@uu.nl

**Abstract.** Celiac disease affects an estimated 1% of the population. The only existing treatment is a strict gluten-free diet but there are myriad aspects of managing the disease that affect the lifestyle of both the CD patient and those close to them. The goal of this study was to design, develop and test a prototype of a mobile application to promote wellness and support for individuals with CD. The proposed application's aim is to serve as a platform for CD patients and members from their social circle, to help with sharing general and specific information about four lifestyle aspects: social, emotional, food, and wellness. The application aids with the management of a gluten-free diet from the social circle perspective for the specific CD patient. Perceptions towards the usability of the application were gathered from 22 participants and analyzed via a USE questionnaire. The results from the survey reported overall satisfaction of the prototype and useful insights were gathered for subsequent versions. The general expected benefit of this evidence-based application is improved quality of life for the CD patient due to their social circle being well informed about the management of the disease and its potential complications.

**Keywords:** Mobile application · mHealth · Celiac disease · Medical informatics · Gluten-Free

## 1 Introduction

Autoimmune diseases (AID) include a wide variety of illnesses targeting different parts of the human body. The American Autoimmune Related Disease Association (AARDA) has classified more than 100 AID, making it the third most common type of disease in the United States. The AARDA identifies AID as a major health problem affecting up to 50 million individuals in the United States alone, which translates to an alarming 15% of the population. Some AID are within the top 10 leading causes of death among women aged 65 and older, and 75% of Americans with AID are women. According to the AARDA website, AID are responsible for more than 100 billion US dollars annually in direct healthcare costs and most AID patients see four doctors over three years before a correct diagnosis [8].


G. M. P. O'Hare et al. (Eds.): MobiHealth 2019, LNICST 320, pp. 18–35, 2020.
https://doi.org/10.1007/978-3-030-49289-2_2

Many autoimmune diseases seem to vary in incidence by region or ethnicity. For instance, Southern European and Asian countries have a lower incidence of type 1 diabetes and multiple sclerosis than do Northern European countries. This variation may be caused by the irregular prevalence in specific ethnic groups of a gene associated to a particular AID. Likewise, dissimilarities in diet or in the existence of a triggering pathogen or chemical agent due to geographic factors may affect the frequency of an AID [22]. Regardless of the public health scale of the problem, the unknown aetiology of AID, the complexities involved in diagnostics, the increased costs, and the unavailability of cures, scientific research has focused on a small portion of more than 100 known AID [12].

Celiac Disease (CD) is an AID that requires effective self-management in adherence to a strict gluten-free diet (GFD), which is the only existing treatment for the disease. The list of symptoms that CD patients have is extensive and varies from childhood to adulthood. Some of the symptoms that are commonly experienced by children are abdominal pain and stunted growth issues. Moreover, symptoms that adults can experience are diarrhea, fatigue, anemia and reduced bone disease, among many others [27]. The proportion of people with CD varies among regions in the world. The reported prevalence of CD in South and North America was 0.4%–0.5% whereas the value for Asia was 0.6%. However, the prevalence in Europe and Oceania was slightly higher at 0.8%.

One of the authors of this study has CD and understands the importance of technological support for the management of the condition. As with any chronic disease, support is a team effort in conjunction with the social circle of the patient. With CD, the patients find themselves having to explain their condition numerous times, and providing the same CD information repeatedly. Therefore, a one-stop platform that centralizes accurate and readily-available information, personalized to each CD patient and their social circle, is of utmost importance. With feedback from other CD patients and analysis of well-reputed CD websites, we designed and developed a prototype of a mobile application to promote wellness and support for patients suffering from CD. A total of 22 CD patients and members from their social circle tested the initial prototype of the mHealth application and responded to a survey after the trial. The survey acquired perceptions towards the features of the app and usability of the design. The prototype contains general CD information due to the broad spectrum of CD symptoms. However, in future versions, the app will include information personalized to each patient. The patients will, therefore, be able to share individual pre-approved food and restaurants with their social circle, along with preferences and information about the disease and other psychological disturbances that accompany the disease, for each specific case.

The remaining sections of the study are as follows: Sect. 2 entails information about CD and how social support can aid the patient managing the disease thus explaining the problem statement and the need for the mHealth app. Related mobile applications for gluten intolerant people and CD patients are described in Sect. 3. In Sect. 4, the design of the application is visualized and explained in detail. The results from the survey are reported and analyzed in Sect. 5. Finally, Sect. 6 details the findings along with potential benefits, limitations of this study, and future work.

## 2 Problem Statement

In countries like the United States, the United Kingdom, and Germany, approximately 20% of the population has been reported to experience adverse reactions to foods such as wheat, nuts, fruits, and milk [13]. Historically, wheat-related disorders have been identified as CD and wheat allergy or non-celiac gluten sensitivity [23], referred as gluten intolerance in this study. Gluten-related conditions vary significantly in aetiology, but adherence to the GFD is of utmost importance for CD patients due to gluten reactivity involving autoimmune mechanisms [28].

Celiac disease is a systemic autoimmune disorder activated by gluten in genetically-predisposed individuals and affects an estimated 0.5 to 1.0% of the population worldwide [19]. Gluten is a protein found in cereals such as wheat, rye, and barley. CD is characterized by an extensive range of symptoms, a specific serum auto-antibody response, and variable damage to the small intestinal tract. Diagnosing CD can be difficult because some of the symptoms overlap with myriad other diseases, such as irritable bowel syndrome, chronic fatigue syndrome and depression. Since CD is hereditary, it is recommended that family members get tested as well. The longer the individual remains undiagnosed and untreated, the greater the chances of developing complications [15].

The treatment for CD is a lifelong GFD. However, some people do not improve on this diet and face additional health complications due to their deteriorating health. The adherence to this strict dietary regime varies among patients and is the main cause of persistent symptoms [15,18]. Therefore, it is advised to develop effective strategies to help patients follow a strict GFD, manage their various symptoms, and deal with all the implications of CD [16]. Participation of a close support group for the CD patient has been associated with higher quality of life scores, especially when face-to-face interaction may improve long-term quality of life and health outcomes [25]. Therefore, we recognize the need for a mobile application that helps CD patients manage their specific condition with support from their immediate social circle. We leave aside the search functionality through a catalog of gluten-free (GF) foods, because the majority of mobile health (mHealth) applications on the market today for CD patients are focused on finding GF food.

Following a strict GFD has a significant negative impact on quality of life in social settings for CD patients. Particularly related to social aspects such as traveling, eating out, and family life. Lee et al. [24] reported that CD patients, even though they know it will cause damage, typically cheat on their GFD because: 46.3% think the diet limits their social life, 55.3% perceive the diet as embarrassing, 24.9% say dining out is too difficult, 30.8% say the diet is socially isolating, and 33.3% report family and friends do not understand the need to follow the diet. Social support is therefore crucial for adherence to the GFD. Some solutions suggested by Lee et al. [24] are accommodation by family and friends, school and community support, group support, and others in their circle following a GFD.