Proposal for innovative and integrated approaches to the unmet needs of patients with irritable bowel syndrome.

Preliminary Vigour report

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Maurizio Gentile [1], Vincenzo De Luca [2/3], Roberta Patalano [1], Daniela Laudisio [1], Giovanni Tramontano [3/4], Sonja Lindner-Rabl [5], Lorenzo Mercurio [2], Elena Salvatore [6], John Farrell [4], Regina Roller-Wirnsberger [5], Lutz Kubitschke [7], Maria Triassi [2], Annamaria Colao [1/8], Maddalena Illario [2/3/4], on behalf of Vigour Consortium*

1 Dipartimento di Medicina Clinica e Chirurgia, Università degli Studi di Napoli Federico II, Napoli, Italy;
2 Dipartimento di Sanità Pubblica, Università degli Studi di Napoli Federico II;
3 Unità Operativa Semplice Ricerca e Sviluppo, Azienda Ospedaliera Universitaria Federico II;
4 EIP on AHA Reference Site Collaborative Network, Brussels, Belgium;
5 Department of Internal Medicine, Medical University of Graz, Graz, Austria;
6 Dipartimento di Scienze biomediche avanzate, Università degli Studi di Napoli Federico II;
7 Empirica Gesellschaft für Kommunikations- und Technologieforschung mbH, Bonn, Germany;
8 United Nations Educational, Scientific and Cultural Organization (UNESCO) Chair for Health Education and Sustainable Development, Federico II University, Napoli, Italy.

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Proposal for innovative and integrated approaches to the unmet needs of patients with irritable bowel syndrome. Preliminary Vigour report

Irritable bowel syndrome (IBS) is a common multifactorial condition that affects the large intestine and is characterized by chronic and relapsing abdominal pain and altered bowel habit. IBS is due to a combination of genetic, environmental and dietary factors. It's usually a lifelong problem very frustrating to live with and can have a big impact on quality of life, as single-agent therapy rarely relieves bothersome symptoms for all patients. The objective of this study was to analyze the approaches and solutions that address the social and health unmet needs of patients with IBS. A qualitative approach was adopted in the current study to identify and specify key digital solution and high impact user scenarios applied to IBS patients, through an adaptation of the "Blueprint on Digital Transformation in Health and Care in an Ageing Society" persona methodology. A Survey was administered to a group of patients in anonymous form. The theoretical elaboration IBS personas was developed through an interdisciplinary Focus Group, which also mapped the pathway for the patient's management. Three main needs were identified to be met to improve IBS patient's lifestyle: access to psychological support, mHealth solutions supporting diet and adapted physical activity, and home-based digital health support. mHealth intervention has been identified for diet adherence, physical exercise and psychological well-being. The process has been mapped and adapted to integrate the new solutions into the care pathway. Further research is needed to evaluate how mHealth services enable IBS patients to manage their conditions and improve their quality of life.

KEY WORDS: Digital Health, Irritable bowel syndrome, mHealth, Nutrition, Physical activity, Psychological support

Introduction

Irritable bowel syndrome (IBS) is a common multifactorial condition that affects the large intestine and is characterized by chronic and relapsing abdominal pain and altered bowel habit. The symptoms of IBS can over-

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Correpondence to: Prof. Maurizio Gentile M.D., Dipartimento di Medicina Clinica e Chirurgia, Università degli Studi di Napoli Federico II; UOC Chirurgia Generale ind.Endocrino-Metabolico, Università Federico II Napoli, Napoli, Italy (e-mail:magentil@unina.it)

lap with those of other functional gastrointestinal disorders (FGIDs), indeed up to a third of patients show more than one feature, suggesting a common underlying etiology [1]. IBS is due to a combination of genetic, environmental and dietary factors. Symptom-based diagnostic criteria [2] include symptom severity and frequency (sporadic, daily) and stool characteristics [3], that are also used to classify patients with IBS according to Rome IV criteria, depending on their predominant bowel habit: diarrhea-predominant (IBS-D), constipation-predominant (IBS-C), mixed diarrhea/constipation (IBS-M), and unclassified (IBS-U). The parameters for the diagnosis of IBS are based on abdominal pain and altered bowel habit in the absence of specific pathology [4]. However, bloating, passage of mucus and incomplete rectal evacuation, nausea, back-ache, tiredness, which are common and troublesome symptoms in people with IBS, are not among the Rome criteria [5].

IBS is usually a lifelong problem very frustrating to live with and can have a big impact on quality of life, as single-agent therapy rarely relieves bothersome symptoms for all patients. It is a prevalent disorder that greatly reduces patients' quality of life (QOL) and adversely affects the medical economy [6]. A recent epidemiological survey using the Rome IV criteria revealed that the prevalence of IBS in the general population globally is 4.1% [7], with a higher prevalence of 7.7 in Italy [8], where this scenario was further worsened by the Covid-19 pandemic.

The impact of IBS on the individual, in terms of quality of life, and on health-care delivery and society, in terms of economic costs, are considerable [9].

Anxiety and depression are frequent mental health disorders worldwide [10], that have been increasing in the past 20 years and show a global prevalence of 12.9% [11]. The emergence of the COVID-19 pandemic has created an environment where many determinants of poor mental health are exacerbated. Indeed, two COVID-19 impact indicators, specifically daily SARS-CoV-2 infection rates and reductions in human mobility, were associated with increased prevalence of major depressive disorder, and a total prevalence was 4802·4 cases (4108·2 to 5588·6) per 100 000 population. Altogether, major depressive disorder caused 49·4 million (33·6 to 68·7) DALYs and anxiety disorders caused 44·5 million (30·2 to 62·5) DALYs globally in 2020 [12].

In IBS a visceral hypersensitivity related to altered processing of sensory stimuli along the brain-gut axis has been shown, especially in several brain areas like insula. Like for anxiety and depressive disorders, abnormal brain network synchrony that correlates with self-bodily consciousness, measured by hypochondriasis and enteroception evaluation scales have been evidenced [13,14]. Meditation and yoga like practice have been suggested as lifestyle practice that help to mitigate anxiety and IBS symptoms [15] and so they may be used to reduce drug prescriptions and improve quality of life. Digital health solutions bring the potential of supporting health interventions through mobile apps, wearable devices, telemedicine, or video games [16-18]. Mobile apps can promote a healthy lifestyle, encourage individuals to be healthier and more active, and offer smartphone-based personalized interventions for diet and physical activity coaching [19]. The objective of this study was to propose some models of the policies, approaches, and solutions that address the social and health unmet needs of patients with irritable bowel syndrome.

Method

A mixed qualitative-quantitative method was adopted in the current study to identify and specify key digital solution and high impact user scenarios applied to IBS patients, through an adaptation of the "Blueprint on Digital Transformation in Health and Care in an Ageing Society" methodology [20] to the outpatient colo-proctology clinic of the Department of Clinical Medicine and Surgery, referral for IBS patients. The personas approach is a patient-centred methodology to design or identify key digital solutions and usage scenarios, which have a high impact on an individual's specific and unmet needs [21,22]. A persona is defined as a single, specific hypothetical/fictitious person who represents a segment of the population [23] with a realistic name, a face, and a description of their character (needs, goals, hopes, dreams, and attitudes). The Blueprint personas also include behavioral characteristics, which could affect both short-term and long-term success with interventions directed toward managing a disease or adopting wellness [24], for example, a persona's trust or lack of trust in care professionals, their self-management capabilities, and specific details about their character (e.g., being prone to aggressive behavior or having the tendency to reject outside support). In the present study, a collaborative approach has been implemented to outline a Blueprint persona affected by irritable bowel syndrome and identify the digital solutions to integrate in their care and cure (Fig. 1). A Survey was administered to a group of patients in anony-

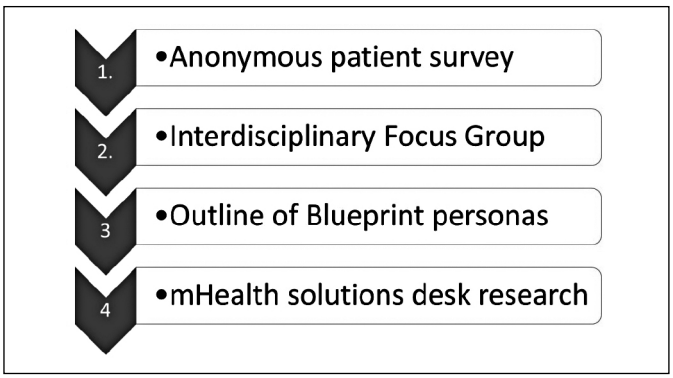

Fig. 1: Collaborative approach phases.

mous form, and no need for Medical Ethical Committee approval was identified, so as no data were used, neither were references made to a specific single patient. The theoretical elaboration of prototype representative of IBS patients was developed through an interdisciplinary Focus Group (25-26) involving:
– n. 1 Proctology specialist;
– n. 2 Clinical Psychologist specialist;
– n. 2 Nutritionists;
– n. 2 Experts in Digital Health;
– n. 1 Expert in Healthcare organization.

Results

The Blueprint Survey was administered to a group of 50 patients diagnosed with IBS. The group included 22 males and 28 females, with a mean age of 41,33 (range 18-70). 34 of these (15M, 19F) were active workers, 6 were retired (5M, 1F), 5 unemployed and 5 were household. Diagnosed according to Rome IV criteria, 27 patients suffered of IBS with predominant constipation (12M, 15F), 12 with predominant diarrhea (2M,10F), 11 patients had mixed bowel habits (2M, 9F). A group of 12 patients showed a positive test for lactose intolerance and were excluded from the study. All patients were treated with a change of the diet increasing the amount of fibers and fluids intake. All patients were advised to exercise regularly. In 12 out 50 a FODMAP diet was administered and in 38 a high fiber rate diet was prescribed with medical therapy for constipation (macrogol, psyllium) or diarrhea (loperamide, anticholinergic). In three cases antidepressant (SSRI) were associated. 13 patients (10M, 3F) complained for more complex associated symptoms and they needed surgery. 8 complete or single node hemorrhoidectomy and 5 lateral internal sphincterotomy were performed.

IBS Personas

Based on the characteristics of the population of 50 patients included in the study, the Focus Group developed one Persona, following the Blueprint methodology to identify Digital Health models that had an intervention strategy for IBS treatment and management. Antonio, has been developed who somewhat embodies all the recurring issues and needs in these patients. Age, general information, personal and life, hobbies, working condition, health concerns, and health needs have been taking in consideration to design a global picture. More in details, Antonio is a 40 years-old man with an active life. When adolescent he underwent surgery for a bowel occlusion due to a lipoma, with a bowel resection. He is generally well, but anxious about his health condition, and quite often comes back for controls due to fear of a colon cancer. He currently suffers from IBS and haemorrhoids, for which he undergoes local treatments. Three main needs were identified to be met to improve Antonio's lifestyle: access to psychological support, need to use one or more mHealth solution supporting diet and adapted physical activity, and home-based digital health support to manage IBS (Fig. 2).

mHealth Interventions

Despite the differences in the symptoms, all IBS Personas might take advantage of a support for adherence to diet, physical exercise, and psychological wellbeing. These common, unmet needs informed the Focus Group search for mHealth solutions.
Lifestyles are the first level of intervention for IBS patients. Personalized coaching solutions may allow patients to prevent and avoid a sedentary lifestyle and receive useful and comprehensive long-term coaching. Personalized coaching mobile apps allow patients to receive advice on nutrition and other lifestyles (such as smoking, drinking, drug abuse and others), in line with personal preferences [27]. Interactive coaching makes it possible to measure progress and classify a patient's behavior in order to identify possible warnings to be communicated to users.

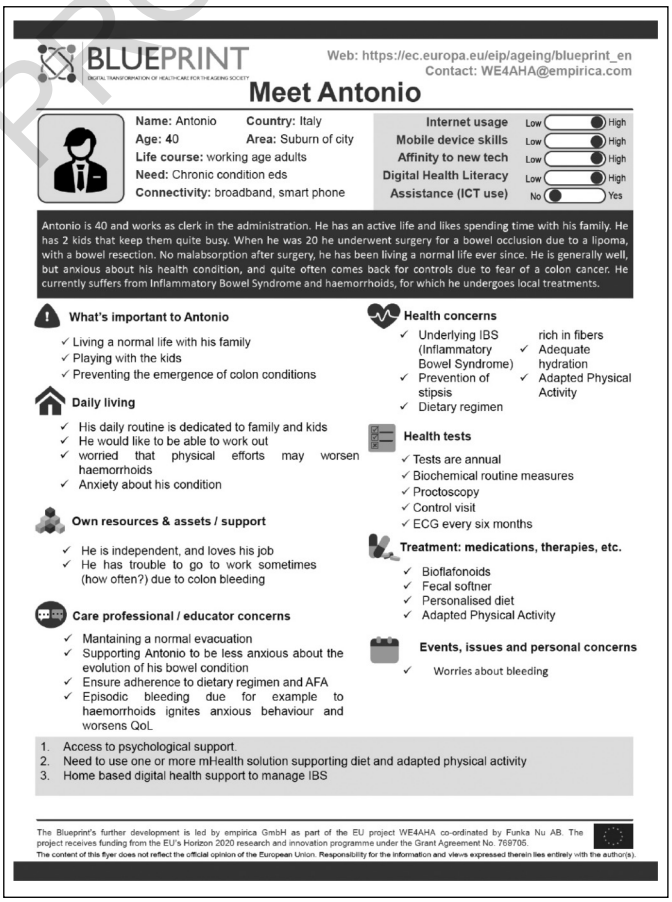

Fig. 2: IBS Blueprint personas poster

Healthy nutrition coaching is based on the patient's meal intake data. The medical staff establishes the nutritional plan and the goals to be achieved. Other parameters such as body weight and weight variations, as well as concomitant diseases the patient may have, are considered in setting the goals. It is important to take the patient's preferences into account. The solution monitors the patient's adherence to nutritional prescriptions [28].
Similarly, physical activity coaching is based on the data provided by the patient regarding physical activity. Mobile apps are connected with validated devices through which the patient records his or her data (SmartWatch, FitBit, etc.). The system continuously monitors the patient's physical activity, keeping track of goals. The system provides warnings to the patient (e.g. low daily activity or excessive sedentariness in activities of daily living) [29].
Mobile apps also help patients in managing mental health problems and treatments supporting them to think differently. Apps make meditation easier by offering a series of audio lessons and programs that improve sleep, breathing exercises, relaxation, and mindful movement, to better cope with stress [30-33].

Discussion

Patients affected by IBS usually include working age adults who complain about quality of life and the impact of disease reacutization on their work capacity. IBS symptoms are intertwined with stress, bio-psychological triggers and lifestyles, and mobile solutions provide the opportunity to facilitate service integration to address unmet IBS patient needs. Towards this goal, the "Personas" approach developed by the EU Blueprint on digital transformation of health and care combines quantitative methodologies and techniques with more synthetic and intuitive inference processes. This approach facilitates addressing the challenges and needs proposed by the design of digital experiences in an original way. Indeed, when developing services supported by digital solutions, it is important to consider the socio-economic context, skills and integration gaps, both technological and organizational, that may influence the adoption of innovative solutions: in our study we design an approach to personalize lifestyles support along the nutritional, physical and psychological domains, to integrate the diagnostic therapeutic pathway of IBS patients. Our approach is informed by the inputs emerging from a real outpatient practice but requires further validation through an implementation protocol.

Conclusions

The person-centered approach we implemented through the adaptation of the Blueprint persona methodology applied to IBS patients was implemented through a multidisciplinary Focus group that enabled the identification of the need for a mHealth intervention, based on the promotion of healthy lifestyles, nutrition, adapted physical activity, meditation practice and psychological support. Further research is needed to evaluate how mHealth services enable IBS patients to manage their conditions and change in quality of life and be integrated into the current service provision flow. Feasibility, usability and adoptability studies on innovative, integrated, personalized care paths, suitable for a wide range of patients, as well as cost studies, will highlight the impact of mHealth interventions on patients health outcomes, quality of life and possible reduction of health-related cost over time.

Riassunto

La sindrome dell'intestino irritabile (IBS) è una condizione multifattoriale comune che colpisce l'intestino crasso ed è caratterizzata da dolore addominale cronico e recidivante e alterazione delle abitudini intestinali. L'IBS è dovuta a una combinazione di fattori genetici, ambientali e dietetici.
Di solito è un problema che permane per tutta la vita, molto frustrante per conviverci e può avere un grande impatto negativo sulla qualità della vita, poiché la terapia con un solo farmaco raramente allevia i sintomi fastidiosi per tutti i pazienti.
L'obiettivo di questo studio era di analizzare gli approcci e le soluzioni che affrontano i bisogni sociali e sanitari insoddisfatti dei pazienti con IBS. Nel presente studio è stato adottato un approccio qualitativo per identificare e specificare la soluzione digitale chiave e gli scenari utente ad alto impatto applicati ai pazienti con IBS, attraverso un adattamento al singolo della metodologia "Blueprint on Digital Transformation in Health and Care in an Aging Society". Un sondaggio è stato somministrato a un gruppo di pazienti in forma anonima.
L'elaborazione teorica IBS personale è stata sviluppata attraverso un Focus Group interdisciplinare, che ha anche tracciato il percorso per la gestione del paziente. Sono state identificate tre esigenze principali da soddisfare per migliorare lo stile di vita dei pazienti affetti da IBS: accesso al supporto psicologico, soluzioni di mHealth a supporto della dieta e dell'attività fisica adattata e supporto sanitario digitale domiciliare. L'intervento mHealth è stato identificato per l'aderenza alla dieta, l'esercizio fisico e il benessere psicologico.
Il processo è stato mappato e adattato per integrare le nuove soluzioni nel percorso assistenziale.
Sono necessarie ulteriori ricerche per valutare in che modo i servizi di mHealth consentano ai pazienti con IBS di gestire le loro condizioni e migliorare la loro qualità di vita.

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