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Diabetes and technology: A pilot study on the management of patients with insulin pumps during the COVID-19 pandemic



Fabio Petrelli^a, Giovanni Cangelosi^b, Stefania Scuri^a, Paola Pantanetti^b, Francesca Lavorgna^b, Federica Faldetta^b, Cristina De Carolis^b, Renato Rocchi^b, Giulia Debernardi^c, Alexandra Florescu^b, Giulio Nittari^{a,*}, Getu Gamo Sagaro^a, Giulia Garda^a, Cuc Thi Thu Nguyen^d, Iolanda Grappasonni^a

^a School of Medicinal and Health Products Sciences, University of Camerino, Camerino, Italy^b Asur Marche, Area Vasta 4, Fermo, Italy^c Ospedale Maggiore Ausl Bologna, Italy^d Department of Pharmaceutical Administration and Economics, Hanoi University of Pharmacy, Hanoi, Viet Nam

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ABSTRACT

Background: The recent COVID-19 pandemic has accelerated the treatment process through IT/technological supports, useful in the management of chronic patients such as those affected by type 1 Diabetes Mellitus (T1DM). Specific routes for fragile patients such as those with micro-infusers have been created thanks to the application of "Diabetes Technology," which allows patients to monitor blood glucose quickly and easily. The present pilot study aimed to assess the quality of care provided to patients with micro-infusers in a delicate phase such as a pandemic lockdown.

Materials and methods: A mixed-methods approach was used. In the first part, with prior written consent, patients with insulin pumps enrolled voluntarily. In the second part, the focus group discussion (FGD) was carried out with the voluntarily enrolled participants. The FGD data were organized and analyzed by the thematic areas.

Results: The number of patients with afferent insulin pumps at the center was 50 individuals. Among them, 20 patients voluntarily joined the first part of the study by completing the PACIC questionnaire, which gave an average result of 3.34 (min. 2.2 and max. 4.2). In the second part, the application of the focus group technique demonstrated that technology is decisive in the management of diabetic pathology, not only in the emergency phase.

Conclusions: At the time of public health crises, alternative strategies such as Tele-Nursing or Telemedicine could be crucial for the management of patients with micro-infuser not only in critical moments, such as lockdown, but also in ordinary health management.

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* Corresponding author at: School of Medicinal and Health Products Sciences, University of Camerino, Via Madonna Delle Carceri 9, 62032 Camerino, MC, Italy.

E-mail address: giulio.nittari@unicam.it (G. Nittari).

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1. Introduction

Diabetes and certain cancers kill millions of people prematurely a year, according to the World Health Organization, which warns of "a slow-motion catastrophe for public health [1]. Lifestyle factors such as eating behavior, overweight/obesity, smoking, low level or lack of exercise, alcohol consumption, and stress play an important role in these pathologies [1–6]. In terms of prevention, the development of prevention strategies in order to modify risky lifestyle behaviors could reduce the burden of these pathologies. Patients with type 1 diabetes mellitus (T1DM) are particularly sensitive individuals, with a continuous need for monitoring and adjustment of therapy.

The recent COVID-19 Pandemic has created problems of continuity of care for these patients and, consequently, necessarily stimulated, by health professionals, the acceleration of the treatment process through IT and technological supports. Therefore, specific pathways have been organized for fragile patients, such as those with micro-infusers who require highly professional specialist assistance [7,8]. Telemedicine and Tele-Nursing could be decisive for the overall improvement of care even after the recent COVID-19 pandemic. These supports for the management of chronic diseases such as T1DM will necessarily require specific investments both in cultural and economic terms and could favor patient compliance and the overall clinical picture, especially for the most fragile categories of the population [9,10]. The use of technology for the administration of insulin, which began towards the end of the seventies of the last century, has found in particular - compared to the multi-injection mode - benefits on glycemic control with an average reduction from 0.3% to 0.6% for Glycated Hemoglobin (HbA1c) and a consequent reduction in the doses of insulin administered [11–15].

In Italy, ISTAT data of 2018, more than 300,000 subjects with T1DM live. Of these, just under 10% (about 27,000) manage the disease with the help of a continuous subcutaneous insulin infuser (CSII). Only 39% also have a sensor for monitoring blood sugar connected to the pump and, even where the sensor is present, the use of this device is constant in just 14% of cases [7]. Today, the development of "Diabetes Technology" seeks to make glycemic monitoring ever faster and easier for patients to use, also thanks to the aid of specific media usually used in daily life such as smartphones and/or digital applications [8,16]. However, it is necessary to concretely evaluate the actual usefulness of introducing new technologies in the management of T1DM without distinction to all patients. The most important contraindication, in fact, is to make the management of the disease even more complex and, in some situations, even dangerous for any severe hypoglycemia. Patients most likely to have some contraindications are those who show difficulties in the rapid IT advancement of products with a high overall technological level [17]. Patients who, on the contrary, derive considerable benefits from technology, can lower their stress levels, consequently improving the overall glycemic picture and

the satisfaction of the treatments received [18,19]. Also, as mentioned by the American Diabetes Association (ADA), it is desirable that the use of "Diabetes Technology" is increasingly widespread among patients with T1DM due to the evident clinical benefits that they are able to bring directly to the treatment of the disease and indirectly to the subject's social life as a whole [8,20].

In consideration of what has been said so far, it was decided to set up a pilot study aimed at observing and evaluating the specialized assistance provided to patients with T1DM with insulin pumps. This study also aimed to provide evidence-based information to health facilities in terms of the application of protocols that can help make the realities to which they belong more effectively. The choice fell on patients with these characteristics, belonging to the Asur Marche Diabetes Center - Area Vasta 4 Fermo. Furthermore, the aim of this pilot study was to investigate the organizational strategies necessary to satisfy the care needs of those with devices for the management of T1DM even in delicate phases such as a pandemic lockdown.

2. Materials and methods

A mixed-methods approach was employed. In the first, with prior written consent, the patients enrolled voluntarily among the population affected by T1DM and carrying a micro-infuser belonging to the Diabetes Center of Asur Marche - Area Vasta 4 Fermo, filled out a validated questionnaire for the cross-evaluation observational of the service offered by a specific "multi-disciplinary technological space at T1DM (Sportello Amico)". This is a dedicated service that involves doctors, nurses, dieticians, and technical experts of the individual devices. Given the socio-assistance completeness of the aspects taken into consideration and the organizational principles and self-care of chronic pathologies typical of the Chronic Care Model (CCM) [21], the choice fell on the Italian version of the PACIC questionnaire [22]. The questionnaire consists of 26 multiple-choice questions (Likert scale from 1 "almost never" to 5 "almost always") and investigates the assistance provided to subjects suffering from chronic diseases according to the principles of the CCM (community resources, innovative care processes, support for self-care, the organization in specific teams, support for Evidence-Based decisions, efficient and modern information structures) (Table 1) [21]. The survey, with a view to continuous Evidence-Based development, has the main objective of observing and addressing the specific interventions to improve the treatment of chronic diseases such as T1DM according to the results obtained. Descriptive statistics of the first part, including the mean of PACIC questions responses and characteristics for patients, were analyzed, and the results of PACIC questions responses were reported in Figures.

The second phase, through the videoconference focus group technique, involved in two specific meetings, a part of the study cohort who completed the compilation of the PACIC questionnaire. The sample was enrolled, given the emergency, for convenience (the first subjects who gave the

Table 1 – Lists of the Patients Assessment Chronic Illness Care Questionnaire (PACIC) questions.

No	Lists of questions
1	My opinion was asked when we developed a treatment plan.
2	Various therapeutic alternatives have been proposed to me to reflect on.
3	I have been asked to talk about any problems I have experienced with the drugs or their effects.
4	I have been given a written list of things to do to improve my health.
5	I was able to see that the assistance that was given to me was well organized.
6	I was shown how what I did to take care of my illness affected my health.
7	I have been asked to talk about the goals I have set for the treatment of my disease.
8	I was helped to set specific goals to improve my nutrition or physical activity.
9	I have been given a copy of my treatment plan.
10	I was encouraged to attend a specific class or group that can help me cope with my chronic illness.
11	I have been asked questions, either directly or through a survey, related to my habits for staying healthy.
12	I was sure that, in recommending the appropriate therapies to me, my doctor or trusted Nurse took my values and traditions into account.
13	I was helped to develop a feasible treatment plan every day.
14	I have been helped to make plans for the future so that I can take care of my illness even in times of difficulty.
15	I have been asked how my chronic illness affects my life.
16	I have been in contact after a visit to see how the situation was progressing.
17	I was encouraged to attend local programs that may help me.
18	I have been referred by a dietician, health educator, or counseling specialist.
19	It was explained to me that my visits to other specialists (ophthalmologist, surgeon, etc.) have improved the treatment of my disease.
20	I was asked how my visits to other specialists were proceeding.
21	I was asked what aspects of my illness I wanted to talk about during the visit.
22	I have been asked what extent work, family, or social situation relates to my management of the disease.
23	I have been helped to develop plans to understand how to get support from friends, family or the community in which I live.
24	I have been told how important the things I do to take care of my illness (e.g., physical activity) are important to my health.
25	A goal has been set for me to pursue together with the health personnel who take care of me to manage my disease.
26	I have been given a diary in which to record my progress.

willingness to join in both proposed appointments were enrolled). For the development of the Focus, the consent given in written form for the administration of the PACIC questionnaire was considered valid. However, it was requested verbally from each participant - after having clearly explained the objectives of the individual Focus Group - before each session. The first meeting investigated, intending to improve, the "multi-disciplinary technological space at T1DM (Sportello Amico)" service offered by the Asur Marche Diabetes Center - Area Vasta 4 Fermo to subjects affected by T1DM with micro-infusors. The second meeting focused attention on recent COVID-19 issues and consequently tried to share the organizational strategies for improvement among all stakeholders. The meetings were moderated by a professional in the sector and lasted about 2.5/3 h overall. Given the body of the contents produced, the summary of the Focus was elaborated by three experts according to the statistical principles of Cohen's Kappa Coefficient [23].

3. Results

3.1. PACIC questionnaire

Of the 50 patients in the center with micro-infuser, 20 voluntarily joined the first part of the study and were equally distributed between males and females, the mean age was 39.25 ± 17.25 years. The study cohort gave a mean result on

the PACIC Survey at 26 items of 3.34 ± 1.14 . The three questions that obtained the highest average results were no. 9 "I was given a copy of my therapeutic plan" (4.6), no. 13 "I was helped to elaborate a feasible therapeutic plan in my daily routine" (4.3) and no. 5 "I was able to see that the assistance that was provided to me was well organized" (4.2) while those that found the worst scores were no. 23 "I have been helped to develop plans to understand how to receive support from friends, family, or the community in which I live" (2.1), no. 16 "I was contacted after a visit to see how the situation was proceeding" (2.4), no. 10 "I was encouraged to attend a specific class or group that could help me cope with my chronic illness" (2.6) and no. 17 "I was encouraged to attend local programs that could help me" (2.6) (summary of results Figs. 1 and 2).

It is evident that the cohort examined has highlighted how the health professionals involved in the individualized therapeutic plan focused more on purely clinical aspects than on socio-health aspects on the management of the disease. The average scores are to be considered good overall, but the gaps that have emerged in terms of sharing information and common treatment strategies are certainly those to be improved. Specific interventions may be necessary aimed at the overall satisfaction of the service offered, perhaps adopting alternative strategies of education to care that put the subject at the center according to the founding principles of the CCM [21].

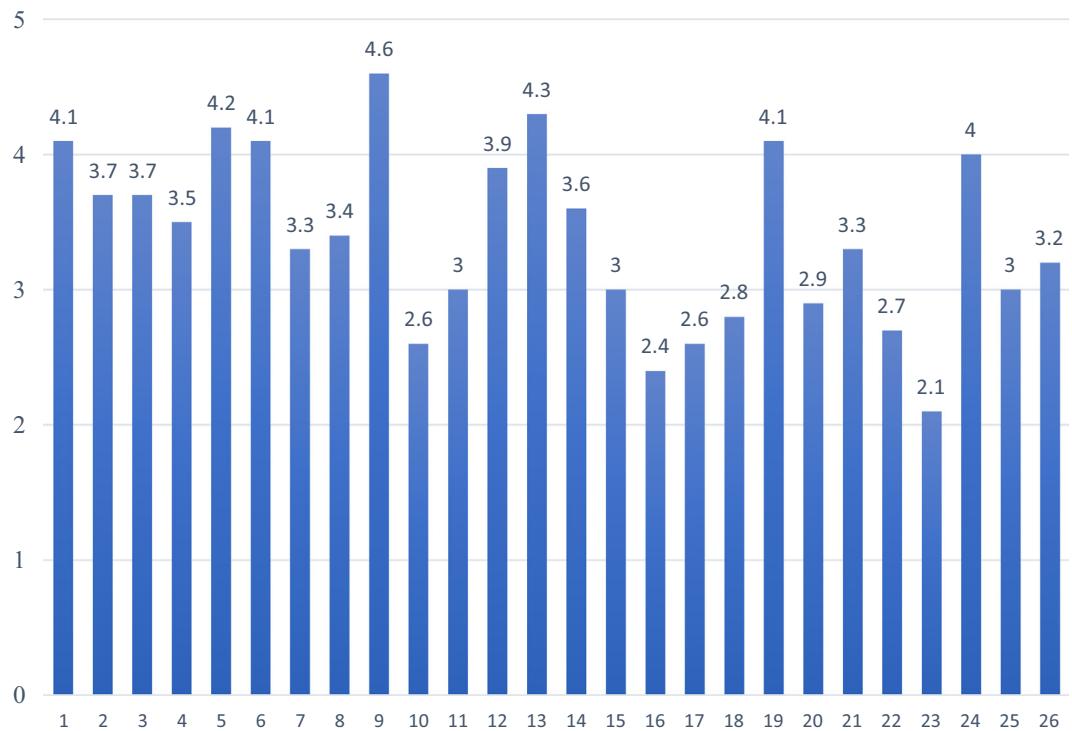


Fig. 1 – Mean scores of each survey question (Q1–26).

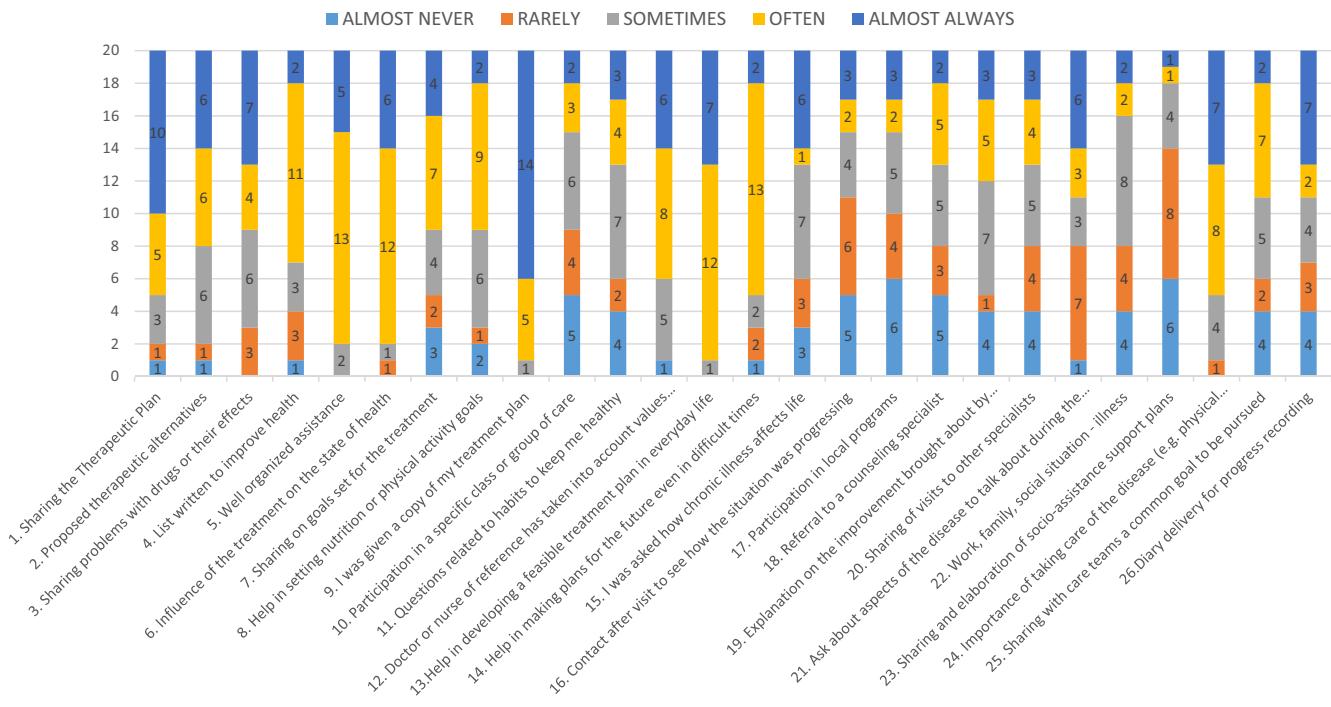


Fig. 2 – Frequencies of PACIC questionnaire responses.

3.2. Focus group summary

Ten patients (six females and four males) participated in this second part of the study. The first meeting dealt with general issues of the management of the disease using a

micro-infuser. The group has expressed different opinions on the matter, but this alternative treatment is significant support in everyday life:

"I had many prejudices about the insulin pump, and from the beginning, I had rejected it several times because I saw it as a

constant and bulky appendix. However, the instability of diabetes necessarily pushed me to try it about two years ago, and I found positive sides like taking a long 6–7 km walk in the mountains" (52-year-old woman, Psychologist);

"At first, I rejected the idea of the insulin pump because I saw it negatively. About two years ago, I was convinced by the fact of associating constant glycemic monitoring with a sensor, which, even for an old diabetic like me (has diabetes for 32 years), allows me to better control the disease and allow me a practically normal life. Today I couldn't do without it" (a 55-year-old man, has diabetes for 32 years).

Numerous skills are required of healthcare personnel involved in the care of type 1 diabetic patients with insulin pumps. Above all, it emerged that these must have a good degree of experience both in the relational field but also updated from a technological/IT point of view:

"I have noticed that on many aspects of the management of the T1DM with an insulin pump, the healthcare professionals are not all up to date even if I understand that some processes evolve very quickly. It would be useful to enter the mentality of managing type 1 diabetes with insulin pumps as we patients need to be listened to and supported by trained and competent professionals" (51-year-old woman, diabetic since 2007, with insulin pump since 2011);

"The problem with these still relatively new tools is that healthcare professionals do not always know how to give the right indications for the treatment of type 1 diabetes with technological support. We, diabetic patients of the first type with insulin pumps, need a close bond of trust with the healthcare professional" (36-year-old woman, diabetes since 1991, insulin pump since 2008).

In particular, the Nurse could support T1DM patients with micro-infusers thanks to clear and modern organizational and specialist processes. This health professional could represent a reference figure for the organization and clinical care of patients with devices, not only for purely technical aspects:

"As for the insulin pump, the Nurse ("Specialist in Diabetes Technology"), could represent a valid interlocutor in the education of the insulin pump, especially in the initial technical stages, perhaps through specific training on the operation and management of the machines. All of this would obviously be to our advantage." (43-year-old woman, diabetic since the age of 16 and insulin pump carrier since 2018); "It would be important to have regularity, frequent contacts, and a person as a specialist referent. A professional who acts more as a "collector and solver" of non-exclusively technical problems. Periodicity and continuity with a referral Nurse could help us in the management of the disease across the board." (31-year-old man, diabetic from the age of 11 for 20 years - and practically on the debut with an insulin pump).

In the second meeting, issues related to the recent Covid-19 pandemic were addressed, which, in this particular care context, has certainly influenced the normal daily

activities and care of an extremely fragile population such as patients with T1DM with insulin pumps. The major impediments to the continuation of care have revealed organizational gaps that have compromised the normal care process:

"It was certainly a revolution in our daily life. I was unable to carry out the checks that were planned because the clinic was closed, some meetings were skipped. I am therefore looking forward to future appointments. As far as the pathology is concerned, I have not registered any major changes except for the question relating to the movement which, obviously, has necessarily been drastically reduced. The sensor made the difference because I was able to assess my blood glucose in real-time and immediately act on any blood glucose fluctuations. After a few days of adaptation, the blood sugar levels returned; perhaps the body has got used to the new rhythm." (33-year-old man, 21-year-old diabetic and 18–19 year old with an insulin pump); "Normally in the morning, I always do some physical activity, but during the lockdown, sedentary lifestyle increased, and consequently, I suffered from hyperglycemia. There was also the difficulty in being able to continue the planned follow-ups with the reference health personnel, which certainly increased the anxiety about the overall management of the disease." (63-year-old woman, 57-year-old diabetic and 25 living with an insulin pump)

This emergency of care has suggested alternative methodologies to normal face-to-face visits. It also highlighted previous gaps in the nutritional field, which in this period were filled by forced regularity:

"Is a connection with doctors also conceivable with new technologies such as Telemedicine?" (31-year-old man, employee, diabetic from the age of 11 for 20 years - and practically on his debut with an insulin pump); "As far as attention to monitoring is concerned, there is now greater availability of time than when you work and you easily 'forget' the disease; now I have more attention to devote to diabetes. For example, on working days, I often miss meals or not be prompt in making some interventions, while in these days of forced social isolation, you are much more attentive to details. Overall, I was able to regulate myself better with meals. During my employment, I usually have a maximum hour and a half of lunch break, and often my lunch was a sandwich 'on the go.' Now, however, I have the time to prepare a meal suitable for diabetes." (36-year-old woman, diabetes since 1991, insulin pump since 2008).

Concerning the information that patients absorbed during the pandemic, especially at the beginning, there was almost common agreement on the fact that the huge flow of unclear and often not authoritative news has probably filled important spaces in the lives of patients:

"It was really a bombardment of information and protecting me from the uncontrolled flow of news was not easy. I had a refusal to go into further detail and only adhered to official channels such as the Ministry of Health." (42-year-old woman, diabetes from the age of 6, insulin pump from the age of 29).

On the future management of diabetic pathology using insulin pumps, it emerged how decisive the reorganization of increasingly flexible and modern services, such as Tele-Nursing and Telemedicine, can be decisive:

"We can see this situation as an opportunity. The fact that we necessarily have to carry out remote checks by sending data could help us in the management of the disease as a whole. What I would like is that, after this emergency situation, instead of queuing for hours for a quick check-up, we could 'institutionalize' a web consultation from home or from the workplace." (33-year-old man, has diabetes for 21 years and with insulin pump from 18 to 19 years); "Certainly there are situations, such as the onset of a complication, in which the contact in person remains absolutely necessary and cannot be postponed to alternative tools, but to hypothesize to reorganize future routine checks also with new operating methods for our Country could be advantageous for everyone (health workers and patients)"; "Telemedicine or similar organizational methods could be valid, but even for small doubts or perplexities direct contact with the reference professional remains far better than video or telephone." (63-year-old woman, 57-year-old diabetic and 25 living with an insulin pump); "The direct relationship with the doctor must necessarily remain in particular moments of the disease, such as complications and specific diagnostic tests, but for routine checks, the web way could represent a valid alternative." (42-year-old man, diabetic from the age of 12 years with an insulin pump for about 10 years).

The patients involved in the FGD concluded, summarized the particular moment experienced as "Revolution" (52-year-old woman, Psychologist); "Mutation and transformation" (51-year-old woman, diabetic since 2007, with insulin pump since 2011); "Tragedy" (63-year-old woman, 57-year-old diabetic and 25 years of living with an insulin pump); "Awareness" (55-year-old man, 32-year-old diabetic - since 1988 -, insulin pump wearer for about a couple of years).

4. Discussion

The results of this pilot study are in line with the results of similar studies relating to the remote assistance of diabetic patients [20,24]. The application of wireless systems such as the transmission of glucose values to a nursing station or the sending of instructions to patients for the use of pumps/CGM remotely has made it possible to reduce the risk of contagion from COVID-19 for patients particularly at risk, such as the diabetic and to prevent their clinical picture from worsening.

This result also occurred in our pilot study and is evident from the responses provided by remotely assisted patients during the focus-group. In fact, despite no significant differences in the health of the diabetic subjects who participated in the study were highlighted, the application of remote assistance protocols represented preventive measures capable of avoiding the worsening of the disease and psychological support to the patient in lockdown.

All this demonstrates how in this challenging healthcare context, alternative treatment management strategies such

as Tele-Nursing or Telemedicine can be strategic for the management of all fragile subjects such as patients with micro-infusers, especially in delicate moments such as social isolation [25].

5. Conclusions

The recent COVID-19 Pandemic, declared by the World Health Organization in March 2020 [26], has emphasized the continuation of the treatment of all chronic diseases, even in delicate phases such as a lockdown. Italy, with 239,627 cases, 33,498 deaths, and 29,282 health workers who tested positive (data as of June 22, 2020), is one of the most affected countries in the world [27]. Taking into due consideration that this pandemic situation may also repeat itself in the years to come, other specific studies are deemed necessary for an overall qualitative/quantitative evaluation of spaces dedicated to web management in diabetic patients of the first type with micro-infuser even after the recent Covid-19 Pandemic.

6. Ethical approval and consent to participation

The study has been approved by the Ethics Committee of the Marche Region (CER) in accordance to Resolution 618/DG of 14/07/2017. In compliance with all privacy regulations (Legislative Decree 196/2003), written consent has been obtained, and data processing has been carried out in a completely anonymous manner.

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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