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ORIGINAL ARTICLE

BLUEPRINT PERSONA AND INFORMATION AND COMMUNICATION TECHNOLOGY INTERVENTIONS: ADDRESSING UNMET NEEDS IN BURNING MOUTH SYNDROME CARE

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ABSTRACT

OBJECTIVES

This study aimed to create a Blueprint Persona for Burning Mouth Syndrome (BMS) patients, focusing on Unmet needs that digital solutions can address.

METHODS

An interdisciplinary focus group formulated the BMS Blueprint Persona by discussing clinical data and survey results regarding education, informatics skills, and perceived unmet needs, collected from 500 BMS patients between 2022 and 2023.

RESULTS

The BMS Blueprint Persona, named Anna, represents a typical BMS patient profile: a young-old woman with limited computer skills who experiences anxiety, depression, and insomnia, has memory issues leading to medication adherence challenges, is obese due to overeating, and spends much time watching TV at home. Anna's primary concern is receiving inadequate treatment and not achieving disease remission. She also feels misunderstood and lacks family support. This persona reveals several areas where Information and Communication Technology (ICT) interventions, like telemedicine, anxiety and insomnia treatment, drug adherence improvement, and nutritional and lifestyle guidance, could be beneficial. The focus group also outlined the essential features for a prospective mHealth app to meet BMS patients' diverse needs.

CONCLUSION

The development of the BMS Blueprint Persona successfully identified patient characteristics and unmet needs, offering valuable insights for creating personalized diagnostic-therapeutic pathways and digital health solutions for BMS.

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KEYWORDS

Burning mouth syndrome, Blueprint persona, Chronic pain, Digital health, mHealth, EIP on AHA, Telemedicine, telehealth

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INTRODUCTION

Burning mouth syndrome (BMS) is a chronic orofacial pain disorder of multifactorial origin, characterized by a persistent burning in the mouth lasting more than 3 months, with no identifiable local or systemic pathological alterations.[1] BMS clinical presentation may be complicated by a multiplicity of additional oral and extraoral symptoms[2] which occur in various combination and include, respectively, dry mouth (xerostomia), changes in taste perception, a metallic taste, mouth soreness, itching, a feeling of a lump in the throat (globus), and vulvodynia, ophthalmodynia, and tinnitus.[3,4]

The unpleasant sensations associated with these symptoms may disturb physiological activities such as eating, speaking, and sleeping, and have a substantial impact on social interactions, personal relationships, and work productivity, ultimately affecting psychological well-being and overall quality of life.[4,5] Moreover, mood disorders, sleep disturbances, and cognitive impairment often coexist with BMS, further exacerbating the burden of the condition.[6–8]

Since most of the BMS patients are older adults, they often suffer from age-related comorbidities[9,10] which complicate the management of this disease not only because they may be treated with drugs that could impact on oral health, for instance affecting salivation, but also because they decrease the ability to cope with chronic pain, increase the vulnerability to mood disorders, and the risk of cognitive impairment.[11,12] The intersection of BMS and the aging process underscores the importance of comprehensive care and support for affected individuals to address the unique difficulties that may arise as they become older.[13]

Considering the multidistrict localization of symptoms, and often undiagnosed or inadequately treated systemic comorbidities, BMS patients present significant challenges for healthcare providers.[3,14] This complexity extends from planning and administering treatment to ongoing monitoring over the years also with the aim of slowing the progression with aging of worrying accompanying conditions such as cognitive impairment.[10]

In this context, digital health solutions offer promising avenues to enhance health outcomes in BMS patients for multiple reasons: they could facilitate accurate diagnose, enable the monitoring of disease activity and guide data-driven treatment decisions.[15–17]

Moreover, digital supports may help controlling pain, reduce anxiety and insomnia, treat depression, and improve cognitive impairment. Finally, dedicated ICT solutions can improve drug adherence, which is often an issue in BMS patients. Nonetheless, no integrated ICT solution specifically designed to address the health needs of BMS patients has been developed so far. An important tool that could help designing such a disease-tailored digital solution is represented by the so-called Blueprint persona (https://blueprint-personas.eu/). Blueprint personas are fictional characters that reproduce the typical features of patients affected with a specific disease. Prototypical Blueprint personas have been developed by a team of experts coordinated by EMPIRICA, a private company devoted to promoting the implementation of digital health as part of the initiative of the European Commission known as European Blueprint on Digital Transformation of Health and Care for the Ageing Society. The aim of Blueprint personas is to illuminate the "unmet needs" of patients, thus directing the efforts to design key digital solutions. Therefore, the profile of a specific Blueprint persona includes not only essential clinical information about symptoms, necessary medical procedures, and therapy, but also on the impact of the disease on daily living, social life, unmet needs and, importantly, on patient informatic literacy. Based on this comprehensive information ICT solutions that address the diverse patient needs can be designed. Unfortunately, no Blueprint persona has been developed so far for BMS. Therefore, we brought together experts in the field with the aim of developing the first BMS Blueprint persona and discussing the characteristics that an ICT solution should have to effectively address the multifaceted needs of BMS patients. In the present manuscript we report the results of the work of this focus group.

METHODS

Study Design

In the present study, carried out at the Department of Neuroscience of Federico II University of Naples (Oral Medicine Unit), we used a mixed-method research design to develop a BMS Blueprint persona. Briefly, a survey was carried out in 500 patients with BMS attending our institution to identify their unmet needs. Thereafter, a focus group made by experts examined the results of the survey and the medical files of the patients taking part in the survey to extrapolate the general features to be incorporated in the BMS Blueprint Persona. Finally, based on the principles of "Blueprint on Digital Transformation in Health and Care in an Ageing Society," the focus group elaborated the general structure for an ICT solution that could help BMS patients.

Patient Survey

A structured survey investigating perceived individual functional and social needs was administered to 500 patients attending the BMS outpatient clinics of our institution. Our approach involved conducting in-depth interviews and focus groups to gather qualitative insights, supplemented by a comprehensive survey analysis.[18,19] We engaged a diverse participant pool, carefully selected based on specific criteria to ensure a broad representation of the BMS patient population.

An anonymous survey was administered to a group of 500 BMS patients, eliminating the need for Medical Ethical Committee approval since the research did not involve personal data or reference specific individuals. Participants were given informed consent that explained the criteria for inclusion and the privacy measures in place regarding the use of their data.

The BMS group inclusion criteria were, in line with the [International Classification of Orofacial Pain, 1st edition (ICOP), 2020], 1st edition:

1. patients experience of symptoms of oral burning recurring daily for > 2 hours per day for > 3 months without any clinical mucosal alterations.
2. patients with age between 18 and 80.
3. patients with normal blood test findings (including blood count, blood glucose levels and glycated haemoglobin, folic acid, zinc, serum iron, ferritin and transferrin).
4. patients were not in treatment with psychotropic drugs.
5. patients not involved in other nutritional programs.

The BMS group exclusion criteria were as follows:

1. patients suffering from diseases that could be recognized as a causative factor of BMS.
2. patients under 18 and over 80 years of age.
3. patients unable to understand the questionnaires.
4. patients undergoing treatment with psychotropic drugs.
5. patients having a history of alcohol or substance abuse.
6. patients in treatment with systemic drugs possibly associated with oral symptoms.
7. patients suffering from Obstructive Sleep Apnoea Syndrome (OSAS)..

All the participants signed an informed consent form that clearly explained the aim and design of the study, inclusion criteria and the measures taken to guarantee the respect of privacy regarding the use of personal data. Medical Ethical Committee approval was deemed not necessary since the questionnaires were totally anonymous.

The survey (Supplementary file) included questions concerning age, gender, marital status, number of sons, place of residence (rural area, suburban area or city), education, internet usage, mobile device skills, affinity to new tech, Digital Health Literacy, daily habits, the use of alcohol and tobacco, and social environment with special reference to supporting people. Specific questions were dedicated to understanding what BMS patients consider important to improve the quality of their life, and what are their main worries about their health and the impact of their disease on their daily living.

Blueprint Persona

The Blueprint stands as a cornerstone among the three horizontal initiatives set forth by the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA).[20] Its formation is the result of a collaborative effort by EMPIRICA-coordinated experts who bring diverse backgrounds to the table, ensuring a comprehensive approach to innovation in aging. This strategic plan proved integral to fostering a digital single market that supports active and healthy aging through enhanced healthcare services, more sustainable healthcare systems, and the generation of economic growth.[21–23]

The Blueprint operates within the context of the digital single market and is focused on the betterment of healthcare services, the sustainability of healthcare systems, and the stimulation of economic growth, particularly within the context of the Silver Economy.[21,24] The Silver Economy refers to the economic opportunities arising from the public and consumer expenditures related to the population of people aged 50 and older.[25] This economic domain not only pertains to the healthcare industry but also includes leisure, finance, transportation, housing, and education, among others. The growth in this sector is propelled by the increasing number of older adults and their significant contribution to consumer spending.[26]

The Blueprint outlines a future where digital technologies significantly enhance the living standards of the older adults by fostering their independence, enhancing their quality of life, and enabling their active economic participation.[27,28] It highlights the critical role of digital advancements in developing sustainable, efficient, and accessible healthcare solutions, which not only benefit Europe's ageing population but also stimulate economic growth through the Silver Economy.[29,30] This approach views the ageing population not merely as a challenge but as an opportunity for both economic and social development. By integrating the digital single market with the needs of older adults, the Blueprint aims to maximize the potential of the Silver Economy, leading to better health outcomes and a stronger economy through innovative solutions.

A hallmark of the Blueprint's innovative approach to healthcare is the creation of a dynamic, multidimensional matrix categorizing 12 distinct personas.[31] These personas are methodically arranged in a table covering 4 life stages (horizontal axis) and 3 health conditions (vertical axis). This matrix acts as a crucial analytical tool, aiding healthcare professionals in comprehending the complex and diverse needs of the aging population across different life phases and varying health statuses.

The Blueprint “Personas” method is a patient-focused strategy designed to illuminate the “unmet needs” of patients and to design key digital solutions and usage scenarios.[22,29] The "Persona" is a distinct, individual, conceptual patient, designed to embody a particular patient group.[32] This crafted "Persona" is given a believable name, a visual representation, and a succinct summary of their needs, objectives, aspirations, desires, and perspectives. Included in this portrayal are behavioral traits, as these can significantly impact the outcomes achieved through the suggested intervention, both in the immediate and extended future.[31,33]

In an effort to continuously refine and enhance this healthcare model, the Blueprint actively incorporates new personas to represent emerging medical conditions and evolving healthcare needs. This practice is not only crucial for staying abreast of the latest developments in geriatric healthcare but also plays a vital role in promoting a deeper understanding among healthcare providers of the diverse array of diseases and conditions that can affect the older adults.

A noteworthy inclusion is the persona of a female older adult with BMS, acknowledging the importance of addressing less prevalent but impactful conditions. This addition not only adds complexity to the matrix but also demonstrates the Blueprint’s commitment to comprehensive, inclusive, and personalized healthcare solutions. It emphasizes the necessity to address a spectrum of conditions that, while not widespread, significantly impact the affected individuals’ quality of life.

The healthcare matrix is not static; it grows and evolves, as highlighted by the integration of personas like those with BMS. This reflects the Blueprint’s dynamic and responsive approach to healthcare provision. Recognizing that health needs are fluid, varying widely across individuals and changing over time, the Blueprint adapts. It confronts the unique challenges encountered by diverse segments of the aging population head-on. In doing so, the Blueprint cements its role as a leader in empathetic, forward-thinking healthcare strategies.

Clinical Data

At the time of survey, patients underwent clinical and laboratory evaluation according to standard protocols in use at our BMS outpatient clinics. Briefly, after collecting anamnestic information about comorbidities, past blood tests, and drug therapy, the following psychometric test were administered to the patients by an oral medicine specialist: the Numeric Rating Scale (NRS) and the Short Form McGill Pain Questionnaire (SF-MPQ) to evaluate the intensity and quality of the pain/burning,[34,35] the Hamilton Depression Rating Scale (HAM-D) and the Hamilton Anxiety Rating Scale (HAM-A) to evaluate the level of anxiety and depression [36,37]; and the Pittsburgh Sleep Quality Index (PSQI) and the Epworth Sleepiness Scale (ESS) to evaluate the sleep quality[38,39] were administered to all BMS patients. The Mini Mental State Exam (MMSE) has been administered to all BMS patients to evaluate the global cognitive function.[40]

Patients were also asked whether they did regular physical exercise, defined as at least 30 min of aerobic activity, 3 times a week.[41]

A general physical and neurological examination was performed, and arterial blood pressure was measured with an aneroid sphygmomanometer. Blood samples were collected for blood chemistry tests with a special reference to the determination of blood glucose, plasma lipids and homocysteine.[42,43]

Focus Group and Blueprint Persona Design

To develop a BMS Blueprint Persona we brought together a group of experts in the different fields related to this multifaceted disease.[44]

Specifically, the focus group included:

- n.3 Specialist in Oral Medicine or a related field with expertise in BMS.
- n.2 Clinical Psychiatrists with experience in chronic pain.
- n.1 Neurologist with experience in cognitive impairment.
- n.1 Clinical Cardiologist with expertise in metabolic disorders.
- n.1 Psychologist with a specific experience in the psychometric tests given to BMS patients.
- n.1 Nutritionist with a specific knowledge of BMS-related nutritional issues.
- n.2 Digital Health Specialists expert in the development of patient support tools.
- n.1 Clinical Pharmacologist, expert in the management of polypharmacy.
- n.1 Professional specialized in Healthcare organization to ensure a holistic approach to patient care.
- n.3 nurses specialized in Healthcare organization and with experience in administering questionnaires.

The experts of the focus group were asked to analyze BMS clinical data and the results of the survey to identify, upon collective discussion, the main characteristics to be incorporated in a comprehensive representation of a typical BMS patient. After harmonization of opinions among reviewers regarding any items that were scored differently, focus group experts filled-out the various sections of the form for new persona submission available at the URL https://blueprint-personas.eu/new-persona/. Specifically, they first compiled and introductory section in which a fictional identity is given to the BMS persona by assigning to her name, age, gender, country, area where she lives (rural, suburban,

urban or residential) and life course (child, young adult, working age adult, retired person, person aged 80+). Then, the general condition of the persona was specified by filling the field "need" with any of the following options: Generally, well / good wellbeing, Chronic conditions and / or social needs, Complex needs, Improve care delivery in the community. In this introductory section, the following fields concerning the acquaintance of the Blueprint person with informatics and new technologies had to be filled in by focus group experts: Connectivity, Internet usage, Mobile device skills, Affinity to new tech, Digital Health Literacy and Assistance (ICT use).

Then, Focus Group experts had to write a "persona story," which shortly describes the patient, her social and familial context and, importantly, her clinical story from the onset of the disease to the actual status. After this introductory section, the experts had to come out with an agreed short text for each of the following sections:

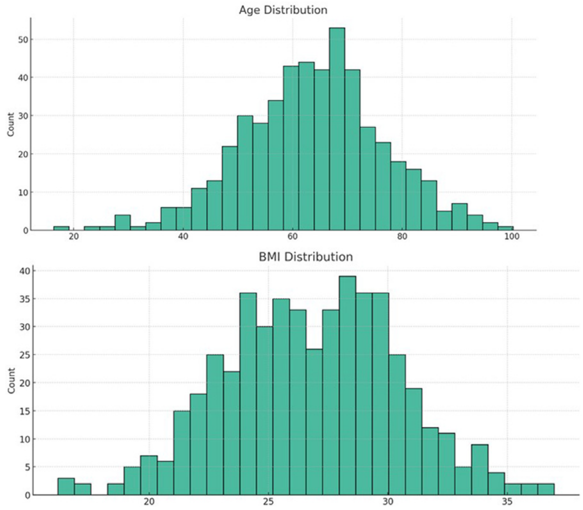
a) "What's important" for the patients.
b) "Health concerns."
c) "Daily living."
d) "Health tests."
e) "Events, issues & personal concerns."
f) "Treatment: medications, therapies, etc."
g) "Own resources & assets / support."
h) "Care professional concerns."
i) "Needs."

As a matter of fact, the work of the focus group goes well beyond mere data aggregation, offering a comprehensive understanding of the patient journey and the psychosocial dynamics within the BMS community and identifying major unmet needs. This information was used by the experts to draw a general description of an integrated ICT suite to address BMS patient needs.[45]

Statistical Analysis

The statistical analyses in this study were conducted using R software (version 4.1.2; Team Rcore, 2016). This included computing descriptive statistics such as means, standard deviations (SDs), medians, and interquartile ranges (IQRs) for all the examined variables. To assess the relationships between the listed quantitative and qualitative predictors and the onset of the disease, Spearman's correlation and the Wilcoxon-Mann-Whitney test were applied. Quantitative predictors included age, years of education, BMI, NRS, SF-MPQ, HAM-A, HAM-D, PSQI, ESS, while qualitative predictors encompassed gender, marital status, employment status, menopausal status, smoking habits, alcohol consumption, prevalent oral symptoms in patients, pain location, diurnal variation in symptoms, common comorbidities, history of psychiatric disorders, and the development of sleep disorders before BMS onset. p-values below 0.05 and 0.01 were deemed to indicate moderate and strong statistical significance, respectively.

Figure 1. Histograms and Box Plots for Age and Body Mass Index (BMI) distribution.



RESULTS

BMS Patients

The Blueprint Survey was administered to 500 BMS patients (129 [25.8%] males and 371 [74.2%] females), with a mean age of 64.5 ± 12.94 (range 18-85) and an average BMI of 26.76 ± 3.51 (Figure 1-Table S1). All patients complained of a burning sensation in their mouth with the tongue (91.2%) and lips (62.2%) being more frequently affected (Table S2). The most prevalent additional oral symptoms included a sensation of a foreign object in the mouth (78.8%), dry mouth (61.6%), and altered taste (45%) (Figure 2A). In 33.8% of patients, these oral symptoms were accompanied by various extraoral clinical manifestations, with an average of 2.8 extraoral symptoms per individual. The most frequent among them were irritable bowel syndrome (9.6%), fibromyalgia (7.2%), and tinnitus (6.4%) (Figure 2B). Many BMS patients also suffered from comorbidities including hypertension affecting 49.8% of the patients (n = 249), hypercholesterolemia and hyperhomocysteinemia, which were observed respectively in 38.6% (n = 193) and 31.1% (n = 181) of the patients (Figure 3). Consequently, 44.8% of the patients (n = 224) were on antihypertensive drugs, 27.4% (137) on statins and 29% (n = 145) on antiplatelet drugs (Table S3).

The median and interquartile range (IQR) of the NRS and the SF-MPQ were 10 [9-10] and 10 [7-12], respectively, indicating that patients with Burning Mouth Syndrome (BMS)

Figure 2. A comprehensive overview of various oral and extra-oral symptoms and their prevalence.

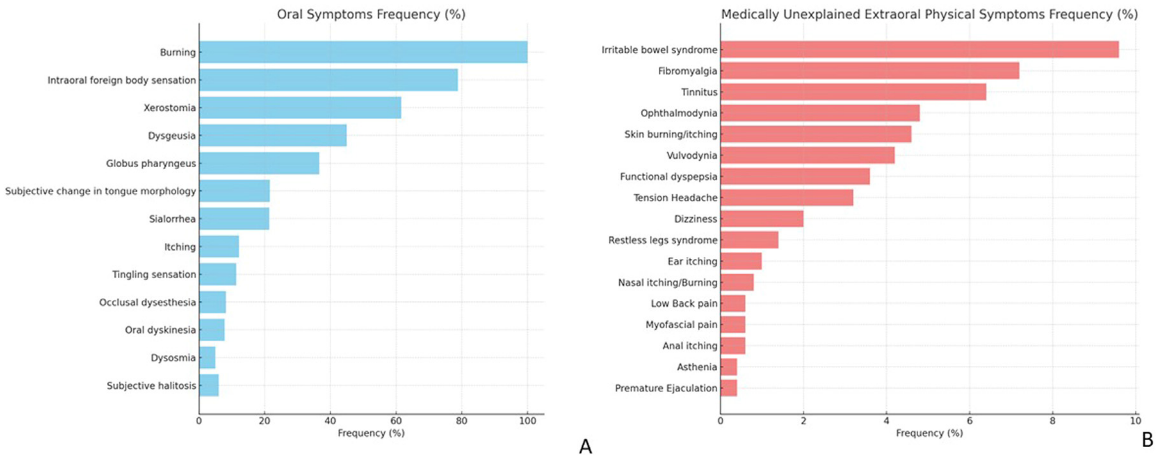
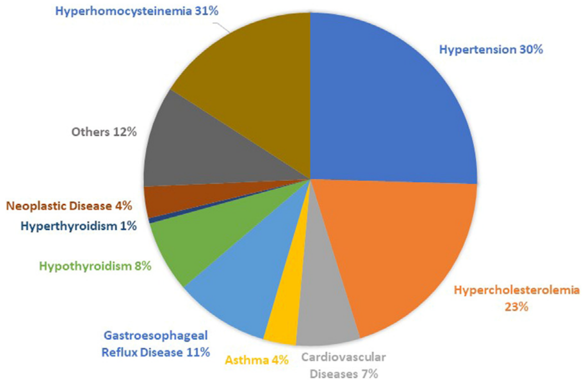


Figure 3. Prevalence of comorbidities in BMS patients.



experienced severe pain. Pain relief during meals was reported by 280 (56%) participants. On average, the time from symptom onset to accurate BMS diagnosis was 29.71 ± 47.19 months, with each patient consulting an average of 2.61 ± 1.65 healthcare practitioners. The median and IQR of the NRS, at 10 [9-10], further underscored the high intensity of pain experienced by BMS patients. Additionally, patients with a longer duration of symptoms tended to report higher NRS scores.

HAM-A, HAM-D scores were 17 [15-20] and 17 [14-20] respectively suggesting that they suffered from anxiety and depression.

Poor sleep was observed in 451 (90.2%) of patients as indicated by the PSQI and ESS values (8 [7.75-10] and 7 [5-9], respectively). In 53.8% (n = 269) of the patients, insomnia appeared before the other symptoms that lead to BMS diagnosis. (Figure 4 Table S4)

BMS patients showed a decrease in the global cognitive function as indicated by the low average MMSE scores [23.35 (21.1-25.2)]. A score below 24, indicating possible cognitive impairment, was observed in 58.8% (n = 294) of patients.

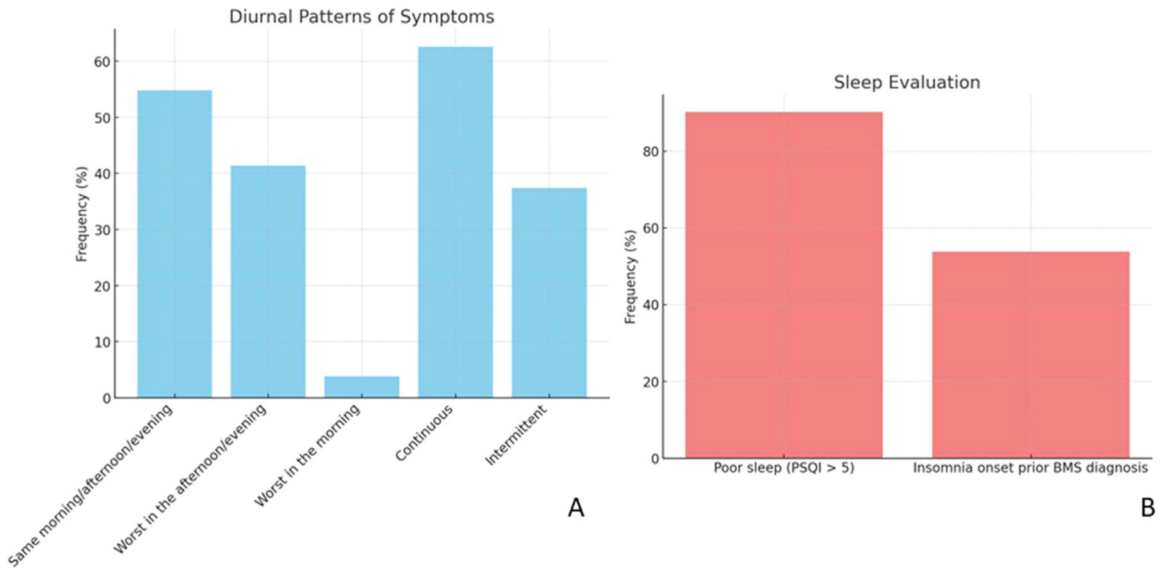
Patient Survey

As described in the methods section, the questions of the survey that we administered to our BMS patients investigated their daily life, education level, digital literacy, subjective perception about their health and unmet needs. The results obtained showed that 80% (n = 400) of the patients lived in suburban, 10 % (n = 50) in urban and 10% (n = 50) in rural areas. Patients' years of education mean was 9.2 ± 4.55 and 43.4% (n = 217) were unemployed. Most of the of the patients were married (76.2%, n = 381).

Twenty percent (n = 100) of patients reported an active social life, whereas 70% (n = 350) of them referred having social interactions only with their family members and 10% (n = 50) only with caregivers. Most of the patients did not smoke (74%, n = 370) or drink alcohol (85.2%, n = 426).

Regarding acquaintance with ICT technologies, 30 % had broadband domestic access and 90% of them owned a smartphone or a tablet. Mean reported values assessing patients comfort with new technologies (Supplementary) were: 2.1 for "Feel comfortable using the internet"; 3.1 for "Feel comfortable using a smart phone or tablet," 2.0 for "Feel comfortable with learning how to use a new gadget." Reported "Overall digital health literacy" mean value was 1,1. 92% of our patients declared that they could rely on some-

Figure 4. Diurnal pattern of symptoms of BMS patients (A); Sleep evaluation according to PSQI scores and insomnia onset (B).



one (sons, caregivers, neighbours) to assist them in using a smartphone or a tablet.

Most of the patients (60.4%; n = 302) referred that the major worry about their health was that they couldn't receive the most appropriate treatment for their disease and consequently they couldn't achieve remission. In addition, 56% of the patients (n = 280) complained about the lack of family support, as their relatives did not understand the severity of their condition.

The unmet needs most frequently reported in patients' survey were an effective BMS treatment (98%; 490), an easy access to clinical information (70%; n = 350) and medical assistance (82%; n = 410).

The BMS Persona

After examining the results of the survey and the clinical data of the 500 BMS patient's cohort, the Focus Group designed a BMS Persona, named Anna, whose detailed description according to the Blueprint format, is reported in Figure 5. Anna is a 65-year-old housewife who lives with her husband in a small apartment. She is overweight, anxious and hypochondriacal and spends most of her time at home. She suffers from hypertension, hypercholesterolemia, and vitamin D deficiency. After menopause, she began to have sleep disturbances and started feeling sad, often crying uncontrollably. Two years ago, Anna started suffering from chronic orofacial pain characterized by a burning sensation throughout her entire oral mucosa accompanied by a bitter taste, dry mouth (xerostomia), and a sensation of a lump in her throat (globus). These symptoms prompted her to consult several specialists, but she has not received a proper diagnosis. Therefore, Anna feels misunderstood, also because her family does not seem to give the right weight to her health problem. Anna noticed that her symptoms improve when she takes food, and therefore she is eating frequently and she is gaining weight. She has also started experiencing fatigue and the unpleasant perception of becoming forgetful, for instance occasionally missing her medications. Anna has a limited digital literacy, but she would like to learn more about new digital health resources if they could help her stay in touch with her doctors and get a better treatment for her disease.

BMS Patients' Unmet Needs and ICT Interventions Envisaged by the Focus Group

The analysis of the results of the survey unravelled important health and social unmet needs in BMS that the experts of the focus group incorporated in Anna's portrait and are listed in Table 1 Amongst them, one of the most frequently reported in our patient survey was a better control of disturbing symptoms including not only oral pain but also anxiety, depression, and sleep disorders. The patients also felt that contacting the staff of BMS specialists to discuss with them and refer about disease activity and response to treatment can be extremely difficult especially for those of them who live in rural or extra urban areas. In addition, they complained

Figure 5. BMS persona.

BLUEPRINT

DIGITAL TRANSFORMATION OF HEALTH AND CARE FOR THE AGEING SOCIETY

Meet Anna

Web: https://ec.europa.eu/eip/ageing/blueprint_en
Contact: WE4AHA@empirica.com

Name: Anna
Age: 65
Life course: Retired people
Need: Chronic condition and social needs
Connectivity: broadband, smart phone
Country: Italy
Area: Suburb of city

Internet usage Low High
Mobile device skills Low High
Affinity to new tech Low High
Digital Health Literacy Low High
Assistance (ICT use) No Yes

Anna is a 65-year-old housewife who lives with her husband in a small apartment. She is overweight and spends most of her time at home. Anna also experiences anxiety and is hypochondriacal. After reaching menopause, she began to have sleep disturbances and started feeling sad, often crying uncontrollably. Additionally, she suffers from hypertension, hypercholesterolemia, and vitamin D deficiency. Two years ago, Anna developed chronic orofacial pain characterized by a burning sensation throughout her entire oral mucosa. She also experiences a bitter taste, dry mouth (xerostomia), and a sensation of a lump in her throat (globus). These symptoms prompted her to consult several specialists, but she has not received a proper diagnosis. Anna feels misunderstood, especially in the absence of family support. Interestingly, Anna's symptomatology improves when she eats, leading her to eat frequently and contributing to her weight gain. She has also reported memory loss, fatigue, and occasionally misses a dose of her medication. Anna is interested in learning more about new digital health resources that could help her stay in touch with her doctors.

What's important to Anna

- ✓ Staying healthy
- ✓ Living a normal life with her family and friends
- ✓ Reducing her pain burden
- ✓ Being not depressed anymore
- ✓ To count on her family support
- ✓ Frequent access to healthcare services

Daily living

- ✓ She frequently eats
- ✓ She sleeps badly
- ✓ The oral burning compromises her household tasks
- ✓ She spends most of her time e day watching tv series on sofa or in the bed

Own resources & assets / support

- ✓ Support from her husband and daughter
- ✓ Going to church every week

Events, issues and personal concerns

- ✓ She concerned about her oral burning because she thinks to have a deadly disease
- ✓ She feels stressed, anxious and depressed
- ✓ She feels misunderstood by her family
- ✓ She worries about any treatment possibilities for her condition
- ✓ Her husband can use the computer

Health concerns

- ✓ Pain Anxiety Depression and sleep disturbance
- ✓ Cognitive impairment
- ✓ Obesity
- ✓ Hypertension
- ✓ Hypercholesterolemia
- ✓ Hyperhomocysteinemia
- ✓ Adherence to treatment

Health tests

- ✓ Annual or bi-annual laboratory tests: Blood cells count, lipid profile, glucose, renal and hepatic function, iron, vitamins levels (E, C, B12, D), homocystein and folate
- ✓ Blood pressure checks
- ✓ MRI of the brain and brainstem (every four years)
- ✓ Cognitive and psychometric tests every year

Treatment: medications, therapies, etc.

- ✓ Multimodal Antidepressants
- ✓ Antiepileptics
- ✓ Selective drug for sleep disturbance
- ✓ Antihypertensive
- ✓ Statins
- ✓ Vitamin D supplements
- ✓ Folate supplementation
- ✓ Try to be more active: start walking every day
- ✓ She needs to change her lifestyle and to follow a healthy diet.

Care professional / educator concerns

- ✓ Anna sometimes forgot to take drugs and medical appointments with specialist
- ✓ She is unable to change her lifestyle behaviours

Needs

(1) To learn to use of telehealth in order to keep in touch with multidisciplinary team
(2) To learn the use of digital health resources in order to access nutritional, psychological plans
(3) To learn to use apps that could engage her in social and cognitive activities

This persona was developed by Daniela Adamo , Maddalena Illario and her team, A.O.U Policlinico II of Napoli, with the kind support of the WE4AHA Blueprint and expert team.

The Blueprint's further development is led by empirica GmbH as part of the EU project WE4AHA co-ordinated by Funka Nu AB. The project receives funding from the EU's Horizon 2020 research and innovation programme under the Grant Agreement No. 769705.

Table 1. Impacts of integrated care technologies (ICT) in healthcare.

Impact of ict in healthcare	Description
Improved Access to Care	Enables telemedicine and remote consultations, allowing access to medical expertise in remote areas.
Enhanced Patient Engagement	Allows individuals to access health records, manage appointments, and communicate with healthcare providers.
Better Health Monitoring	Wearable devices and apps monitor health parameters, alerting to potential health issues.
Personalized Medicine	Facilitates collection and analysis of health data for personalized treatment plans.
Efficient Data Management	Electronic health records improve accuracy and availability of patient information.
Decision Support Systems	Provides healthcare professionals with clinical decision support and alerts.
Education and Awareness	Offers patients and healthcare providers up-to-date information and educational materials.
Collaborative Care	Facilitates collaboration among healthcare professionals for coordinated care.

feeling lonely and they referred that having somebody to talk with about their disease could be of great help. Examining patient clinical data, focus group experts concluded that overeating and obesity are important issues that should be properly addressed. Likewise, from expert discussions it clearly emerged that the frequent occurrence of memory impairment with signs of impending cognitive impairment and the consequent poor drug adherence are unmet needs that must be properly addressed.

As part of the planned activities of the Focus Group, the experts also discussed possible digital health interventions that could help to address these unmet needs. They agreed that each of the aforementioned unmet needs can be effectively satisfied by using ICT tools. More specifically, the experts acknowledged that specific apps are already available to reduce stress, decrease anxiety and, possibly, increase pain threshold (eg Calm, Headspace, Mindshift, sleep easy, Mesmerize, and Wave), whereas chatbots like ChatPal may help fight loneliness. Likewise, a wealth of ICT solutions has been developed and validated to improve memory and possibly slow down the progression of cognitive impairment such as BRAIN-HQ, Cognifit, Cogniplus or HAPPY NEURON. Eating habits can be normalized by using apps such as MyNet Diary, Noom or Yazio. Apps like Flaredown, Symple or Care Clinic simplify symptom recording and monitoring. Finally, specific solutions are available to improve drug adherence including, among the others, My Therapy, Medisafe, Mr Pillster, and Take your pills. Focus group experts also agreed that telemedicine offers unprecedented opportunities to address the unmet need of being in touch with the BMS specialists.

After a long discussion the focus group concluded that even though all the ICT solutions that we mentioned before could be indubitably helpful, the development of a dedicated, disease specific suite, specifically designed for BMS would be highly desirable. Such a suite would indeed give the advantage of incorporating into a single ICT solution what, instead, has now to be found in multiple different apps. Moreover, specific features, such as BMS-specific symptom monitoring and scoring systems could be incorporated in such a product. Based on these considerations the focus group elaborated a general model of the BMS-specific suite that they tentatively named the "BMS Balance." According to the focus group experts, the "BMS Balance" should be designed as an AI-powered personal health assistant that would support day-to-day management of this condition by holistically addressing its multifaceted needs. More specifically, it should seamlessly integrate the following features: 1. symptom recording and analysis, 2. robust psychological support, 3. digital therapeutic tools for behaviour therapeutics of cognitive impairment, 4. personalized lifestyle modification advice, including tailored dietary guidance. In addition, the app should incorporate general health monitoring, also through the help of wearable devices, medication adherence reminders, and physical activity tracking, ensuring a well-rounded approach to both mental and physical aspects of BMS management. All these features should be largely customizable to fit with patient-specific needs. Collected data should be stored in a Health information portal where patients can access their medical records, lab results, and other health information. An essential feature of the "BMS Balance" would be the ability to share these data with the specialist BMS healthcare team to allow timely adjustments to treatment plans. In this perspective, the focus group suggested that the "BMS Balance" should be also integrated with a telemedicine platform: this feature could solve the problems related to the difficult accessibility to specialist care which is a major issue for patients in rural and suburban areas.

DISCUSSION

Managing BMS requires a detailed and multidisciplinary evaluation, focusing on personalized patient care and a holistic treatment approach. Clinicians should address the oral symptoms and any related psychological, cognitive, or metabolic comorbidities by building a strong therapeutic relationship with the patient.[46,47] Recent research supports the efficacy and tolerability of vortioxetine in treating BMS, suggesting it as a promising option for managing this condition and other chronic pain disorders. This therapy is noted for its good safety profile and quick onset of action, particularly benefiting older patients with additional medical issues, while also enhancing cognitive function. Furthermore, the effectiveness of this treatment can be enhanced with digital solutions, aiming to address and resolve the unmet needs of these patients.

In this study, we have introduced the inaugural Blueprint persona for BMS, a significant advancement akin to similar endeavors undertaken for other orofacial pain conditions, such as temporomandibular disorders.[48] This development marks a pivotal step in the realm of orofacial pain management and research. The Blueprint persona for BMS not only provides a comprehensive and nuanced understanding of this condition but also paves the way for more effective and personalized treatment strategies. Additionally, the creation of this persona facilitates the collection of valuable data, which is instrumental in both clinical and research settings. This innovative approach underscores the importance of tailored interventions and highlights the potential for improving patient outcomes in various orofacial pain diseases. To develop this persona, we had to bring together a group of experts in different fields since BMS is a complex disease with a wide range of heterogeneous clinical manifestations going from neurological, to psychiatric, to metabolic problems. The work of our focus group was data-driven since it relied on the analysis of both the medical records of 500 BMS patients and on their response that they gave to a questionnaire on their unmet clinical and social needs. The main reason why we decided to design a BMS Blueprint persona was that it could greatly help identifying unmet needs in this disease and designing ICT solutions to address them. As a matter of fact, based on the BMS persona, the focus group outlined the general profile of an ICT suite that could address the multiple unmet needs of this disease. This suite was tentatively named the "BMS balance."

This app is poised to revolutionize the diagnostic and therapeutic pathways for BMS patients, promoting a model of care that is both innovative and highly personalized.[49] Its design and functionality, featuring medication reminders, lifestyle advice, and more, are tailored to meet the unique needs of each patient, acknowledging the diverse manifestations of BMS and their varying impacts on individuals' lives. A sophisticated AI-driven analytics should be incorporated in the app to enable it to adapt continually to each patient's evolving symptoms and treatment responses. A noteworthy feature of the app is its integration of psychological support modules, an essential component given BMS's significant impact on mental health.[50] In fact, a relevant feature of the disease that emerged from these data was the deep feeling of loneliness and of being misunderstood which is often accompanied by signs of impending cognitive impairment and by alterations in eating behavior: all these problems can benefit of ICT interventions. To address these problems, the BMS balance was designed to include AI-powered chatbots and online support groups, provide immediate psychological support, fostering a sense of community among patients and helping to mitigate feelings of isolation and misunderstanding. In addition, a specific section of the app engages patients in mentally stimulating activities, to slow down or prevent cognitive impairment, whereas another is devoted to normalize patient overeating.

The present study underscores the critical need for enhancing TM capabilities to improve access for older BMS patients, particularly those with comorbidities, limited mobility, or those residing in remote or rural areas.[51,52] By integrating TM into this customized app, the study ensures that these patients have seamless access to care, facilitating timely intervention in case of complications or adverse events.[53]

To date, no published articles exist that provide a control group for comparison, making it challenging to benchmark our data against existing studies. However, in this study, we observed that while the broad BMS population might experience mild cognitive impairment, the implications are particularly pronounced for patients progressing toward degenerative disorders such as dementia, Parkinson's disease, or Alzheimer's disease. This progression presents significant challenges in the usability of digital health solutions. To address these challenges, our research is pioneering patient-centered design strategies, focusing on developing more intuitive user interfaces and involving caregivers actively in the health management process. These adaptations are crucial as they could significantly enhance the accessibility and functionality of digital tools for this vulnerable group. However, there remains a pressing need for further research to refine these solutions, ensuring they are both practical and accessible for patients and their caregivers, thereby democratizing the benefits of technological advancements in healthcare for all affected individuals. Taking into account the critical role of cultural and linguistic diversity in assessing the efficacy of digital health solutions, in future research we plan to establish international focus groups and incorporate participants from various countries, enhancing our understanding of the

Table 2. (Strengths – weaknesses – opportunities – threats) S.W.O.T. analysis of ICT.

Strengths	Weaknesses	Opportunities	Threats
Enhancing interaction between patients and clinicians	Requirement for funding and database expansion for tech prototyping and testing	Involvement in national events	Risk of service exclusivity
Improving the ease of access to data	Shortage of financial and human resources	Developing a connected care system for practical student learning	Resistance to adoption by patients and medical professionals
Developing predictive models for early diagnosis and preventive treatments	Patients' limited understanding of technology's benefits	Encouraging interoperability and standardization in healthcare	Potential loss of the psychological and emotional connection in patient care

Abbreviation: ICT, Integrated Care Technologies.

Figure 6. Community and healthcare worker welfare mHealth: mobile health.

Psychological Assistance

Patients receiving ongoing mental health support are more likely to engage in their treatments, leading to better health outcomes

mHealth solutions

This cost-effective approach minimizes the emotional distress of hospital stays for patients, particularly beneficial for the residents of rural area

Home Care

This service provides necessary medical attention to individuals who cannot access hospital facilities, ensuring they receive proper care

distinct needs and challenges faced by patients across diverse cultural and linguistic landscapes.

In the broader context of healthcare, the study highlights the critical role of digital infrastructure in enhancing the quality of care and the lives of both patients and healthcare providers.[54] By leveraging digital tools such as mHealth solutions and TM, healthcare providers can offer more accessible support and therapy from home, thereby improving the reach and efficiency of healthcare services.[55] The integration of these digital solutions into local communities is identified as a key strategy, focusing not just on healthcare service provision but also on prevention, education, and awareness campaigns that are sensitive to the unique needs of different patient demographics.[56]

Strength and Weaknesses

This study confronts several limitations that impact its outcomes and generalizability. To dissect Strength and weaknesses of the proposed digital health approach we performed a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis, whose results are reported in Table 2. This SWOT analysis[57] could serve as a valuable tool for healthcare providers and policymakers, aiding in the decision-making process and in optimizing healthcare outcomes for individuals suffering from BMS.

Among the weaknesses, a major problem is the need to modify existing practices and protocols by integrating new digital solutions. This reorganization demands significant changes in workflow and possibly the structure of healthcare teams, which can be difficult to implement effectively in a short time frame. Secondly, the lack of funding is a critical constraint. Insufficient financial resources limit the ability to acquire necessary digital devices, invest in robust software solutions, and maintain these technologies over time. Lastly, the issue of device distribution and the preparation of staff and patients is a significant limitation. Ensuring that all participants have access to the required technology, and that they are adequately trained to use it, is essential for the success of digital supports. The effectiveness of digital interventions hinges on user competence and comfort with the technology, which can vary greatly among different groups of staff and patients.

Moreover, our study's findings are primarily applicable to the Italian population, as the research did not include participants from diverse cultural backgrounds, limiting its generalizability to other groups.

Future research endeavors will focus on incorporating more granular analyses and tailored approaches that address the distinct needs of different age and gender demographics.

Finally, it is important to emphasize that before adopting digital therapeutic approaches for BMS, randomized controlled clinical studies will have to be performed to gather solid evidence of safety and efficacy.

CONCLUSION

In conclusion, this study comprehensively explored the transformative role of digital health solutions in advancing care and the quality of life for patients with BMS. Central to this was the innovative use of the "Blueprint Personas" methodology particularly the development of the "BMS persona." This strategic approach was crucial in deconstructing and understanding the individual patient's journey, characterized by a spectrum of complex symptoms and a lack of adequate support, thereby simplifying the identification of unmet needs. (Figure 6) The "BMS persona" development is set to transform patient care in BMS using digital health solutions like the "BMS balance" that we described in the present paper. These apps offer a multidisciplinary, personalized approach, focusing on the unique needs of patients with BMS and extending to individuals with all types of chronic pain. Featuring comprehensive, patient-centric designs, they represent a paradigm shift in healthcare, emphasizing the integration of technology and personalization. While these digital solutions are promising, their implementation into existing healthcare systems faces several challenges, including technical, economic, and accessibility issues. Future research will be essential in developing sustainable, user-friendly, and cost-effective models to integrate these technologies seamlessly into mainstream healthcare, benefiting a broad range of chronic pain patients.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jebdp.2024.102047.

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