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User Experience Testing of *My ePRO App* in a Diabetes Mellitus Type 2 Focus Group

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Abstract: *Background*: Type 2 Diabetes Mellitus affects patients' quality of life. The *my ePRO app* was constructed to collect patient-reported outcomes in an investigator free study - DePRO study. We aimed to describe the qualitative and quantitative feedback received during user experience testing in a diabetes mellitus type 2 focus group. *Methods*: Metformin containing drug taking patients aged 18 years or older completed a 37-item qualitative questionnaire as the quantitative 6 scales and 26 items containing User Experience Questionnaire (UEQ) in a single focus group interview. The qualitative interview addressed feedback to 1) the download of the app, 2) scanning the 2D matrix code, 3) informed consent form, 4) demographic questionnaire and the 3 PRO instruments EQ-5D-5L, SDSCA and DTSQ. *Results*: Nine T2DM patients, 3 female and 6 male, aged 55-88 years were interviewed for 45 to 65 minutes. Patients expressed their need of lay language within the app, criticized the length of the informed consent form, the amount of health information, missed pictures of the drugs they scanned and judged the questions to income and education as too indiscreet. As positive feedback patient reported that everything was fine, the questions were self-explaining and could be read without glasses. The UEC scales (mean; variances) Perspicuity (0.722; 1.73), Efficiency (0.5; 0.89) and Novelty (0.25; 1.13) were rated neutral, Attractiveness (0.854: 0.63), Dependability (1.031; 0.1) and Stimulation (1.094; 0.39) represent a positive evaluation. *Discussion*: User experience testing provided insight into usage, challenges and areas of improvement of *my ePRO app* in a type 2 Diabetes Mellitus focus group. User experiences were implemented in the final app. The quantitative feedback was compared to a benchmark data set, to which the *my ePRO app* means were below average in all scales. Understanding patient view, leads to a better design of health apps and study conduct.

Keywords: User Experience, Diabetes Mellitus, Type 2, Patient Reported Outcome Measures, App

1. Introduction

Diabetes mellitus (DM) is one of the most common non-communicable diseases, with a growing prevalence impacting global healthcare systems negatively [1]. The International Diabetes Federation calculated, that DM affected 463 million people globally in 2019. This number may increase up to 578 million patients in 2030 [2]. Due to aging population the prevalence of type 2 DM (T2DM) is increasing to 90–95% of all patients with DM [2, 3]. The comorbidities of DM are impacting patients' quality of life (QoL) [4, 5]. QoL is only one aspect of patient-reported outcomes (PRO) which easily can be assessed directly with patients using standardized and validated instruments. These include, for example, the summary of diabetes self-care activities scale (SDSCA), the diabetes treatment satisfaction questionnaire (DTSQ) and the 5-level, 5-dimension EuroQol questionnaire (EQ-5D-5L) [6-8]. To capture such PROs, BAYER and Institut Dr. Schauerte (IDS) co-developed the *my ePRO app*. This is a data capturing tool to be used for collecting patient reported outcomes in randomized controlled trials (RCTs) and observational studies (OS). The *my ePRO app* uses the 2D matrix code on the outer

packaging of the drug as a patient identifier (Figure 1). The Falsified Medicine Directive (Directive 2011/62/EU) "enables the authenticity of medicinal products to be verified and individual packs to be identified" [9]. The 2D matrix code is placed on the outer packaging of a prescription drug by each marketing authorization holder. It codes the country, the product, the serial number, the expiry date and the charge of the medication. Once a patient received the drug package by his pharmacist, the 2D matrix code identifies the medication and the patient as the user of this medication. Before using the *my ePRO app* in the proof-of-concept study "Digital collected Patient Reported Outcomes in a Diabetes population - DePRO study (CT.gov ID NCT04383041)", user experience testing was conducted, which is widely used in medical app development [10-12]. User experience is defined in ISO 9241-210 as "a person's perceptions and responses that result from the use or anticipated use of a product, system or service" [13].

The objective of this study is to describe the qualitative and quantitative feedback received during user experience testing of a new mobile application (*my ePRO app*) that enables the conduct of investigator free studies by capturing patient reported outcomes in a diabetes mellitus type 2 focus group.

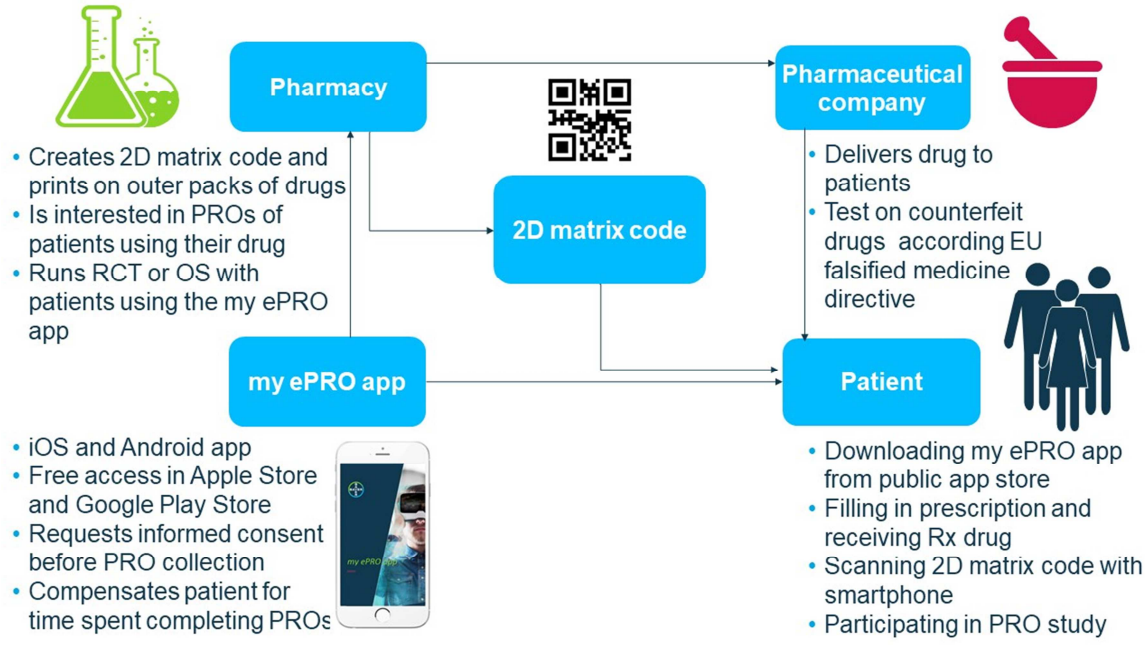

Figure 1. *Workflow of 2D matrix code usage with my ePRO app.*

2. Methods

2.1. Design and Setting

To design the initial prototype of the *my ePRO app*, an iterative workflow was completed by the staff of CRO Institute Dr. Schauerte (IDS) and BAYER. The developers used design-thinking methodologies to identify key requirements of the application and demonstrate value to patient needs.

A qualitative and quantitative research design with focus group methodology was chosen to test the usability of the app and the feasibility of the DePRO study workflow and patients understanding of the content of *my ePRO app*. The focus group interviews with T2DM patients were conducted at Westdeutsches Diabetes- und Gesundheitszentrum (WDGZ) Düsseldorf, Germany on 6th of March 2020. The focus group was moderated by staff experienced with direct patient interaction. It was not recorded but documented with a pencil and paper user experience questionnaire.

2.2. Sample and Recruitment

T2DM patients who routinely were treated at WDGZ were eligible for focus group interviews if they: 1) provided written informed consent, 2) were prescribed a Metformin containing drug and 3) aged 18 years or older. Participants fulfilling these criteria were provided with study details and were consecutively recruited after routine visits in the WDGZ. After being instructed by their treating physician and giving informed consent focus group interviews were conducted by the research team. No out-of-pocket expenses were paid. All participants were reimbursed with a €60 voucher for their participation.

2.3. Ethical Considerations

Before the start of the interview written informed consent was obtained from all patients. The facilitators introduced the project again and explained objectives and general interview rules. The DePRO study has been approved by the ethics committee of the Medical Association North Rhine (approval no. 2020084).

2.4. Workflow

The user experience testing of *my ePRO app* required the completion of the entire study workflow of DePRO study, which contained 1) the download of the app, 2) scanning the 2D matrix code, 3) accepting the informed consent form, 4) completing the demographic questionnaire and the 3 PRO instruments EQ-5D-5L, SDSCA and DTSQ, 5) finalizing the study and requesting the compensation vouchers. Furthermore, patients were asked for navigating through the app, and giving feedback on finding the informed consent form, the withdrawl button and data protection information (Figure 2).

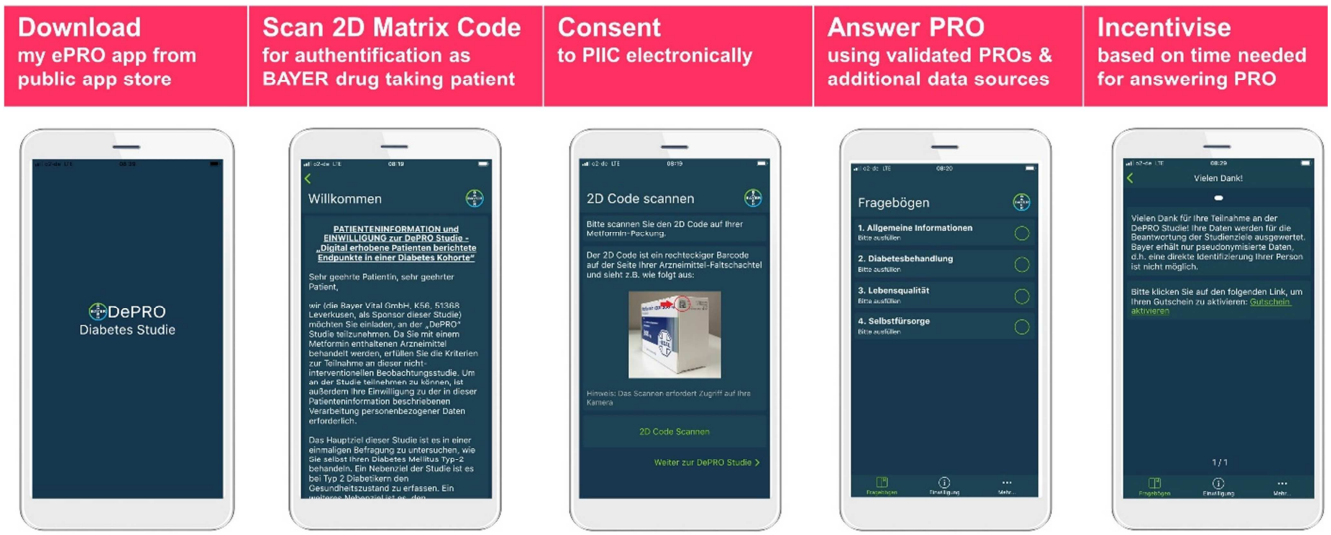

Figure 2. *Study workflow of patients participating at DePRO study, which was tested during UX Design.*

2.5. Instruments

To measure qualitative and quantitative the feedback of the T2DM focus group, patients were given the paper user experience questionnaire requesting their understanding of each app section.

2.6. The Qualitative Instrument

The qualitative instrument was a self-designed 37-item questionnaire separated into 9 sections adapted from Anderson et al. to the needs of *my ePRO app* [14].

1. The initial section was requesting any problems with the download of the app.
2. The section "Opening the app" addressed questions like "What´s to do after opening the app?" and "What problems did you have while scanning the 2D matrix code?" But also feedback if "(Was) the picture of the 2D Matrix code (was) helpful to find the code on the outer package?" or accessing right to camera usage was requested.
3. Entering the "Welcome" section of the app, patients were asked, if they could orientate within the patient information and informed consent form (PIIC). "Were the check-boxes for giving informed consent easy to find?" and if patients intuitively used the pdf download functionality and saved the informed consent form.
4. By entering the "Questionnaires" section patients were asked "What are you doing next?" and "Do you need an instruction what to do next?".
5. Starting the first questionnaire within the app "General information" patients were asked in the qualitative UX questionnaire how they experienced the usability of the selection opportunities (spinning wheel) for age, gender, height, weight and region. Also the completeness of answers has been assessed for education, family income and last available HbA1C value. Furthermore, patients were asked to describe with their own words, what is requested by them answering to lay language comorbidity questions re retinopathy, neuropathy and angiopathy within the app. As next steps patients were instructed to take a photo of their metformin containing drug and to scan their comedication with their camera. Within the qualitative questionnaire they were asked if any problems occurred and what has been their first reaction by being asked to scan the barcodes of the drugs. Finally, patients have been asked if they really double-checked their answers to all questions and what was their impression to the option not to answer all questions.
6. For the validated DTSQM patients were asked if font size was large enough and if radio button usage was intuitively.
7. Within the EQ-5D-5L section patients should comment on the functionality of the slider for selecting their QoL on a visual analogue scale of 0-100.
8. For SDSCA general feedback was requested if any problems occurred during answering the questionnaire.
9. Finally, patients have been asked if they touched the "Consent" and "More" section during the app testing. It was also assessed if patients could describe without any help, how to withdraw from study participation. The last questions addressed a general feedback to the app, "What was good?", "What was bad?" and "What did you

miss?"

Content analysis, a method of analysis, that focuses on the subject and background and explores the similarities and differences between different users was used in this research in order to identify and understand the challenges of users in dealing with the *my ePRO app* [15]. Firstly, the written feedback was professionally transcribed verbatim into a Microsoft Excel file for each question and each user. Grouping of answers was performed to identify patterns of responses. To form themes related to each research question these patterns were summarized and the overall findings were used to update the sections of *my ePRO app* respectively.

2.7. The Quantitative Instrument

As quantitative instrument the User Experience Questionnaire UEQ was used [16-18]. The German version of the UEQ was developed in 2005. The questionnaire follows the form of a semantic differential. Each item is represented by two terms with opposite meaning, both scaled from +3 to -3. Thus, +3 represents the most positive answer, 0 a neutral answer, and -3 the most negative answer. The scale means and the mean and standard deviation per item have been calculated. The UEQ showed a sufficiently high scale consistency (measured by Cronbach's Alpha, [$\alpha = n*r/1+(n-1)*r$, where r is the mean correlation of the items in a scale and n is the number of items in a scale] for the six scales of the UEQ) and a good construct validity of the scales [16].

2.8. The Scales of the UEQ

The UEQ contains 6 scales with 26 items [19]:

1. Attractiveness: Overall impression of the product. Do users like or dislike the product? (Items: annoying / enjoyable, good / bad, unlikable / pleasing, unpleasant / pleas-ant, attractive / unattractive, friendly / unfriendly)
2. Perspicuity: Is it easy to get familiar with the product? Is it easy to learn how to use the product? (Items: not understandable / understandable, easy to learn / difficult to learn, complicated / easy, clear / confusing)
3. Efficiency: Can users solve their tasks without unnecessary effort? (Items: fast / slow, inefficient / efficient, impractical / practical, organized / cluttered)
4. Dependability: Does the user feel in control of the interaction? (Items: unpredictable / predictable, obstructive / supportive, secure / not secure, meets expectations / does not meet expectations)
5. Stimulation: Is it exciting and motivating to use the product? (Items: valuable / inferior, boring / exiting, not interesting / interesting, motivating / demotivating)
6. Novelty: Is the product innovative and creative? Does the product catch the interest of users? (Items: creative / dull, inventive / conventional, usual / leading edge, conservative / innovative)

The standard interpretation of the scale means is that values between -0.8 and 0.8 represent a neutral evaluation of the corresponding scale, values > 0,8 represent a positive evaluation and values < -0,8 represent a negative evaluation [19].

3. Results

The user experience testing of the *my ePRO app* was evaluated in a group of 9 T2DM patients, 3 female and 6 male, aged 55-88 years. Interviews lasted between 45 and 65 minutes.

3.1. Qualitative Instrument

1. Two patients had difficulties in downloading the app from the public app-store, neither having activated the download permission nor activated mobile data.
2. After opening the app, all patients were aware to scan the 2D matrix code on the outer package of their Metformin containing drug, nevertheless one patient could not identify the 2D matrix code without help. Two patients addressed, that a picture of the code would not be necessary. One patient got access to the study only after the second time scanning the code. Feedback from three patients to access rights for camera usage was:

"It would be helpful, as the camera has no scan functionality. QR code scanning is missing."

"Handling is uncommon."

"Personal support would be helpful."

3. Seven out of nine patients realized that they are offered the patient information and informed consent form ("*patient information and consent form – read, read, read and accept").* Two patients identified this section as a data protection section. Three patients mentioned the PIIC was too long, for four patients it was adequately displayed, two patients struggled with the fact, that household income would be captured. All patient had no problems in finding the checkboxes for informed consent, only one downloaded the pdf of the PIIC and no one opened the pdf. In general, six patients had no problems on the "Welcome" page, the other three patients reported:

"Too many questions. Too much text."

"A bit of too much information."

"with help, not without personal help, no further participation; a lot of unknown wording and not understandable to laymen"

4. Even though three patients reported to follow the intended workflow top down and would answer the "General Information" questionnaire, only three patients addressed the need of any instruction. Two discovered the DTSQM questionnaire first. One patient reported:

"Being curious, as no hint. Pressing the first button."

5. Six patients had no difficulties with the spinning wheel functionality, one patient missed a confirmation button, another one the question to religion and two patients would prefer manual entry of numbers. Only three patients did complete the information regarding education, family income and last available HbA1C value. Most patients had concerns and reported:

"Income is too private for many of us."

"Mixing up school education and job training. University of applied sciences entrance qualification is missing."

"Duration of diabetes and HbA1c has to be looked up."
"My income is only my business."
"Graduation and income are not their concerns."

Patients answered in different levels of health literacy on questions to nephropathy, neuropathy and angiopathy, ranging from the simple terms *"feet", "eyes" or "kidney function"* to complex explanations like *"when was the last time I was at the ophthalmologist. If the background of the eyes has changed, I have already lasered or injected medicine in the eye", "Whether my kidney function is impaired or whether I have protein in my urine.", "Whether I have nerve damage on my feet. Whether I have problems with my feet or legs in the evening or at night. Whether a vibration test has taken place."* or "*If I've had a heart attack or a stroke. Would I have had surgery on the neck arteries?*" There was no response showing that patients did not understand the core of the questions.

All patients could take a photo of their Metformin package but had issues as scanning the concomitant medication only displayed a number. One patient scanned all barcodes of his drug package within one shot and wondered:

"I held out all the packs and the software only recognized the middle pack. I cannot delete the recognized numbers."

Another patient got confused:

"I scanned a drug but don't know which one." And another one reported:

"A photo of the scanned drug was not visible. I was confused and mistakenly scanned it 3 times."

Only one patient requested a delete functionality of mistakenly scanned drugs.

Two patients double-checked their entries before finalizing their questionnaires. All participants agreed to the functionality to be reminded on open questions but to be able to finalize the questionnaires incomplete. One patient mentioned:

"Correct. Otherwise I would abort the survey."

6. For the validated DTSQM patients reported that font size was large enough and that the radio button usage was intuitively.
7. Within the EQ-5D section patients reported on the functionality of the slider for selecting their QoL on a visual analogue scale of 0-100. One patient was looking for a confirmation button *("I pushed the dot up, now I don't know if I have to press it again, since there is no green dot, so I'll continue"*), another one has overlooked the slider scale completely.
8. There were no problems in completing the SDSCA questionnaire, except one patient wondered about the content of the questionnaire:

"No possibility to click why you can't do sports."

9. Patients had problems to realize, that "Consent" and "More" sections are located within the toolbar of the app. Consequently, there were different approaches to withdraw from a study participation:

"I would delete the app."
"Trying to contact BAYER giving the reason for calling."
"I would withdraw study participation."
"No idea."
"Immediately deleting the app."
"Did not find the section."

Patients missed lay language within the app, criticized the length of the PICC, the completeness of health information which was requested, missed pictures of the drugs they scanned and judged the questions to income and education as too indiscreet. As positive feedback patient reported:

"For me, everything was explained very well. I could follow the program."
"Could be read without glasses."
"I think everything was fine, the questions were asked in a way, that I could answer easily."
"The app is quite good."
"The answering of the questions was self-explaining."
"With help, everything o.k."

3.2. Quantitative Instrument

All 9 patients completed the UEQ, but one patient only responded to 3 items (item 2, 3 and 21).

The user experience questionnaire contains the 6 scales Attractiveness, Perspicuity, Efficiency, Dependability, Stimulation and Novelty. The mean values per scale and variance as the mean values per item are displayed in table 1 and figures 3 and 4. Perspicuity, Efficiency and Novelty were rated neutral, Attractiveness, Dependability and Stimulation represent a positive evaluation.

Table 1. *Mean and Variance of UEQ Scales.*

UEQ Scales (Mean and Variance)		
Attractiveness	0,854	0,63
Perspicuity	0,722	1,73
Efficiency	0,500	0,89
Dependability	1,031	0,10
Stimulation	1,094	0,39
Novelty	0,250	1,13

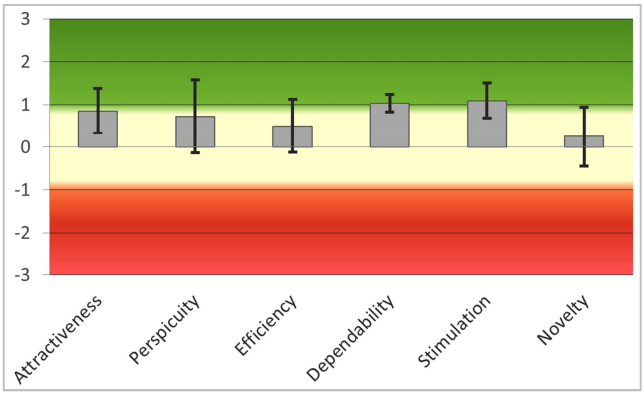

Figure 3. *User experience questionnaire scales Attractiveness, Perspicuity, Efficiency, Dependability, Stimulation and Novelty.*

Table 2. *UEQ item mean values and variances.*

Item	Mean	Variance	Std. Dev.	No.	Left	Right	Scale
1	1,6	1,1	1,1	8	annoying	enjoyable	Attractiveness
2	1,6	1,0	1,0	9	not understandable	understandable	Perspicuity
3	0,9	0,9	0,9	9	creative	dull	Novelty
4	0,0	3,7	1,9	8	easy to learn	difficult to learn	Perspicuity
5	1,1	1,0	1,0	8	valuable	inferior	Stimulation
6	1,0	0,9	0,9	8	boring	exciting	Stimulation
7	1,0	0,9	0,9	8	not interesting	interesting	Stimulation
8	0,6	0,3	0,5	8	unpredictable	predictable	Dependability
9	0,6	2,0	1,4	8	fast	slow	Efficiency
10	-1,0	1,4	1,2	8	inventive	conventional	Novelty
11	1,8	0,5	0,7	8	obstructive	supportive	Dependability
12	0,9	2,1	1,5	8	good	bad	Attractiveness
13	0,6	4,0	2,0	8	complicated	easy	Perspicuity
14	0,8	3,1	1,8	8	unlikable	pleasing	Attractiveness
15	0,5	2,6	1,6	8	usual	leading edge	Novelty
16	1,0	2,6	1,6	8	unpleasant	pleasant	Attractiveness
17	1,0	2,6	1,6	8	secure	not secure	Dependability
18	1,3	0,8	0,9	8	motivating	demotivating	Stimulation
19	0,8	3,4	1,8	8	meets expectations	does not meet expectations	Dependability
20	0,9	1,0	1,0	8	inefficient	efficient	Efficiency
21	0,4	3,0	1,7	9	clear	confusing	Perspicuity
22	0,6	3,1	1,8	8	impractical	practical	Efficiency
23	-0,1	3,6	1,9	8	organized	cluttered	Efficiency
24	0,6	0,8	0,9	8	attractive	unattractive	Attractiveness
25	0,3	1,4	1,2	8	friendly	unfriendly	Attractiveness
26	-0,1	2,1	1,5	8	conservative	innovative	Novelty

4. Discussion

The aim of this study was to describe the qualitative and quantitative outcomes of a user experience testing with *my ePRO app*. Even though the application was ready to use at timepoint of testing, a user experience testing in a focus group of diabetes mellitus type 2 patients showed room for improvement of the app.

4.1. Principal Findings

The qualitative feedback was captured, analyzed and implemented in the final version which was used to run the DePRO study. Therefore, the following changes have been implemented to *my ePRO app*:

1. To better find the 2D matrix code on the outer package, the help text “Scan 2D matrix code” and a real-life photo of a drug package was implemented into the welcome text.
2. The informed consent form has been adapted to a more lay language; despite user comments re the length of the PICC all paragraphs have been kept to fulfill ethic committee standards and data protection requirements.
3. After completing the PICC patients are now instructed to start with the “General Information” questionnaire to ensure a step by step completion of the workflow.
4. To the “General Information” start page a short instruction containing the requirement to completely answer the questions has been added.
5. The University of applied sciences entrance qualification has been added as check box for the topic “Education”.
6. An introduction how to scan comedication (drug by drug) and the functionality to delete drugs has been added.
7. To make patients aware, that they changed the start position of the EQ-5D-5L VAS slider, a colour change after moving the “dot” was implemented and scale size was increased.
8. A help text was added at the executive summary page to instruct patients where and how to withdraw from study participation. Furthermore, awareness was raised to double check completeness of each questionnaire and to “finalize and save” the questionnaires before submission.

The qualitative feedback of T2DM patients increased the awareness to test study applications like the *my ePRO app* in an indication and age specific user group. As the authors tested the application with IT affine BAYER employees before no comparable feedback could be achieved. The study participants improved the convenience of the *my ePRO app*, which has been identified as a necessity for user acceptance of an app in previous studies [14, 20]. There´s a need for further research on app functionalities, like goal setting or self-benchmarking which influence acceptance and convenience in an app-based study conduct setting [21]. Furthermore, the influence of more advanced features within the app, like individual information, feedback and service offerings on the motivation of patients will be of high value to use apps in a long-term setting.

The quantitative feedback was used as a benchmarking to other applications. All scale means have been compared with existing values from a benchmark data set (Figure 4) [18]. This data set contains data from 20190 persons from 452 different studies comparing user experience of business software, web pages, web shops or social networks. Compared

to that benchmark data set, the *my ePRO app* user experience was below average in 3 scales and bad in the 3 remaining scales. An explanation for this result may be the low number of users and the high variances indicating that patients did not realize a randomized distribution of positive and negative expressions of terms on each side of the scale while answering.

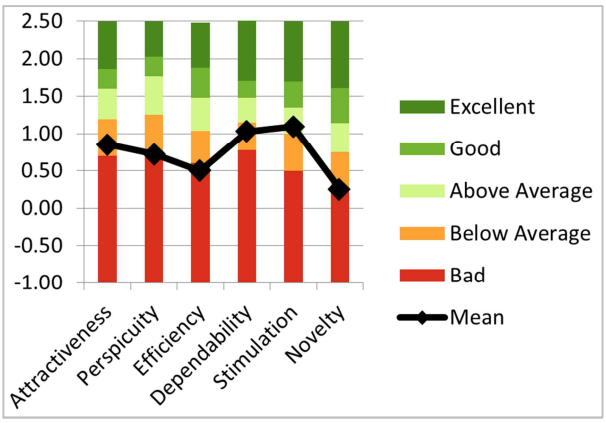

Figure 4. *Benchmarking of my ePRO app UEQ results perUE scales.*

4.2. Limitations

This is the first user experience test of the *my ePRO app*, exploring qualitative and quantitative feedback of patients for usage within DePRO study. One limitation is that only a low number of patients tested the app once, which may lead to an undifferentiated view on the app features. Nevertheless, within the DePRO study it´s exactly this set-up patients are confronted with to provide information about their health status, self-care activities and quality of life. Secondly there´s a selection bias in recruiting patients at only one study site. It is possible that only technophile patients decided to participate in the user experience test. As T2DM affects predominantly older people and this population is still using mobile devices and apps less often, the bias introduced may be considerable. Third the educational level and the health literacy of the participants has not been captured. Even though consecutive recruitment was performed among Metformin taking patients representativeness for a type 2 Diabetes Mellitus cohort is limited. Lastly the influence by the recruiting pharmacist on the patients at point of sale has not been tested in the user experience test and may lead to different levels of perception regarding usability of *my ePRO app* within DePRO study.

5. Conclusion

The user experience testing provided insight into usage, challenges and areas of improvement of *my ePRO app* in a type 2 Diabetes Mellitus focus group. The UX group tested the entire workflow from downloading the app, accepting to terms and conditions of *my ePRO app,* giving informed consent, completing the questionnaires and receiving a remuneration for the time spent. It therefore reduced barriers of study conduct like missing data, drop-out rates or systematic errors in data collection before the DePRO study was initiated. By using a qualitative focus group approach, thematic patterns could be identified, and app features could be improved with a new release. Furthermore, the health literacy of patients was assessed and the wording of medical history questions within the study could be improved. The quantitative questionnaires enabled a comparison of *my ePRO app* with other products or business software now and later, when future releases of the app will have appeared. User experience testing of *my ePRO app* was a simple and effective way to understand the different views, experiences and expectations of patients processing a study workflow which can lead to a better design of health apps and a successful study conduct.

Authors' Contributions

CM is responsible for the study design and drafting of this article and is responsible for the initiation and conduct of the study.

IS contributed to the implementation of changing *my ePRO app*, and drafting of this article.

SM contributed to the study design and drafting of this article.

All authors revised the article critically for important intellectual content, and all authors approved the final version.

Conflicts of Interest

CM is employee of Bayer Vital GmbH (Leverkusen, Germany).
IS is COO of Institut Dr. Schauerte.
SM has received support from Bayer Vital GmbH.

Abbreviations

CRO: contract research organization
DM: diabetes mellitus
DTSQ: diabetes treatment satisfaction questionnaire
EQ-5D-5L: 5-level, 5-dimension EuroQol questionnaire
PIIC: patient information and informed consent form
PRO: patient-reported outcome
SD: standard deviation
SDSCA: summary of diabetes self-care activities
VAS: visual analog scale

Study Registration

ClinicalTrials.gov: NCT04383041.

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