

















Satisfaction, Self-management and Usability: Assessment of Two Novel IT Solutions for Type 2 Diabetes Patients' Empowerment

Vincenzo De Luca¹^a, Lutgarda Bozzetto²^b, Clemente Giglio²^c, Giovanni Tramontano²^d,
Carlos Juan Chiatti³^e, Fotis Gonidis⁴^f, Strahil Birov⁵^g, Ozan Beyhan⁶^h, Simon Robinson⁵ⁱ,
Gorka Sanchez-Nanclares⁷^j, Maria del Pilar López-Acuña⁸^k, Adriano Fernandes⁹^l,
Maria Triassi¹^m, Giovanni Annuzzi²ⁿ, Guido Iaccarino¹⁰^o and Maddalena Illario¹^p

¹Dipartimento di Sanità Pubblica, Università degli Studi di Napoli "Federico II", via S. Pansini 5, Naples, Italy

²Azienda Ospedaliera Universitaria Federico II, via S. Pansini 5, Naples, Italy

³Tech4Care Srl, Via Guglielmo Marconi 31, 60015 Falconara Marittima AN, Italy

⁴Gnomon Informatics SA, Antoni Tritsi 21, 57001, Thessaloniki, Greece

⁵empirica Gesellschaft für Kommunikations- und Technologieforschung mbH, Oxfordstr. 2, Bonn, Germany

⁶Ministry of Health Turkey, Üniversiteler Mah. 6001. Cad. No. 9, Ankara, Turkey

⁷Servicio Murciano de Salud, Central, 7 Edificio "Habitamia"- 5ª, 30100 Murcia, Spain


⁸FFIS, Luis Fontes Pagán, 9. 1ª, 30003 Murcia, Spain


⁹Misericordia of Amadora, Innovation Department, Estrada da Portela-Quinta das Torres, Amadora, Portugal


¹⁰Dipartimento di Scienze Biomediche Avanzate, Università degli Studi di Napoli "Federico II",
via S. Pansini 5, Naples, Italy


Keywords: ICT, Diabetes Mellitus, Management, Satisfaction, Usability, mHealth.


Abstract: The growing digitalization of health and care calls for the development of ICT tools and mHealth solutions to monitor and control the patient's health parameters and lifestyles. ProEmpower is a Pre Commercial Procurement project aimed at procuring research and development services to develop innovative solutions for patient empowerment and self-management of Type 2 Diabetes Mellitus. The project consortium launched a call for tenders, articulated in 3 phases to select solutions. During Phase III, two solutions have been selected to be tested by end-users: DM4All and DiaWatch. A pilot study has been carried out to evaluate direct and indirect outcomes linked to the use of the novel solutions. Among these, we assessed the post-intervention satisfaction, self-management and usability of the two novel solutions, using a 5-point


^a  <https://orcid.org/0000-0002-6115-931X>


^b  <https://orcid.org/0000-0001-6549-4476>


^c  <https://orcid.org/0000-0003-3121-7504>


^d  <https://orcid.org/0000-0002-0441-699X>


^e  <https://orcid.org/0000-0003-4810-9630>


^f  <https://orcid.org/0000-0002-5605-4249>


^g  <https://orcid.org/0000-0002-4575-0492>


^h  <https://orcid.org/0000-0002-4337-3232>


ⁱ  <https://orcid.org/0000-0002-8572-3595>


^j  <https://orcid.org/0000-0002-1797-9660>


^k  <https://orcid.org/0000-0002-0986-3633>

^l  <https://orcid.org/0000-0003-3644-7544>

^m  <https://orcid.org/0000-0002-9420-9571>

ⁿ  <https://orcid.org/0000-0002-9324-6047>

^o  <https://orcid.org/0000-0002-8997-835X>

^p  <https://orcid.org/0000-0001-9834-6517>

Likert scale questionnaire. Users expressed a favourable opinion on both solutions, evaluating the experience during the pilot phase as positive. DM4All results are better, however, the questionnaire completion rate was higher in DiaWatch. Users appreciated DM4All for its usefulness in managing their conditions.

1 INTRODUCTION

The growing digitalization of health and care, combined with an increasing Information and Communication Technologies (ICT) literacy of citizens and patients, calls for the development of tools and mobile-health (mHealth) solutions to monitor and control the patient's status and, in general, health parameters and lifestyles. A new generation of software, apps and algorithms for managing patient's data, has paved the way for the implementation of new ways to collect and process health-related data, helping both professionals and patients to manage disease, improving the quality of healthcare.

“Procuring innovative ICT for patient empowerment and self-management of type 2 diabetes mellitus” (ProEmpower) is a Pre Commercial Procurement (PCP) project, financed by European Commission (EC)'s Horizon 2020 Programme (European Commission, 2019), aimed at procuring research and development (R&D) services to develop innovative ICT solutions for patient empowerment and self-management of Type 2 Diabetes Mellitus (T2DM). The project involved four public procurers across Europe (Turkey, Portugal, Campania - Italy and Murcia - Spain) that cooperated to develop detailed specifications, based on user-centred approach (De Luca V, et al., 2019), for new diabetes management processes supported by fully integrated ICT solutions. As part of ProEmpower PCP, the project consortium launched a call for tenders, articulated in 3 phases to select solutions. During Phase I, the technical, economic and organizational feasibility of five alternative solutions has been assessed. Phase II aimed to verify the main characteristics of three prototypes. During phase III two solutions have been tested by end-users (patients and health professionals) enrolled by healthcare organisations of the four procurers: DM4ALL and DiaWatch (De Luca, V., et al., 2020).

DM4ALL digital platform includes web and mobile interfaces along with intelligent medical devices, able to support all the diverse needs of the T2DM care pathway. Patients, Informal Caregivers, and Healthcare professionals are able to manage, communicate, and monitor the disease progression

through the system. Thus, this multi-pronged and integrated approach promotes self-care practices and continuous monitoring. DM4ALL is developed based on the Shared Care Plan (SCP), a “document” including information about lifestyles, treatment plan, and disease-related markers. Furthermore, it collects information and feedback from the patients through validated questionnaires aiming at increasing impact and personalization.

DiaWatch is a mHealth and telemedicine solution to provide a more effective and personalized T2DM management. DiaWatch presents a sensing system platform, that operates using a smartphone optionally integrated with other devices such as a wristband, a glucose monitoring sensor, a blood pressure meter and a scale. The DiaWatch's Virtual Coach based on an artificial intelligent system to profile the patient and make appropriate recommendations for diabetes treatment, exercises and healthy lifestyles. A patient personal profile and related data-entry functions are embedded in a SCP progressively updated with new data from different sources. The desktop and mobile interface for clinicians allows professionals to monitor compliance to treatment and goals, to communicate with patients (via textual messages, audio and video features) directly from the healthcare facility, and to identify people at risk of developing diabetes or acute conditions. DiaWatch presents a social community tool for interaction, communication and peer training. A cloud-based platform ensures data exploitation for risk prediction.

Here we show the results of a questionnaire built to capture the patients' opinions about satisfaction, usability and acceptance of the solutions.

2 METHODS

The aim of the pilot study was to test the feasibility, effectiveness and usability of incorporating the two solutions into the current care pathway for patients with type 2 diabetes. Study objectives were to evaluate direct and indirect outcomes linked to the use of the novel solutions, including:

- a) behavioural changes:
 - i. smoking habits;
 - ii. physical activity;
 - iii. steps;
 - iv. meals;
 - v. medication adherence;
- b) clinical and quality of life (QoL) outcomes:
 - i. HbA1c;
 - ii. weight;
 - iii. blood pressure (BP);
 - iv. blood lipids;
 - v. cholesterol;
 - vi. quality of life;
- c) satisfaction, self-management and usability.

The pilot study took place in all four pilot sites, involving 50 participants for each solution per pilot site, with a total of 400 participants. All participants were adults with a previous diagnosis of type 2 diabetes mellitus (from recently diagnosed to long-standing diabetes), that received insulin therapy and/or diabetes medication. During the enrolment of patients, the criteria in the Table 1 were taken into consideration.

Table 1: Patients inclusion and exclusion criteria.

Inclusion criteria	Type 2 Diabetes diagnosis
	Aged between 45 and 79
	Ability to provide written informed consent
Exclusion criteria	Chronic renal replacement therapy (Haemodialysis, peritoneal dialysis or transplantation)
	History of active malignancy within the last 12 months
	Pregnancy
	Chronic viral hepatitis
	HIV infection

Eligible participants were offered the opportunity to use one solution as part of their care pathway and underwent evaluations by a research assistant at baseline (enrollment) and post intervention. The phase III of ProEmpower was carried out from July 2019 to July 2020(Figure 1).

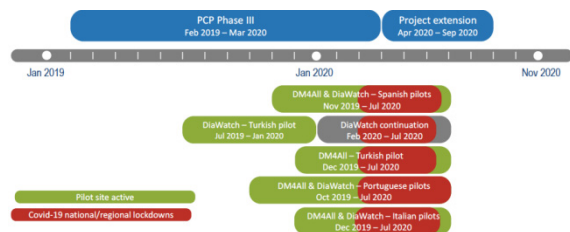


Figure 1: ProEmpower Phase III timeline.

An eleven-questions survey was administered post-intervention to patients for the assessment of satisfaction, self-management and usability (Nielsen, J., 1994). In order to build the questionnaire we used a 5-point Likert scale as a psychometric scale to assess patients’ opinions regarding the two novel solutions (Joshi, A., 2015)(Sullivan, G.M., 2013) for the T2DM self-management. The consortium developed the questionnaire based on the Questionnaire for User Interaction Satisfaction (QUIS7) instrument (Harper, B.D., 1993). The questionnaire was implemented as an online survey and administered to the patients taking part in the four pilots. The following elements have been considered for each category:

- a) Satisfaction
 - Experience with the solution during the pilot;
 - Satisfaction with the overall solution;
 - Ability to get along with diabetes;
 - Worth the effort involved.
- b) Self-management
 - Usefulness in managing the patient’s condition;
 - Self-management quality improvement;
 - Overall fit with the way of life.
- c) Usability
 - Usability from terrible to wonderful;
 - Usability from frustrating to satisfying;
 - Usability from dull to stimulating;
 - Usability from difficult to easy.

3 RESULTS

3.1 DM4all

The DM4all local pilot managers distributed the questionnaire to the patients participating in the pilot study. During July 2020, they were able to collect the answers of n=56 patients (from all the 4 pilot sites).

The experience with the DM4All during the testing period is considered positive by 46.4% of the patients and 33.9 % of them considered that it as was very positive (Figure 2).

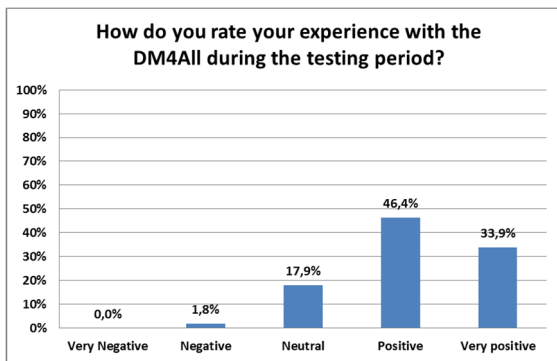


Figure 2: DM4All Satisfaction survey, Question 1.

The vast majority of interviewed patients were fairly satisfied (58.9%) or very satisfied (25%) with it (Figure 3).

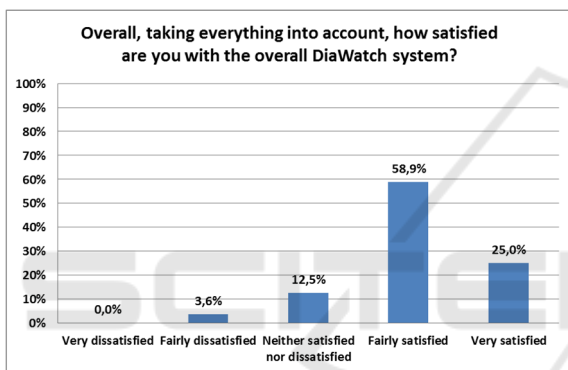


Figure 3: DM4All Satisfaction survey, Question 2.

The results regarding the way that the participation in the project affected the patients ability to manage their condition on a day-to-day basis were also very encouraging: 46.4% of the patients considered that by participating in the study they increased a little bit their ability to manage their condition; and 26.8% considered that that by participating in the study they increased a lot their ability to manage their condition (Figure 4).

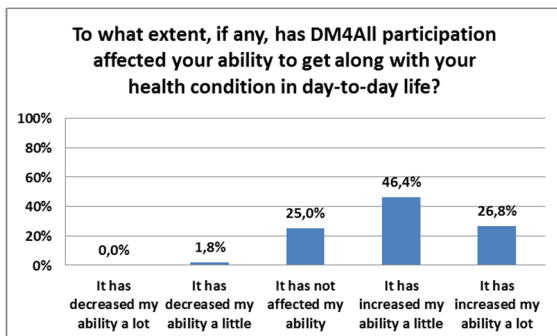


Figure 4: DM4All Satisfaction survey, Question 3.

Using the DM4All system, 50% of the patients considered that effort is mostly worth it and, more importantly, 33.9% of the patients considered that effort as totally worth it (Figure 5).

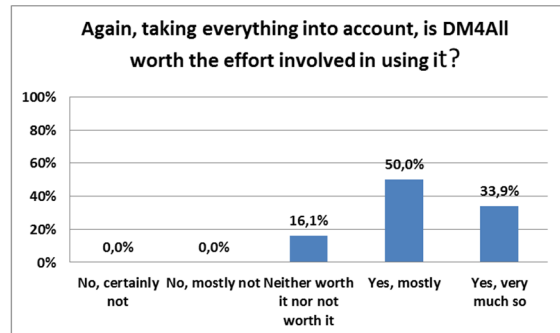


Figure 5: DM4All Satisfaction survey, Question 4.

When questioned about the usefulness of the DM4All system in the management of their clinical condition, 47.3% of the patients agreed that it is useful while 36.4% of the patients strongly agreed that is useful (Figure 6).

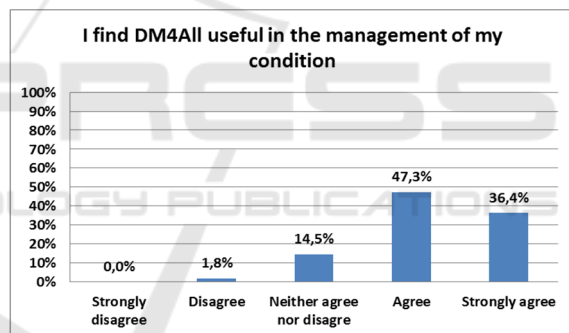


Figure 6: DM4All Self-management survey, Question 1.

The patients agreed with the fact that the DM4All system increased the quality of the self-management of their condition, 55.4% of them agreed and 28.5% strongly agreed with that sentence (Figure 7).

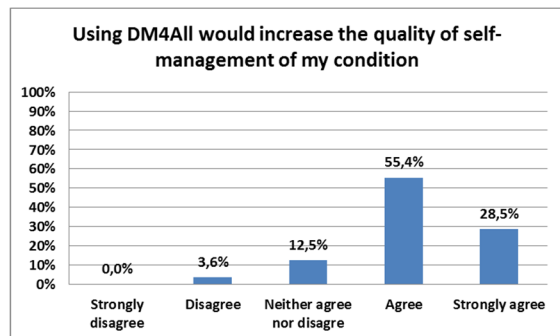


Figure 7: DM4All Self-management survey, Question 2.

The patients agreed with the fact that the DM4All system fitted with their way of living (78.6 %) (Figure 8).

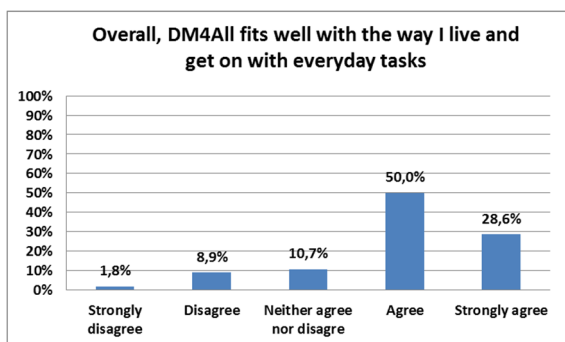


Figure 8: DM4All Self-management survey, Question 3.

Regarding the way that the patients perceive the DM4All system: 30.4 % considered it as being wonderful; 36.4 % considered it as being satisfying; 33.9% considered it as being stimulating; more than 39% considered it as being easy (Figure 9).

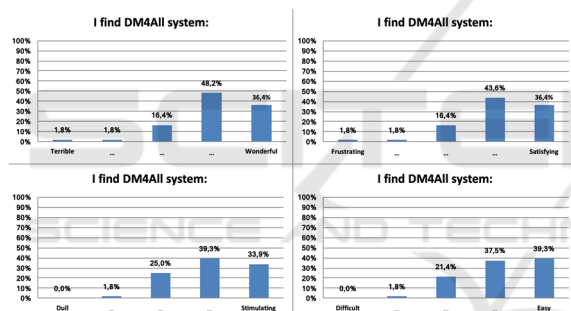


Figure 9: DM4All Usability survey.

Overall, we can say that the patients that were inquired and answered the questionnaire were very happy with the DM4all system in terms of usability, acceptance and satisfaction.

3.2 DiaWatch

The DiaWatch local pilot managers collected the answers of n=158 patients (from all the 4 pilot sites). A good majority of patients (69.0%) reported a positive or very positive experience with DiaWatch, whereas only few people (3.8%) indicated a negative experience (Figure 10).

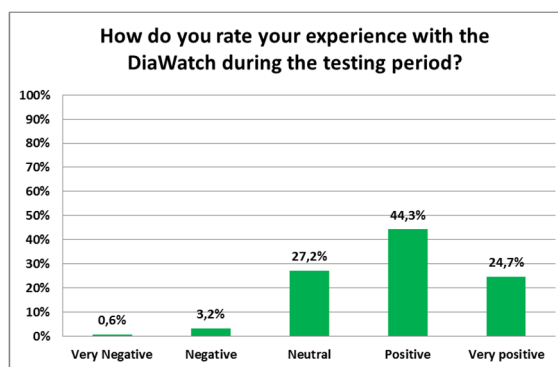


Figure 10: DiaWatch Satisfaction survey, Question 1.

The general satisfaction with the DiaWatch system was high, with 61.2% of patients indicating to be fairly or very satisfied with it. Dissatisfaction with the solution (i.e. being fairly or very dissatisfied) was reported only in few cases (Figure 11).

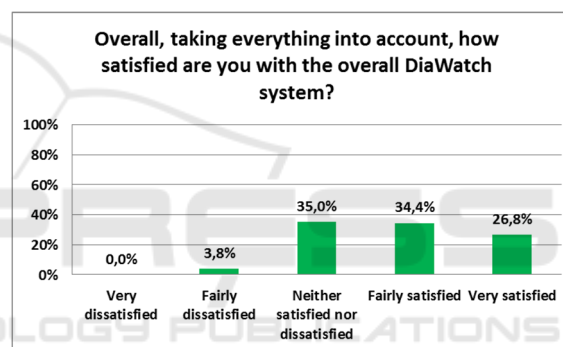


Figure 11: DiaWatch Satisfaction survey, Question 2.

Answers from users emphasized a very positive perception of the DiaWatch impact on self-management of health condition. In total, 61.2% of patients reported a little or big increase of individual ability, whereas 38.6% said that the system did not have a substantial impact. No negative answers were given (Figure 12).

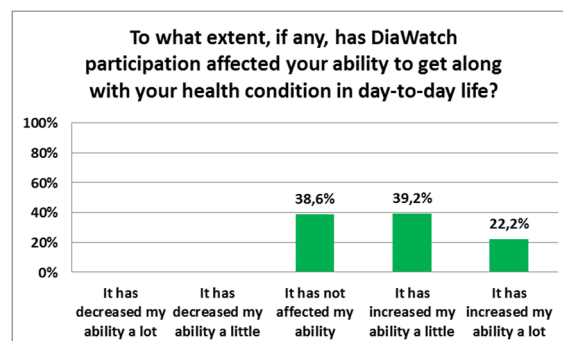


Figure 12: DiaWatch Satisfaction survey, Question 3.

In line with previous results, the general feeling by patients was that the DiaWatch solution is certainly worth to be used. 67.7% of all respondents said that the solution is either mostly or very much worth to be used, whereas only 5% indicated a negative answer (Figure 13).

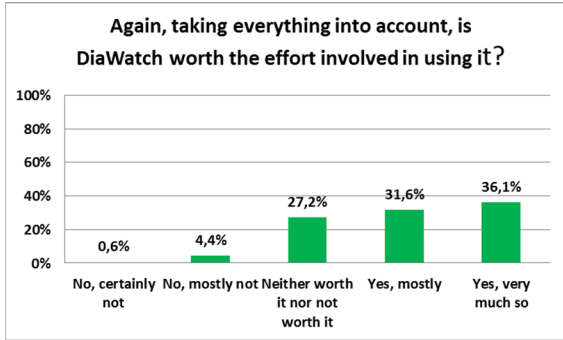


Figure 13: DiaWatch Satisfaction survey, Question 4.

More than two thirds of users (70.0%) confirmed that they found DiaWatch useful for the management of their condition (Figure 14).

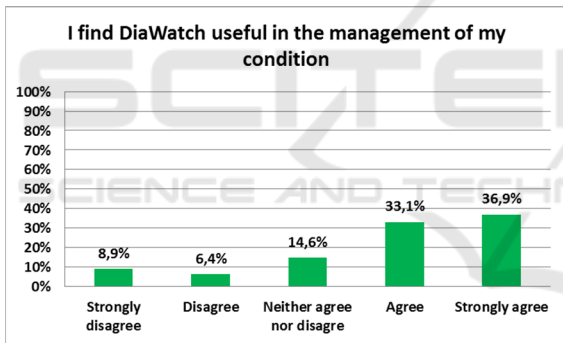


Figure 14: DiaWatch Self-management survey, Question 1.

In terms of quality of self-management, overall DiaWatch helped patients to increase it. 64.7% of users agreed or strongly agreed with this statement, whereas a minority (14.6%) disagreed or strongly disagreed (Figure 15).

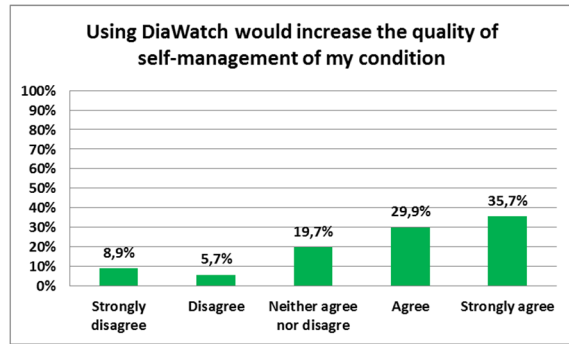


Figure 15: DiaWatch Self-management survey, Question 2.

Finally, a good majority of users (64.9%) reported that DiaWatch fits well their way of living (agree or strongly agree) (Figure 16).

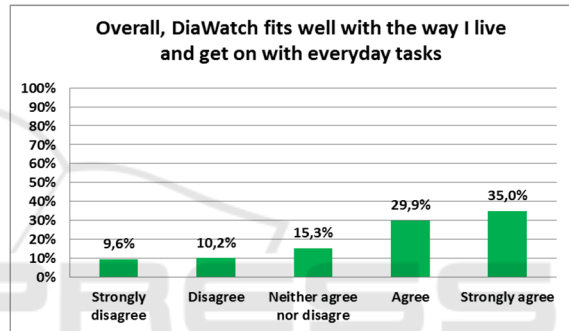


Figure 16: DiaWatch Self-management survey, Question 3.

The perceived usability of the DiaWatch system is fair: 22.9% considered it as being wonderful; 25.8% considered it as being satisfying; 15.4% considered it as being stimulating; 19.4% considered it as being easy (Figure 17).

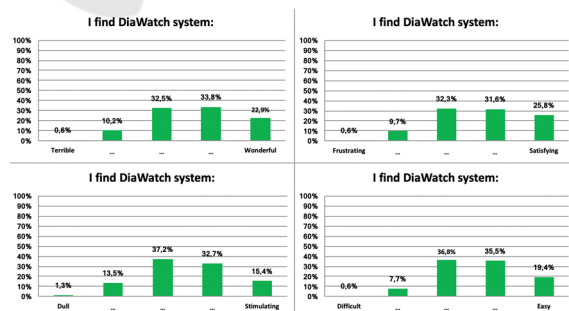


Figure 17: DiaWatch Usability survey, Question 1.

4 CONCLUSIONS

The collected data regarding each question for each

solution are quite similar but DM4ALL is generally represented better. However, it must be considered that the rate of questionnaire completion was higher in DiaWatch. Both solutions created a positive experience during the testing phase and increased patients' ability to manage their condition. For DM4All, the scores varied between 4.04 and 4.18, while for DiaWatch, the scores varied between 3.5 and 4.01. DM4All was appreciated mostly for its usefulness in managing patients' condition, and users considered that the effort involved in using DiaWatch was worth it (Figure 18).

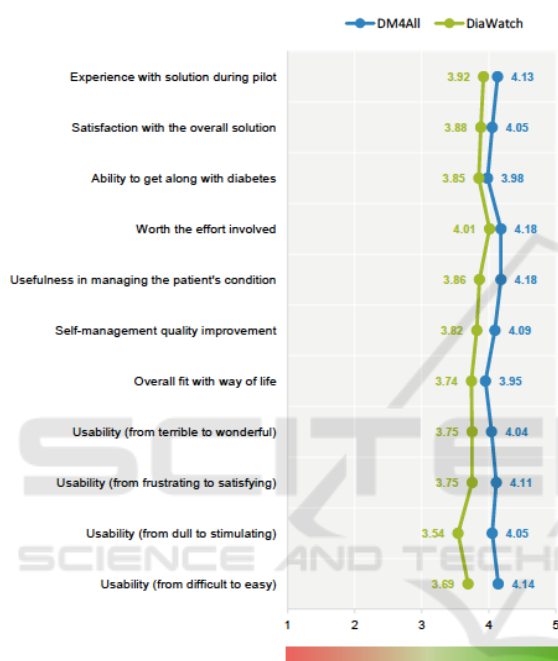


Figure 18: Summary graph of the results of the patient's questionnaire.

ProEmpower solutions were developed iteratively, taking into account user-centered design. User-friendliness of the interfaces for digital health solutions play a key role in ensuring adherence. The two solutions developed in ProEmpower are not yet mature for large-scale adoption. Building the key elements for usability since early stages of solutions design may be related to moderate adaptations, including meanings and formats, or extensive adaptations with changes such as the removal of items or the addition of more sophisticated functions. Adequate further testing needs to be ensured for any changes, to collect patient's feedback.

This is particularly important considering the burden of the disease these patients face every day dealing with a chronic and severe condition such as

type 2 diabetes. These solutions may help reducing this burden and improving quality of life. Our results are encouraging, although further study will be required, to assess correlations between specific features and outcomes.

ACKNOWLEDGEMENTS

The ProEmpower project has received funding from the European Union's Horizon 2020 research and innovation programme under the Grant Agreement No. 727409.

REFERENCES

European Commission, 2019. Pre-commercial Procurement: Driving innovation to ensure sustainable high quality public services in Europe. *COM(2007) 799 final*.

European Commission, 2019. Horizon 2020 Work Programme 2018-2020. *European Commission Decision C(2019)4575*.

De Luca, V., et al., 2019. European Specifications for Value-based Pre-Commercial Procurement of Innovative ICT for Empowerment and Self-management of Diabetes Mellitus Patients. *Proceedings of the 5th International Conf. on Information and Communication Technologies for Ageing Well and e-Health (ICT4AWE 2019)*, pages 19-27.

De Luca, V., et al., 2020. Developing a Digital Environment for the Management of Chronic Conditions: The ProEmpower Experience of a Horizon 2020 PCP for Type 2 Diabetes. In: Ziefle M., Maciaszek L. (eds) *Information and Communication Technologies for Ageing Well and e-Health. ICT4AWE 2019. Communications in Computer and Information Science, vol 1219. Springer, Cham*. https://doi.org/10.1007/978-3-030-52677-1_1.

Nielsen, J., 1994. Usability engineering. *Morgan Kaufmann*.

Joshi, A., et al., 2015. Likert Scale: Explored and Explained. <https://doi.org/10.9734/bjast/2015/14975>.

Sullivan, G.M., et al., 2013. Analyzing and Interpreting Data from Likert-Type Scales. *J. Grad. Med. Educ. 5*, 541-542. <https://doi.org/10.4300/JGME-5-4-18>.

Harper, B.D. and Norman, K.L. 1993. Improving User Satisfaction: The Questionnaire for User Interaction Satisfaction Version 5.5. *Proceedings of the 1st Annual Mid-Atlantic Human Factors Conference*, (pp. 224-228), Virginia Beach, VA.

Aiyegbusi, O.L., 2020. Key methodological considerations for usability testing of electronic patient-reported outcome (ePRO) systems. *Qual Life Res 29*, 325-333. <https://doi.org/10.1007/s11136-019-02329-z>.