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**ACCEPTABILITY, ADHERENCE, AND DESIRABILITY OF
TELEMEDICINE PROGRAMS IN DIABETES MANAGEMENT**

ABSTRACT

SCIENTIFIC COORDINATOR

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Diabetes is a chronic condition with significant implications for the health and quality of life of affected patients while having a major impact on public health. However, the impact of diabetes on these patients' health can be reduced through early, appropriate, and sustained therapeutic interventions and diagnosing diabetes at the earliest stages. One of the management peculiarities of diabetes mellitus (DM) is the measures that patients must undertake for the rest of their lives, namely treatment adherence, lifestyle optimization, and regular follow-ups to monitor and adjust the therapeutic strategy.

Telemedicine systems provide the interventions necessary for remote diagnosis and treatment of diabetes using advanced communication technology. In a general medical context, telemedicine solutions have either been accepted to augment classic medical consultations or to provide remote medical interventions where classical medical acts could not be performed for social, economic, or geographical reasons. Given the particular characteristics of diabetes, the chronic character of the disease, a predictable and stable evolution of the disease in many cases, monitoring long-term patients by the same attending physician, as well as the possibility of monitoring many remote parameters the field of telemedicine appears even more suited for the management of this disease. For instance, health care providers could remotely monitor blood glucose values, continuous glucose monitor (CGM) patterns, subcutaneous continuous insulin infusion rates, the amount of carbohydrates consumed by the patient, body mass index, or blood pressure.

The particular scenario of this study is the COVID-19 pandemic. The World Health Organization (WHO) defined the coronavirus disease 2019 (COVID-19) as a condition caused by a new coronavirus called severe acute respiratory coronavirus syndrome 2 (SARS-CoV-2). The virus was first identified in Wuhan City, Hubei Province, China. The Chinese authorities initially reported the disease to the WHO on December 31, 2019. The WHO declared the COVID-19 epidemic a global health emergency on January 30, 2020, and a global pandemic on March 11, 2020. COVID-19 is a condition that predominantly causes respiratory manifestations. Approximately 15% of cases were reported to have severe manifestations (hypoxia, dyspnea, damage to over 50% of the pulmonary territory), approximately 5% of patients developed critical manifestations (shock, respiratory insufficiency, multiple organ dysfunction), respectively, 2-3% of cases resulted in patient death. COVID-19 is a highly contagious condition, and it registered 19,584,576 cases, with 60,623 of these in Romania, from its onset until August 8, 2020. Treatment of infection with SARS-CoV-2 is nonspecific:

symptomatic, using nonspecific antiviral therapy or hyperimmune plasma collected from patients cured of COVID-19 who developed sufficient titer antibodies against SARS-CoV-2.

The aggressiveness of COVID-19 is significantly higher and associated with a worsened or even fatal prognosis of disease progression in vulnerable patient groups: a much higher rate of death and development of severe or critical forms of the disease has been observed in elderly, obese, and diabetic, oncological, or renal replacement patients.

Although diabetes does not influence the risk of infection, in case of contracting the infection, the disease's evolution has a much less favorable prognosis than in the general population. The risk of death or development of a severe form increases with the synergistic action of other risk factors commonly encountered in diabetic patients, especially with type 2 diabetes (T2DM), e.g., old age, obesity, or cardiovascular comorbidities.

It becomes evident that preventing SARS-CoV-2 infection is even more critical among patients with diabetes. Therefore, the "Pius Brînzeu" County Emergency Hospital in Timișoara implemented a telemedicine service to reduce epidemiological risk among patients with DM. Through the medical platform: <http://telediabet.ro>, implemented for all patients with DM in Romania, any patient could request free medical consultations on diabetes, nutrition, and metabolic diseases, from the safety of their own home.

Physical and social distancing in the country's general population and organizational measures of granting medical services and prescriptions in an outpatient setting have been taken to minimize the spread of the SARS-CoV-2 infection. Among the measures of increased interest for patients with diabetes, we can list the possibility of issuing medical prescriptions remotely, doubling the number of consultations possible to be performed per unit of time, with no need to sign medical services with the patients' insurance card, and the possibility of billing medical consultations utilizing telemedicine.

Based on this data, we performed an observational, non-interventional, exploratory, multicenter, transversal study with a consecutive-population enrolment. The main objectives of the proposed study are the following:

1. The development of a questionnaire to assess the desirability, acceptability, and adherence of diabetes patients to telemedicine solutions in general conditions, respectively, in particular conditions.

2. To validate the previously mentioned questionnaire on the population of patients with diabetes in Romania.
3. The dissemination of the questionnaire in the scientific community (medical and IT).
4. The assessment of desirability, acceptability, and adherence to telemedicine solutions of patients with diabetes in Romania, using the questionnaire developed in point 1.

CLINICAL TRIAL

1. MATERIALS

Patient recruitment

Patients who previously used the diabetes-care telemedicine platform (telediabet.ro), developed by the “Pius Brînzeu” Emergency Hospital from Timișoara and who provided consent for further contact were invited to participate in the study via an email message provided at the time of first access to the platform during a 2-month frame (May–June 2021). The email message contained the electronic questionnaire's address (URL).

One hundred fourteen patients agreed to participate in completing the main questionnaire as well as the external reliability instrument. Thirty-five of them accepted to participate in the test/re-test validation. The test/re-test consisted of completing the main questionnaire at the initial moment and the external reliability instrument, as well as a re-test after one month, by completing the main questionnaire to evaluate the response reproducibility.

Patients' participation in the study was exclusively voluntary, therefore, deciding to participate in the study did not affect the access or quality of medical care. The consent form was included in the electronic form and was a sine qua non-condition for enrolment in the study.

All patients completed the standardized informed consent form online. No identification data of the participants were collected in the study. Participation in the study was anonymized before data collection.

2. METHODS

2.1. Study design

The study has an observational, non-interventional, exploratory, multicentric, transversal character, with a consecutive-population enrolment.

In order to obtain a confidence level of at least 95% in terms of a statistical power of at least 80%, the estimated sample size for the questionnaire validation was 30 participants. For the assessment of acceptability, desirability, and adherence to medical solutions for patients with diabetes, the estimated size of the sample was 110 participants.

2.2. Stages of the study

1. Development of a questionnaire to assess the acceptability, adherence, and desirability of the use of telemedicine solutions among patients with diabetes. The questionnaire was composed of items for:

- a. Socio-demographic characteristics
- b. Medical history
- c. Previous use of telemedicine solutions
- d. The degree of interest in the use of telemedicine solutions
- e. Subjective opinion on the use of telemedicine solutions
- f. The type of data considered useful to be shared with the doctor
- g. Accepted technical solutions
- h. Expected difficulties and barriers

2. Validation of the questionnaire by assessing internal consistency, external validity, reproducibility, and inter-item approval. During the validation process, inconsistent items were excluded, and new possible questionnaire components were captured.

3. The validated form of the study questionnaire was translated into languages of international circulation and disseminated in the academic community through scientific journals of interest, presentations at scientific events in the field, and by publishing on the website telediabet.ro both on the Romanian as well as the English version.

4. The questionnaire was used to investigate the desirability, acceptability, and adherence of patients with diabetes to the use of telemedicine solutions in managing diabetes. Patient patterns regarding desirability, acceptability, and adherence to telemedicine solutions will be analyzed.

The study results were published in original scientific papers. The Ethics Committee of the “Pius Brînzeu” Emergency Hospital, Timișoara, Romania approved the study protocol and informed consent template. Therefore, the study was conducted according to the guidelines of the declaration of Helsinki.

2.3. Questionnaire Development

A group of 6 experts (3 medical experts, one social sciences expert, one linguistic and semantics specialist, and one biostatistician) was involved in developing the questionnaire. The development process was divided according to the stepwise algorithm proposed by Stone in the British Medical Journal, as follows:

1. Decide what data you need: the questionnaire aimed to assess three major components regarding the use of telemedicine as complementary care in patients with diabetes: desirability, acceptability, and adherence.
2. Select items for inclusion: the three main evaluated components were sub-divided into multiple clustered questions, aiming to assess all the desirability, acceptability, and adherence aspects regarding telemedicine as a complementary healthcare instrument, focusing on the diabetes-specific patient-to-healthcare provider interaction. Furthermore, relevant demographic, anthropometric, and clinical diabetes-related data were added to the questionnaire.
3. Design of the individual questions: each data collection item was analyzed, and based on the optimal collecting variable's type, the answer's type was accordingly designed: for nominal and scale variables, the response was collected using a free-text form, for ordinal variables, the response was collected using a Likert scale, while for dichotomous variables the response was collected using a yes/no field.

4. Compose wording: questions and answers were composed using a sequential backward feedback procedure, first between the medical experts and then validated by the social sciences and linguistic experts.
5. Design the layout and presentation: after reaching the alpha-version of the question bank of the questionnaire, the layout and presentation were developed for printed and electronic data collection forms.
6. Pilot and evaluate: the instrument developed was tested for internal consistency, construct validity, external reliability, and test re-test consistency. Based on the resulting statistics, the questionnaire's phrasing, question order, and flow were optimized.

2.4. Questionnaire Design

After identifying the aspects of interest, the questionnaire was divided into three major sections: one for the main evaluated component (acceptability, desirability, and adherence), one for the collection of socio-economic and demographical information, respectively, and one for diabetes history-related data.

The corresponding data for these sections were collected using 29 questions (Q1-Q9 evaluating the main component, Q10-Q19 evaluating socio-economic and demographical data, respectively Q20-Q29 evaluating diabetes-related information).

Q6, Q7, Q8, and Q9 were clustered Likert-scale questions, each main question containing 7, 8, 9, respectively 6 sub-questions. Each Likert question or sub-question was scored from 1 to 5 points (Q6 being scored on a reverse scale). Dichotomous responses were scored with 1 point for “no” and 5 points for “yes” responses. Multiple choice answers regarding the acceptability of use for several telemedicine components were scored with one point for each accepted component.

The main outcome of the questionnaire is the global telemedicine desirability, adherence, and acceptance score, QTelemeDiab. The QTelemeDiab score is the sum of Q1 – Q9 individual scores.

The telemedicine desirability sub-score is the sum of Q6, Q7, and Q8 (minimum score: 24, maximum score: 120). The telemedicine acceptability sub-score is the sum of Q1, Q2, Q4,

and Q5 (minimum score: 5, maximum score: 25). The telemedicine adherence sub-score is the sum of Q3 and Q9 (minimum score: 8, maximum score: 40). The total score ranges from 34 to 185. The sub-scores are not proportional. Thus, the percentage from the scale's maximum should be used to compare sub-scales, not the absolute score obtained.

2.5. Patient assessment

The desirability, acceptability, and adherence to telemedicine solutions of patients with diabetes were assessed using the QTelemeDiab instrument. A higher score is associated with higher desirability, acceptability, and adherence to telemedicine use in diabetes care respectively.

Also, the QTelemeDiab instrument included queries related to patients' socio-demographic characteristics and medical history (including specific diabetes-related history), used in analysis to identify patterns for patients more prone to use telemedicine in diabetes care.

Data regarding the presence and severity of depression and anxiety were assessed using the PHQ-9, respectively GAD-7 instruments. The PHQ-9 questionnaire is a shortened version of the Patient Health Questionnaire used to quantify depression severity. The GAD-7 Questionnaire was applied to studied patients to assess the presence and degree of anxiety. Both translated versions of PHQ-9 and GAD-7 questionnaires were previously validated in the Romanian population.

The PHQ-9 scores of 4, 9, 14, 19, and 27 represent the cut-point for absent or minimal, mild depression, moderate depression, moderately severe depression, and severe depression. GAD-7 scores of 5, 10, and 15 represent cut-points for mild, moderate, and severe anxiety, respectively.

3. RESULTS

The resulting questionnaire has three major sections: one for the main evaluated component (acceptability, desirability, and adherence to telemedicine in diabetes), one for collecting socio-economic and demographical information, and one for diabetes history-related data, respectively. The corresponding data for these sections are collected using 29 questions. The developed instrument has a good reliability (Cronbach's alpha = 0.890), reproducibility (total

score 164 vs 166 points at re-test vs test; Mann–Whitney U p-value = 0.394) and external validity (Spearman's $\rho = -0.580$; $p < 0.001$ for correlation with Patient's Health Questionnaire –9; and Spearman's $\rho = -0.516$; $p < 0.001$ for correlation with Generalized Anxiety Disorder Questionnaire – 7).

Left-skewed score distributions were observed for the QTelemeDiab total score (median = 166; skewness = -1.738), as well as all its components, thus denoting a high desirability, acceptance, and adherence towards telemedicine use. The presence of severe depression was associated with significant decreases in the QTelemeDiab score (148 vs. 167; $p < 0.001$), as well as on the desirability sub-score (101 vs. 115; $p < 0.001$) and adherence sub-score (30 vs. 35; $p < 0.001$), but had no significant impact on patient's acceptability to use telemedicine interventions in diabetes (18 vs. 15; $p=0.359$; Mann-Whitney U test). The presence of severe anxiety was associated with significant decreases in QTelemeDiab score (150 vs. 166), as well as the desirability sub-score (104 vs. 114; $p = 0.008$) and adherence sub-score (30 vs. 34; $p = 0.012$). On the other hand, the presence of severe anxiety had no significant impact on the acceptability sub-score (15 vs. 18; $p=0.141$; Mann-Whitney U test).

4. CONCLUSIONS

- The questionnaire developed in this study is a valid instrument for assessing patients' desirability, adherence, and acceptability to use telemedicine in diabetes care.
- The developed instrument had good internal reliability, external validity, and result reproducibility.
- The use of the instruments to assess patients' desirability, acceptability, and adherence in the development of telemedicine services for diabetes care may improve and optimize the outcomes of telemedicine use by providing valuable information regarding patients' specific needs and preferences by prioritizing the areas of intervention according to those preferences, and by contributing to the design of efficient public health policies regarding telemedicine interventions in diabetes care.
- There is high desirability, acceptance, and adherence to telemedicine interventions in patients with DM, both under special and normal epidemiological conditions. In addition to the particularities of diabetes care, these characteristics emphasize the role and impact of telemedicine in managing diabetes.

- The presence of severe anxiety decreases the patients' desirability, and adherence to telemedicine.
- The presence of severe depression decreases the patients' desirability and adherence to telemedicine interventions in diabetes care.
- The acceptability, adherence, desirability, and QTelemeDiab overall scores had the lowest values in patients who never tested their HbA1c levels.
- The acceptability score was higher in patients who tested their HbA1c levels every 3 months.
- The adherence to telemedicine was higher in patients who tested their HbA1c level once a year.
- The desirability score was similar regardless of HbA1c periodicity.
- Overall, the QtelemeDiab score was similar in patients who performed the HbA1c every three to six months or once a year.
- The QTelemeDiab and its sub-scores were highly associated with an optimal HbA1c < 7% in patients treated with oral antidiabetic molecules or insulin pumps in patients with diabetes aged 38 - 86 years.
- The previously described studies have shown increased desirability, acceptability, and adherence to various telemedicine instruments in patients with DM. It would be interesting to establish whether the results are influenced by different stages of the COVID-19 pandemic, specifically if the increased access to on-site consultations could impact the usage of telemedicine and the patients' preferences.
- Another potential direction for continuing this research is represented by the assessment of different interventions related to mental health, namely anxiety and depression, on the desirability, acceptability, and adherence of patients with DM to telemedicine since the two conditions have been shown to influence these parameters in our study.
- Follow-up of the patients already included in the research regarding their further interactions with telemedicine instruments and the impact of using these interventions on their glycemic control and other cardiovascular risk factors, designed as a prospective study, would bring clarity with regards to the effects of eHealth in diabetes care.
- The usage of telemedicine interventions in diabetes care is associated with economic advantages through lower costs generated by eliminating, at least temporarily, the

need for transportation to and from the healthcare facility, optimizing healthcare professionals' schedules, and contributing to the prevention of acute and chronic complications of DM through a periodic evaluation, regular feedback and diabetes self-management education support and, therefore, to improved metabolic control.

- Some technical disadvantages of integrating telemedicine interventions in daily clinical practice are related to internet connectivity problems, inadequate technological education, and a potentially negative attitude towards using devices such as smartphones or tablets, especially in healthcare. However, all of the previously mentioned barriers could be overcome through educating healthcare professionals and patients alike regarding the usage of technology in diabetes care and through programs that could ensure availability and ease of access to devices, software, and a reliable internet connection.
- The inclusion of telemedicine in standard diabetes care could become a reality if the problems regarding the internet access of patients and healthcare facilities, the availability of devices, and literacy regarding technology would improve, as previously suggested, through the development of short- and long-term strategies to improve the availability of these resources and also through the design and implementation of educational programs.

5. PERSONAL CONTRIBUTION

- The development of a questionnaire, QTelemeDiab, for assessing patients' acceptability, desirability, and adherence to telemedicine programs in diabetes care.
- The assessment of the acceptability, desirability, and adherence to telemedicine in patients with DM and the identification of some factors that can influence these indicators.
- The increased awareness regarding the importance, diversity, and benefits of telemedicine interventions in the routine clinical practice of patients with DM during the COVID-19 pandemic.