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Commentary





Psychological Aspects in the Use of Telemedicine in Diabetes Mellitus

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Abstract

Chronic diseases are the most common causes of death and disability worldwide, their management often requires a long-term care plan and adherence to disease management is critical to improve health outcomes, quality of life, and cost-effective health care. Ideally, telemedicine improves healthcare outcomes by providing services and education overcoming geographic barriers to treatment. It is out of the question that today the means of communication between doctor and patient and between doctors is more extensive than in the past. In a time when human resources are under severe stress due to chronic staff shortages, telemedicine has been reputed to lower healthcare costs and increasing access for underserved populations while providing more effective management of chronic diseases. Chronic diseases due to their character of incurability contribute to create a relationship of dependence, of affiliation with the treating figures of reference, in this sense telemedicine can be a means to ensure that solution of therapeutic continuity. The success of telemedicine is surely dependent on having previously established a valid personal medical-patient relationship with a consolidated therapeutic efficacy. By its nature the human being has the need of proximity and this need is rewarded, strengthened and consolidated through the relationship, an empathic attitude with listening and sharing the project of care, built prior to the use of telemedicine, is much more likely to be effective. Where these characteristics are more nuanced or not yet reached, the clinician must be able to motivate the patient through an attitude of trust that helps him to overcome the initial distrust and only then propose telemedicine.

Keywords: mHealth; Mobile health; Patient compliance; Patient adherence; Chronic disease; Diabetes mellitus

Introduction

Chronic diseases are the most common causes of death and disability worldwide, their management often requires a long-term care plan and adherence to chronic disease management is critical to achieving improved health outcomes, quality of life, and cost-effective health care. Due to COVID-19 emergency, mobile technologies have been increasingly used in health care and public health practice (mHealth), for patient communication and monitoring, in order to overcome the health restrictions due to the pandemic. Indeed these system of health communication have largely been used, at least in United States, since a long period even before COVID-19, besides communication with

the patients and monitoring, also for education, and to facilitate adherence to chronic diseases management [1]. Telemedicine, as described by the World Health Organization (WHO) and the American telemedicine Association, is characterized by the remote exchange of medical information and/or services between patient and clinician through electronic information communication technologies [2-4].

Technical Aspects

Ideally, telemedicine improves healthcare outcomes by providing services and education, and overcoming geographic barriers to treatment. Reflective of the rapidly evolving nature of technology, potential approaches to telemedicine are expanding exponentially. These electronic resources have included, but are not limited to, real-time video conferencing, email, websites, mobile phones, Bluetooth, and other telecommunications devices.

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The Italian Ministry of Health definition of telemedicine is the following: "Telemedicine means a way of providing health care services, through the use of innovative technologies, in particular Information and Communication Technologies (ICT), in situations where the health professional and the patient (or two professionals) are not in the same locality. Telemedicine involves the secure transmission of medical information and data in the form of text, sound, images or other forms necessary for the prevention, diagnosis, treatment and subsequent monitoring of patients. Telemedicine services should be assimilated to any diagnostic / therapeutic health service. However, the service in Telemedicine does not replace the traditional health service in the personal doctorpatient relationship, but integrates it to potentially improve efficacy, efficiency and appropriateness. Telemedicine must also comply with all the rights and obligations of any health act. It should be noted that the use of Information and Communication Technology tools for the processing of health information or the online sharing of data and / or health information do not in themselves constitute Telemedicine services. As a way of example, Telemedicine does not include health information portals, social networks, forums, newsgroups, e-mails or other."(https:/www.salute.gov.it). In other words, the definition of telemedicine is in a certain way more restrictive for the Italian government, more regulated by guidelines and with the search for security in the transmission of sensitive data. In fact, whatever the way to define it, it is out of the question that today the means of communication between doctor and patient and between doctors is more extensive than in the past. The regulation of these systems, with the possibility of tracing the accesses of health professionals and of patients, while ensuring the security of data transmission, also according to the need to remunerate such activity must be regulated. In addition to increasing access for underserved populations, telemedicine, in the workshop held in Washington in 2012 on the Role of Telehealth in an Evolving Health Care Environment has been reputed to lower healthcare costs while providing more effective management of chronic diseases. The potential of tele monitoring technologies in improving management of chronic diseases and reducing cost to the healthcare system has been extensively researched over the last three decades [5-8]. Most of these studies have focused on the most diffuse chronic diseases such as congestive heart failure (CHF), diabetes, hypertension, stroke, end stage renal failure and chronic obstructive pulmonary disease (COPD). It has been long discussed how telemedicine might significantly improve the outcome of intervention and reduce cost of care if timely applied [8-12], but so far no clear conclusions are available, mainly due to the differences in the types of interventions and the different types of patients on which they have been applied. Vital signs that have been monitored include electrocardiogram, blood pressure, heart rate, blood glucose (nowadays not only data automatically downloaded in the cloud by glucometers, but also from continuous glucose monitoring sensors, flash glucose monitoring sensors

and insulin pumps), oxygen saturation (SpO₂), weight, and body temperature [13]. In the healthcare sector, e-health and m-health tools are increasingly being used and most studies have reported positive effects of tele-monitoring [14]. E-health typically refers to on-line and off-line computer based applications while m-health refers to applications for mobile phones [15]. Such tools can be used to stimulate a positive health behavior change or assist persons to lead a healthier life style, or to support diagnosis and treatment of diseases. Thus e-health and m-health can be considered any kind of electronic device or monitoring system that is applied by physicians in the healthcare practice or by individuals to monitor or improve their health status. For the Italian Government in any case, as stated above, device such as email, WhatsApp and so on are not considered as telemedicine. For a chronic disease like diabetes that requires recurrent physician consultation, telemedicine can be a viable alternative for patients seeking medical guidance, this might be more evident in type 1 diabetes, where technology at the moment is an important issue, with the generation of a big amount of data that need to be stored and interpreted. Of course there is also the need of a easy access to interactive media without it telemedicine initiatives can be blocked. The solution to the problems of uneasy access to interactive media can be overcome, as in India, with customized mobile van with facility of telemedicine (use of computer and Skype) in underprivileged areas of Delhi, where it has showed success in screening and managing of diabetes [16]. In more privileged areas, telemedicine can be more extensively used, such as for example in Denmark where a report on telemedicine conducted on 5000 T1DM patients at Steno Diabetes Center Copenhagen, proved to be a success with physical visit required only in new onset type 1 diabetic patients or particularly critical patients [17]. E-health and m-health technologies are mostly used by younger people. The potential of this technology for older adults is generally recognized although the application of e-health and m-health tools in health promotion and primary prevention for older persons has been largely unexplored depending a lot on the cultural level of the single person, although just during COVID-19 emergency, a lot of old granny learned technology in order to be able to see and communicate, at least with WhatsApp, with their relatives [18]. The use of e-health and m-health tools in health promotion programs for older adults, is mostly an isolated initiative, especially outside the US. In Italy, that experience a fast population aging, health promotion and primary prevention programs among older adults could specifically benefit from the use of e-health and m-health tools. At the moment it is not clear the cost-effectiveness of these programs [19], if this could be demonstrated and if these programs will be designed to avoid potential barriers, their use could be useful in these older patients. In this regard, more evidence on the effectiveness and cost-effectiveness of e-health and m-health health promotion programs for older adults is needed [20]. Perhaps most critically, if adherence to chronic disease management is not encouraged and actively practiced, it is very unlikely that mAdherence will be successful. M-Health tools are communication platforms and delivery mechanisms, not solutions in and of themselves. In other words, mAdherence will only work where there is already a functioning adherence program in place [21]. Many effective interventions are available that can lead to sustained improvement in patient adherence and in clinical endpoints. Long term success depends on patients assuming responsibility for their own health and can be achieved with the aid of coordinated measures such as patient education and regular follow-up contacts, in this contest telemedicine might help in increasing patients' adherence, different psychological barriers present in both patients and healthcare professionals must be addressed in order to have a product that leads to the desired final results.

currently follow around 3,920 subjects in telemedicine. 3,800 through exchange of information by e-mail (receiving exams and reports of instrumental investigations, with in reply sending our report made with the electronic medical record in use), 292 are followed by telemonitoring (patients with insulin pumps and / or glucose sensors) and 120 by televisit (in a peripheral clinic on the island of La Maddalena). In the near future we will try to implement this technique auxiliary to the face-to-face visit, but both from the technological point of view and from the cultural preparation of both the operator and the patient, it will be necessary to take further steps forward. Considering that cultural differences, age, sex etc could influence the satisfaction and also the ability to access telemedicine, we launched a web-based small survey for type 1 diabetics. One hundred-twenty-eight patients responded to this survey with the results summarized below.

Survey

In our diabetic unit out of a population of about 18,349 diabetic patients (of which 20% in intensive insulin therapy) we

| DIABETE | TYPE 1 | | | |
|------------------------------|---------------|--------------|-------|-------|
| | 128 | | | |
| DIABETES DURATION (YEARS) | 1-5 | 6-10 | 11-20 | >20 |
| | 4,1% | 18,4% | 18,4% | 59,1% |
| SEX | MALE 46,9% | FEMALE 53,1% | | |
| AGE (YEARS) | 18-25 | 26-40 | 41-65 | >65 |
| | 4,1% | 22,5% | 53,1% | 20,3% |

Data are % of sample, in order from top to bottom: all subjects, female, diabetes duration over 20 years, age over 65 years

| QUESTIONS | NO | RARELY | SOME TIME | OFTEN | VERY OFTEN | ALWAYS | |
|--|-------|--------|--------------|-------|---------------|--------|--|
| Could telemedicine be useful to improve your illness? | 2,0% | 4,0% | 24,6% | 22,4% | 24,7% | 22,3% | |
| | 3,8% | 3,8% | 11,5% | 26,9% | 28,9% | 23,1% | |
| | 3,4% | 6,7% | 13,8% | 17,2% | 24,1% | 34,5% | |
| | 0% | 10% | 40% | 10% | 10% | 30% | |
| Could telemedicine be useful, regardless of your illness, to improve your quality of life? | 0% | 2,0% | 14,7% | 29,2% | 31,2% | 22,9% | |
| | 0% | 3,8% | 11,5% | 30,7% | 30,7% | 23,1% | |
| | 0% | 3,4% | 10,3% | 31,2% | 34,4% | 20,7% | |
| | 0% | 0% | 20,0% | 30,0% | 30,0% | 20,0% | |
| Telemedicine gives the possibility of having more frequent contact with the treating staff (doctor, nurse, psychologist etc): do you see this as a plus? | 0% | 4% | 24,5% | 20,4% | 26,5% | 24,6% | |
| | 0% | 0% | 23,1% | 19,2% | 34,6% | 23% | |
| | 1% | 6,8% | 19,2% | 13,8% | 24,7% | 34,5% | |
| | 60,0% | 20,0% | 20,0% | 0% | 0% | 0% | |

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| would it be difficult for you to access telemedicine (need for PC + internet or smartphone or other)? | | 61,3% 42,3% 69,1% 0% | | | 11,2% 19,2% 6,8% 30,0% | 4,5% 3,8% 6,9% 30,0% | 3,3 | 6% 8% 4% 0,0% | 0% 0% 0% 0% 20,0% | |
|--|----------------------|-------------------------------|-----------------------------|----------------------------------|----------------------------------|----------------------------------|----------|--------------------------------|----------------------------------|--|
| according to the definitions given at the beginning, how much do you think tele-visit could be useful for you? | 0% 0% 0% 0% | | 4,1% 7,6% 3,5% 0% | | 22,5% 19,2% 13,8% 20,0% | 28,6% 38,4% 37,9% 30,0% | 19 34 | 5,5% 0,2% 1,5% 0,0% | 18,4% 15,4% 10,3% 20,0% | |
| according to the definitions given at the beginning, how much do you think telemonitoring can be useful? | 1 3 X V/A | | 2%% 15,4% 3,4% 0% | | 15,3% 16,3% 10,4% 20,0% | 26,5% 18,6% 31,3% 30.0% | 19 24 | 2,5% 0,2% 1,1% 0,0% | 33,7% 26,7% 31% 20,0% | |
| according to the definitions given at the beginning, how much do you think teleconsulting can be useful? | 0% 0% 0% 0% | | 8,1% 11,5% 6,9% 0% |) | 15,3% 15,4% 13,7% 20,0% | 28,6% 30, % 31,1% 40,0% | 26 31 | 7,5% 5,9% ,1% 0,0% | 20,5% 15,4% 17,2% 2,0% | |
| | | | visit | telemonitoring | | teleconsulting | | all three | | |
| Which of the previous three do you think would be more important to you? | | 2,0% 3,8% 3,5% 10,0% | | 20,4% 26,9% 13,7% 20,0% | | 10,2% 7,8% 6,8% 10,0% | | 67,4% 61,5% 76% 60,0% | | |

Table 1: Web-based small survey for type 1 diabetics.

Most frequent comments of the patients at the end of the compilation of the survey were:

- Especially in times of pandemic, it is essential not to lose contact with the center and the specialists; generally useful for optimizing time and making contact more frequent.
- The tools that are used for video games, marketing and many other less useful areas should be offered to everyone to better heal themselves. The technology exists and if we do not use it is only the fault of a serious political choice.
- What else to add if not ... to extreme odds, fortunately, extreme remedies!!
- Before we can talk about telemedicine, we need an adequate standardization of protocols and an interconnection of data between the various departments so that every specialist can have a more complete picture of the patient's condition.
- Given the period it is very useful to avoid direct contact with doctors to date, telemedicine would allow a faster relationship with the clinician. this allows us patients to be followed more consistently.

Ultimately, the data of this small survey indicate that telemedicine is appreciated by the majority of patients, who expect both an improvement in diabetic disease and in the quality of life,

increasing the possibility of contacts with healthcare personnel. The three types of telemedicine, televisit, telemonitoring and teleconsultation are equally appreciated by patients, without any particular preference. These data are present regardless of gender and duration of illness. Elderly people, over 65, as expected, are much more skeptical about the fact that telemedicine can give more contacts with health personnel, also indicating that they have more difficulty in accessing hardware for the use of telemedicine. Some differences in terms of expectations and propensity to use telemedicine are present. Among different barriers in wide spreading mhealth the psychological ones have to be considered as mostly important, in the next chapters we will try to analyze the psychological aspects that can affect the outcome of a successful use of telemedicine in the field of chronic diseases such as diabetes.

The use of telemedicine in the diabetic patient

The treatment of diabetes makes use of various types of devices, allowing remote evaluation of glycemic balance. Therefore, in this pandemic period, telemedicine in diabetes operative units provided an excellent example of its use, as it has allowed the continuous exchange of data even at the most critical times, when access to the units was strongly denied. In this, telemedicine has been really a mean of guaranteeing therapeutic continuity, without generating a sense of abandonment in the

patient. Another important aspect to underline is that the success of telemedicine is surely dependent on having previously established a valid personal medical-patient relationship with a consolidated therapeutic efficacy. By its nature the human being has the need of proximity and this need is rewarded, strengthened and consolidated through the relationship, an empathic attitude, listening and sharing of the project of care, that if well-built prior to the use of telemedicine is much more likely to be effective. Where these characteristics are more nuanced or not yet reached, the clinician must be able to motivate the patient through an attitude of trust that helps him to overcome the initial distrust and only then propose telemedicine.

Psychological Aspects in Telemedicine

Health care has undergone an important structural and conceptual metamorphosis in recent years, which has required the knowledge of new and transversal skills to operate in particular situations. From a traditional approach based on a patient-centered biomedical model now the vision has changed, placing health and disease as the result of interactions between psychosocial and biological factors [22]. In this last model the awareness of the patient, with the increase of the scientific knowledge regarding the care received, has become more careful and demanding. The advent of technology has increased patients' medical-scientific knowledge and desire to know his health state, just think of forums in which patients have a "place" to confront each other to dispel doubts and uncertainties, without the presence of a medical doctor. Unfortunately, in recent times, because of Covid pandemic, health care worldwide had to deal with a massive requests for acute care that have literally sent chronic care facilities to collapse, leading to increasing abandonment. In this circumstance telemedicine has been an aid for the potentialities tied to its use in the chronic pathologies thus allowing to continue the assistance [23]. Where telemedicine had a solid and structured implant, satisfactory answers have been found but in many other situations telemedicine is still an impractical and deficient reality.

In order to better understand its type and scope, we have to know that telemedicine definition over time and has been the subject, depending also on the context, of about 104 different peer-reviewed definitions [24]. As mentioned above, in this paper we use the definition provided by the Italian Ministry of Health, because it is our context (https://www.salute.gov.it). We also use it because it emphasizes how telemedicine services must ensure the safe transmission of medical information and therefore can be assimilated to any diagnostic therapeutic health service, with all the rights and obligations of a health act. Telemedicine has the advantage of making available and accessible basic and specialist health care services, especially to that type of care that is not guaranteed easy accessibility. In fact in some forms of chronic pathology, telemedicine is extremely useful, because whenever it is not necessary to carry out an objective examination of the

patient, the exchange of "numbers" or "feelings" by the patient can be done with telemedicine, avoiding unnecessary travel and reducing the time spent on the visit. Its use requires appropriate skills and technologies, not always easily acquired. This has led to the search for alternative practices to communicate between doctor-patient and doctor-doctor, such as the use of phone, mail, apps etc. that are not devices for telemedicine, as sanctioned in Italy. The hope is that this practice will not be exhausted with the end of the pandemic, but will become a further instrument to support the effectiveness, efficiency and appropriateness of the visits that are in presence, with the final hope of overcoming the challenges and the objective and ideological obstacles, which are still the subject of a dissertation between clinicians and patients [25].

The influence of the emotional factors of chronic diseases as a successful "predictive" factor in the treatment and use of telemedicine

Health is certainly the greatest thing that each of us has, but we do not question ourselves deeply, we take it for granted and, very often, we do little to take care of it. There are many factors that can influence a good result in treatment. One of these is represented by the different stages of life. For young people, more technologists, defined as "digital natives", access to the various types of telemedicine is certainly more feasible and more understandable than for older people. Despite this, young people need also the cure in presence due to the fact that both the emotional and the cognitive vulnerability as well as the physical changes that characterize them in this developing phase, must be supported. Telemedicine can be rejected by some of teen patients because it can be seen as a constant control by adults or, more simply, because at this age teen patients are not at all concerned about their pathology. The adolescent type 1 diabetic patient is exposed to greater stress, being already in a period of life when he is trying to make choices of autonomy with respect to the family, in order to build his personal and social identity. On the other hand, older people show a more evident vulnerability to health issues, and often demonstrate this with an attitude of fear. Often they have no technological skills, but above all, for them, the examination in presence can have an indispensable and irreplaceable value because, given their lower life expectancy, the direct relationship with the doctor is necessary to compensate for the greater fear of the disease. This figure is in agreement with the data of our mini survey, which confirm in subjects over 65 years of age both the least openness to technology towards telemedicine and also that telemedicine does not represent for this category of patients a plus. In these cases, in fact, telemedicine could mean an intolerable distance. That's why, before implementing its use in this type of patients, it is important to clearly explain its motivation and usefulness. In this regard it is interesting to note the different response of the female sex that could indicate how for them telemedicine can be an additional added value to the visit

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in the presence, because of the daily commitments that differs between men and women, with the last deeply involved also in family management besides work.

For people with chronic illness breaking down the wall of non-contact presence using telemedicine need the empathy previously established in the doctor-patient dyad. There are four possible dyads depending on the sex of the doctor and the patient (M/M, M/F, F/F, F/M). In this regard, some authors assumed female doctors showing more attention in taking care of the person besides than curing the person [26]. Unfortunately, in literature there is no clear analysis related to the possible differences in patient outcomes in relation to the dyad [27]. The possibility of carrying out studies to observe the dyads in the use of telemedicine would be desirable.

In addition, we can identify other possible factors beyond those already listed above, which may prevent and/or interfere with the establishment of a good therapeutic relationship. Among these we can include mood disorders such as depression, which in diabetes is greater in the measure of two/three times compared to the general population [28]. Another situation is when the patient uses insulin restriction or omission in order to control body weight with consequent adverse effects leading to ketoacidosis and becoming the eating behavior disorder with the highest mortality, the so called Diabulimia [29-32]. Finally, alexithymia, an alteration of affective regulation that seems to be common in several psychiatric and autoimmune diseases, included type 1 diabetes [33], which is not included in the DMS V [34] since it is not recognized as a disorder in itself, but it has some peculiarities of response to the disease because they are compromised coping strategies that leads them to have a worse glycemic compensation [35]. People with alexithymia, even if they present a good social adaptation, often have relational difficulties, their empathic abilities are reduced and their attitude is very concrete. These characteristics may interfere negatively in creating a good therapeutic alliance relationship, but it cannot be excluded that in some of them the aid of telemedicine might allow them to have a relationship with more therapeutic continuity, improving their compliance, particularly in the unstable type 1 diabetes known as Brittle diabetes [36] where alexithymia has been described more frequently than in the rest of the diabetic population and as a factor that must be corrected to have a better outcome of the disease [37].

The attitude towards illness depends on the mental elaboration that the subject attributes to it, therefore the thoughts that arise affect the emotional experience and create the starting point of how the process of care will evolve. This mechanism is one of the assumptions of the cognitive-behavioral psychotherapy that explains how from the processing of thoughts and emotions, a specific behavior takes shape predicting how the person will decide to cure himself or not. The entire span of human existence is exposed to infinite possibilities that life events and adaptive

responses to the contingent situations, take place at the expense of another area of the patient's life. For example if a marital separation occurs it is plausible that all energies go to counter and support this new condition, regardless of whether it is wanted or suffered, leading to not following the therapeutic prescriptions. The caregivers must interpret it not in absolute terms of drop out and therefore also feeling it as a personal failure as professionals, but as adaptive or otherwise personal responses with which patients react to events that essentially change their lives, overshadowing the disease. In general we can consider adversity as an opportunity to develop stress tolerance, resilience and post traumatic growth [38]. Due to the difficulty to use adversity as an opportunity it is important to rely in a multidisciplinary approach with, in these cases, the figure of the psychologist who could help the patient to find adaptive answers, which are present in each of us but of which we are not always aware [39]. That is the set of expectations that we have about our ability to face situation and solve problems and therefore derives also the aspects related to physical health and life in general. Individuals who have a high self-efficacy are also able in a state of disease to adopt behaviors and strategies conducive to improving the state of health. If as Bowlby claims, [40] the need to establish meaningful relationships is inherent in the nature of man, in all ages human beings are able to react better if in case of need they know they can count on the help of people, such figures are known as "attachment figures". The moment we become fragile by nature, we try to find emotional support, a secure base, [41] we can imagine that a diagnosis reveals the individual of his fragility and that most likely the patient seeks in his caregiver the safe base and his "attachment figure" theorized by Bowlby in the caregiver, which becomes determinant to address, contain and modulate the future outcome of the treatment.

At the end of this chapter we can firmly assert that both actors, doctor and patient, bring into the field relational dynamics impregnated with professional and human experiences.

We can therefore summarize that once a solid therapeutic relationship between patient and doctor has been established, telemedicine will be experienced as a complement to therapy in the presence, and not as a total delegation to it, becoming a tool to further consolidate the therapeutic relationship. In this case the use of telemedicine would increase the safety and improve the ability and the degree of response in reactivity to the stress caused by the disease.

Human resources in health in the use of telemedicine: focus on the training of operators

We live in a time when human resources are under severe stress due to chronic staff shortages and future forecasts suggest that there will be a serious shortage of health workers in the next 5/10 years [42]. It is therefore essential to motivate health professionals in the first place to use telemedicine and being able to use it, this

would mean in the near future to be able to meet the requests for care in a situation of insufficient resources. If such practice will survive this pandemic era, the "care" of the chronic patient will increase considerably, therefore telemedicine should be used even when the pandemic emergency period, hopefully, will end. In this regard the shortage of nursing staff for example can be filled by the use of collective education techniques via the web, optimizing the time and results obtained. If we link telemedicine to the difficulties that the pandemic has imposed on us subverting many schemes that in their execution were before always quite rigid, for example in addition to the classic doctor-patient interview, it will become possible to conduct the medical interview sharing with different actors such as specialist doctor, patient, general practitioner, nurse and so on. Although telemedicine is a great help and absolutely little expensive it is not the cure-all for excellence. The enhancement of care also passes through gestures, looks, postures and especially human warmth, that a screen can inhibit and make it more easily sterile. Therefore it is important to understand that telemedicine cannot replace traditional medicine in the presence, but must integrates it. This presupposes a prior knowledge of the patient, with whom a relationship based on trust has already been established.

Conclusions

We have tried to identify on the basis of personality characteristics the style of attachment of patients whose characteristics help to define a model of interaction in the therapeutic doctor/ patient relationship. The knowledge of these characteristics, especially in the contexts of care in which in the team is not present the figure of the psychologist, could facilitate the clinician in establishing a good therapeutic alliance and above all should guide in the selection of possible candidates for the use of telemedicine that, as already stated, must be a supplement to the care in the presence and not simply a substitute.

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