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| **WP7 - Bulgaria**  **Individual pilot action report** |
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1. **Title**

Empowring People with Diabetes within the framework of JA CHRODIS Recommendations and Criteria through the Use of mHealth Technology

1. **Abstract**

Diabetes self-management is considered a cornerstone in preventing long-term complications. Every individual can succeed in achieving good control over diabetes when following several rules. This pilot was designed within the framework for the implementation of actions using JA CHRODIS Recommendations and criteria to promote self-management via momentary and daily assessments with the help of a mobile app as a means towards sustainable and scalable patient care.

The recruited participants (N=19) were allocated to two versions of the app – an enhanced version (with personalized feedback and embedded health education module – group T; N=11) and a basic version (without feedback and education module – group C; N=8). The intervention’s objectives were to investigate whether the app enables people with diabetes to obtain more control over their disease; to examine the extent to which personalized feedback and a health education module contributes to patients’ compliance; and to assess practitioner’s satisfaction on patients’ performance.

The quantitative data derived from the momentary and daily assessment of participants revealed higher involvement and lower dropout rate for group T and an unusual increase of physical exercises for group C. The end-of-study interviews showed that 11 participants reported improved control of their disease, while 12 of them said that the application met their diabetes needs. The practitioner’s interview indicates satisfaction of patients’ performance and further explains the importance of the two-way communication with patients. Based on the implementation experience within the JA CHRODIS Recommendations and Criteria framework, future impementation recommendation are reported.

**Short summary**

Diabetes self-management is considered a cornerstone in preventing long-term complications. Every individual can succeed in achieving good control over his/her diabetes when following several rules - taking prescribed medications, monitoring blood sugar levels, having a healthy diet, and exercising regularly. Nowadays, mHealth technology are widely used and serve to assist patients to adhere to diet, exercise, and medication plans. The current project strives to implement a mobile healthcare application to empower and assist people with diabetes.

This pilot is designed within the framework for the implementation of actions using JA CHRODIS Recommendations and Criteria[[1]](#footnote-1) through a mobile health application that allows patients to record their momentary assessments several times a day*.* It aims to promote self-management via momentary and daily assessments with the help of a mobile app as a means towards sustainable and scalable patient care. For this purpose, two groups of participants were recruited – the first group received the enhanced version of the mobile app (with personalized feedback and embedded health education module; N=11), and the second group received the basic version (without personalized feedback and embedded education module; N=8). The pilot aims to examine the extent to which the mHealth app contributes in making patients obtain more control over their disease in their daily life; it also investigates the extent to which the personalized feedback offered by a practitioner and by an embedded health education module contributes in making patients obtain more control over their disease; and it further examines the extent to which the practitioner is satisfied with the patients’ performance at the end of the study.

The impact of the intervention was evaluated through analysis of the participants’ performance from the basic and the enhanced intervention and through structured end-of-study questionnaires with all participants and with the involved practitioner. The results in the current report are based on approx. 22 days of interaction on average for group C and 60 days of interaction on average for group T. In terms of compliance, the impact by juxtaposing the 1st week of the intervention to the 4th (mid of intervention) and the 8th (end), participants of group T indicated higher involvement and lower dropout rate. The indicator of patient performance demonstrated an unusual increase of physical exercises as well as better control over the disease for group C at week 4. However, the data cannot be relied upon, since it refers to low number of participants at the time of the analysis. Further results and analysis are to be conducted as participants from group C entered several weeks after the beginning of the pilot and were still using the mobile application during the first preliminary statistical results.

The reports from the end-of-study interviews indicate that participants benefited from the intervention in place. 12 out of all 19 participants said that the mHealth tool met their diabetes needs and 11 of them indicated that their control over the disease had improved. The participants from the enhanced intervention praised the fact that a practitioner was involved in the provision of feedback and thought that the feedback had to be organized in a more personalized manner.

This perspective was reinforced by the practitioner’s view of the importance of the two-way communication between a patient and a physician. The practitioner was satisfied by the weekly statistical reports of patients’ data (which were extracted from the app) and was further satisfied by the performance of the participants. Additionally, the practitioner highlighted the fact that close relationship has to be considered as a prerequisit for motivation and that mHealth technology has to include a more comprehensive connection, which can also lead to better understanding of the role of the medical specialist.

Overall, the targeted population has benefited through the easy-to-use mobile application and the shared decision-making and education-information available in the process. The pilot involved different stakeholders that were available to the users and that was further reinforced by the support of the technical team.

The current intervention provides an alternative support for people with diabetes and offers suggestions and future implementation recommendations.

**Introduction**

1. **Problem Description**

Diabetes has become an increasing public health issue in Bulgaria, affecting 8.3% of the population.[[2]](#footnote-2) 75% of patients with diabetes are reported to have poor control over their condition, related to worse diabetic outcomes, particularly in the development and progression of diabetic complications. Long-term complications include, but not limit, cardiovascular complications, nephropathy, neuropathy, retinopathy, etc., and may severely reduce the quality of life of the patient. Indisputably, prevention is the pathway to limit these complications.

Self-management and care are considered a cornerstone of diabetes care in preventing acute and long-term complications. Important components of self-management include careful monitoring, healthy eating, physical activity, diabetes education, medical plans and others. Every individual can succeed in achieving good control over his/her diabetes when following several rules - taking prescribed medications, monitoring blood sugar levels, having a healthy diet, and exercising regularly – all on a daily basis.

The current project strives to implement a mobile healthcare application to empower and assist patients with diabetes. The pilot action focuses on alternatives to traditional healthcare for patients with chronic diseases with electronic support and information technologies. Its purpose is to facilitate and stimulate therapeutic compliance and metabolic control by the patients themselves with the aim to reach comprehensive self-management ability regarding their condition.

The National Center of Public Health and Analyses (NCPHA), Bulgaria, is a structure within the national healthcare system and performs public health activities, promoting health and preventing diseases, providing information for healthcare management in the country.  NCPHA is responsible for the National Programme for Prevention of Noncommunicable Diseases (NPPNCDs), where diabetes and its complications are a main focus. NCPHA team strives to promote self-management and self-promotion for people with diabetes, and serves as a bridge between the mobile application and the patients together with the assistance of the Bulgarian Association Diabetes.

1. **Available knowledge**

Once diagnosed, diabetes creates a great burden for the patient. Medical care is associated with time and cost. A major part for a successful treatment is the detailed information and the medical advice provided by healthcare professionals. Likewise, quality healthcare outcomes depend upon patients’ adherence to recommended regimens. Another However, medical appointments are associated with time and cost, whereas compliance to treatment is in accordance with the patient’s will. But, if patients are guided towards better self-management, they fell more motivated, may need less medical attention, which in return, will also lower the financial impact. Thus, a competent professional at the patient’s side, ensuring his/her compliance and supporting him/her with feedback, would be of considerable value for the treatment. Many studies[[3]](#footnote-3),[[4]](#footnote-4),[[5]](#footnote-5) indicate that e-health is a good tool for self-management and empowerment for diabetes patients.

NCPHA, Bulgaria in collaboration with MoH and all 28 regional health inspectorates within the country design and implement activities within the NPPNCDs, where diabetes and its complications act as a main focus. This pilot action is aligned to the Programme and will be conducted with the support of the leading diabetes association in the country. The pilot action aims to contribute in limiting the difficulties related to the lack of specialists in small towns, by promoting self-control and self-discipline among diabetes patients. It builds upon the assertion that every individual can succeed in achieving good control over his/her diabetes, by adhering to really simple rules on a daily basis. The pilot will give patients a daily companion to monitor and control their disease and will provide professionals the means of giving feedback in a simpler and easier way.

Important details on local background knowledge sources include insights from the NPPNC, from collaboration between NCPHA and the Bulgarian Association Diabetes, from surveys conducted by NCPHA, from intervention activities and training workshops conducted by NCPHA, from close interaction between NCPHA and the 28 RHI with respect to practitioners’ availability, information dissemination materials on healthy living, willingness of diabetes patients to participate in actions that promote self-management.

1. **Rationale**

The informal framework of the intervention followed the "Health 2020: Education and health through the life-course" of the WHO Regional Office for Europe that "public health challenges faced by countries of the European Region require an effective life-course strategy that gives priority to new interdisciplinary approaches to promoting health and preventing disease, based on the principles of engagement and empowerment." This pilot was further designed considering the framework for the implementation of actions using JA CHRODIS Recommendations and Criteria[[6]](#footnote-6) to promote self-management via momentary and daily assessments with the help of a mobile app as a means towards sustainable and scalable patient care.

Based on findings from research studies, the pilot relied on Ecological Momentary Assessment(EMA)[[7]](#footnote-7), and on continuous glucose monitoring to reduce hypoglycemia and hyperglycemia and to improve patients’ quality of life. The study has two groups of participants - one receiving practitioner’s feedback (enhanced intervention group) and one receiving no feedback (basic intervention group). We expect to identify tendencies that reflect the effects of EMA on how patients control their disease by:

* Giving the patients the opportunity to monitor their disease at a daily basis, we expect that they will be more motivated to monitor the disease, to increase physical activity and to control the disease better. [basic intervention, all participants]
* Giving the patients the opportunity to receive feedback from their professional via the mobile app and in response to their momentary assessments concerning their disease, we expect that they will control their disease better than if they receive no feedback. [enhanced intervention]
* Offering the patients a health education module via the mobile app, we expect that they will be assisted better than those who do not receive the assistance. [enhanced intervention]

1. **Specific aims**

This pilot uses EMA methodology with supportive mHealth infrastructure, which allowed the patients to record their momentary assessments on blood sugar levels, nutrition and physical activity more than once a day. Additionally, there was an evening momentary assessment, allowing them to report the extent to which they feel in control of their disease. Our specific aims were to:

* **A1**. To investigate whether the mHealth app enables patients to obtain more control over their disease;
* **A2**. To investigate the extent to which the practitioner’s personalized feedback and the health education module contributes in making the patients obtain more control over their disease;
* **A3**. To investigate the practitioner’s satisfaction on patients’ performance.

**Methods**

1. **Context**

The pilot was conducted taking into consideration the strategic tool of identifying strengths, weaknesses, opportunities, and threats. The use of mHealth technology was considered an important factor and a strength in the daily self-management of patients’ disease. This approach of managing diabetes through the recording of their daily assessments on blood sugar levels, nutrition and physical activity more than once a day will give patients the opportunity to take more control over their diabetes, and, at the same time, to record information on their disease at a level of granularity (momentary assessment). Another strength is the widespread familiary of people in relation to mobile technology embedded in smartphones, which will allow them to easily feel in control of their assessment and consequently, their disease.

The SWOT analysis identified two opportunities. Mobile health technology and communication could offer the practitioner the opportunity to closely monitor patients and at the same time the opportunity to acquire information that leads to personalized feedback.

A weakness for the healthcare professional could be the need for education to use the technology. An analogous issue applies also for patients with diabetes, so there is risk that patients become weary and face new solutions with distrust. The LIWG would provide special training for the practitioner and for the participants to overcome these threats.

The team also indicated the reliability of momentary assessments as weakness, as they are recorded entirely by the patients themselves and are not observed behaviours in a laboratory environment. This weakness is accompanied by another factor related to momentary assessments. Momentary assessments are elements which require patients to exhibit perseverance and self-discipline, which may be challenging. However, these weaknesses can be overcome by the mobile app’s popping notifications that remind patients to assess and record their daily blood sugar levels, their nutrtion as well as their physical activity.

Self-management via a mobile app does not annulate the overhead of patient monitoring. Healthcare professionals need to acquire insights about the nature, time and cost of patient monitoring via a mobile app. This may be a barrier to the deployment of self-management solutions, but could be overcome through the healthcare’s feedback and through the assistance provided by the LIWG team.

1. **Intervention**

The JA CHRODIS Recommendations and Criteria was used as a framework to design and implement the use of mHealth thechnology to reach the aim of empowering people with diabetes. The NCPHA team acquired ethics approval for both versions of the mHealth app - basic and enhanced interventions. NCPHA was supported by knowledge expertise by the Bulgarian Association Diabetes, which is the nationally represented association with more than 20 years of history in Bulgaria. The decision-making activities were conducted by the local implementation group, which included healthcare specialists in the field of health promotion and disease prevention, representatives from patient association groups as well as physicians.

In order to reach the specific aims, two groups of participants were recruited by the NCPHA with the close collaboration of the Bulgarian Association Diabetes assistance. Diabetes patients’ criteria included: patients over 18 years of age, availability of smartphone and familiarity with smartphone technology basics. The target population consisted of diabetic patients diagnosed both with Type I and Type II diabetes.

The participants were reached via an email or/and a telephone call. They received a detailed instruction package via an email containing information about the nature of the pilot study, information sheet also containing data protection issues, detailed video and written instructions (both in Bulgarian language) on how to use the mobile application and instructions on how to download the mobile application. If necessary, they were given the opportunity for further assistance to be tutored through the use of the mobile application.

Participants that started using the application had to report their momentary assessment in the mHealth app. On the first use of the app, all participants had to fill in the following questionnaires:

1. Registration questionnaire 1 – demographic information ;
2. Registration questionnaire 2: Diabetes Self-Management Questionnaire[[8]](#footnote-8), 21 items;
3. Registration questionnaire 3: Diabetes Distress Screening Questionnaire[[9]](#footnote-9), 18 items;
4. EMA questionnaire 1 on measuring sugar level (3 items) – recommended to be filled in 3 times a day;
5. EMA questionnaire 2 on food (4 items) – recommended to be filled in 2 times a day;
6. Questionnaire end-of-day (5 items) - to be filled once a day, in the evening.

The physician involved in the study was offered instructions in a face-to-face meeting guided through the use of the mHealth app. The NCPHA team introduced the specific objectives of the pilot and presented the important feature in relation to the pilot. The practitioner was provided additional information for the use of the mHealth tool.

The first group of participants received the enhanced version on the mobile app (with personalized feedback and embedded health education module), while the second received (still in process) the basic version of the mobile app (without personalized feedback and embedded education module). Thus, the intervention has two arms:

* Arm T contains the mHealth application with patients receiving feedback from the app and from the physician and getting also the chance to acquire information on diabetes from the embedded health education module. The automatic feedback items were specified by the teams involved. The practitioner can sends personalized messaged on the basis of the recorded data from the EMA questionnaires and the registration questionnaires.
* Arm C contains the mHealth application without a personalized feedback and an embedded health education module.

The patients in each arm are termed „Group T” and „Group C” respectively. With the juxtaposition of the two arms, we can find whether the arm C (which requires no physician’s involvement) is as satisfactory as arm T (which involves physican’s involvement). This intervention was evaluated with respect to patient performance (according to the introduced measures) and physician satisfaction.

The UULM team together with the OVGU team were provided troubleshooting support and deliver insights on the performance of the participants involved.

At the end of the study, the NCPHA team conducted interviews with (1) the involved practitioner and (2) the participants from the two groups (Arm C – in process).

1. **Study of the Intervention**

The anticipated methods for the study of the intervention are:

* For the specific aims A1, A2, A3: Study involving participants both from the basic and the enhanced intervention.
* For the specific aim A3: A structured interview with the practitioner.
* For the analysis of the participants’ performance: Machine learning methods, including supervised and unsupervised learning on time series, statistical analysis to assess the significance of signal in the derived models and in the contribution of predictor variables.

To ensure that the observed outcomes are due to the intervention, the study relies on baselines:

* Comparison of the values of the measures on the first day of the intervention (baseline 1) to the last day of the intervention.
* Comparison of the values of the measures for arm C (baseline 2) to arm T

The measures to establish whether the observed outcomes are due to the intervention(s) is designed to identify differences between the performance of the participants at the beginning of the study and at the end of the study, including:

* Juxtaposition of performance change between first and last day of participation
* Juxtaposition of the performance for both interventions
* Interviews with the study participants at the end of the study

1. **Measures**

The measures are based on performance change:

* Change of performance across the 5 items of the end-of-day questionnaire, juxtaposing first and last day of participation in the study
* Juxtaposition of Measures for participants in basic vs enhanced intervention
* Drop-out rate, juxtaposing basic and enhanced intervention
* Satisfaction of the involved practitioner, as captured by the end-of-the-study interview.

1. **Pilot action plan**

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| Improvement area(s) | Objective(s) | Change Package  Describe the activities | Timeline  (months) | Key performance indicator(s) |
| A1 To investigate whether the mHealth app enables patients to obtain more control over their disease + A2 To investigate the extent to which the practitioner’s personalized feedback and the health education module contributes in making the patients obtain more control over their disease [[10]](#footnote-10) | Improve-  ment for  patients  based on the  daily assessments | S-E1: Acquire ethics approval for the intervention on the participants who do not get feedback, nor educational module, i.e. for group C [NCPHA]  S-E2: Acquire ethics approval for the intervention on the participants who get feedback and educational module, i.e. for group T [NCPHA]  S1: Install and test the mHealth app at the pilot site [UULM, CERTH]  S2: Recruit the participants who do not get feedback and educational module, i.e. group C [NCPHA]  S3: Offer tutorials to the participants of group C [UULM, CERTH, NCPHA]  S4: Run the study on group C [NCPHA]  S5: Troubleshooting support and data collection [UULM]  S6: Weekly reports/statistical plots for patients’ performance [OVGU]  S7: Analyse data of groups C with ML methods [OVGU]  S8: Deliver insights on the performance of groups C [OVGU]  S9: Design of after-study structured interviews for the participants [NCPHA, UULM, CERTH, OVGU]  S10: Design of after-study structured interviews for the practitioners [NCPHA, UULM, CERTH, OVGU] | 03/2019 - S-E1, S-E2  04/2019 - 07/2019: S1  12/2019 – 02/2020 – S2, S3, S4, S5, S6, S7, S8, S9    Milestone 1 (recruitment of group C, app installed, study run on group C)  3 months | 1. Change of performance across 5 indicators (namely, the 5 questions of the daily assessments), juxtaposing first and last day of participation in the study  2. Juxtaposition of Measures for item1 for participants from C group vs participants from T group.  3. Compliance, juxtaposing participants from control and test groups.  4. Satisfaction of the involved professionals, as captured by structured interviews. |
| A2 To investigate the extent to which the practitioner’s personalized feedback and the health education module contributes in making the patients obtain more control over their disease + A3 To investigate the practitioner’s satisfaction on patients’ performance[[11]](#footnote-11) | Improvement for patients based on personalized feedback | S11: Specify the forms and wording of the feedback to be delivered by the practitioners via the app [NCPHA, UULM]  S12: Recruit practitioner for the study [NCPHA]  S13: Offer tutorial to the practitioner who will participate in the study [UULM, CERTH, NCPHA]  S14: Recruit the participants who get feedback and educational module, i.e. group T [NCPHA]  S15: Offer tutorials to the participants of group T [UULM, CERTH, NCPHA]  S16: Run the study on group T [NCPHA] with troubleshooting support [UULM, CERTH] and data collection [UULM]  S17: Analyse data of group T with ML methods and juxtapose with the patterns of group C [OVGU]  S18: Deliver insights on the performance of group T, also in comparison to group C [OVGU] | 07/2019 - 11/2019: S11, S12, S13, S14, S15, S16, S17, S18    Milestone 2 (30/08/2019): study on group T  8 months | Same as for improvement area 1.  In addition, compare the changes of improvement area 1 and 2 |
| A2 To investigate the extent to which the practitioner’s personalized feedback and the health education contributes in making the patients obtain more control over their disease + A3 To investigate the practitioner’s satisfaction on patients’ performance[[12]](#footnote-12) | Improvement for professional using structured interviews | S19: Run the after-study structured interviews towards participants of groups C and T [NCPHA]  S20: Run the after-study structured interviews towards the practitioners [NCPHA]  S21: Analyse the data of the structured interviews (of participants and of practitioners) [OVGU]  S22: Derive recommendations from the findings [NCPHA, UULM, CERTH, Myra] | 12/2019 – 02/2020: S19  12/2019 – S20  01/2020 – 02/2020: S21, S22    Milestone 3 (06/12/2019): study on group T completed, interviews done, analyses continue  10/2019: CSR starts    2 - 3 months | 1. Satisfaction of the involved professionals, as captured by structured interviews.  2. Identification of factors that contribution to significant differences in the improvement areas. |

1. **Analysis**

**12.1.Data collection**

Promoting self-management via momentary and daily assessments with the help of a mobile app is a means towards sustainable and scalable patient care. The use of mHealth technology was considered an important factor and a strength in the daily self-management of patients’ disease. This approach of managing diabetes through the recording of their daily assessments on blood sugar levels, nutrition and physical activity more than once a day gives patients the opportunity to take more control over their diabetes, and, at the same time, to record information on their disease at a level of granularity (momentary assessment).

First, we did the study with the participants from group T and then with participants from group C. Second, after a participant ended the 2-month intervention period, the LIWG conducted an interview with this individual based on a pre-defined structured questionnaire, consulted with professionals and designed during the LIWG meetings. For the analysis of the participants’ performance, machine learning (ML) methods were used, statistical analysis to assess the significance of signal in the derived models and in the contribution of predictor variables.

**12.2. Methods**

The pilot study including both basic and enhanced intervention groups for the objective of A1 – A3 relied on collecting data through qualitative and quantitative methods. Data was derived through the mobile application and presented the health measurement data. The data from the end-of-study questionnaire was collected through participants’ answers via a telephone conversation or an email correspondence (if insisted by the participant).

To ensure that the observed outcomes were due to the intervention, the study relied on baselines:

* Comparison of the values of the measures on the first day of the intervention (baseline 1) to the last day of the intervention.
* Comparison of the values of the measures for arm C (baseline 2) to arm T

For the measures to establish whether the observed outcomes were due to the intervention(s), differences between the performance of the participants at the beginning of the study and at the end of the study were designed through:

* Juxtaposition of performance change between first and last day of participation
* Juxtaposition of the performance for both interventions
* Interviews with the study participants at the end of the study

However, it has to be considered that data variations cannot be controlled for samples of this size, but this was reflected in the choice of measures; effect of time was captured by the KPIs measuring compliance.

1. **Ethical considerations**

Ethics approval was obtained for the basic intervention and for the enhanced intervention on January, 15th 2019 by an Ethical Committee at the National Center of Public Health and Analyses. The documentation necessary for the pilot study was designed to guarantee transparency towards the target population.

Recruitment of participants started immediately. The practice was implemented equitably (i.e. proportional to needs). The patients were aware of any possible consequences of the study. The objectives and strategy were transparent to the target population. Potential burdens of the practice (i.e. psychosocial, affordability, accessibility, etc.) were addressed. Target population rights were informed, to decide about their care, participation and issues regarding confidentiality.

The processing of personal data in line with the General Data Protection Regulation (GDPR), and in accordance with our country-specific data protection regulations applicable to the mHealth app. By means of this data protection declaration, our organisation informed the target population about the nature, scope, and purpose of the personal data we collected, used and processed. Each participant had the right granted by the European legislator to withdraw his or her consent to processing his or her personal data at any time.

The data collected for the study was identified by a code so that the identification of the patient was not possible. Only the researcher and authorized persons related to the study had access to codes and used this information exclusively for the purposes stated in the study.

1. **Results**

Planned steps of the intervention were followed. LIWG meetings were conducted, followed by implementation of planned activities, data collection and monitoring of the implementation. One PDSA cycle was performed. The LIWG discussed the measurements over time and evaluate the possible change and impact of the pilot.

The mHealth application intervention went according to the time-line and according to the planned activities. Insignificant delay in the time-line was indicated due to the small number of recruited participants at the start of the implemenation phase. The delay was overcome with the assistance of Bulgarian Association Diabetes and their close collaboration in the recuitment phase.

In terms of contextual elements, the health measurement of blood sugar levels at the beginning of the study was designed to be entered in mg/dl in the mobile application. Two participants contacted the LIWG and the issue was immediately solved out by the technical team, engaged with the development of the mobile application, so that the measuring units were allowed to be entered in mmol/L. This had to be figured out during the recuitment and education step, discussing the blood sugar measurement devices that the participants had and the corresponding measuring units.

Another contextual factor that has to be considered was related with difficulties in the installation and registration process (for example storage space of the mobile devices). Some participants reported to have problems during the installation phase and this resulted in having a participant to registered more than once. It was importnat to identify whether there are individuals who were duplicated in the system. At the same time, this observation indicated that regardless of experienced technical issues, participants were motivated to use the technology in order to have the opportunity to monitor and manage their diabetes electronically.

Unitended consequences such as continuation of people’s use of the technology was observed after the 2-month period. In furture implementation of the sudy, the mobile tool will need to inform the users that it will automatically close or uninstall after the consented period of use.

When examining the end-of-study questionnaire answers, the LIWG observed that overall participants reported improved control over their diabetes and further explained that the mobile application met their diabetes needs.

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|  | Basic intervention | Enhanced intervention |
| No. participants | 8 | 11 |
| Improved control over diabetes | 6 | 5 |
| App met needs | 6 | 6 |

Participants, who had the opportunity to use the embedded health education module and received personalized feedbacks, designed to empower people, found them encouraging and motivating, but at the same time, it was reported that they needed further and more concrete diabetes-related feedbacks and recommendations. However, when exploring the answers by participants from the control group, it came out that 6 out of the 8 people using the basic intervention would like to use an embedded health education module in the future. Overall, participants from the basic intervention were more satisfied with the mHealth technology to control their disease. It can be speculated that the participants from the enhanced intervention had expectations related with more precise and detailed feedbacks (e.g. „Would like to have more personalized feedback from a practitioner..”; „The answers were predictable”; „..use to get the same automatic feedback...”) which resulted in low percentage of satisfied person in comparison to the ones from the basic intervention.

Considering the qualitative data on the basis on the end-of-study interviews, there are important reflections that have to be mentioned:

* More than half of the patients reported feeling encouraged and motivated to use the mHealth app.
* Most patients liked the process of tracking their disease and found it easy to use.
* Participants from the test group praised the fact that a practitioner was involved in the pilot study but thought that the feedback had to be organized in a more personalized manner and to be more distinguishable from the automatic feedbacks.
* Participants from the control group reported that they liked the electronic way of monitoring their disease and defined it as a “convenient” and an “easy to use” way to monitor their disease, and they “checked blood sugar levels more often”.
* Participants from the control group wanted to use food-related automated feedbacks, data entry option through synced monitoring devices, and would like greater self-auditing capabilities through app that support visualization of entered data over time.
* Participants stressed that app should not be intrusive in notifications, and should allow editing previous entries.

The report from the end-of-study interview with the healthcare specialist indicates satisfaction in terms of the two-way communication between the practitioner and the patients and in terms of the weekly reports (patients’ data was extracted from the mobile app). The involved medical specialist was satisfied by the performance of the participants. However, the practitioner highlights the fact that close relationship is a prerequisit for motivation and that mHealth thechnology has to include a more comprehensive connection, which can also make the patient to understand the role of the medical specialist.

**First preliminary statistical results on Group C and Group T as of January 25, 2020[[13]](#endnote-1)**

The results are based on approx. 22 days of interaction on average for group C and 60 days of interaction on average for group T. This is because group C patients started long after group T patients. The blood sugar levels measured in the two groups are comparable, so the patients do not differ in their physiology.

We investigated the impact by juxtaposing the 1st week of the intervention to the 4th (mid of intervention) and the 8th (end).

**Insights on KPI Compliance:**

1. The **average number of sessions** between groups C and T was the same in the 1st week and increased slightly at the 4th. However, the average was sustained to above 5 sessions for the group T but dropped to 1 for group C. This indicates a higher involvement among the participants exposed to the enhanced intervention.
2. The **number of participants** in group T decreases from 11 (1st week) to 8 (4th week) and then to 6 (8th), indicating a **dropout rate** of less than 50%. In contrast, the number of participants in group C decreases from 6 (1st week) to 2 (4th week). However, group C started later, hence its participants cannot yet be termed as dropouts (state: January 25, 2020).

**Insights on KPI Patient Performance:**

1. The **average minutes of physical exercise** increased from 49 to 56 min for group T. For group C, an unusual increase was observed at the 4th week, while no data are available on the 8th week for group C. The increase for group C cannot be relied upon, since it refers to 2 participants only.
2. The **average** **perceived control of the disease** improved slightly for the group T at the 4th week but deteriorated at the 8th week. The improvement for the group C at the 4th week was larger than for the group T; no data are available on the 8th week of group C. The increase for group C cannot be relied upon, since it refers to 2 participants only.

**Conclusion on the enhanced intervention (group T), as of Jan. 25, 2020**: Compliance of group T, measured as interaction with the mHealth app, was almost constant with respect to the number of sessions, while the dropout rate was less than 50%. Physical exercise remained almost constant to 49 min per day, with a slight increase towards the end - possibly an artefact, due to the number of dropouts. Control of the disease remained almost constant at the 4th week but deteriorated at the 8th week. This might be due to a seasonal phenomenon (weather conditions) but might also indicate that even an enhanced interaction with the mHealth app does not replace human interaction.

**Conclusion on the basic intervention (group C), as of Jan. 25, 2020:** The study is ongoing, and the 6 participants started at different time points. So, it cannot be decided whether they are dropouts or not. Since 4th week data are available for only two participants, the aggregations are unreliable and no conclusions are possible.

Threats to validity:

* Group C is much smaller in number of active users and has less days of interaction in total, so the averages are not yet reliable.
* No statistical testing performed yet.

An exhaustive list of computed measures are listed in the table below.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  | Measurement Timepoint | | |
| Group | *Measure* | *1st week* | *Mid (4th week)* | *8th week* |
| Group C | #Avg sessions | 4.3 | 5 | 1 |
| Group T | #Avg sessions | 4.45 | 5.86 | 5.8 |
| All | #Avg sessions | 4.12 | 5.67 | 5 |
| All | #Participants | 17 | 10 | 7 |
| Group C | #Participants | 6 | 2 | 1 |
| Group T | #Participants | 11 | 8 | 6 |
| All | Avg PhysE | 56.36 | 131.34 | 56.57 |
| Group C | Avg PhysE | 72.92 | 375.83 | N/A |
| Group T | Avg PhysE | 49 | 49.84 | 56.57 |
| All | Avg\_Control | 62.1 | 66.44 | 50.52 |
| Group C | Avg\_Control | 60.75 | 75.58 | N/A |
| Group T | Avg\_Control | 62.7 | 63.39 | 50.52 |

Further results and analysis are to be extratced as participants from group C entered several weeks after the beginning of the pilot and were still using the mobile application during the first preliminary statistical results.

**Discussion**

1. **Implementation process**

The implementation framework of the JA CHRODIS Recommendations and Criteria presented in this report served as a tool to support implementation of the practice, and to improve, monitor, and evaluate the quality of diabetes care. The selected Quality Criteria and Recommendations were Practice design, Target population empowerment, Evaluation, Education and traing, Ethical considerations, Governance, Interaction with regular and relevant systems and Sustainability and scalability.

Facilitators to the implementation process included the follwoing:

* Bulgarian Association Diabetes association delivered advice and support in the recruitment.
* Physician showed involvement and dedication.
* Videos and educational material for patients and physician helped in preparing the data collection and measurement of the intervention.
* Troubleshooting during deployment of the intervention was fast.

Barriers during the implementation process:

* Inexperience on measuring insulin levels the way it was expected by the software: may have blurred the recordings at the very beginning
* Patients did not know why they had to make pictures of food
* Patients needed more instructions on the purpose of making pictures of food; also the produced files were too big. Pictures were not analysed as part of the evaluation, but the evaluation was not affected
* Problems with the app software and the download: caused frustration among the early recruited patients, but no dropouts
* Patients of type I diabetes and type II diabetes received the same functionalities, although they have slightly different needs.
* Some users lack storage space for using the app
* Some users had outdated Android or iOs versions to use the app, thus, encounter problems of compatibility with the mHealth service
* Privacy considerations prevented the connection of patient IDs to the embedded health education module data, so the effect of this function could not be assessed.

The recommendations :

* It would be better to get a quick access to the most frequent tools/questionnaires that the participant is using instead of to look for the three dots every time that s/he enters the application.
* Immediate interaction, when facing tech problem with the app
* More precise feedback. For example, when uploading photos of the meal, to receive more detailed explantion on how to manage insulin levels.
* Insulin dose tips for raising or lowering blood sugar.
* Nutrition and calorie intake to be described in more detail.
* There are differences between type I and type II diabetes; for people with type II diabetes the application contains the necessary information, but for people with type I, it needs further information. For example, for type I it is important to specify the type of therapy from the beginning, and based on the thrapy, there should be different ways to measure carbohydrates in grams. It would be good to have a participant with the relevant diabetes type in the project, who is the application's target group. Thus, at the development stage, it would be possible to verify that the application matches the expectations of the user, and the developer can make the necessary adjustments.
* Consideration could be given to facilitating users’ input - with default values, drop-down menus, etc.
* The feedback was considered as too general in the beginning, and in that way some the users started closing the coming feedback without even reading it; at the next moment a patient could receive a message from the practitioner, but thinking that this is the system's regular feedback again, s/he starts ignoring the upcoming messages. Participants’ attention has to be attracted in some way in order to keep them interested and motivated to use mHealth technology.

Suggestions for future implementation:

* Mobile application users will benefit more if they reply on their own practitioner for advice.
* More advice on how to use the embedded health education module.
* To get quick access (a shortcut) to the most common user actions.
* An online material/video that shows a situation of how a patient uses the mobile app.
* An online material/video that show how a practitioner is virtually interacting with patients.
* The mobile application has to be downloadable via the relevant appstore.
* Consider dedicated installations that deal with Barrier 1 (not compatible with the CHRODIS policy of "no new software development").
* Run follow up actions to complete the picture on the differences in the impact of basic interaction vs enhanced interaction (which requires physician involvement).
* AN option to write directly to the technical staff that are supporting the app.
* Identify means of supporting patients that do not have the financial means to acquire state-of-the-art smartphones .
* Consider opt-in / opt-out policies for dedicated functionalities that require data linking (not compatible with the CHRODIS policy of "no new software development").

1. **Summary**

Diabetes self-management is considered a cornerstone in preventing long-term complications. Every individual can succeed in achieving good control over his/her diabetes when following several rules - taking prescribed medications, monitoring blood sugar levels, having a healthy diet, and exercising regularly. Nowadays, mHealth technology are widely used and serve to assist patients to adhere to diet, exercise, and medication plans. This pilot was designed within the framework for the implementation of actions using JA CHRODIS Recommendations and Criteria aiming to empower people with diabetes through a mobile health application that allows them to monitor their disease.

The intervention results indicated that benefits for the patients were in place. 12 out of 19 particiapnts reported that the mHealth tool met their needs and 11 of them indicated that their control over the disease had improved. The targeted population has benefited through the easy-to-use mobile application and the shared decision-making and education-information available in the process. The pilot considered and involved different stakeholders that were available to the users and that was further reinforced by the support of the technical team. The participants involved in the enhanced intervention praised the fact that a practitioner was involved in the pilot and thought that the feedback has to be organized in a more personalized manner, which is also leading to the practitioner’s view of the importance of the two-way communication between the patient and the physician.

1. **Interpretation**

The planned activities within the original action plan were followed. In general, the enhanced mHealth application intervention went according to the planned time-line and according to the planned activities. Insignificant delay can be observed in the table above due to the small number of recruited participants at the very beginning. As the basic intervention was due to start after the first group of participants (after enhanced intervention), the interpretation of the results frm goup C is still in process.

Overall, patients reported that they felt encouraged and motivated to use the mHealth app and even went further in considering their daily control as being improved. Most of them liked the process of tracking their disease and found it easy to use, which may lead to further encouragement and motivation to control the disease.

The participants and the practitioner emphasized the importance of the two-way communication of patient-doctor and the personalized, “emotional and moral” characteristics that it conveys. A deeper reflection and a more personalized and intense communication may contribute to better outcomes and quality of life for patients and for stronger satisfaction for the practitioner.

1. **Limitations**

The anticipated impact of the pilot refers to minimize and adjust limitations that limit *the generalizability of the work*.

* Momentary assessments, recorded by the patients, is not as reliable as measurements performed in a lab. To deal with this, the daily assessment questionnaire contained 4 items about measurable quantities and one item about the patients' subjective impression on how well they control their disease. By comparing the patient responses in the first days vs last days of the clinical study, and by identifying tendencies, it was possible to identify the use of the mobile app in the context of a supervised study (basic intervention), and it could be controlled through personalized feedback (enhanced intervention).
* The assessment of patient’s perseverance and self-discipline was traced by drop-outs and juxtapose the drop-out likelihood of participants from the enhanced intervention to that the basic intervention.
* Healthcare professionals need education for technology and assistance in providing clear feedbacks to people with diabetes. To deal with this, the pilot study implementers were involved in the design of the questionnaires for the momentary assessments and worked on the specification of the feedback to be delivered to the patients (consulted with healthcare specialists and translated in Bulgarian language).

1. **Conclusions**

The current intervention provided the opportunity for people with diabetes to track their diabetic’s routine via a mobile health application that was meant to serve as their daily companion and motivate their control over the disease. The current pilot provides an alternative therapeutic support for people with diabetes and gives them the opportunity to benefit from an easy-to-use application meant to facilitate and stimulate the monitoring of one’s daily condition not only through monitoring features, but also through feedback and educational features.

The study was desgined and implemented within the framework of JA CHRODIS Recommendations and Criteria that assisted the process of implementation, monitoring and evaluation. The report describes the baseline and the context analyses, providing further deliverables of leasons learnt, including enablers and barriers and identifying next steps for fostering quality of care for people with diabetes. The sustainability strategy considered a range of contextual factors (e.g. innovation, cultural trends and general epidemiological trends) and there was further a broad support for the practice amongst the implementation group and all the relevant stakeholders.

The potential impact on the population targeted was assessed and the outcomes for the patients were positive. Based on the implementation experience, main suggestions for future impementation are summarized:

* Mobile application users’ will benefit more if they reply on their own practitioner for advice
* More advice on how to use an embedded health education module
* To get quick access (a shortcut) to the most common user actions instead of searching the three-point menu at the top right
* Communicate the purpose of each offered functionality better
* An online material/video that shows how a practitioner is virtually interacting with his/her patients in order to raise awareness
* The mobile application has to be downloadable via relevant appstores
* Different mHealth apps (or different funtionalities) for patients with type I vs type II diabetes;
* Option to write directly to the technical staff that are supporting the app

The JA CHRODIS Recommendations and Criteria provides a comprehensive and purposeful tool to effective implementation for the benefit of people with chronic diseases.

1. **Funding**

JA CHRODIS+ initiative is financed through the funding instrument under the third EU Health Programme 2014-2020. The current joint action is funded by the European Commission and participating organisations. The activities within the JA CHRODIS+ aim to implement interventions from the first joint action (JA CHRODIS) in a cross-country manner. The sources of financing the implementation of the pilot in Bulgaria is managed through the joint action’ funding mechanism, aiming to support European member states and to reduce the burden of chronic diseases by using knowledge more effectively.

Annex 1: Individual pilot action plan

## Annex 5: Barriers, Enablers and Suggestions for future implementations

|  |  |  |  |
| --- | --- | --- | --- |
| **Quality Criteria and Recommendations** | **Barriers** | **Enablers** | **Suggestions for future Implementations** |
| **1. Practice design** | Participants with type I and type II diabetes need different automatic feedbacks and recommendations | All funtionalities were developed on science-based science in order to encourage daily self-management. The LIWG and the technical team supported the participants | Mobile application users’ will benefit more if they reply on their own practitioner for advice and if the app software distinguishes people with type I from people with type II |
|  | Problems with the app software and the download: caused frustration among the early recruited patients, but no dropouts | Troubleshooting during deployment of the intervention was fast. | The mobile application has to be downloadable via the relevant appstores. |
| **2.Target population empowerment** | Half of the participants using the enhanced intervention reported to have used the embedded health education module | 12 out of 19 particiapnts reported that the mHealth tool met their needs and 11 of them indicated that their control over the disease had improved | More advice on how to use the embedded health education module and distinguished features between the automatic feedbacks and the personalized feedbacks provided by a practitioner |
| **3. Evaluation** | Data variations cannot be controlled for samples of this size | The practice was evaluated quantitatively and qualitatively with a variety of instruments, namely data analytics tools, structured interviews and questionnaires. | N/A |
| **4. Comprehensiveness of the practice** | Inexperience on measuring insulin levels the way it was expected by the software: may have blurred some of the recordings | Practitioner’s monitoring of patients through weekly reports and through provision of personalized feedback enables a two-way communication between patients and practitioners | Communicate the purpose of each offered functionality better |
| **5. Education and training** | Patients needed more instructions on the purpose of making pictures of food | Videos and educational material for patients and physician were translated. Training was provided for the practitioner. LIWG was available for assistance | An online material/video that shows a situation of how a patient uses the mobile app. An online material/video that show how a practitioner is virtually interacting with patients. |
| **6. Ethical considerations** | Privacy considerations prevented the connection of patient IDs to the embedded health education module data, so the effect of this function could not be assessed. | The practice has designed according to the applicable regulations and laws, approved by an ethics committee.  Participants were given informed consent, ensuring the rights to be informed, to decide about their care, participation and issues regarding confidentiality | Consider opt-in / opt-out policies for dedicated functionalities that require data linking (not compatible with the CHRODIS policy of "no new software development") |
| **7. Governance** |  | Broad support for the practice amongst the implementation group and strong collaboration (intra- and intersectoral) | Run follow-up actions to complete the picture on the differences in the impact of basic interaction vs enhanced interaction (which requires physician involvement) |
| **8.Interaction with regular and relevant systems** | N/A | Troubleshooting during deployment of the intervention was fast. | Option to write directly to the technical staff that are supporting the app |
| **9.Sustainability and scalability** |  | Satisfaction by all the stakeholders, involved in the practice. | Identify means of supporting patients that do not have the financial means to acquire state-of-the-art smartphones |

## Annex 6: Sustainability and Replicability/Transferability(maximum 4 pages)

**The continuation of the practice has been ensured through institutional anchoring and/or ownership by the relevant stakeholders or communities:**

The study was conducted with the support of Bulgarian Association Diabetes. Thus, the continuation of the practice has been ensured through institutional anchoring by the relevant stakeholders. However, although the shared vision of the effectiveness of the practice, the study is not planned to be scaled-up at the moment.

**The sustainability strategy considered a range of contextual factors (e.g. health and social policies, innovation, cultural trends and general economy, epidemiological trends).**

The intervention used innovation mHealth technology which not only assist patients in their motivation, but also act as a tool for reaching patients in small and difficult-to-reach regions. However, some mobile application barriers like lack of storage space for using the app or outdated version of smartphones may be removed if means of support to provide state-of-the-art smartphones are be considered.

For improvements and sustainable gain, opt-in/opt-out policies that require data linking connections between the embedded health education module and the patient could lead to better evaluation outcomes.

**There is broad support for the practice amongst those who implemented it**

The practice was implemented with the close support and collaboration of the Bulgarian Association Diabetes who contributed to the recruitment and the cooperation between relevant stakeholder. Different healthcare specialists were informed about the practice and were further interested in getting details about its implementation and post-implementation activities.

**Potential impact on the population targeted (if scaled up) is assessed.**

Measurers for impact assessment were in place. Overall, participants were satisfied by the app and 11 out of the 19 participants reported that their control over the disease was improved, which is crucial for the successful control of diabetes and can lead to improved quality of life.

**Institutional: describe if, as effect of the activities, there was a further involvement of key institutions at the sub national and national level and the related effects in terms of strategies, policies regarding the project’s objectives and expected results;**

N/A

**Stakeholder’s involvement: describe the involvement of beneficiaries, institutions and actors important for the development and continuation of the activities beyond the implementation;**

The Bulgarian Association Diabetes were in a close contact with the potential participants from the very beginning of the study. They contributed to the planning and the regulation of the process. Several practitioners from different regions within the country were aware of the process implementation and disseminate information in terms of the pilot action experience. During the implementation, participants were in close contact with the LIWG.

**Intersectoral collaboration: if relevant, describe the involvement of relevant sectors (health, social, community, others);**

Collaboration on different levels was observed. The recruitment phase drew the attention of different stakeholders in the process, including various healthcare specialists and the targeted population.

**Allocation of Resources: describe if, as effect of the project activities, funding and resources were allocated to continue the activities beyond the implementation;**

N/A

**Organizational changes: describe if, as effect of the activities, decisions of changes in the design and delivery of services were taken.**

There were no significant changes.

**Replicability/Transferability : a successful transferability of the practice maybe facilitated by a clear definition of the context, sustainability, intersectorality and participation of stakeholders .**

As the pilot received a broad support from different stakeholder groups and indicated a positive impact on the target population, successful transferability maybe facilitated.

## Annex 7: Essential elements of pilot action report

Please describe the component(s) of the **Quality Criteria and Recommendations** implemented:

|  |
| --- |
| * Practice design * Target population empowerment * Evaluation * Education and traing * Ethical considerations * Governance * Interaction with regular and relevant systems * Sustainability and scalability |

The “Short Template for Final Reporting" below (based on the EC logical framework), aims to provide a snapshot with the description of the essential aspects of the Pilots: objectives, activities, results (indicators), the benefits for the beneficiaries and major stakeholders and the recommendations for future Sustainability and Replicability/Transferability of the **Quality Criteria and Recommendations**.

**Practice design:** The practice aims, objectives and methods were specified by the pilot team in interaction with all relevant stakeholders, taking evidence-based research into account as well as contextual elements. **Target population empowerment**: Objective of the practice was to empower patients by providing them handy means (on mHealth app basis) to monitor and keep diary of their disease.

**Evaluation:** The practice was evaluated quantitatively and qualitatively with a variety of instruments, namely data analytics tools (by OVGU team), structured interviews and questionnaires.

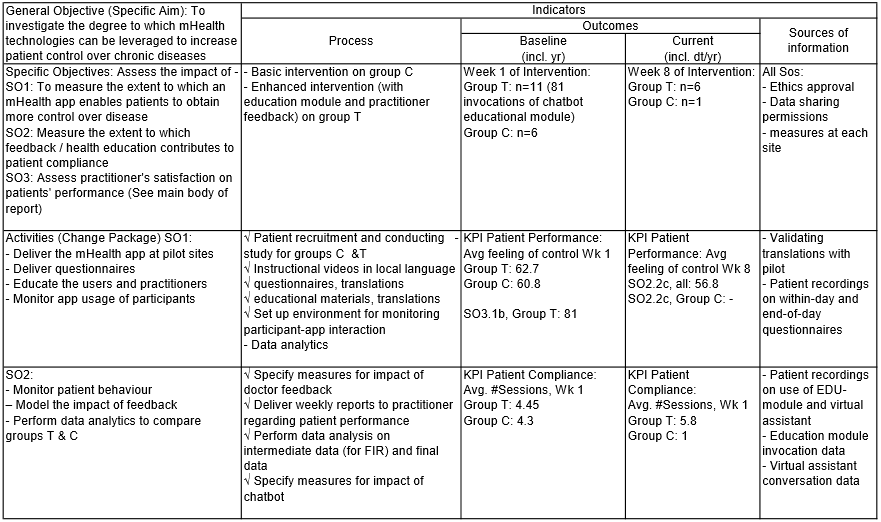
**Education and training:** A health educational component was incorporated into the mHealth app. Tutorials and instructions of use were offered to involved professionals and to pilot study participants.

**Ethical considerations:** The practice was designed according to the applicable regulations and laws, having been approved by the ethics committee. Study participants were given informed consent, ensuring the rights to be informed, to decide about their care, participation and issues regarding confidentiality.

**Governance:** The practice was appropriately planned, all relevant stakeholders were involved. The practice was aligned to workflows and technologies in place in the area of deployment.

**Interaction with regular and relevant systems:** The practice was aligned with systems in place.

**Sustainability and scalability:** The continuation of the practice has been ensured through institutional anchoring in the National Center of Public Health and Analyse, Sofia with the close cooperation of Bulgarian Association Diabetes.



Summarize the **major Barriers and Enablers** identified during the implementation of the **Quality Criteria and Recommendations** (*Annex 5)*

* **Major barriers include** – technical problems related to smartphone characteristics like outdated versions or phone storage space and minor software issues; user-related issue concerning the use of mHealth technology like input of insulin levels and food pictures taking.
* **Major enablers include** – strong collaboration (intra- and intersectoral); adequate educational and training materials; strong technical support

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s for future Sustainability and Replicability and Please describe the major **Results of the Implementations** (*from section 16.Summary of Individual pilot action report*):

**-Benefits for Patients** (improved access to care, health status and quality of life):

* Opportunity of using a daily companion for diabetes routine which facilitate and stimulate **better control**
* Enhanced intervention resulted in better patient’s involvement which is crucial for raising one’s control and consequently, to **improve one’s quality of life**
* Overall, patients were satisfied and reported their experience as **beneficial in terms of their needs**
* Patients benefited through the easy-to-use mobile application and the shared decision-making and education-information available in the process, leading to a potential **improved access to care**.
* The pilot considered and involved different stakeholders that were available to the users and that was further contributed by provided technical support.

**-Stakeholders and Policy Makers Involvement and Actions:**

* Healthcare specialist in the field of health promotion and disease prevention
* Bulgarian Association Diabetes
* Practitioners in the field of diabetes
* Other NGOs in the process of dissemination

**Suggestions for future Implementations,** **Sustainability and Replicability/Transferability of the Quality Criteria and Recommendations** (*from section 19. Conclusions of Individual pilot action report, Annex 5, Annex 6)***:**

* The sustainability strategy considered a range of contextual factors (health policies, innovation) and there was further a broad support for the practice amongst the implementation group. The potential impact on the population targeted was assessed and the overall outcomes for the patients are positive.
* Based on the implementation experience, major suggestions for future impementation include to communicate the purpose of each functionality better and to consider more personalized features as a personalized shortcuts to the most commonly users actions, to communicatre directly with the technical staff and a better personalized communication with the practitioner.

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    *People responsible*: Plamen Dimitrov, Mirela Strandzheva, Doroteya Velikova, Maya Viktorova [↑](#footnote-ref-10)
11. *People involved:* Rüdiger Pryss Schobel, Annika Stampf, Julian Haug, Fabian Haug; Vassilis Koutkias, Konstantinos Votis, Eleftheria Polychronidou; Myra Spiliopoulou, Vishnu Unnikrishnan, Miro Schleicher

    *People responsible*: Plamen Dimitrov, Mirela Strandzheva, Doroteya Velikova, Maya Viktorova [↑](#footnote-ref-11)
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    *People responsible*: Plamen Dimitrov, Mirela Strandzheva, Doroteya Velikova, Maya Viktorova [↑](#footnote-ref-12)
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