ΠΑΝΕΠΙΣΤΗΜΙΟ ΘΕΣΣΑΛΙΑΣ
ΣΧΟΛΗ ΕΠΙΣΤΗΜΩΝ ΥΓΕΙΑΣ
ΤΜΗΜΑ ΙΑΤΡΙΚΗΣ

ΟΥΡΟΛΟΓΙΚΗ ΚΛΙΝΙΚΗ ΠΓΝΛ

Διευθυντής: Καθηγητής Τζώρτζης Βασίλειος

Διδακτορική Διατριβή

«The feasibility and acceptability of a (mobile) application for men with LUTS/BPH: a pilot study»

υπό

ΧΑΣΙΩΤΗ ΓΕΩΡΓΙΟΥ

Χειρουργού Ουρολόγου

Υπεβλήθη για την εκπλήρωση μέρους των

απαιτήσεων για την απόκτηση του

Διδακτορικού Διπλώματος

Λάρισα, 2025

Εγκρίθηκε από τα Μέλη της Επταμελούς Εξεταστικής Επιτροπής (22η/28-05-2025 ΣΤΙ):

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CHASIOTIS GEORGIOS

ΣΥΝΤΟΜΟ ΒΙΟΓΡΑΦΙΚΟ ΣΗΜΕΙΩΜΑ

Ο Χασιώτης Γεώργιος γεννήθηκε στη Λάρισα το 1992.

Αποφοίτησε από την Ιατρική Σχολή του Πανεπιστημίου Θεσσαλίας το 2017 και έπειτα υπηρέτησε τη στρατιωτική του θητεία.

Το 2019, έχοντας ολοκληρώσει 1 έτος ειδικότητας Γενικής Χειρουργικής στην Πανεπιστημιακή Χειρουργική Κλινική του Π.Γ.Ν. Λάρισας, ξεκίνησε την ειδικότητα της Ουρολογίας στην Πανεπιστημιακή Ουρολογική Κλινική του Π.Γ.Ν. Λάρισας (Διευθυντής: Τζώρτζης Βασίλειος).

Μετά την επιτυχή συμμετοχή του στις Εξετάσεις Ειδικότητας παρέμεινε και υπηρέτησε για 1 έτος στην Πανεπιστημιακή Ουρολογική Κλινική του Π.Γ.Ν. Λάρισας, λαμβάνοντας με το πέρας, απαλλαγή από την υποχρεωτική Υπηρεσία Υπαίθρου.

Παρακολούθησε επιτυχώς το Μεταπτυχιακό Πρόγραμμα Σπουδών «Χειρουργική Ελάσσονος Πυέλου και Περινέου» (Καθηγητής: Τεπετές Κωνσταντίνος).

Εκπαιδεύτηκε και συμμετείχε σε μεγάλο αριθμό χειρουργείων μικρής, μεσαίας και μεγάλης βαρύτητας.

Συμμετείχε ενεργά στη συγγραφή επιστημονικών άρθρων.

Παρακολούθησε πληθώρα επιστημονικών συνεδρίων και υπήρξε ομιλητής σε 5 από αυτά.

Είναι μέλος της SIU Academy Residents Sub-Committee.

SHORT CURRICULUM VITAE

George Chasiotis was born in Larissa in 1992.

He graduated from the Faculty of Medicine at the University of Thessaly in 2017 and subsequently completed his military service.

In 2019, having completed one year of General Surgery residency at the University General Surgery Department of the University General Hospital of Larissa, he began his Urology residency at the University Urology Department of the same hospital

(Director: Vasileios Tzortzis).

Following his successful completion of the Specialty Exams, he continued to serve for an additional year at the Urology Department of the University General Hospital of Larissa, after which he was exempted from the mandatory Rural Service.

He successfully completed the Postgraduate Program in "Surgery of the Minor Pelvis and Perineum" (Prof. Konstantinos Tepetes).

Throughout his training, he gained extensive experience by participating in a large number of surgical procedures of varying complexity.

He was actively involved in the authorship of scientific articles.

He attended numerous scientific conferences, being a speaker at five of them.

He is a member of the SIU Academy Residents Sub-Committee.

«Η δυνατότητα εφαρμογής και η αποδοχή μιας Εφαρμογής (κινητού) για άνδρες με συμπτώματα κατωτέρου ουροποιητικού / καλοήθη υπερπλασία προστάτη: μια πιλοτική μελέτη»

ΧΑΣΙΩΤΗΣ ΓΕΩΡΓΙΟΣ

Πανεπιστήμιο Θεσσαλίας, Τμήμα Ιατρικής, 2025

ΤΡΙΜΕΛΗΣ ΣΥΜΒΟΥΛΕΥΤΙΚΗ ΕΠΙΤΡΟΠΗ

1. **Σταύρος Γκράβας**, Καθηγητής Ουρολογίας, Πανεπιστήμιο Λευκωσίας **(Επιβλέπων)**
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«The feasibility and acceptability of a (mobile) application for men with LUTS/BPH: a pilot study»

CHASIOTIS GEORGIOS

University of Thessaly, Faculty of Medicine, 2025

THREE-MEMBER ADVISORY COMMITTEE

1. **Stavros Gravas**, Professor of Urology, University of Nicosia **(Supervisor)**
2. **Jean de la Rosette,** Professor of Urology, Medipol University
3. **Anastasios Karatzas**, Assistant Professor of Urology, University of Thessaly

ABSTRACT

Background

The increasing prevalence of smartphone use presents a valuable opportunity to monitor patients experiencing lower urinary tract symptoms (LUTS) and benign prostatic obstruction (BPO) through well-designed medical applications.

Objectives

Primary: Assess the feasibility and the acceptability of a mobile app (MyBPHCare) for men with LUTS/BPO.

Secondary: Capture medical adherence using electronic reminders, record if treatment provided is in compliance with guidelines.

Design, Setting, and Participants

This observational cohort pilot study was conducted in Greece, Türkiye, and Italy, involving men aged over 40 years with LUTS, either untreated or under treatment.

Patients with previous LUTS/BPO invasive treatment – pelvic surgery - radiotherapy, history of neurological disease, history of bladder or prostate cancer, as well as patients unable to provide informed consent, analphabet, unable to operate a smartphone / tablet / computer and unable to understand the language were excluded.

Patients received standard care according to the physician's practice. Duration was 6 months. Standard questionnaires, diagnostic tools, medication, and follow-up visits were employed.

Quality of the app was assessed by the patients using a standardized, translated and validated app rating user questionnaire known as the uMARS. No intervention was made.

Results and Limitations

Overall, 68.15% filled in the uMARS questionnaire and the uMARS mean scores were: App Quality (3.43), Engagement (3.21), Functionality (3.47), Aesthetics (3.37), and Information (3.68), all ranging between “Acceptable” and “Good”. 96.3% of the participants would recommend using the app.

Limitations of the study: younger patients were keener to participate, internet connection was required.

Conclusions

The MyBPHCare app demonstrates potential as a feasible and well-accepted tool for virtually monitoring men with LUTS/BPO.

Patient Summary

This study is the first to assess a digital app designed to manage a benign urological condition. The results suggest that the app meets the criteria for potential feasibility.

A. GENERAL PART

1. mHealth

Information and communication technologies (ICT) provide patients and healthcare professionals with innovative ways to enhance well-being, promote preventive care, and alleviate disease-related suffering. Over the past few decades, technological advancements have led to a paradigm shift in healthcare delivery, offering more efficient, accessible, and personalized solutions. Digital transformation in healthcare has accelerated, driven by the growing need for efficient management of chronic diseases, enhanced patient engagement, and the ability to deliver healthcare beyond traditional clinical settings.

The World Health Organization (WHO) defines eHealth as "the use of information and communication technologies (ICT) for health" [1]. Within eHealth, mobile health (mHealth) has emerged as a rapidly evolving subset. The WHO Global Observatory for eHealth describes mHealth as "medical and public health practices supported by mobile devices, such as mobile phones, patient monitoring devices, and other wireless technologies" [2]. This definition encompasses a wide range of applications, from telemedicine to patient self-monitoring and remote diagnostics.

Owing to its intuitive design and extensive adoption, mHealth is recognized as a crucial instrument in facilitating patient-centered care. By integrating patient-reported preferences, experiences, and outcomes, it effectively supports the core goals of contemporary healthcare systems and global standards [3]. This approach fosters more meaningful patient-provider interactions, improves health literacy, and encourages active participation in one’s own health management.

One of the key advantages of mHealth is its ability to deliver healthcare that transcends geographical, temporal, and organizational barriers. By leveraging mobile technology, healthcare services can reach underserved populations, including those in rural and remote areas, where access to traditional healthcare facilities is limited. mHealth relies on scalable solutions such as mobile apps and online platforms that can be accessed using widely available devices like smartphones and tablets, reducing healthcare costs while increasing efficiency. As a result, mHealth has the potential to foster socio-economic inclusion, enhance equality, improve quality of life, and empower patients by increasing transparency and access to services and information. Additionally, mHealth can support alternative methods of care delivery, such as virtual consultations (telemedicine), which are particularly effective in situations like disasters and pandemics (e.g., COVID-19) [4].

mHealth encompasses a wide range of applications, with successful, evidence-based interventions including medication adherence, disease prevention, lifestyle modifications, and remote diagnostics. For instance, text messaging interventions have proven effective in smoking cessation programs, while mobile-based reminders help patients manage chronic conditions like hypertension and diabetes by improving adherence to prescribed medications [5]. In low-resource settings, mHealth has demonstrated its effectiveness in bridging healthcare gaps. Mobile-phone-based clinical guidance for rural health providers in developing countries has enabled timely diagnosis and management of various medical conditions, ensuring that patients receive appropriate care [6]. The adaptability of mHealth allows it to overcome geographical and environmental challenges, reaching communities where access to clean water or electricity may be limited [7].

Furthermore, mHealth has a broad demographic appeal, as evidenced by its successful use in promoting physical activity, encouraging healthy behaviors, and engaging both young and

older adults in managing their health. Wearable devices that track physical activity, heart rate, and sleep patterns empower users to take a proactive approach to their well-being. For elderly patients, fall detection systems and medication reminders integrated into mobile applications contribute to improved safety and adherence to treatment plans [8,9].

With the rise of the internet and electronic devices, many industries have embraced digitalization, and healthcare is no exception. However, the healthcare sector has traditionally been cautious in adopting digital solutions due to concerns related to patient confidentiality, data security, and regulatory compliance. The implementation of electronic medical records (EMRs) and other digital strategies has been a relatively recent development. While healthcare applications aimed at the general public are widely available, most are educational in nature. In the field of urology, for example, electronic applications are rarely developed by healthcare professionals (13.4%) or urological associations (1.9%) [10], raising concerns about their accuracy and clinical utility.

Recent literature highlights the lack of involvement of healthcare professionals in the development of mobile health applications across various medical specialties, including urology, despite evidence showing that their participation improves content accuracy, increases app downloads, and fosters greater buy-in [11]. The growing number of available healthcare apps presents a challenge in identifying safe, effective, and well-designed options. Another concern is the involvement of commercial companies in the development of mHealth solutions, raising questions about funding sources, conflicts of interest, and product promotion biases [12]. Without proper oversight, there is a risk that commercial interests may overshadow patient-centered care. To address these concerns, experts propose that healthcare professionals play a central role in the design, development, review, certification, and endorsement of mHealth applications. Establishing standardized guidelines for app

development and evaluation can enhance the credibility and reliability of digital health solutions [13].

In urology, as in other medical fields, mHealth is still in its early stages. Current applications focus on enhancing and streamlining existing medical practices, such as patient self-management and decision-making support. Shared decision-making models, which empower patients to actively participate in their treatment plans, have been shown to improve communication between patients and healthcare providers. Research indicates that cancer patients who take an active role in healthcare decisions are more satisfied with their choices [14]. Despite the strong association between patient engagement and improved quality-of-life outcomes—and its recognition as an ethical imperative, a health policy priority, and a guideline-endorsed approach—shared decision-making remains underutilized in clinical practice [15].

There is an urgent need to maximize the potential of health information technology, and urology can play a pioneering role in this effort. Decision aids, such as interactive tools that provide information on treatment options, risks, and benefits, can support shared decision-making by increasing patient knowledge and encouraging a more active role in healthcare decisions [16].

A recent systematic review analyzing the success and failure of eHealth interventions found a direct link between design quality and outcomes [17]. When patients take an active role in their healthcare decisions, they gain a greater sense of empowerment, leading to improved adherence to treatment plans, better clinical outcomes, and lower healthcare costs. For instance, an effectively implemented eHealth solution has demonstrated success in enhancing glycemic control among diabetic patients. [18,19]. Patients increasingly favor decision-

support tools over traditional care methods because these tools provide them with greater confidence in their available healthcare options while simultaneously bridging gaps in their understanding of medical conditions, treatments, and potential outcomes. These tools empower individuals by presenting complex medical information in an accessible, user-friendly manner, enabling them to make more informed and personalized healthcare decisions. By fostering greater autonomy in the decision-making process, decision-support tools contribute to a more engaged and proactive patient population, ultimately enhancing adherence to treatment plans and improving overall health outcomes. This shift towards digital healthcare solutions signifies a transformative move away from a passive patient experience to one that is dynamic, interactive, and driven by informed choices.

In this context, mHealth seamlessly integrates with the principles of patient-centered care by facilitating real-time communication, providing personalized health recommendations, and offering easy access to medical resources and support systems. The rapid evolution of mobile technology, artificial intelligence, and data analytics further enhances the capabilities of mHealth, ensuring that healthcare services become more tailored, efficient, and responsive to individual patient needs. As digital healthcare continues to advance, the future of patient empowerment will increasingly be shaped by innovations in technology that enhance accessibility, usability, and effectiveness. Enhanced connectivity, wearable health monitoring devices, AI-driven health assistants, and interactive mobile applications will play a pivotal role in making healthcare more patient-centric. These innovations will not only support better health management but also foster a collaborative relationship between patients and healthcare providers, ensuring that individuals have the tools they need to take an active role in their well-being. Ultimately, the continued integration of mHealth solutions into

mainstream healthcare systems will drive a new era of personalized medicine, where technology serves as a bridge to more informed, engaged, and empowered patients [20].

2. Lower Urinary Tract Symptoms and Benign Prostatic Obstruction

2.1. Introduction

Lower urinary tract symptoms (LUTS) are a common set of urinary issues that affect both men and women, although they are particularly prevalent in aging men due to benign prostatic obstruction (BPO). LUTS prevalence is estimated to range from 15% to 60% among men aged 40 years or older, with BPO affecting approximately 70% of men aged 60–69 years and nearly 80% of those aged 70 years and older in the United States [21]. The impact of LUTS on quality of life is profound, often surpassing that of other chronic diseases, as evidenced by assessments using the 36-item Short Form Health Survey (SF-36) questionnaire [22,23].

2.2. Classification of LUTS

LUTS are broadly classified into three main categories: storage symptoms, voiding symptoms and post-micturition symptoms.

Storage symptoms, also known as irritative symptoms, include frequent urination (a need to urinate more often than usual during the daytime), nocturia (frequent nighttime urination, which disrupts sleep patterns and can lead to fatigue), urgency (a sudden and strong need to urinate that is difficult to delay), and urinary incontinence (involuntary leakage of urine, which may range from mild dribbling to complete loss of bladder control) [24].

Voiding symptoms, also known as obstructive symptoms, involve hesitancy (difficulty in initiating urination despite the urge to void), a weak or slow urine stream (noticeable reduction in urine flow strength), straining (the need to push or apply abdominal pressure to initiate or maintain urination), and intermittency, (a stop-and-start pattern in urine flow, often resulting in incomplete emptying) [24].

Post-micturition symptoms occur after urination and indicate incomplete bladder emptying or persistent dribbling. They include post-void dribbling (the involuntary release of urine after completing urination) and the sensation of incomplete bladder emptying (a feeling that the bladder is not fully emptied, leading to repeated restroom visits) [24].

2.3. BPO and its Impact on LUTS

Among the most common causes of LUTS in men is benign prostatic obstruction (BPO), which results from the progressive enlargement of the prostate gland. As the prostate grows, it can compress the urethra, leading to restricted urine flow. This obstruction can cause significant voiding dysfunction. The exact cause of prostate enlargement is not fully understood, but hormonal changes, particularly those involving testosterone and dihydrotestosterone (DHT), play a key role in its development. Other contributing factors include genetic predisposition, lifestyle choices, and metabolic conditions such as obesity and diabetes [24].

2.4. Complications of Untreated LUTS/BPO

If left unmanaged, LUTS caused by BPO can lead to serious complications, including urinary retention, recurrent urinary tract infections (UTIs), bladder stones, and in severe cases, kidney damage due to prolonged urinary obstruction. Acute urinary retention (AUR) is a particularly distressing and painful condition in which a person suddenly becomes unable to urinate, often requiring emergency catheterization to relieve the obstruction. Studies indicate that the risk of AUR increases with age, with men over 70 facing a significantly higher likelihood of experiencing this complication [24].

2.5. Diagnosis of LUTS and BPO

Diagnosing LUTS and BPO requires a comprehensive assessment, which typically includes a patient history, physical examination, and various diagnostic tests. One of the most widely used tools for assessing LUTS severity is the International Prostate Symptom Score (IPSS), a questionnaire that evaluates symptom impact on daily life. A digital rectal examination (DRE) is often performed to assess prostate size and consistency, while a prostate-specific antigen (PSA) test may be conducted to rule out prostate cancer. Additional diagnostic tests such as uroflowmetry, post-void residual volume measurement, and urodynamic studies can provide further insight into bladder function and the extent of obstruction [24].

2.6. Management and Treatment Options for LUTS/BPO

The management of LUTS/BPO depends on symptom severity, patient preference, and overall health status. Treatment options range from lifestyle modifications and medical therapy to

minimally invasive procedures and surgical interventions.

2.6.1. Lifestyle Modifications

Mild LUTS can often be managed with simple lifestyle changes, such as reducing caffeine and alcohol intake, maintaining a healthy weight, engaging in regular physical activity, and avoiding excessive fluid consumption before bedtime. Bladder training exercises and pelvic floor muscle therapy can also help improve urinary control [24].

2.6.2. Pharmacological Treatment

Pharmacological treatment is the most commonly used approach for managing LUTS due to BPO. The primary classes of medications include:

2.6.2.1. Alpha-blockers

Alpha-blockers are one of the most commonly prescribed first-line pharmacological treatments for lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO). They work by relaxing the smooth muscle in the prostate and bladder neck, thereby improving urine flow and reducing urinary obstruction. These medications provide rapid symptom relief and are generally well-tolerated [25]. Alpha-blockers target alpha-adrenergic receptors, specifically the α1-adrenergic receptors found in the smooth muscle of the prostate, bladder neck, and urethra. By blocking these receptors, the medications cause muscle relaxation, leading to reduced urethral resistance, improved urine flow, and relief from voiding symptoms such as hesitancy, weak stream, intermittency, and straining. However,

alpha-blockers do not shrink the prostate gland itself; instead, they act on muscle tone to alleviate symptoms. Because of this, they provide faster symptom relief than 5-alpha reductase inhibitors but do not prevent long-term disease progression [25,26].

The Non-Selective Alpha-Blockers (Doxazosin, Terazosin, Prazosin - Older Generation) block α1 receptors throughout the body, including in the blood vessels, which can lead to systemic side effects like hypotension (low blood pressure). They are less commonly used for LUTS today due to these side effects (higher risk of dizziness, orthostatic hypotension, fatigue, and retrograde ejaculation) [27].

The Selective Alpha-1 Blockers (Tamsulosin, Alfuzosin, Silodosin - Newer Generation) target α1A-adrenergic receptors in the prostate and bladder neck, reducing urinary obstruction with fewer systemic side effects compared to non-selective alpha-blockers [27]. Their benefits include a reduced risk of hypotension compared to non-selective alpha-blockers, greater uroselectivity as they primarily target the prostate rather than the overall cardiovascular system, and rapid symptom relief, typically within days to weeks [27]. Potential side effects of selective alpha-1 blockers include dizziness, particularly when standing up quickly due to a drop in blood pressure (orthostatic hypotension), retrograde ejaculation, where semen enters the bladder instead of being expelled through the urethra, and mild nasal congestion, which may cause a sensation of nasal blockage or stuffiness [27].

Alpha-blockers offer several advantages, including rapid symptom improvement (often within 2-4 weeks), reduced urinary retention risk, improved urinary flow rate, and a less invasive alternative to surgical options. Additionally, they can be combined with 5-alpha reductase inhibitors for greater long-term benefits. Alpha-blockers are best suited for patients who need

fast relief from LUTS. They work quickly and are well tolerated but do not shrink the prostate, so symptoms may return if discontinued. Alpha-blockers are one of the most effective and widely used treatments for LUTS/BPO, offering rapid symptom relief by relaxing prostate and bladder neck muscles. However, they do not shrink the prostate, so symptoms may return once the medication is discontinued [27].

2.6.2.2. 5-alpha reductase inhibitors

5-alpha reductase inhibitors (5-ARIs), such as finasteride and dutasteride, are commonly used to manage lower urinary tract symptoms (LUTS) associated with benign prostatic obstruction (BPO). These medications work by inhibiting the 5-alpha reductase enzyme, which is responsible for converting testosterone into its more potent form, dihydrotestosterone (DHT). Since DHT plays a key role in prostate growth, blocking its production results in a gradual reduction in prostate size, typically by 20–30% over 6 to 12 months. As the prostate shrinks, pressure on the urethra decreases, leading to improved urinary flow and symptom relief [28].

There are two main types of 5-ARIs: finasteride, which selectively inhibits type II 5-alpha reductase and reduces DHT levels by approximately 70%, and dutasteride, which inhibits both type I and type II 5-alpha reductase, making it more potent with a DHT reduction of about 90%. Although dutasteride is more effective in shrinking the prostate, both medications have similar side effect profiles [28].

The clinical benefits of 5-ARIs include significant prostate shrinkage, long-term symptom relief, and a reduced risk of acute urinary retention and the need for surgery. Additionally, these medications lower prostate-specific antigen (PSA) levels by approximately 50%, which

has implications for prostate cancer screening. However, one of the key limitations of 5-ARIs is their slow onset of action, as noticeable symptom improvement can take three to six months. They are also associated with potential side effects such as erectile dysfunction, decreased libido, reduced ejaculate volume, and, in some cases, mood changes and an increased risk of depression. Moreover, because 5-ARIs suppress PSA levels, careful monitoring is required to avoid masking potential cases of prostate cancer [29,30]. For men with moderate-to-severe LUTS/BPH, combination therapy with an alpha-blocker, such as tamsulosin, is often recommended for enhanced symptom relief and long-term benefits. While alpha-blockers work quickly by relaxing prostate smooth muscle, 5-ARIs reduce prostate size over time and prevent disease progression. An example of this combination therapy is the fixed-dose formulation of dutasteride and tamsulosin, which has been shown to be more effective than either drug alone [31]. 5-ARIs are most suitable for men with larger prostates (typically >40 mL volume), those experiencing progressive BPO symptoms, or individuals at risk of acute urinary retention. However, they may not be the best choice for patients who require immediate symptom relief due to their delayed onset of action. Overall, 5-alpha reductase inhibitors are an effective long-term treatment option for BPH, particularly when combined with alpha-blockers, providing significant improvements in urinary symptoms and reducing the likelihood of disease progression and surgical intervention [31].

2.6.2.3. Anticholinergics and beta-3 agonists

These play an important role in the management of lower urinary tract symptoms (LUTS), particularly when bladder overactivity is a contributing factor. These medications are primarily used in patients experiencing storage symptoms, including urinary urgency, increased frequency, and urgency-related incontinence, which are often associated with

overactive bladder (OAB). While LUTS can result from an enlarged prostate in men, bladder dysfunction is also a significant factor, and addressing both components can improve patient outcomes [32].

Anticholinergics, also known as muscarinic receptor antagonists, work by blocking the action of acetylcholine on muscarinic receptors in the bladder. Acetylcholine is the neurotransmitter responsible for stimulating bladder contractions during the process of voiding. When there is excessive bladder muscle activity, such as in overactive bladder syndrome, this leads to involuntary contractions, causing symptoms like urgency, frequency, and incontinence. By inhibiting these contractions, anticholinergic medications help to increase bladder capacity and reduce urgency episodes, allowing for better urinary control [32].

Some commonly prescribed anticholinergic medications include: Oxybutynin, Tolterodine, Solifenacin / Darifenacin, Fesoterodine and Trospium. While anticholinergics are effective, they are associated with potential side effects, particularly because muscarinic receptors are found not only in the bladder but also in the salivary glands, gastrointestinal tract, and central nervous system. Common side effects include dry mouth, constipation, blurred vision, and cognitive impairment, particularly in elderly patients. Due to concerns about cognitive decline, caution is advised when prescribing these drugs to older adults or individuals at risk of dementia [33].

On the other hand, beta-3 agonists, such as mirabegron, offer a newer and more selective approach to managing bladder overactivity with a better side effect profile compared to anticholinergics. Beta-3 adrenergic receptors are primarily found in the detrusor muscle of the bladder, and stimulation of these receptors leads to bladder relaxation during the filling phase. Unlike anticholinergics, mirabegron does not inhibit bladder contractions directly but instead enhances bladder storage capacity, reducing the urgency and frequency of urination while

allowing for more controlled voiding [34,35]. Mirabegron offers several advantages over anticholinergics, including fewer systemic side effects, as it does not significantly affect salivary glands or the central nervous system. Unlike anticholinergics, it has no impact on cognitive function, making it a safer option for older adults at risk of dementia. It is also better tolerated, with lower rates of dry mouth and constipation, and has minimal effects on heart rate and blood pressure, though caution is advised in patients with uncontrolled hypertension.

In clinical practice, both anticholinergics and beta-3 agonists can be used alone or in combination to manage storage symptoms in LUTS. For patients who do not respond adequately to a single medication, a combination therapy (such as mirabegron plus solifenacin) may be more effective in controlling urgency, frequency, and incontinence while minimizing side effects. Additionally, these medications can be used in combination with alpha-blockers or 5-alpha reductase inhibitors when LUTS is caused by both bladder dysfunction and prostate enlargement [35, 36].

2.6.2.4. Phosphodiesterase type 5 inhibitors

Phosphodiesterase type 5 (PDE5) inhibitors, commonly used to treat erectile dysfunction (ED), have gained increasing attention as a therapeutic option for lower urinary tract symptoms (LUTS) associated with benign prostatic obstruction (BPO). Medications such as tadalafil, sildenafil, vardenafil, and avanafil have been shown to improve LUTS by enhancing smooth muscle relaxation in the lower urinary tract, leading to improved urinary flow and symptom relief [37].

The mechanism of action of PDE5 inhibitors in LUTS management is based on their ability to increase cyclic guanosine monophosphate (cGMP) levels by inhibiting the PDE5 enzyme,

which is highly expressed in the prostate, bladder, and vascular endothelium. This leads to smooth muscle relaxation in the bladder, urethra, and prostate, reducing urinary symptoms such as urgency, frequency, hesitancy, and weak urine stream. Additionally, PDE5 inhibitors improve pelvic blood flow and endothelial function, which may contribute to better bladder function and overall lower urinary tract health [37]. Among PDE5 inhibitors, tadalafil (5 mg daily) is the only one currently approved for the treatment of both BPH-related LUTS and erectile dysfunction. Studies have shown that daily tadalafil significantly improves International Prostate Symptom Score (IPSS) and urinary flow rate, making it an effective alternative or adjunct to traditional treatments such as alpha-blockers and 5-alpha reductase inhibitors. Unlike alpha-blockers, which primarily relieve voiding symptoms, PDE5 inhibitors have been found to improve both voiding and storage symptoms, making them particularly beneficial for patients with BPH and overactive bladder (OAB).

The clinical benefits of PDE5 inhibitors in LUTS/BPH treatment include improved bladder and prostate smooth muscle tone, enhanced blood circulation in the lower urinary tract, and reduced inflammation and fibrosis, which are key factors contributing to LUTS. Furthermore, PDE5 inhibitors are well tolerated and do not cause significant orthostatic hypotension, a common side effect of alpha-blockers, making them a viable option for men with coexisting LUTS and ED who may not tolerate traditional therapies well.

However, there are some limitations to the use of PDE5 inhibitors in LUTS treatment. While they improve urinary symptoms, they do not shrink the prostate like 5-alpha reductase inhibitors and may not be effective in men with severe prostatic enlargement. Additionally, PDE5 inhibitors can cause side effects such as headache, flushing, nasal congestion, and dyspepsia. They should also be used with caution in patients taking nitrates or alpha-blockers, as the combination can lead to a significant drop in blood pressure [38].

In clinical practice, combination therapy involving PDE5 inhibitors and alpha-blockers or 5-alpha reductase inhibitors may be recommended for men with moderate-to-severe LUTS who also suffer from erectile dysfunction. Research suggests that the combination of tadalafil with tamsulosin provides superior symptom relief compared to either medication alone, making it a promising approach for patients requiring comprehensive LUTS management [39].

2.6.3. Alternative Treatment - Phytotherapy

Phytotherapy, or the use of plant extracts, has been explored as a treatment option for lower urinary tract symptoms (LUTS), particularly in men with benign prostatic obstruction (BPO). These herbal preparations are derived from various plant parts, including roots, seeds, bark, pollen, and fruits. They may be used as mono-preparations (single plant extracts) or combination preparations that include multiple plant-based compounds. Some key active components found in these extracts include phytosterols, β-sitosterol, fatty acids, and lectins, which have been studied for their potential anti-inflammatory, anti-androgenic, and estrogenic effects. Laboratory studies suggest that plant extracts may also inhibit 5-alpha reductase, α-adrenoceptors, and oxidative stress, which could contribute to their proposed benefits in LUTS management. However, their precise mechanism of action in humans remains unclear [40]. The efficacy of phytotherapy is complicated by the variability in extraction methods and product formulations. Different brands of the same plant extract may contain inconsistent concentrations of active ingredients, leading to variations in biological effects. For instance, Serenoa repens (saw palmetto) is one of the most widely used plant-based therapies for LUTS, but clinical studies have reported mixed results [41]. A meta-analysis of 30 randomized controlled trials (RCTs) involving over 5,000 men found that Serenoa repens was not superior to placebo, finasteride, or tamsulosin in improving LUTS severity, urinary flow

(Qmax), or prostate size [42]. Further studies comparing hexane-extracted Serenoa repens (HESr) with alpha-blockers showed comparable improvements in International Prostate Symptom Score (IPSS) and Qmax, supporting its potential role as an alternative or adjunctive therapy [43]. The European Medicines Agency (EMA) has established the Committee on Herbal Medicinal Products (HMPC) to regulate herbal treatments. According to the EU herbal monographs, Serenoa repens has been classified under “traditional use”, meaning there is sufficient historical evidence supporting its safety, but well-established efficacy data is lacking. However, hexane-extracted Serenoa repens (HESr) has been recommended for "well-established use", warranting further clinical evaluation. Despite this, the lack of standardization across products and inconsistencies in study endpoints (such as variations in IPSS measurements) limit broad clinical recommendations [44].

2.7. LUTS medication adherence

European studies have shown that approximately 74.9% of patients diagnosed with Lower Urinary Tract Symptoms (LUTS) associated with Benign Prostatic Obstruction (BPO) receive some form of pharmacological therapy as the primary approach to symptom management and disease control [45]. This high percentage underscores the reliance on medical treatment as the standard of care for addressing LUTS/BPO. However, despite the widespread adoption of pharmacotherapy, medication adherence continues to pose a significant challenge within this patient population. Many individuals fail to fully grasp the critical importance of maintaining consistent treatment adherence, often underestimating its role in achieving optimal symptom relief and preventing disease progression.

One of the key barriers to successful medical management lies in the difficulty patients experience in sustaining long-term adherence to their prescribed medication regimens. This challenge frequently leads to treatment discontinuation, which, in turn, results in the resurgence or worsening of symptoms. Studies examining this phenomenon provide sobering insights: research conducted in the Netherlands revealed that 26% of patients discontinued their pharmacological therapy prematurely, highlighting the fragile nature of patient commitment to long-term medication use. Similarly, a study from California reported that only one-third of patients adhered to their initially prescribed medication regimen, reflecting a broader trend of poor compliance. Furthermore, long-term adherence to any LUTS-related medication was found to be as low as 40%, which is particularly concerning given the chronic and progressive nature of the condition. However, interestingly, data suggests that patients prescribed multiple medications demonstrated better adherence; approximately 62% of these patients remained compliant with at least one of their prescribed treatments [46,47].

A comprehensive evaluation of 38 systematic reviews published between 1990 and 2005, focused on interventions aimed at improving patient adherence to medical treatments. The review categorizes adherence interventions into four main types: technical, behavioral, educational, and multi-faceted or complex [48].

Technical interventions, such as simplifying dosage regimens or improving medication packaging, consistently showed positive effects on adherence across various diseases. However, these approaches generally lacked a solid theoretical explanation of why they work, highlighting a need for further exploration in this area.

Behavioral interventions, including the use of reminders, incentives, monitoring, and feedback, were also found to be effective. These strategies align well with behavioral theories that focus on stimulus-response mechanisms and reinforcement. For example, financial

incentives and reminder systems improved appointment keeping and medication adherence, particularly among patients prone to forgetfulness.

Educational interventions, aimed at increasing patient knowledge about their disease and treatment, demonstrated moderate success. While they improved knowledge and had some positive effects on adherence, their impact often diminished over time. Theoretical foundations of educational approaches were mixed, drawing from communication models, cognitive theories, and self-regulation frameworks. However, many educational programs were poorly described, making it difficult to identify which components contributed most to their success.

Multi-faceted or complex interventions, combining elements of technical, behavioral, and educational strategies, showed greater effectiveness than single-focus approaches but were often labor-intensive and resource-demanding. The review also noted limited research on affective interventions focusing on empathy and emotional support, suggesting this area warrants further investigation.

One of the key findings of the review is the lack of comparative studies that explicitly evaluate the relative effectiveness of different theoretical models or intervention components. This gap makes it challenging to determine which approaches are most powerful in improving adherence. Additionally, the majority of studies had short follow-up periods, making it difficult to assess the sustainability of adherence improvements over the long term.

In conclusion, it is implied that structured, multi-faceted treatment strategies, especially when combined with robust patient education and support, may enhance adherence rates and ultimately improve clinical outcomes. Future research should prioritize developing and testing clear theoretical models, conducting comparative studies, and focusing on long-term

adherence outcomes. Collaboration between medical, psychological, and technical fields is recommended to better understand the mechanisms behind effective adherence interventions and to design more robust and sustainable strategies [48].

The consequences of poor medication adherence extend well beyond mere persistence of symptoms. Inadequate management of LUTS/BPO significantly increases the risk of disease progression, leading to a cascade of potentially severe complications. If left untreated or poorly controlled, BPO can cause a gradual worsening of urinary symptoms, an increased likelihood of recurrent urinary tract infections (UTIs), and even deterioration of renal function due to the persistent strain on the urinary system. One of the most serious complications is the development of acute urinary retention (AUR)—a painful, sudden inability to urinate that requires immediate medical attention.

Cohort studies evaluating BPO outcomes have reported a cumulative incidence of AUR of 6.8 per 1000 person-years over a five-year period. Alarmingly, the risk of AUR increases substantially with age, with incidence rates rising to 10% among men aged 70–79 years within the same timeframe [49,50]. This data underscores the heightened vulnerability of elderly populations to severe urinary complications when treatment adherence falters. The onset of AUR often necessitates urgent interventions, such as urinary catheterization or surgical procedures, which not only elevate the healthcare burden but also negatively impact the patient's overall quality of life.

Ultimately, these findings highlight the critical need for healthcare providers to actively promote medication adherence through personalized treatment plans, patient counseling, and ongoing monitoring. By addressing these challenges, there is potential to significantly improve clinical outcomes, reduce the risk of complications, and enhance the long-term well-being of patients suffering from LUTS/BPO.

3. Optimizing treatment efficacy and compliance – Looking into the future

Given these challenges, there is an increasing emphasis on the need for objective and systematic monitoring of patient health outcomes to optimize treatment efficacy and prevent complications. The International Prostate Symptom Score (IPSS) remains one of the most widely utilized tools for assessing the severity of LUTS/BPO. However, a critical limitation of the IPSS is its reliance on subjective patient perception, which can introduce variability in treatment evaluation. Additionally, because the IPSS is traditionally completed on paper during in-person consultations, opportunities for continuous monitoring and early intervention are often missed. Real-time collection of patient-reported data could significantly enhance clinical decision-making, allowing healthcare providers to detect symptom deterioration early and make timely adjustments to treatment plans. Patients with stable symptoms may not require frequent in-person visits, whereas those experiencing worsening LUTS could benefit from closer monitoring and prompt medical intervention.

The COVID-19 pandemic served as a catalyst for the rapid adoption of telemedicine and remote healthcare solutions, fundamentally reshaping the traditional approach to patient management. During the pandemic, non-urgent and non-life-threatening urological conditions, including LUTS/BPO, were deprioritized, leading to delays in routine care and underscoring the critical need for alternative patient monitoring strategies [51]. Telemedicine has since emerged as a viable and effective solution, enabling virtual consultations, remote symptom tracking, and improved access to medical guidance [52].

With the increasing ubiquity of smartphones and portable electronic devices, there is a growing opportunity to integrate digital health solutions into LUTS/BPO management. These technologies offer a cost-effective and scalable means of enhancing symptom tracking, treatment adherence, and patient engagement. Several digital interventions have demonstrated

the potential to improve patient outcomes. For instance, mobile applications designed for medication adherence provide automated reminders, reducing forgetfulness and reinforcing treatment consistency. Digital symptom tracking tools, such as electronic versions of validated assessment scales—including the IPSS, International Index of Erectile Function (IIEF), and SF-36—allow patients to record their symptoms remotely, enabling clinicians to monitor their progress in real-time. Moreover, personalized feedback mechanisms based on patient-reported data can further engage individuals in their treatment, fostering improved self-management and better long-term health outcomes.

Telemedicine and virtual consultations also play a critical role in modern LUTS/BPO management, allowing for timely and efficient communication between patients and healthcare providers. This approach not only reduces the burden of unnecessary hospital visits but also ensures that those with worsening symptoms receive immediate medical attention. The ability to combine digital health monitoring with conventional treatment pathways presents an opportunity to create a hybrid model of care that optimizes both accessibility and effectiveness.

Looking ahead, the future of LUTS/BPO management lies in leveraging advancements in digital health technologies, artificial intelligence (AI), and big data analytics to enhance predictive modeling, automate treatment recommendations, and develop smart medication adherence strategies. By embracing these innovations, healthcare providers can revolutionize the management of LUTS/BPO, reducing the disease burden, improving treatment outcomes, and ultimately enhancing the quality of life for millions of individuals affected by these conditions.

B. SPECIFIC PART

This pilot study evaluated the feasibility and acceptability of use of a mobile app for men presenting to their urologist with LUTS/BPO who are either under treatment or who may require medical therapy for the first time. The app is called MyBPHCare and was created by Ydeal®. Via this app, physicians record their patients' baseline characteristics and comorbidities. Patients record their urinary symptoms, sexual function, and quality of life by completing the IPSS, IIEF-15, and SF-36. They also record their daily medication intake after receiving automated reminders from the app. This allows physicians to monitor adherence levels and identify any inconsistencies or missed doses. If a patient exhibits low or irregular compliance, the physician can promptly reach out via the built-in MyBPHCare Messenger to provide guidance or intervention. Similarly, patients have the option to communicate with their physicians through the Messenger for any concerns or questions related to their medication. All recorded information is securely transmitted and stored in a data management system using an encrypted connection, ensuring privacy and data protection. Advancements in healthcare are fueled by strong collaborations. This is a project of uCARE, which is the Research Office of the Société Internationale d'Urologie (SIU), in which five participating centers from Greece, Spain, Italy, Türkiye, and Portugal were intended participants, with Dr. Stavros Gravas from Greece leading this research. The final study comprised data from patients in Greece, Italy, and Türkiye only.

1. OBJECTIVES

1.1. Primary

The primary objective of this study is to evaluate both the feasibility and acceptability of a mobile health application (MyBPHCare) specifically designed for men who present to their urologist with lower urinary tract symptoms (LUTS) associated with benign prostatic obstruction (BPO). The target population includes patients who are currently undergoing treatment as well as those who are newly diagnosed and may require medical therapy for the first time.

1.2. Secondary

1. To monitor medication adherence through the use of electronic reminders.
2. To record whether physicians' treatments align with guideline recommendations.
3. To evaluate the communication between physicians and supervising urologists.

2. RESEARCH METHODOLOGY

2.1. Study Design

This was an observational cohort pilot study conducted at three centers in three countries: 1) the Institute for Monitoring of Urogenital Diseases in Larissa, Greece; 2) the Istanbul Medipol University in Türkiye; and 3) the University of Florence in Italy. Patients presenting at their physician’s office with LUTS/BPO symptoms were eligible for participation if they were LUTS/BPO treatment-naïve or under treatment. The included subjects received standard care for their symptoms according to the physician’s practice.

The duration of the pilot study was 6 months for every included subject. As this was an observational cohort study, standard diagnostic tools, medication, and follow-up visits were

employed. In addition, several questionnaires were completed at the beginning and end of the study for information collection (See Figure 1).

2.2. Data Source / Data Collection

Sources of data included information inputted by physicians on the MyBPHCare app as well as completion of patients reported outcome measures (PROM) questionnaires, inputted by patients on the MyBPHCare app and the evaluation questionnaires (hard copy).

2.3. Study Population

The study population included men, aged ≥ 40 yrs presenting at their physician's office with LUTS/BPO symptoms at one of three centers in three countries (Greece, Türkiye, and Italy). The original design of the study included participation by centers in Spain and Portugal. These centers, unfortunately, were unable to participate in the final analysis. The Spanish center failed to recruit any participants, and the data from patients recruited in the Portuguese center could not be included because they failed to validate a Portuguese translation of the user Mobile Application Rating Scale (uMARS). Participating physicians and patients were from the same country as their participating center.

2.3.1. Inclusion Criteria

In order to be eligible to participate in this study, patients met all of the following criteria:

- Male
- Age ≥40
- Bothersome LUTS
- No previous LUTS/BPO invasive treatment
- In possession of a smartphone, tablet, or computer with internet connection

- Access to email
- Fluent speaking and reading of the national language
- Signed informed consent

2.3.2. Exclusion Criteria

Potential patients who met any of the following criteria were excluded from participation in this study:

- Previous LUTS/BPO treatment with surgery
- Previous pelvic surgery or radiotherapy
- History of neurological disease
- History of bladder or prostate cancer
- Unable to provide informed consent
- Analphabet
- Unable to operate a smartphone / tablet / computer
- Incapable of understanding the language in which information for the patient is given

2.4. Variables

2.4.1. uMARS translation, adaptation and validation

To assess feasibility, acceptance, and satisfaction with the MyBPHCare app, including the subjective quality and perceived impact, patients completed a standardized and validated app rating user questionnaire known as the uMARS [53].

The questionnaire is included in Annex 1.

In order to be employed in all countries participating in this study, it was necessary to use translations of the uMARS into Turkish, Italian, and Greek.

There is published evidence for the validity of the Italian, Turkish and Greek translations [54,55,56].

We aimed to translate and validate the User Version of the Mobile Application Rating Scale (uMARS) into Greek, addressing the growing need for standardized tools to assess mobile health (mHealth) applications. The Mobile App Rating Scale (MARS) was developed in 2015 as a structured and validated tool to assess health app quality, and its simplified version, uMARS, allows end-users to evaluate applications. Despite its international adoption, a Greek-language version had not been developed before this study, making it difficult for Greek-speaking users to assess mHealth apps effectively.

To ensure accurate translation and adaptation, the study followed the WHO guidelines for cross-cultural adaptation, consisting of multiple phases. The process began with a forward translation of the original English uMARS by two bilingual native Greek speakers (one with a medical background and one without) to ensure the most accurate representation of both medical and general terminology. A consensus discussion among researchers refined the translation, ensuring that the meaning remained as close as possible to the original version. A backward translation into English was then performed by another bilingual expert to check for consistency. Finally, the original developers of uMARS reviewed the translation to verify its accuracy and provided feedback, which was incorporated into the final Greek version. This rigorous translation and validation process aimed to ensure that the Greek uMARS was both linguistically accurate and culturally appropriate.

For validation, the study recruited 91 medical students from the University of Thessaly, all native Greek speakers. The participants tested the Greek uMARS using "UTHme", a non-medical university app that was chosen due to its interactive features resembling those commonly found in mHealth apps, such as notifications, tracking, and engagement tools. The

study required participants to use the app for one month and then complete the Greek uMARS questionnaire twice—once at the end of the first month and again after 4-6 weeks. This test-retest process helped assess the tool's reliability and consistency over time [56].

2.4.2. Primary Study Parameter / Endpoint

The primary study parameter was determined by calculating percentage of patients who completed the study and the qualitative assessment of the app via questionnaires. The MyBPHCare app was determined to be Definitely Feasible if the study was completed by >70% eligible patients, Possibly Feasible if completed by 50-69% eligible patients, or Not Feasible if completed by <50%.

The uMARS questionnaire provided an overall mean score as well as an Engagement sub-score, Functionality sub-core, aesthetics sub-score, and Information sub-score. In addition, it provided Subjective Quality and Perceived Impact scores. Descriptive statistics were used to assess these parameters.

2.4.3. Secondary Study Parameters/Endpoints

To assess medication adherence, data were collected by the MyBPHCare app on medication intake, as reported by the patient. The percentage of medication adherence was calculated as the total days of medication adherence registered in the application divided by the total number of days of participation in this study.

To assess physician compliance with guidelines, data were collected by the MyBPHCare app on the treatment choices of the physician. The percentage of agreement between treatment started by physicians and suggestions by the current guidelines was calculated.

Initially, the plan was to have physicians also complete questionnaires, to evaluate communication between physicians and supervising urologists. Unfortunately, this portion of

the study was eliminated because of differences in national healthcare systems. In Italy, Greece, and Türkiye, patients can visit urologists without a referral from a GP. Only experienced urologists participated in the study, and they did not need to communicate with the national supervisor for assistance. In Portugal, patients are obliged to visit GPs first before seeing a urologist, but data from the Portuguese site were not included in the final analysis due to their failure to validate a Portuguese version of the uMARS.

An overview of the questionnaires used in this study are presented on Table 1. The IPSS is an 8-item questionnaire about LUTS. A score of 0-7 indicates mild symptoms, 8-19 indicates moderate symptoms, and 20-35 indicates severe symptoms. The IIEF is a 15-item questionnaire about erectile function. Top scores for each domain range from 10-30, which higher scores indicating better functioning. The SF-36 is a 36-item questionnaire about general quality of life. A shorter version (SF-12) contains 12 questions. Each domain is scored from 0-100, with a higher score defining a more favorable health state. These questionnaires can be found in Annex 1.

It is important to note that electronic versions of the IPSS [57] as well as the IIEF-5 and IIEF-15 and SF-36 have been validated against the paper version [58,60]. In addition, a systematic review and meta-analysis has demonstrated equivalence between electronic and paper administration of patient-reported outcome measures for studies conducted between 2007 and 2013 [60].

2.5. Sample Size/Power Calculations

There is little published guidance on pilot trial sample size. Sample sizes between 24 and 50 have been recommended [61,63]. As this study is set up as a pilot study and there is a paucity of data to guide sample size calculation, a traditional sample size analysis has not been

performed. Instead, a confidence interval (CI) approach was utilized to determine the necessary sample size for assessing feasibility.

According to the predefined primary endpoints, the app is considered Definitely Feasible if at least 70% of eligible patients with lower urinary tract symptoms (LUTS) due to benign prostatic obstruction (BPO) successfully complete the study. To determine the appropriate sample size needed to establish feasibility, a confidence interval (CI) approach was used.

A 95% confidence interval was applied to estimate the proportion of eligible patients expected to complete the assessment form. Key statistical parameters included a margin of error (ME) of 0.05, a lower bound of the CI set at 0.70, and an expected completion rate of 75%, which was derived based on an informed assumption. These values guided the calculation of the necessary sample size for the pilot study.

Using a well-established formula for calculating a 95% confidence interval for a single proportion—$p \pm 1.96 \sqrt{p(1-p)/n}$, where "p" represents the estimated proportion of interest and "n" denotes the sample size—the minimum required sample size was determined to be at least 75 patients. This sample size ensures that the study has sufficient statistical power to assess the feasibility of the app while maintaining a reasonable level of precision in estimating the true completion rate among eligible participants.

Since the study was initially designed to be conducted in five countries and communication between physicians was also evaluated, it was decided to double the sample size to 200 patients. This increased the power of the study allowed for the evaluation of the secondary objectives. Unfortunately, due to unforeseeable circumstances, two of the five original study sites were not included in the final analysis. The Spanish site was unable to recruit any subjects, and the Portuguese site failed to validate a Portuguese version of the uMARS questionnaire. Thus, we were left with a sample size of 157 which is still double of the required sample size for the primary endpoint.

3. DATA ANALYSIS CONSIDERATIONS

3.1. Subject Withdrawal

Participants had the right to voluntarily withdraw from the study at any time, for any reason, without facing any penalties or adverse consequences. Their decision to discontinue participation would not affect their medical care or any other entitlements.

Additionally, the study investigators retained the authority to withdraw a participant if deemed necessary for urgent medical reasons. This could include situations where continued participation posed a risk to the participant's health or well-being, or if new medical conditions emerged that made further involvement inappropriate. In such cases, investigators would assess the situation carefully and ensure that appropriate medical support or alternative interventions were provided as needed.

3.1.1. Replacement of Withdrawn Subjects

Subjects who withdrew from the study were replaced by new subjects.

3.1.2. Follow-Up of Withdrawn Subjects

Subjects withdrawn from the study continued to be followed by their primary care provider and received standard of care according to the physician’s practice.

3.2. Premature Termination of The Study

Since the study is observational in nature and the app does not interfere with or alter the standard medical care provided to patients, the likelihood of prematurely terminating the study was considered minimal. Unlike interventional studies, which may involve experimental treatments or procedures that could introduce unforeseen risks, this

observational study solely focuses on monitoring and assessing patient adherence and outcomes without modifying their usual course of treatment.

Furthermore, because the app functions as a supplementary tool rather than a determinant of clinical decisions, its use does not pose any additional medical risks or ethical concerns that might necessitate early study termination. Given these factors, researchers concluded that there was no significant threat to study continuity, ensuring a stable and reliable data collection process throughout the research period.

3.3. Randomization

As this study was an observational cohort study, randomization was not applied.

4. STUDY CONDUCT, MANAGEMENT AND ETHICS

Treatment was administered based on the standard clinical practices followed by the treating physicians. As this study was purely observational, it did not interfere with or influence the medical decisions regarding patient care. Physicians continued to provide treatment as they normally would, ensuring that patient management remained consistent with established medical guidelines and individual clinical judgment.

4.1. Regulation Statement

This study was conducted according to the principles of the Declaration of Helsinki (2013 version, date 4-7-2017), in accordance with the Medical Research Involving Human Subjects Act (WMO), Good Clinical Practice (ICH-GCP), and in compliance with the approved research protocol.

Participating centers obtained ethical approval at their local Institutional Review Boards (IRBs). Amendments are changes made to the research after the IRB approval. The local IRB committees were notified of all amendments, and updated information was also uploaded on ClinicalTrials.gov.

4.2. Recruitment and Consent

4.2.1. Preferred Option

Eligible subjects were selected by participating physicians. The WMO recommends a time period of approximately seven days between subject informing and inclusion, but as we recruited patients directly from participating physicians' practices, it was not considered feasible to make them wait seven days to start treatment. It was considered unreasonable to expect patients to wait to receive therapy, and this waiting period would result in a change in therapeutic strategy as a direct result of participation in the study.

The solution employed was to inform patients about the study when they were in contact with the clinic to make their appointment, which usually took place at least one to three days prior to the appointment itself. During the consultation, the physician decided whether the patient met the inclusion criteria. If so, the patient was included immediately.

In our opinion, this approach is acceptable, as this study is observational, and we anticipated only positive effects of participation. Furthermore, it was possible for subjects to quit at any time.

4.2.2. Alternative Option 1:

An alternative recruitment strategy was for the physician to determine whether the patient was eligible for the study during the consultation, without first informing the patient about the study at the time the appointment was arranged. Eligible subjects completed the

questionnaires using the app on their phone or iPad at the physician's office. The physician then informed the patient about the study and prescribed the adequate medical treatment. The patient was then contacted seven days later to return the informed consent (IC) form, if he agreed to participate in the study. Patients downloaded the app, and physicians downloaded the same app but with a different interface, to access the version for physicians and supervising urologists.

4.2.3. Alternative Option 2:

During the COVID-19 pandemic, patients already undergoing treatment were offered the chance to participate in the study. They were informed about the study during their phone consultations. The IC and information packages were sent by email to the patient. The patient was contacted seven days later to return the IC form, if he agreed to participate in the study. Patients downloaded the app, and physicians downloaded the same app but with a different interface, to access the version for physicians and supervising urologists.

4.3. Incentives

This study was free of charge for every patient. There were no special incentives provided.

4.4. Adverse Event (AE), Pregnancy Exposure, and Incident Reporting

4.4.1. AEs or Serious AEs

Adverse events (AEs) were defined as any unintended or unfavorable occurrences experienced by a participant during the study, regardless of whether they were deemed related to the investigational product. Since patients were receiving well-established, standard medical treatment, the management of AEs followed national guidelines and protocols to ensure appropriate care and intervention..

4.4.2. Pregnancy Exposure

As there were no women of childbearing potential included in this study, there was no pregnancy exposure risk.

4.4.3. Data Safety Monitoring Board (DSMB) / Safety Committee

Since this was an observational study in which patients were treated according to the physician's standard practice, no safety concerns were expected. Consequently, a DSMB was not utilized in this study.

4.4.4. Summary of Known and Potential Risks and Benefits

As this was an observational study design, there were no direct risks for the patient associated with participation in this study. Physicians were asked to provide treatment in line with their standard practice with respect to medication selection and follow-up frequency. As a result, quality of care remained unaffected, with no additional risks. As the app provided warnings for non-answered questions, it only had the potential to increase the quality of information obtained on patient welfare. The daily medication reminder was intended to increase medication adherence. The app was also designed to ease information exchange between physicians and the supervising urologist. Thus, there were no direct risks for the patients associated with participation in this study. Indeed, there was only potential for them to benefit from using the study app in the form of improved therapy adherence and better symptom follow-up.

There is a risk security risk inherent in use of digital technology to collect and share confidential patient information. Maximal risk reduction for data hacking was reached by implementation of all relevant guidelines and laws (see Section 4.5.1 Data Safety).

4.4.5. Compensation for Injury

As this was an observational study and therapy was prescribed based on standard clinical practice, there was no compensation for injury.

4.4.6. Temporary Halt for Reasons of Subject Safety

The sponsor had the authority to suspend the study if there were valid concerns that its continuation could compromise the health or safety of participants. In such a case, the sponsor would promptly inform the accredited Medical Ethics Review Committee (METC) of the temporary suspension, providing a clear justification for the decision. The study would remain on hold until the METC issued a positive decision allowing it to resume.

Additionally, the investigator was responsible for ensuring that all participants were kept informed about the situation. However, given that this study was purely observational and did not involve experimental interventions, no safety risks were anticipated, and no safety concerns were observed throughout the study.

4.5. Legal Basis for Processing Individual Human Data

4.5.1. Data Safety

Data security and privacy were rigorously ensured throughout the study. To maintain a high level of data protection, the app directed participants to a secure, validated, web-based platform to complete questionnaires. This ensured that sensitive health information was collected in a controlled and protected digital environment. All submitted data were immediately stored in a dedicated data management system (DMS), eliminating any risk of data loss or unauthorized local storage on user devices.

The DMS, along with the app supplier, adhered to strict international standards for medical data storage and security. Both entities were certified under ISO 9001 (quality management),

ISO 14001 (environmental management), and ISO 27001:2013 (information security management), demonstrating compliance with industry best practices. Additionally, the system met the stringent data protection regulations established by the European Commission's General Data Protection Regulation (GDPR) and the United States Health Insurance Portability and Accountability Act of 1996 (HIPAA). These certifications and regulatory alignments ensured that patient data remained secure, confidential, and accessible only to authorized personnel.

Medication reminders were managed autonomously by the app, ensuring that users received timely notifications without manual intervention. Data related to medication adherence were temporarily stored on the user's device for a short period, solely for operational functionality. Once an internet connection became available, this data was automatically and securely transmitted to the DMS. Importantly, questionnaire responses were never stored locally on the device at any point, further safeguarding participant privacy. All communications between the app and the DMS were encrypted, preventing unauthorized access and ensuring the integrity of transmitted data. These robust security measures collectively reinforced the reliability, confidentiality, and compliance of the study's data handling processes.

4.5.2. Data Sharing

4.5.2.1. Annual Progress Report

The sponsor and investigator have committed to submitting an annual progress report to the accredited Medical Ethics Review Committee (METC). This report includes key updates such as the date the first participant was enrolled, the total number of participants recruited, and the number of participants who have successfully completed the trial. Additionally, the report provides details on any serious adverse events (SAEs) or serious adverse reactions, along with

any other significant issues encountered during the study. Any amendments made to the trial protocol are also documented to ensure transparency and regulatory compliance.

4.5.2.2. Temporary Halt and Premature End of Study Report

The investigator and sponsor have committed to informing the accredited Medical Ethics Review Committee (METC) about the study's conclusion within eight weeks of its completion, which is defined as the last visit of the final participant.

Additionally, the sponsor has agreed to promptly notify the METC in the event of a temporary suspension of the study, providing a clear explanation for the decision. In the case of an early termination, the sponsor will inform the METC within 15 days, outlining the reasons for discontinuation.

Furthermore, within one year of the study's completion, the investigator and sponsor will submit a comprehensive final report detailing the study's findings. This report will include any relevant publications, abstracts, or other related materials, ensuring full transparency and compliance with regulatory requirements.

4.5.2.3. Public Disclosure and Publication Policy

The study was registered on clinicaltrials.gov (ID: NCT03228485).

The sponsor and investigator acknowledge the importance of publishing the key findings of clinical trials in a peer-reviewed journal. They are committed to conducting publication activities responsibly and ethically, ensuring that all relevant study information is communicated transparently and in a timely manner.

Furthermore, all principal investigators are required to adhere to the uCARE guidelines concerning authorship, publication standards, data access, and transfer agreements, ensuring compliance with best practices in scientific reporting and collaboration.

5. RESULTS

Regarding the first part of this study, this consisted of the translation and validation of the User Version of the Mobile Application Rating Scale (uMARS) into Greek, addressing the growing need for standardized tools to assess mobile health (mHealth) applications.

The results demonstrated high internal consistency (Cronbach's alpha = 0.86), indicating that the Greek uMARS reliably measures the quality of an app. Furthermore, test-retest reliability was high across all subscales, confirming the stability of responses over time. Even though the validation was conducted using a non-health app, the selected app's interactive features made it a suitable test case, as many mHealth apps incorporate similar elements like reminders, tracking systems, and notifications.

The findings of this study emphasize the growing Greek app market and the need for standardized tools to evaluate health-related applications. The successful validation of the Greek uMARS provides researchers, healthcare professionals, and developers with a reliable tool to assess the quality of health apps, contributing to better-informed decisions regarding app use. Despite some limitations, such as the choice of a non-medical app for validation and a study sample limited to medical students, the research confirms that uMARS is a valuable instrument for evaluating mobile applications in Greek. Future studies could focus on applying the Greek uMARS to actual medical applications to further strengthen its role in mHealth research and app development in Greece. The validated Greek version of uMARS is now available for use in future mHealth studies, helping improve the quality and reliability of health applications for Greek-speaking users.

Results of 24 patients who participated in this observational study at a single center in Italy while under lockdown from COVID-19 (March 2020 - April 2020) have previously been reported [64].

The demographic characteristics of the full study population are presented in Table 2. Among the 157 patients included in the study, 83 (53%) were from Italy, 37 (24%) were from Greece, and 37 (24%) were from Türkiye. Patients' mean age was 58.71 (range: 42-90) years, and mean body mass index (BMI) was 27.07 (range: 21.05-40.91) kg/m2. Mean maximum flow rate (Qmax) was 11.34 (6.80-15.00) mL/s, mean prostate-specific antigen (PSA) was 1.90 (range: 0.26-7.45) ng/mL, mean post-void residual (PVR) was 78.40 (range: 10-380) mL, and mean prostate volume (Vprost) was 48.42 (14-107) mL.

Nearly half of participants (42.7%) had a large prostate on digital rectal exam (DRE). Common comorbidities were hypertension (32.7%) and hypercholesterolemia (32.7%). In addition, 11.9% of patients had diabetes mellitus (see Table 3).

Overall, 68.15% (107 out of the total 157) of patients filled in the uMARS questionnaire (see Figure 2). The percentage of patients who filled in the UMARS in Greece, Italy and Türkiye was 83.8%, 63.9% and 62.2%, respectively. The difference between the countries reached close but did not achieve statistical significance (p=0.064).

Mean scores on the uMARS with respect to App Quality (3.43), Engagement (3.21), Functionality (3.47), Aesthetics (3.37), and Information (3.68) were all the range between "Acceptable" and "Good" (see Table 4 and Figures 3 & 4). In addition, 96.3% of the participants would recommend using the app, whereas only 3.7% of the participants would not recommend the app to anyone. Overall, 34.5% of participants reported that they would definitely not pay for this app. Most patients (80.3%) were prescribed an α-blocker monotherapy for their LUTS/BPO symptoms (see Table 5). The combination of an a-blocker with 5ARI was given to 8.3% of the patients, and phytotherapy in 5.7%. Monotherapy with PDE5-I, 5ARI and combinations of a-blocker with phytotherapeutic agent and a-blocker with antimuscarinic were offered in 2.5%. 1.3%. 1.3 and 0.6%, respectively. Tamsulosin was the

most preferred a-blocker monotherapy (38%) followed by silodosin (28.6%), alfuzosin (25.4%) and doxazosin (7.9%).

Notably, α-blockers were given by urologists as initial therapy in patients who were treatment-naïve, even though according to their baseline characteristics and treatment guidelines, they were eligible for different therapies. The median prostate volume was 46ml and patients with a prostate volume larger than 40 ml represented 61% of the study population. Guidelines recommend the use of a 5ARI in men at risk of progression (e.g. prostate volume >40ml) however, only 9.6% of the total patients received a 5ARI (either as monotherapy or in combination). In addition, even in men with predominant storage symptoms (15.2%), treatment with antimuscarinic was offered in only one case in combination with a-blocker (0.6%), although guidelines recommend treatment with AM or b3-agonist.

Compliance with prescribed medication, as measured by the proportion of the time participants confirmed via the app that they had taken their medication (following an automated reminder) was 47.85%. (see Figure 5). As expected, rates of compliance were higher among those who completed the uMARS, compared with those who did not (51.90% vs. 35.44%).

Mean scores on the IPSS, IIEF, and SF-36 at each study timepoint are presented in Figures 6, 7, and 8, respectively.

Regarding Figure 6, the bar chart presents the Mean IPSS Total Scores and Sub-scores by Timepoint, showing data from three different time points: baseline (T=0), first follow-up (T=1), and six-month follow-up (T=6).

The IPSS Total Score, which assesses the severity of lower urinary tract symptoms, starts at 13.11 at baseline and slightly decreases to 12.44 at T=1, remaining nearly unchanged at 12.43 at T=6.

Examining the Voiding Sub-score, which measures issues related to micturition, the initial value is 7.77 at baseline, dropping to 7.35 at T=1, before slightly increasing to 7.39 at T=6.

The Storage Sub-score, which reflects storage-related urinary symptoms, follows a similar trend, decreasing from 5.34 at baseline to 5.09 at T=1 and remaining almost stable at 5.1 at T=6.

Regarding Figure 7, the bar chart presents the Mean IIEF (International Index of Erectile Function) Sub-scores by Timepoint, comparing data across three different time points: baseline (T=0), first follow-up (T=1), and six-month follow-up (T=6). The five subdomains analyzed - Erectile Function, Orgasmic Function, Sexual Desire, Sexual Satisfaction, and Overall Satisfaction - provide a comprehensive evaluation of sexual health over time.

The Erectile Function sub-score starts at 22.26 at baseline, increases slightly to 23.4 at T=1, and then stabilizes at 22.94 at T=6.

The Orgasmic Function sub-score remains fairly stable, with values of 8.03, 7.96, and 8.35 at T=0, T=1, and T=6, respectively.

Similarly, Sexual Desire scores show minor fluctuations (7.28 → 7.06 → 7.38) throughout the study period.

The Sexual Satisfaction sub-score exhibits a slight peak at T=1 (9.44 → 9.64) before decreasing slightly at T=6 (9.32).

The Overall Satisfaction sub-score, however, shows an upward trend from 6.99 at baseline to 7.4 at T=1, reaching 7.88 at T=6.

Regarding Figure 8, the SF-36 sub-score analysis provides insights into the participants' perceived health-related quality of life over time, comparing baseline (T=0,) with the six-month follow-up (T=6).

Physical Functioning shows a moderate increase from 87.89 at T=0 to 92.2 at T=6.

The Physical Health Problems score, which measures limitations in daily activities due to physical health, sees an improvement from 81.58 to 94.00.

Similarly, Emotional Health Problems improve significantly, increasing from 80.85 to 90.67.

This improvement aligns with gains in Emotional Role Functioning (66.44 to 75.72) and Social Activities (77.11 to 87.5).

The Vitality sub-score, which measures energy levels and fatigue, increases from 62.68 to 71.2. This improvement is complemented by a rise in the Pain sub-score (84.84 to 91.2).

The General State of Health sub-score increases from 63.63 to 72.00.

Subgroup analyses, such as stratifying participants based on treatment status, medication type, or baseline severity, could provide valuable insights into whether the observed changes remain consistent across various patient profiles. By identifying potential variations in response patterns, these analyses could help determine whether certain subgroups experience more pronounced benefits or challenges compared to others. Furthermore, they may uncover differential effects that could be masked in the overall analysis, leading to a more nuanced understanding of treatment efficacy and patient outcomes.

In addition to subgroup analyses, conducting larger-scale studies with a more homogeneous cohort would be essential to validate the trends reported in this study. A well-defined, standardized patient population would minimize confounding variables and enhance the reliability of the findings, thereby strengthening the generalizability of the results. Larger sample sizes would also improve statistical power, allowing for more robust conclusions regarding the effectiveness of specific interventions.

6. DISCUSSION

As the healthcare system recovers from the COVID-19 pandemic, it will be important to develop remote tools to facilitate an individualized approach to care that minimizes the need for face-to-face visits. The European Association of Urology (EAU) has formally recognized this need. Their guidelines on male LUTS explicitly recommend remote consultations for assessment and follow-up when feasible during the COVID-19 era [65]. However, relying on mail and telephone calls to share data carries the risk of inaccuracies and the possibility of overlooking important clinical information. A digital platform accessible by both patients and clinicians provides the opportunity to input data in real-time, reducing risk of recall error. Automated reminders decrease the likelihood that information will be overlooked. A digital platform also affords clinicians the opportunity to review the data at any time, providing the opportunity for a rapid response.

Use of technology to monitor patients in real time, with the possibility of transmitting data to clinicians, has gained traction in a number of clinical settings. Notably, smartwatches that detect atrial fibrillation and other arrhythmias have boomed in popularity and continue to improve in terms of diagnostic accuracy [66]. These devices often have features that allow for direct streaming of data to platforms accessible by clinicians, as do glucose monitors (including wearable continuous glucose monitors) [67] and continuous positive airway pressure machines [68]. All of these devices provide the opportunity for clinicians to follow patients without seeing them in-person, and there is evidence that this feature can improve patient adherence as well as outcomes and quality of life [68].

The use of a smartphone app for the management of asthma [69] and obesity [70,71] has also been evaluated. In the context of asthma therapy, a dynamic, real-time, interactive mobile app was shown to support knowledge translation at the patient and provider levels [69].

With regard to obesity, use of an app that incorporated goal setting, self-monitoring of diet and activity, and feedback was found to be feasible [70]. In a randomised trial, delivery of behavioural interventions via a smartphone app was found to be a feasible tool for self-monitoring when used in combination with behavioural counselling [71].

This is the first study to evaluate use of a digital app to manage a benign urological disorder. A small pilot study of a subset of 24 participants from this study treated in Italy during the COVID-19 pandemic lockdown demonstrated excellent adherence to study. The full dataset of 157 patients from Italy, Greece, and Türkiye confirms these findings, with 68.15% of patients completing the uMARS questionnaire. This meets the criteria for "Possibly Feasible" (50-69%) and approaches the criteria for "Definitely Feasible" (≥70%), as defined in the study protocol. In addition, almost all participants (96.3%) report that they would recommend use of the app to others. In addition, mean ratings of the features of the app were all in the "Acceptable" to "Good" range.

The present study reported some interesting findings related to the current practice for the management of men with LUTS. Monotherapy with a-blockers was the preferred treatment in the majority of the patients (80.3%). Such an approach is in line with the results from real life studies [72]. However, it shows once again that there is a discrepancy between the current Guidelines and real-life practice, since most patients with progression criteria (prostate volume > 40ml) were not receiving treatment with a disease modifying 5-ARI (either in monotherapy or in combination with an α-blocker) as per clinical guidelines. In addition, physicians preferred to initially prescribe a-blockers instead of antimuscarinics in patients with predominant storage symptoms.

Another interesting finding was that monotherapy with a-blocker was the only treatment given to the Turkish participants in the study. No patient in Italy received treatment with antimuscarinics and no patients in Greece received monotherapy with 5ARI. Although the

sample size per country is rather small to draw robust conclusions, these results indicate a variation in clinical practice.

The compliance with medication in the present study was 47.85% as captured by the App. A study on drug adherence in patients receiving pharmacological therapy to treat LUTS/BPH reported a drug adherence rate of 32% and 23% at 6 months and 12 months [73]. Drug adherence was evaluated using the Medication Adherence Questionnaire [73].

This study offers several advantages, including the use of self-reported validated questionnaires, which have been assessed for reliability both in a digital format and in translations to the local language. These questionnaires provide an accurate and standardized method for collecting patient data. Additionally, the study incorporates scheduled medication reminders, which help improve adherence and ensure patients take their prescribed treatments consistently. Another key benefit is the ability for patients to communicate directly with their physicians through Messenger, facilitating timely medical guidance and support. Furthermore, the MyBPHCare app is available for patients to download free of charge, making it accessible to a wider population without financial barriers. To ensure the confidentiality and security of user data, the app employs robust encryption measures, safeguarding personal and medical information against unauthorized access. These features enhance the overall effectiveness and reliability of the study while prioritizing patient convenience and data security

Limitations of the study include the fact that younger patients were keener to participate in this study. This may reflect a general trend among younger people to embrace digital technology ahead of older people. Also, the use of an app for patient follow-up is only feasible among patients with some background familiarity with mobile devices and apps as well as in geographic locations where access to a stable internet connection is widely available, in order to ensure timely receipt of reminders and messages. Nevertheless, the MyBPHCare app was specifically designed with ease of use in mind.

Moreover, there were some challenges regarding the timing of reminders. The app generates reminders 2 hours after the scheduled time for the patient to take their medication. For patients that take their medication before bed, which is common for male LUTS/BPO drugs, that reminder could appear while the patient was asleep. We also experienced problems with missing data in the follow-up visits because some patients were not willing to complete the questionnaires. There was variability regarding this issue among the participating centers, demonstrating the importance of appropriate patient selection. Notably, this problem is not unique to app-based studies. Finally, many patients expressed a preference for direct communication with their physician when they encountered a problem, rather than via the integrated messenger system.

There were also some challenges with respect to subject recruitment. The COVID-19 pandemic introduced unique challenges, as patients could not be recruited via outpatient clinics during lockdown. This necessitated a novel approach to patient recruitment, such as letters to the editor in local newspapers. This required an expansion of the protocol, from recruiting only treatment naïve patients to also accepting those under treatment. Ultimately, the proposed Spanish site of the study was unable to recruit any subjects, and a failure to validate a Portuguese version of the uMARS meant that patients recruited from this site could not be included in the analysis.

Future studies are required to evaluate the effect of the MyBPHCare app on patient adherence to therapy for LUTS/BPO and costs. There is a need for a randomised controlled trial comparing patients using the app with those who undergo classic in-person follow-up, to assess impact on treatment adherence as well as to assess the costs of in-person vs virtual follow-up of patients, such as transportation and time off work, as well as to healthcare systems. In addition, future studies should expand the use of digital platforms for patient

follow-up, using new tools and potentially linking findings directly to electronic medical records (EMR) systems.

For instance, Arjona et al have developed UroSound, a smartwatch-based platform that performs non-intrusive sound-based uroflowmetry. They have demonstrated that their constructed model achieves a good correlation between acoustic and standard uroflowmetry with regard to voiding shape. It also has the capacity to extract relevant voiding parameters and facilitates the collection of a voiding diary by measuring multiple uroflows during the day and night [74]. Technology such as UroSound could be incorporated into the MyBPHCare app to expand the amount on information collected for each patient.

Further research into the utility of predictive models using data collected from virtual platforms such as the MyBPHCare app are being explored. Gravas et al used predictive modelling to determine how well baseline age, total IPSS score, PSA, Vprost, voiding volume, and PVR predicted IPSS and AUR/BPO-related surgery among 9167 men with LUTS/BPO at risk of progression who were participants in clinical trials for dutasteride and tamsulosin, alone or in combination. Their findings suggest that predictive modeling using large datasets, combined with an interactive, web-based educational tool (www.bphtool.com) for visualizing individual risk profiles, can enhance the understanding of how various risk factors for disease progression interact and influence treatment responses. They conclude that these insights further emphasize the significance of a personalized approach to managing LUTS/BPH [75]. Integrating such predictive models into the app could provide patients with more detailed information and a visual representation of their potential response to treatment, improving decision-making and patient engagement.

7. CONCLUSIONS

The preliminary findings of this study provide strong evidence supporting the feasibility, practicality, and clinical relevance of the MyBPHCare app as a novel digital health solution for the remote monitoring and management of benign urological conditions, particularly lower urinary tract symptoms (LUTS) associated with benign prostatic obstruction (BPO). By using intuitive technology to facilitate seamless remote data collection, MyBPHCare reduces the necessity for frequent in-person consultations while maintaining continuous patient monitoring and enabling timely medical interventions. This innovative approach aligns with the broader shift toward telemedicine and personalized digital healthcare, offering a scalable, patient-centered model for long-term disease management.

A significant strength of MyBPHCare lies in its multifaceted functionality, which extends beyond data collection to actively enhance patient adherence, engagement, and communication with healthcare providers. One of its most impactful features is the automated medication reminders, designed to address the common challenges of long-term pharmacological management in LUTS/BPO patients. Poor adherence to prescribed treatments is a well-documented issue in this patient population, and by integrating structured reminders, the app helps achieve better compliance, ultimately improving clinical outcomes.

Additionally, MyBPHCare serves as a communication bridge between patients and their healthcare teams. This capability fosters real-time, interactive disease management, enabling physicians to make informed clinical decisions based on continuous patient-reported data rather than periodic in-person assessments. By providing symptom tracking, early intervention, and individualized treatment adjustments, the app gives patients the chance to take an active role in their own care while allowing healthcare providers to deliver more precise and responsive interventions.

The high levels of acceptability, usability, and practicality reported by patients in this study further underscore the clinical potential of MyBPHCare as a scalable digital health tool for men with LUTS/BPO. These findings are consistent with the growing body of evidence that highlights the transformative role of telemedicine, a field that has undergone rapid expansion—particularly following the COVID-19 pandemic, which accelerated the global adoption of virtual healthcare solutions.

The integration of digital health technologies into standard urological practice marks a paradigm shift in the delivery of care, moving toward more accessible, efficient, and patient-friendly models. By reducing the burden of hospital visits and in-person follow-ups, virtual platforms such as MyBPHCare not only improve patient convenience but also optimize healthcare resource utilization, allowing clinicians to prioritize high-risk cases while still maintaining oversight of lower-risk patients through digital channels.

As personalized medicine and data-driven healthcare continue to shape the future of medical practice, urologists and healthcare providers should actively explore and adopt virtual follow-up strategies for managing benign urological diseases, including LUTS/BPO. The findings from this study suggest that MyBPHCare has the potential to become a cornerstone of digital urology, offering a comprehensive and technology-driven approach to patient monitoring.

Further enhancements to the app could incorporate emerging digital health innovations to improve its diagnostic and predictive capabilities.

For example:

Sound-based uroflowmetry could be integrated to provide objective urinary flow assessments, eliminating the need for in-clinic uroflowmetry tests.

Artificial intelligence-driven predictive models could enhance risk stratification, enabling clinicians to personalize treatment plans based on real-time patient data and historical trends.

Wearable health technologies could be synchronized with the app, providing continuous physiological monitoring and further refining remote disease management.

By embracing such advancements in digital health, MyBPHCare and similar technologies could contribute to a more holistic, integrated framework for virtual urological care, ultimately leading to better clinical outcomes, improved patient engagement, and reduced healthcare system burdens.

While these initial findings are promising, ongoing research and validation are essential to fully realize the potential of MyBPHCare and other digital health solutions in urology.

Future studies could focus on:

- Assessing the long-term clinical efficacy and cost-effectiveness of digital platforms for LUTS/BPO management.
- Investigating the scalability of virtual care models across diverse patient populations.
- Evaluating user experience and engagement metrics to refine app functionalities.
- Exploring integration with electronic health records (EHRs) to enhance interoperability within routine clinical workflows.
- Examining potential synergies with biometric and wearable technologies to provide a more comprehensive and real-time monitoring system.

By advancing telemedicine research and optimizing digital health strategies, the urological community can make significant strides in redefining the management of benign urological conditions. The evolution of tools like MyBPHCare represents a pivotal step toward a more connected, efficient, and patient-centric future, reinforcing the role of technology-driven medicine in shaping the next generation of urological care.

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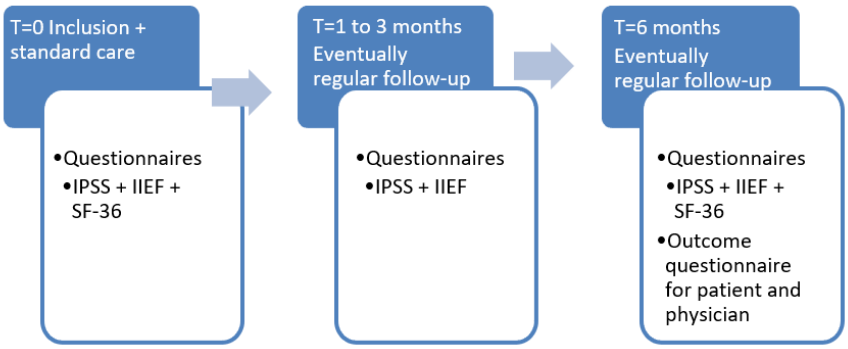
9. TABLES, FIGURES AND IMAGES

Figure 1: Questionnaire completion & patient follow-up during the 6-month study.



IIEF, International Index of Erectile Function; IPSS, International Prostate Symptom Score; SF-36, 36-item Short Form Health Survey; T=0, time of study inclusion; T= 1-3 at 1-3 months; T=6, at 6 months/study end

Table 1: Questionnaires, time of completion, and estimated duration of completion

Questionnaire	Time of Completion	Estimated Duration of Completion	Completed by
IPSS	Study inclusion (T=0) 1-3 months (T=1-3) Study end (T=6)	5 minutes	Patient
IIEF	Study inclusion (T=0) 1-3 months (T=1-3) Study end (T=6)	5 minutes	Patient
SF-36	Time of inclusion (T=0) Study end (T=6)	10 minutes	Patient
uMARS	Study end (T=6)	20 minutes	Patient

IIEF, International Index of Erectile Function; IPSS, International Prostate Symptom Score; SF-36, 36-item Short Form Health Survey; T=0, time of study inclusion; T=1-3 at 1-3 months; T=6, at 6 months/study end; uMARS, user version of the Mobile Application Rating Scale

Table 2: Baseline Characteristics – Total and by Region

	Total (N=157)		Italy (n=83)		Greece (n=37)		Türkiye (n=37)	
Variable	**Mean (Range)**	**SD**	**Mean (Range)**	**SD**	**Mean (Range)**	**SD**	**Mean (Range)**	**SD**
Age	58.71 (42-90)	9.06	61.53 (42-90)	9.10	60.62 (42-76)	8.85	52.03 (43-63)	5.14
BMI (Kg/m^2)	27.07 (21-41)	3.73	27.34 (21.47-40.91)	3.65	27.72 (21-40)	4.28	26.14 (21-34)	3.10
Vprost (mL)	48.42 (14-107)	19.18	50.00 (23-85)	15.97	53.88 (23-107)	20.41	40.62 (14-73)	16.53
Qmax (mL/s)	11.34 (6.8-15.0)	2.35	12.09 (6.8-15.0)	2.69	10.34 (6.8-15.0)	2.26	12.52 (9.8-15.0)	1.67
PVR (mL)	78.40 (10-380)	70.70	73.33 (10-247)	57.97	60.68 (11-250)	44.66	112.30 (18-380)	100.78
PSA (ng/mL)	1.90 (0.3-7.5)	1.52	1.93 (0.7-6.0)	1.71	2.41 (0.4-7.5)	1.63	1.30 (0.3-5.6)	1.02
Glucose (mg/dL)	112.65 (76-370)	46.75	100.17 (90-110)	8.50	105.03 (76-162)	16.29	154.5 (96-370)	113.68
Waist Circ. (cm)	99.44 (55-144)	12.41	98.94 (55-144)	13.26	100.94 (73-138)	14.17	98.26 (81-115)	9.17

BMI, body mass index; Qmax, fastest flow rate; PSA, prostate-specific antigen; PVR, post-void residual; SD, standard deviation; Vprost, prostate volume

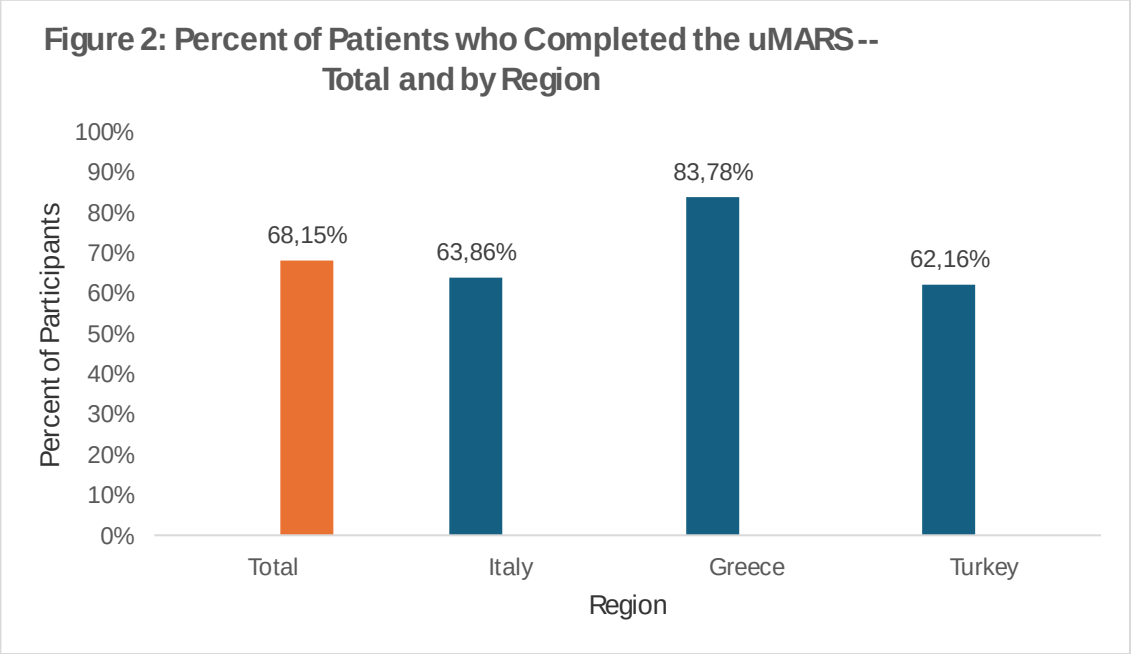
Table 3: Comorbidities – Total and by Region

	Total	Italy	Greece	Türkiye
Large Prostate on DRE (%)	42.7	50.0	51.4	27.0
Hypertension (%)	32.7	40.5	52.8	5.4
Hypercholesterolaemia (%)	32.7	51.4	44.4	2.7
Diabetes Mellitus (%)	11.9	13.9	16.7	5.4

DRE, digital rectal examination

Table 4: uMARS results (N=107)

uMARS components	**Mean (Range)**	**SD**
Engagement sub-score	3.21 (1.0-5.0)	0.83
Functionality sub-score	3.47 (1.5-5.0)	0.68
Aesthetics sub-score	3.37 (1.33-5.0)	0.74
Information sub-score	3.68 (2.5-5.0)	0.69
Overall App quality	3.43 (1.9-5.0)	0.64



uMARS, user version of the Mobile Application Rating Scale

Figure 3: Components of Each App Feature, As Measured by uMARS

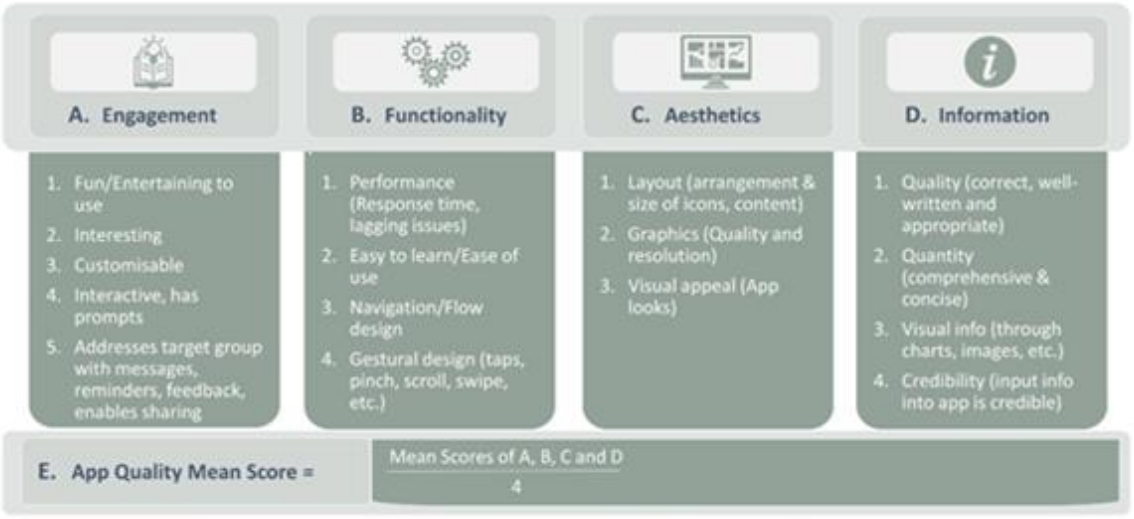
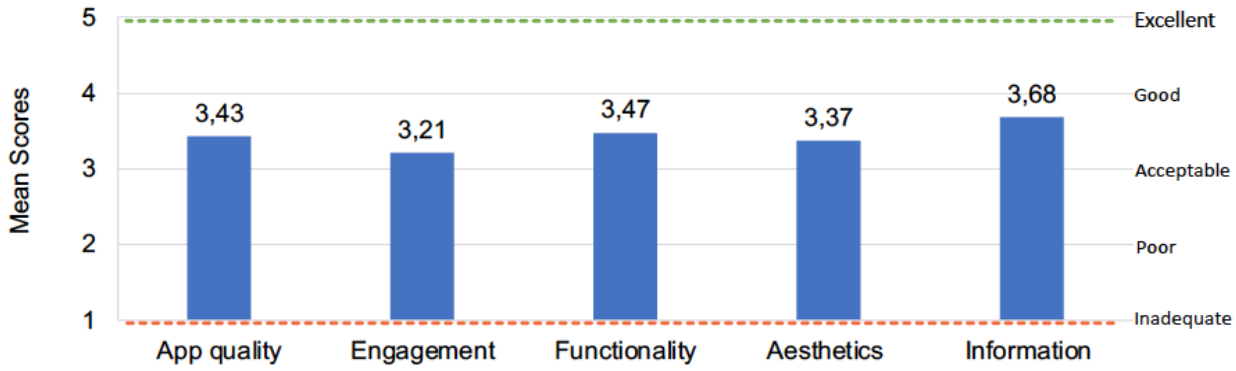


Figure 4: Mean Responses to uMARs

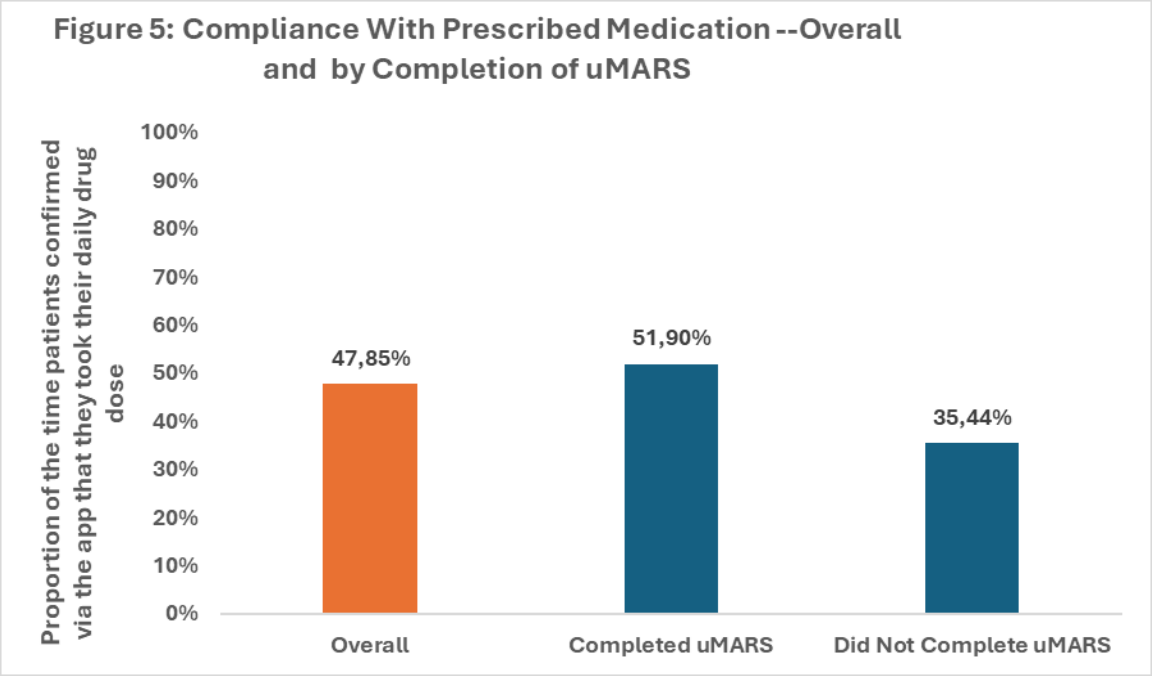


uMARS, user version of the Mobile Application Rating Scale

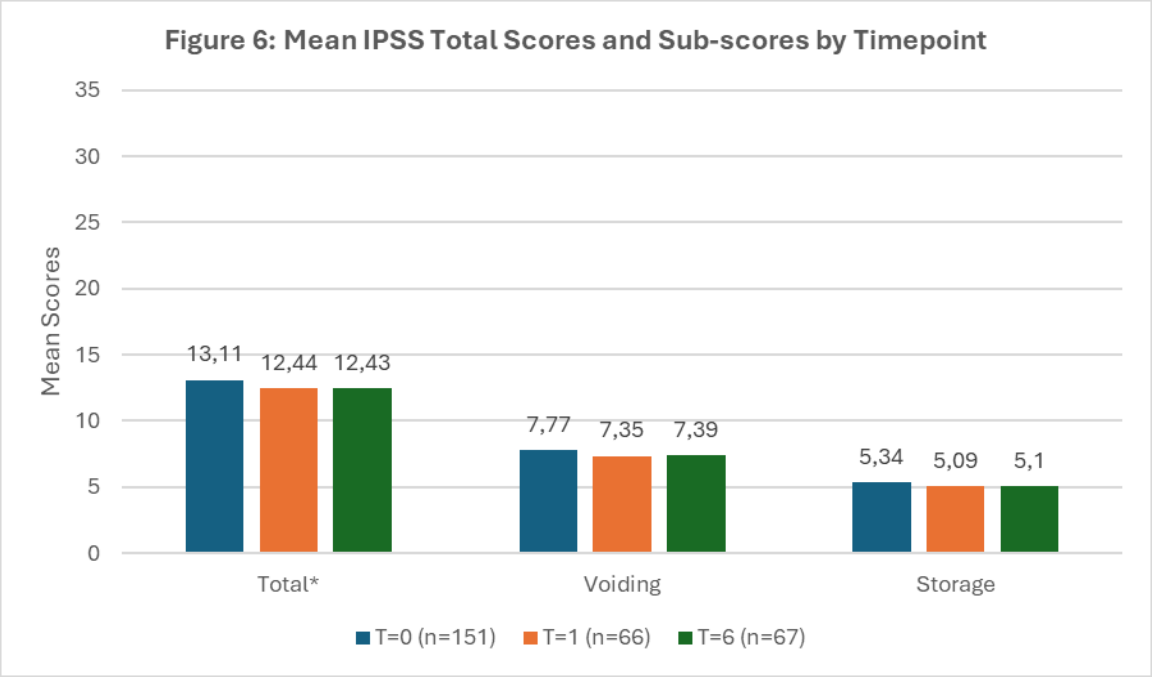
Table 5: Drugs Prescribed for LUTS/BPH Total and by Region

Drug Combination	Total N=157 Number (%)	Italy (n=83)	Greece (n=37)	Türkiye (n=37)
α-blocker	126 (80.3)	61	28	37
α-blocker + 5-ARI	13 (8.3)	10	3	0
Phytotherapy	9 (5.7)	5	4	0
PDE5-inhibitor	4 (2.5)	3	1	0
5-ARI	2 (1.3)	2	0	0
α-blocker + AM	1 (0.6)	0	1	0
α-blocker + Phytotherapy	2 (1.3)	2	0	0

5-ARI, 5α-Reductase inhibitor; AM: Antimuscarinic; PDE5, phosphodiesterase 5

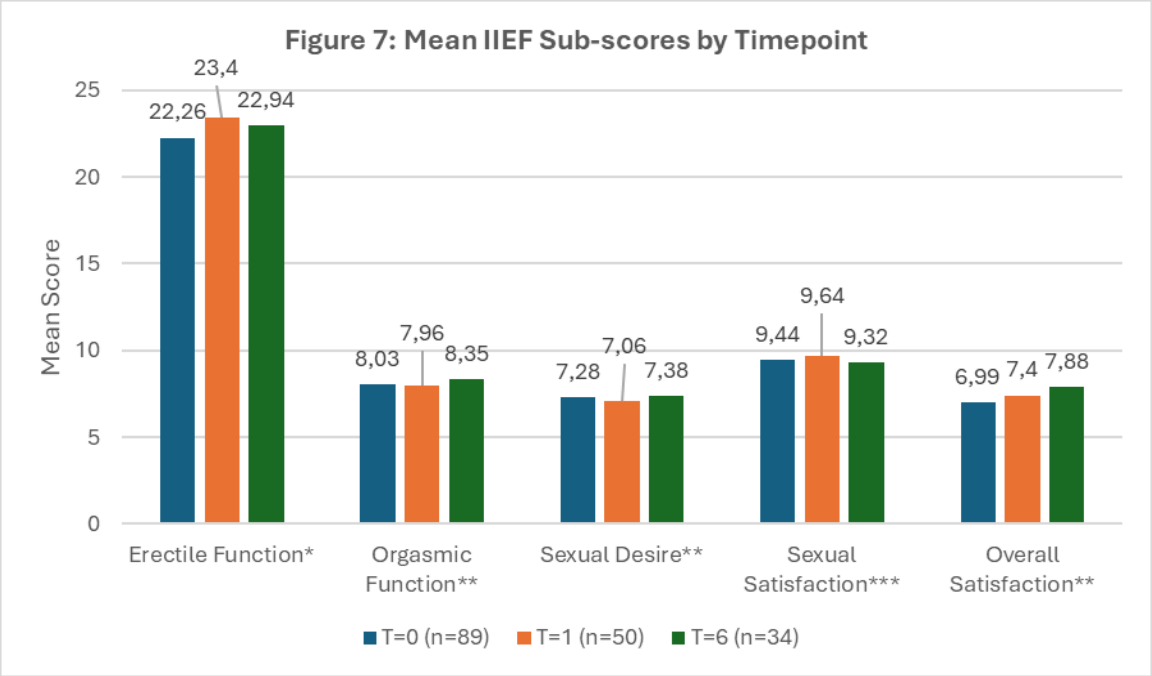


uMARS, user version of the Mobile Application Rating Scale



IPSS, International Prostate Symptom Score; T=0, time of study inclusion; T= 1-3 at 1-3 months; T=6, at 6 months/study end.

*A total score of 0-7 indicates mild symptoms, 8-19 indicates moderate symptoms, and 20-35 indicates severe symptoms.

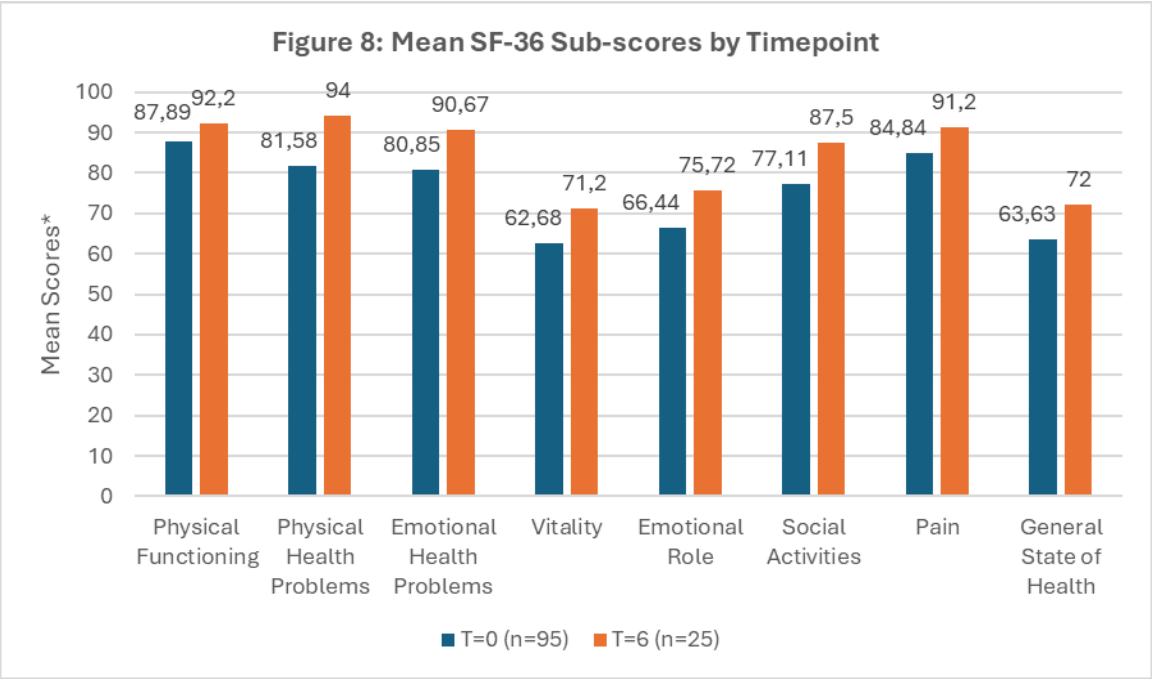


IIEF, International Index of Erectile Dysfunction; T=0, time of study inclusion; T= 1-3 at 1-3 months; T=6, at 6 months/study end

*Top score / highest level of function=30

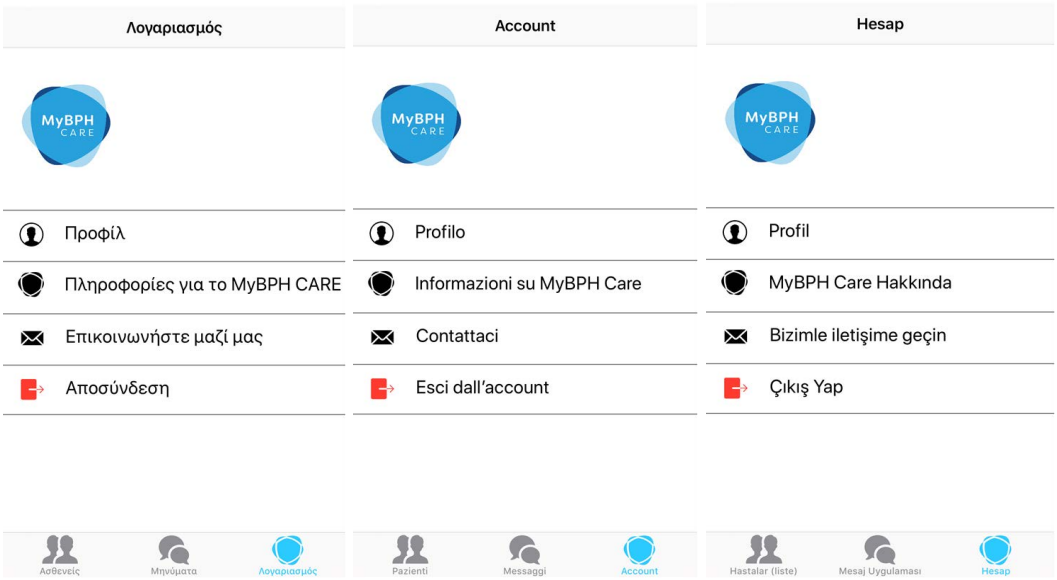
**Top score / highest level of function=10

***Top score / highest level of function=15

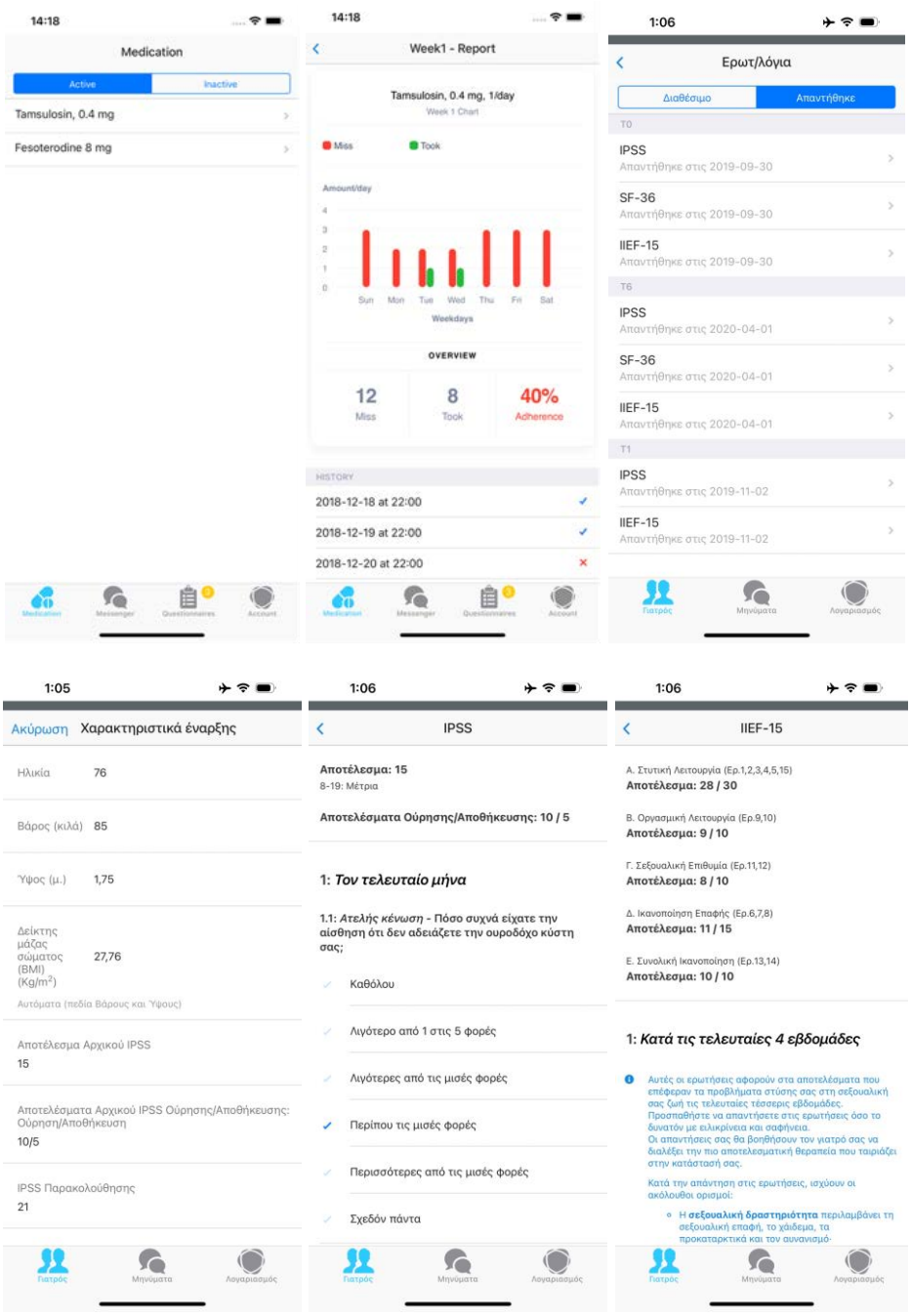


SF-36, 36-item Short Form Health Survey; T=0, time of study inclusion; T=6, at 6 months/study end.

*Scores for each domain range from 0 to 100, with a higher score defining a more favorable health state



App available in different languages



App interface

10. ANNEX 1: LIST OF STAND-ALONE DOCUMENTS

1. uMARS – Greek version

Οδηγίες χρήσης:

Οι κριτές θα πρέπει:

1. Να χρησιμοποιήσουν την εφαρμογή και να τη δοκιμάσουν διεξοδικά για τουλάχιστον 10 λεπτά.
2. Να καθορίσουν πόσο εύκολη είναι στη χρήση σας, πόσο καλά λειτουργεί και κατά πόσο πραγματοποιεί αυτά που ισχυρίζεται ότι κάνει
3. Να αξιολογήσουν σας ρυθμίσεις σας εφαρμογής, σας πληροφορίες του κατασκευαστή, σας εξωτερικούς συνδέσμους, τα χαρακτηριστικά ασφάλειας κτλ.

Βαθμολόγηση

Α: Μέσος Όρος Ενασχόλησης = ……..

Β: Μέσος Όρος Λειτουργικότητας= …….

Γ: Μέσος Όρος Αισθητικής = ……

Δ: Μέσος Όρος Πληροφορίας *= …….

* Εξαιρέστε από τον υπολογισμό του μέσου όρου σας ερωτήσεις που έχουν βαθμολογηθεί με «Μ/Δ – Μη Διαθέσιμο».

Μέσος Όρος Ποιότητας Εφαρμογής …….. = Α + Β + Γ +Δ / 4

Η Κλίμακα Υποκειμενικής Ποιότητας σας εφαρμογής μπορεί να αναφερθεί ως επιμέρους στοιχεία ή ως μέσος όρος ανάλογα με σας σκοπούς σας έρευνας.

Τα στοιχεία που αφορούν την Αντιληπτή Επίδραση μπορεί να προσαρμοστούν και να χρησιμοποιηθούν για να ληφθούν πληροφορίες ως σας το πώς ο χρήστης αντιλαμβάνεται την επίδραση σας εφαρμογής σας γνώσεις, σας στάσεις και σας προθέσεις του αναφορικά με τη συμπεριφορά υγείας - στόχο.

Κλίμακα Βαθμολόγησης Εφαρμογών Κινητών:

Έκδοση για χρήστη (uMARS)

Όνομα Εφαρμογής: ……

Κυκλώστε τον αριθμό που αντιπροσωπεύει με μεγαλύτερη ακρίβεια την ποιότητα σας εφαρμογής που βαθμολογείτε. Όλα τα στοιχεία αξιολογούνται με μία κλίμακα 5 βαθμών από το «1. Ανεπαρκής» μέχρι «5. Εξαιρετικός». Επιλέξτε Μ/Δ (Μη Διαθέσιμο) εάν το στοιχείο σας εφαρμογής είναι άσχετο ή δεν υπάρχει.

Βαθμολόγηση Ποιότητας Εφαρμογής

ΤΜΗΜΑ Α΄

Ενασχόληση – ευχάριστη, ενδιαφέρουσα, εξατομικεύσιμη, διαδραστική, παρέχει ειδοποιήσεις (π.χ. στέλνει ειδοποιήσεις, μηνύματα, υπενθυμίσεις, αιτήματα ανατροφοδότησης, επιτρέπει να το μοιραστείς)

1. Ψυχαγωγία: Είναι η εφαρμογή διασκεδαστική/ευχάριστη στη χρήση σας; Έχει χαρακτηριστικά που την κάνουν πιο ευχάριστη από σας παρόμοιες εφαρμογές;
   1 Βαρετή, καθόλου ευχάριστη ή διασκεδαστική
   2 Κυρίως βαρετή
   3 Εντάξει αρκετά ευχάριστη για να απασχολήσει το χρήστη για μικρό χρονικό διάστημα (<5 λεπτά)

4 Μέτρια διασκεδαστική και ευχάριστη, θα μπορούσε να απασχολήσει το χρήστη για κάποιο διάστημα (5 – 10 λεπτά συνολικά)

5 Ιδιαίτερα διασκεδαστική και ευχάριστη, θα μπορούσε να οδηγήσει σε επαναλαμβανόμενη χρήση

2. Ενδιαφέρον: Είναι η εφαρμογή ενδιαφέρουσα στη χρήση; Παρουσιάζει σας πληροφορίες σας με έναν ενδιαφέροντα τρόπο σε σύγκριση με σας παρόμοιες εφαρμογές;
   1. Καθόλου ενδιαφέρουσα
   2. Κυρίως μη ενδιαφέρουσα
   3. Εντάξει, ούτε ενδιαφέρουσα ούτε μη ενδιαφέρουσα, θα μπορούσε να απασχολήσει το χρήστη για μικρό χρονικό διάστημα (<5 λεπτά)
   4. Μέτρια ενδιαφέρουσα, θα μπορούσε να απασχολήσει το χρήστη για κάποιο διάστημα (5 – 10 λεπτά συνολικά)
   5. Πολύ ενδιαφέρουσα, θα μπορούσε να οδηγήσει το χρήστη σε επαναλαμβανόμενη χρήση

3. Εξατομίκευση: Σας επιτρέπει να εξατομικεύσετε σας ρυθμίσεις και σας προτιμήσεις που θα θέλατε (π.χ. ήχος, περιεχόμενο και ειδοποιήσεις);
   1. Δεν επιτρέπει καμία εξατομίκευση ή απαιτεί εισαγωγή των ρυθμίσεων κάθε φορά
   2. Επιτρέπει μικρού βαθμού εξατομίκευσης και αυτό περιορίζει σας λειτουργίες σας εφαρμογής
   3. Επιτρέπει βασική εξατομίκευση για να λειτουργήσει επαρκώς
   4. Επιτρέπει σας επιλογές για εξατομίκευση
   5. Επιτρέπει πλήρη ρύθμιση των χαρακτηριστικών / προτιμήσεων του χρήστη, θυμάται σας σας ρυθμίσεις

4. Διαδραστικότητα: Επιτρέπει προσθήκες από το χρήστη, παρέχει ανατροφοδότηση, περιέχει ειδοποιήσεις περιεχομένου (υπενθυμίσεις, δυνατότητες για μοίρασμα, ειδοποιήσεις, κτλ);
    1. Καθόλου διαδραστικά στοιχεία και / ή καθόλου ανταπόκριση σας προσθήκες του χρήστη
    2. Κάποια αλλά όχι αρκετά διαδραστικά στοιχεία, τα οποία περιορίζουν σας λειτουργίες σας εφαρμογής
    3. Βασικά διαδραστικά στοιχεία για να λειτουργεί επαρκώς
    4. Παρέχει μία ποικιλία από διαδραστικά στοιχεία, ανατροφοδότηση και επιλογές για προσθήκες του χρήστη
    5. Πολύ υψηλό επίπεδο ανταπόκρισης μέσω διαδραστικών στοιχείων, ανατροφοδότησης και επιλογών για προσθήκες του χρήστη

5. Ομάδα – στόχος: Είναι το περιεχόμενο σας εφαρμογής (γραφικά, γλώσσα, σχεδιασμός) κατάλληλο για τον πληθυσμό – στόχο;
    1. Εντελώς ακατάλληλο, ασαφές ή προκαλεί σύγχυση
    2. Κατά βάση ακατάλληλο, ασαφές ή προκαλεί σύγχυση
    3. Αποδεκτό αλλά όχι ειδικά σχεδιασμένο για τον πληθυσμό – στόχο. Μπορεί να είναι ακατάλληλο, ασαφές ή να προκαλεί σύγχυση κατά περιπτώσεις
    4. Σχεδιασμένο για τον πληθυσμό – στόχο με μικρά προβλήματα
    5. Σχεδιασμένο ειδικά για τον πληθυσμό – στόχο χωρίς να βρίσκονται προβλήματα

ΤΜΗΜΑ Β΄

Λειτουργικότητα – λειτουργία σας εφαρμογής, ευκολία στη μάθηση, πλοήγηση, λογική ροής και σχεδιασμός ελέγχου σας εφαρμογής με χρήση λειτουργιών αφής

6. Απόδοση: Με πόση ακρίβεια/ταχύτητα λειτουργούν οι υπηρεσίες (λειτουργίες) και τα χαρακτηριστικά (κουμπιά / μενού) σας εφαρμογής;
    1. Η εφαρμογή δεν λειτουργεί. Καθόλου / ανεπαρκής / ανακριβής ανταπόκριση (π.χ. κολλάει / ιοί / έχει σφάλματα, κτλ.)
    2. Κάποιες λειτουργίες δουλεύουν αλλά καθυστερούν ή έχουν σημαντικά τεχνικά ζητήματα
    3. Γενικά η εφαρμογή λειτουργεί. Κάποια τεχνικά προβλήματα ζητήματα απαιτούν επιδιόρθωση ή λειτουργούν αργά κατά περιπτώσεις
    4. Κατά βάση λειτουργική με μικρά / αμελητέα προβλήματα
    5. Τέλεια / ακριβής ανταπόκριση, χωρίς τεχνικά σφάλματα ή παρέχει ένδειξη «υπολειπόμενου χρόνου φόρτωσης» (εάν είναι σχετικό)

7. Ευκολία χρήσης: Πόσο εύκολο είναι να μάθει κανείς πώς να χρησιμοποιεί την εφαρμογή; Πόσο σαφείς είναι οι επικεφαλίδες των μενού, τα εικονίδια και οι οδηγίες;
    1. Καθόλου/περιορισμένες οδηγίες, οι επικεφαλίδες των μενού και τα εικονίδια προκαλούν σύγχυση, πολύπλοκη
    2. Απαιτεί σημαντικό χρόνο ή προσπάθεια
    3. Απαιτεί κάποιο χρόνο ή προσπάθεια
    4. Εύκολη στην εκμάθηση (ή παρέχει σαφείς οδηγίες)

5. Παρέχει τη δυνατότητα άμεσης χρήσης, ενστικτώδης, απλή (δε χρειάζονται οδηγίες)

8. Πλοήγηση: Είναι λογική και απλή η εναλλαγή μεταξύ οθονών; Παρέχει η εφαρμογή σας σας απαραίτητες συνδέσεις μεταξύ οθονών;
   1. Καμία λογική σύνδεση μεταξύ οθονών / η πλοήγηση είναι δύσκολη
   2. Κατανοητή μετά από πολύ χρόνο / προσπάθεια
   3. Κατανοητή μετά από κάποιο χρόνο / προσπάθεια
   4. Εύκολη στην κατανόηση / πλοήγηση
   5. Απόλυτα λογική, εύκολη, σαφής και ενστικτώδης ροή οθονών καθ' όλη τη διάρκεια και / ή παρέχει συντομεύσεις

9. Σχεδιασμός λειτουργιών αφής: Είναι λογική η χρήση ελαφρών χτυπημάτων με το δάκτυλο / συρσίματος / κύλισης σας οθόνης; Παραμένουν σταθερά στη λειτουργία σας σε σας σας υπηρεσίες/οθόνες;
   1. Πλήρως μη σταθερά / προκαλούν πλήρη σύγχυση
   2. Συχνά είναι μη σταθερά / προκαλούν σύγχυση
   3. Εντάξει, με κάποια στοιχεία αστάθειας / πρόκλησης σύγχυσης
   4. Κυρίως σταθερά / ενστικτώδη στη χρήση με αμελητέα προβλήματα
   5. Απόλυτα σταθερά και ενστικτώδη στη χρήση

ΤΜΗΜΑ Γ΄

Αισθητική – σχεδιασμός γραφικών, συνολική ελκυστικότητα εμφάνισης, χρήση χρωμάτων και συνοχή ύφους/στυλ.

10. Διάταξη: Είναι σωστή η τακτοποίηση και το μέγεθος των κουμπιών, των εικονιδίων, των μενού και του περιεχομένου πάνω στην οθόνη;

    1. Πολύ κακός σχεδιασμός, υπερφορτωμένος, κάποιες επιλογές είναι αδύνατο να επιλεγούν, εντοπιστούν, γίνουν αντιληπτές ή διαβαστούν από το χρήστη

    2. Κακός σχεδιασμός, τυχαίος, μη ξεκάθαρος, κάποιες επιλογές είναι δύσκολο να επιλεγούν / εντοπιστούν / γίνουν αντιληπτές / διαβαστούν από το χρήστη

    3. Ικανοποιητικός σχεδιασμός, λίγα προβλήματα με επιλογή / εντοπισμό / αντίληψη / ανάγνωση επιλογών από το χρήστη

    4. Κατά βάση σαφής σχεδιασμός, ο χρήστης μπορεί να εντοπίσει / επιλέξει / αντιληφθεί / διαβάσει τα στοιχεία σας εφαρμογής

    5. Επαγγελματικός, απλός, σαφής, τακτοποιημένος, λογικά οργανωμένος σχεδιασμός

11. Γραφικά: Πόσο υψηλού επιπέδου είναι η ποιότητα / ανάλυση των γραφικών που χρησιμοποιούνται για κουμπιά, εικονίδια, μενού και περιεχόμενο;

    1. Τα γραφικά φαίνονται ερασιτεχνικά, πολύ πτωχός οπτικός σχεδιασμός – ανομοιόμορφος, στυλιστικά ασυνεπής

    2. Χαμηλής ποιότητας / χαμηλής ανάλυσης γραφικά, χαμηλής ποιότητας οπτικός σχεδιασμός – ανομοιόμορφος

    3. Μέτριας ποιότητας γραφικά και οπτικός σχεδιασμός (γενικά ομοιόμορφος σε στυλ)

4. Υψηλής ποιότητας / ανάλυσης γραφικά και οπτικός σχεδιασμός – κατά βάση ομοιόμορφος και με συνέπεια στο στυλ

5. Πολύ υψηλής ποιότητας / ανάλυσης γραφικά και οπτικός σχεδιασμός – συνολικά ομοιόμορφος και με συνέπεια στο στυλ

12. Ελκυστικότητα εμφάνισης: Πόσο όμορφη φαίνεται η εφαρμογή;

1. Άσχημη, μη ευχάριστη οπτικά, πτωχά σχεδιασμένη, αταίριαστα και άσχετα μεταξύ σας χρώματα

2. Κακή – πτωχά σχεδιασμένη, κακή χρήση χρωμάτων, οπτικά βαρετή

3. Εντάξει – μέτρια, ούτε ευχάριστη ούτε δυσάρεστη οπτικά

4. Ευχάριστη – άψογη χρήση χρωμάτων – επαγγελματικά σχεδιασμένη και με συνέπεια

5. Πανέμορφη – πολύ ελκυστική, αξιομνημόνευτη, ξεχωρίζει – η χρήση των χρωμάτων βελτιώνει περαιτέρω την ποιότητα των λειτουργιών και μενού εφαρμογής

ΤΜΗΜΑ Δ΄

Πληροφορία – Περιέχει υψηλής ποιότητας πληροφορίες (π.χ. κείμενο, ανατροφοδότηση, δείκτες, αναφορές) από μία έγκυρη πηγή

13. Ποιότητα πληροφοριών: Είναι το περιεχόμενο σας εφαρμογής ακριβές, καλογραμμένο και σχετικό με το στόχο / αντικείμενο σας εφαρμογής;

    Μ/Δ Δεν παρέχονται πληροφορίες μέσα στην εφαρμογή

    1. Άσχετο / ακατάλληλο / μη συναφές / λανθασμένο περιεχόμενο
    2. Πτωχό περιεχόμενο. Οριακά σχετικό / κατάλληλο / με συνάφεια / μπορεί να είναι λανθασμένο
    3. Μέτρια σχετικό περιεχόμενο / κατάλληλο / με συνάφεια / σωστό
    4. Σχετικό περιεχόμενο / κατάλληλο / με συνάφεια / σωστό
    5. Πολύ σχετικό περιεχόμενο / κατάλληλο / με συνάφεια / σωστό

14. Ποσότητα πληροφοριών: Είναι οι πληροφορίες εντός σας εφαρμογής πλήρεις αλλά και περιεκτικές;

    Μ/Δ Δεν παρέχονται πληροφορίες μέσα στην εφαρμογή

    1. Οι πληροφορίες που παρέχονται είναι ελάχιστες ή υπερβολικές
    2. Ανεπαρκείς ή πιθανώς υπερβολικές
    3. Εντάξει αλλά όχι πλήρεις ή περιεκτικές
    4. Προσφέρει ένα ευρύ φάσμα πληροφοριών, έχει κάποια κενά ή αχρείαστες λεπτομέρειες, ή δεν παρέχει συνδέσμους για περισσότερες πληροφορίες και πηγές
    5. Πλήρης και περιεκτική, παρέχει συνδέσμους για περισσότερες πληροφορίες και πηγές

15. Οπτικές πληροφορίες: Είναι η οπτική εξήγηση των εννοιών – μέσα από γραφήματα / σχέδια / εικόνες / βίντεο κτλ. – σαφής, λογική, σωστή;

Μ/Δ Δεν παρέχονται επιπλέον οπτικές πληροφορίες από την εφαρμογή (π.χ. περιέχει μόνο ήχο ή κείμενο)

1. Η οπτική εξήγηση που παρέχεται είναι εντελώς ασαφής, συγκεχυμένη, λανθασμένη ή απούσα, αν και απαραίτητη
2. Κατά βάση ασαφής / συγκεχυμένη / λανθασμένη
3. Εντάξει αλλά συχνά ασαφής / συγκεχυμένη / λανθασμένη
4. Κατά βάση σαφής / λογική / σωστή με αμελητέα προβλήματα
5. Απόλυτα σαφής / λογική / σωστή

16. Αξιοπιστία πηγής: Οι πληροφορίες που παρέχονται μέσα στην εφαρμογή προέρχονται από μία αξιόπιστη πηγή;

Μ/Δ Δεν παρέχονται πληροφορίες μέσα στην εφαρμογή

1. Ύποπτη πηγή
2. Λείπει η αξιοπιστία
3. Η πηγή δεν είναι ύποπτη αλλά η εγκυρότητα σας είναι ασαφής
4. Οι πληροφορίες πιθανώς προέρχονται από έγκυρη πηγή
5. Οι πληροφορίες σίγουρα προέρχονται από έγκυρη / εξειδικευμένη πηγή

Υποκειμενική ποιότητα Εφαρμογής

ΤΜΗΜΑ Ε΄

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17. Θα συνιστούσατε αυτήν την εφαρμογή σε άτομα που μπορεί να ωφελούνταν από τη χρήση σας;

1. Σε καμία περίπτωση. Δε θα συνιστούσα αυτήν την εφαρμογή σε κανέναν
2. Υπάρχουν πολύ λίγα άτομα στα οποία θα συνιστούσα αυτήν την εφαρμογή
3. Ίσως. Υπάρχουν αρκετά άτομα στα οποία θα συνιστούσα αυτήν την εφαρμογή
4. Υπάρχουν πολλά άτομα στα οποία θα συνιστούσα αυτήν την εφαρμογή
5. Οπωσδήποτε. Θα συνιστούσα αυτήν την εφαρμογή σε όλους

18. Πόσες φορές πιστεύετε ότι θα χρησιμοποιούσατε αυτήν την εφαρμογή μέσα σας επόμενους 12 μήνες εάν ήταν σχετική σας εσάς;

1. Καμία
2. 1-2
3. 3-10
4. 10-50
5. >50

19. Θα πληρώνατε για αυτήν την εφαρμογή;

    1. Οπωσδήποτε όχι

    2.

    3.

    4.

    5. Οπωσδήποτε ναι

20. Με πόσα αστέρια βαθμολογείτε συνολικά αυτήν την εφαρμογή;

    1. * Μία από σας χειρότερες εφαρμογές που έχω χρησιμοποιήσει

    2. **

    3. *** Μέτρια

    4. ****

    5. ***** Μία από σας καλύτερες εφαρμογές που έχω χρησιμοποιήσει

Αντιληπτή επίδραση

ΤΜΗΜΑ ΣΤ΄

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1. Επίγνωση – Αυτή η εφαρμογή έχει αυξήσει την επίγνωση που έχω για τη σημασία σας ανάληψης δράσης για (ενασχόλησης με) αυτή τη συμπεριφορά υγείας

   Διαφωνώ έντονα Συμφωνώ έντονα

   1 2 3 4 5

2. Γνώση – Αυτή η εφαρμογή έχει αυξήσει τη γνώση / κατανόησή μου για τη συμπεριφορά υγείας

   Διαφωνώ έντονα Συμφωνώ έντονα

   1 2 3 4 5

3. Στάσεις – Η εφαρμογή έχει αλλάξει τη στάση μου σχετικά με τη βελτίωση σας σας συμπεριφοράς υγείας

   Διαφωνώ έντονα Συμφωνώ έντονα

   1 2 3 4 5

4. Πρόθεση για αλλαγή – Η εφαρμογή έχει αυξήσει σας προθέσεις / τα κίνητρά μου για ανάληψη δράσης για (ενασχόλησης με) αυτή τη συμπεριφορά υγείας

   Διαφωνώ έντονα Συμφωνώ έντονα

   1 2 3 4 5

5. Αναζήτηση βοήθειας – αυτή η εφαρμογή θα με ενθάρρυνε να αναζητήσω περαιτέρω βοήθεια για να αντιμετωπίσω τη συμπεριφορά υγείας (αν τη χρειαζόμουν)

   Διαφωνώ έντονα Συμφωνώ έντονα

   1 2 3 4 5

6. Αλλαγή συμπεριφοράς – Η χρήση σας σας εφαρμογής θα αυξήσει / μειώσει τη συμπεριφορά υγείας

   Διαφωνώ έντονα Συμφωνώ έντονα

   1 2 3 4 5

Σας ευχαριστούμε!

2. uMARS – English version

Instructions for Use:

Assessors should:

1. Use the application and test it thoroughly for at least 10 minutes;

2. Determine how easy it is to use, how well it works and how successfully it serves its purpose;

3. Evaluate the application's settings, the manufacturer's information, external links, security features, etc.

Rating

A: Involvement Mean Score = ……..

B: Functionality Mean Score = …….

C: Aesthetics Mean Score = ……

D: Information Mean Score* = …….

*Exclude from the calculation of the mean score the questions rated as "N / A - Not Available."

Quality of Application Mean Score..... = A + B + C + D / 4

The Subjective Quality Scale of the application can be reported as an independent additional element or as a mean score depending on the purpose of the research.

The items concerning the Perceived Impact can be customized and used to gain insight into how the user understands the impact of the application according to his / her knowledge, attitudes and intentions regarding the target which is - health behavior.

Mobile Application Rating Scale:

User Edition (uMARS)

Name of Application: ……

Circle the number that most accurately represents the quality of the app you are rating. All items are rated by means of a scale of 5 points from "1.Inadequate" to "5.Exceptional". Select N / A (Not Available) if the application item is irrelevant.

Quality of Application Rating

SECTION A

Involvement - fun, interesting, can be customized, interactive, provides alerts (e.g. sends notifications, messages, reminders, feedback requests, allows you to share it)

1. Entertainment: Is the application fun / enjoyable in its use? Does it have features that make it more fun than other similar applications?

1. Boring, not enjoyable or entertaining at all
2. Mainly boring
3. Ok, fun enough to entertain the user for a short time (<5 minutes)
4. Moderately fun and enjoyable, it could entertain the user for some time (5 - 10 minutes in total)
5. Especially fun and enjoyable, it could lead to repeated use

2. Interest: Is the application interesting to use? Does it present its information in an interesting way compared to other similar applications?

1. Not at all interesting
2. Mainly uninteresting
3. Ok, not interesting or uninteresting, could engage the user for a short time (<5 minutes)
4. Moderately interesting, it could engage the user for some time (5 to 10 minutes in total)
5. Very interesting, it could lead the user to repeated use

3. Customization: does it allow you to customize the settings and preferences you would like (e.g. audio, content, and notifications)?

1. Does not allow any customization or requires the settings to be inserted every time
2. Allows a small degree of customization which may limit the application
3. Allows basic customization which makes it adequately functional
4. Allows multiple options for customization
5. Allows full customization of the user's characteristics / preferences by the user, saves all the settings

4. Interactivity: Does it allow additions by the user, provide feedback, contain alerts (reminders, sharing options, notifications, etc.)?

1. No interactive elements and / or no response to user add-ins
2. Some, but not enough interactive elements, which limit the functions of the application
3. Basic interactive elements in order to function adequately
4. Provides a variety of interactive elements, feedback and options for user add-ins
5. Very high level of responsiveness through interactive elements, feedback and options for user add-ins

5. Target - group: Is the content of the application (graphics, language, design) appropriate for the target- population?

1. Completely inappropriate, unclear or confusing
2. Mainly inappropriate, unclear or confusing
3. Acceptable but not specifically designed for the target - group. It may be inappropriate, unclear, or confusing occasionally
4. Designed for the target - group with minor problems
5. Designed specifically for the target - group without any problems

SECTION B

Functionality - application function, ease of learning, navigation, flow logic and application control design using touch functions

6. Performance: How accurately / fast do the features (functions) and components (buttons / menu) of the application work?

1. The application does not function; at all /it is inadequate / inaccurate response (e.g. crashes / viruses / errors, etc.)
2. Some functions work, but with some delay or have major technical problems
3. The application generally works. Some technical problems require repair or work slowly on occasions
4. Mainly functional with small / negligible problems
5. Perfect / accurate response, without technical errors, or provides indications such as «remaining loading time» (if relevant)

7. Easy to use: How easy is it to learn to use the application; how clear are the menu headings, icons

and instructions?

1. Not at all / limited instructions; menu headings and icons cause confusion; complex
2. It takes a lot of time or effort
3. It takes some time or effort
4. Easy to learn (or provides clear instructions)
5. Provides immediate, intuitive, simple use (no instructions required)

8. Navigation: Is switching between screens logical; does the application provide all the necessary links between screens?

1. No logical connection between screens / navigation is difficult
2. Understandable after a long time / effort
3. Understandable after some time /effort
4. Easy to understand / navigate
5. Totally logical, easy, clear and intuitive screen flow throughout and / or provides shortcuts

9. Design of Touch Features: Is the use of taps / swipes / scrolls etc. of the screen logical? Are they stable on all components / screens?

1. Fully unstable / completely confusing
2. Often unstable / confusing
3. Okay, with some unstable / confusing elements
4. Mainly stable / intuitive use with negligible problems
5. Totally stable and intuitive in use

SECTION C

Aesthetics - graphic design, overall attractive appearance, color use and style consistency.

10. Layout: Is the layout and size of the buttons, icons, menus and content on the screen appropriate?

1. Very poor design, cluttered, some options are impossible to select / locate / see or read
2. Poor design, random, unclear, some options are difficult to select / locate / see / read
3. Satisfactory design, few problems with selecting / locating / seeing / reading options
4. Mainly clear design, can identify / select / see / read application options
5. Professional, simple, clear, neat, logically organized design

11. Graphics: How high is the quality / resolution of graphics used for buttons, icons, menus and content?

1. Graphics look amateur, very poor visual design - not uniform, stylistically inconsistent
2. Low quality / low resolution graphics, low quality visual design – not uniform
3. Moderate quality graphics and visual design (generally uniform in style)
4. High quality / resolution graphics and visual design - mainly uniform and consistent in style
5. Very high quality / analysis of graphics and visual design - overall uniform and consistent in style

12. Attractive Appearance: How good-looking is the application?

1. Ugly, unattractive visually, poorly designed, non matching and irrelevant colors
2. Bad - poorly designed, poor color use, visually dull
3. Okay - moderate, neither pleasant nor unpleasant visually
4. Pleasant - flawless graphics - professionally designed and consistent
5. Beautiful - very attractive, memorable, stands out; the use of colors enhances the features / menus of the application

SECTION D

Information - Contains high - quality information (e.g. text, feedback, indicators, references) from a credible source

13. Quality of information: Is the content of the application correct, well written and relevant to the purpose / topic of the application?

N / A No information is provided within the application

1. Irrelevant / inappropriate / unrelated / incorrect
2. Poor. Marginally relevant / appropriate / related / may be incorrect
3. Moderately relevant / appropriate / related / seems correct
4. Relevant / appropriate / related / correct
5. Very relevant / appropriate / related / correct

14. Amount of information: Is information within the application complete but also comprehensive?

N / A No information is provided within the application

1. Minimal or excessive
2. Insufficient or possibly excessive
3. OK but not complete or comprehensive
4. Offers a wide range of information, has some gaps or unnecessary details; or does not provide links for more information and sources
5. Complete and comprehensive; provides links for more information and sources

15. Visual information: Is the visual explanation of concepts - through charts / graphs / images / videos etc. - clear, logical, correct?

N / A No additional visual information is provided within the application (e.g. contains only audio or text)

1. Totally unclear, confusing, incorrect or absent, although necessary
2. Mainly unclear / confusing / incorrect
3. Okay but often unclear / confusing / incorrect
4. Mainly clear / logical /correct with negligible problems
5. Totally clear / logical / correct

16. Source Credibility: Does the information provided within the application come from a credible source?

N / A No information is provided within the application

1. Suspicious source
2. Credibility is missing

3. The source is not suspicious, but its credibility is unclear
4. The information probably comes from a credible source
5. The information certainly comes from a credible / specialized source

Subjective Quality of Application

SECTION E

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17. Would you recommend this application to people who might benefit from its use?

1. Under no circumstances. I would not recommend this application to anyone
2. There are very few people I would recommend this app to
3. Maybe. There are several people I would recommend this app to
4. There are many people I would recommend this app to
5. Definitely. I would recommend this app to everyone

18. How many times do you think you would use this application within the next 12 months if it was relevant to you?

1. None
2. 1-2
3. 3-10
4. 10-50
5.> 50

19. Would you pay for this application?

1. Definitely not

2.

3.

4.

5. Definitely yes

20. With how many stars do you rate this application overall?

1. * One of the worst applications I've ever used

2. **

3. *** Average

4. ****

5. ***** One of the best applications I've ever used

Perceived Impact

SECTION F

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1. Awareness - This application has increased my awareness of the importance of managing this health behavior

I strongly disagree I strongly agree

1 2 3 4 5

2. Knowledge - This application has increased my knowledge / understanding of this health behavior

I strongly disagree I strongly agree

1 2 3 4 5

3. Attitudes - The application has changed my attitude towards improving this health behavior

I strongly disagree I strongly agree

1 2 3 4 5

4. Intention to change - The application has increased my intentions / motives for managing this health behavior

I strongly disagree I strongly agree

1 2 3 4 5

5. Help seeking - This application would encourage me to seek further help in order to manage this health behavior (if I needed it)

I strongly disagree I strongly agree

1 2 3 4 5

6. Change of behavior - Using this application will increase / decrease health behavior

I strongly disagree I strongly agree

1 2 3 4 5

Thank you!

3. Publications from the present study

a) van Kollenburg RAA, de Bruin DM, Wijkstra H. Validation of the Electronic Version of the International Index of Erectile Function (IIEF-5 and IIEF-15): A Crossover Study. J Med Internet Res. 2019 Jul 2;21(7):e13490.

b) Morselli S, Liaci A, Nicoletti R, Pecoraro A, Gemma L, Polverino P, Zaccaro C, Sebastianelli A, Serni S, Laguna P, De La Rosette JJMC, Gravas S, Gacci M. The use of a novel smartphone app for monitoring male LUTS treatment during the COVID-19 outbreak. Prostate Cancer Prostatic Dis. 2020 Dec;23(4):724-726

c) Morselli S, Sebastianelli A, Domnich A, Bucchi C, Spatafora P, Liaci A, Gemma L, Gravas S, Panatto D, Stoyanov S, Serni S, Gacci M. Translation and validation of the Italian version of the user version of the Mobile Application Rating Scale (uMARS). J Prev Med Hyg. 2021 Apr 29;62(1):E243-E248.

d) Calik G, Kartal BB, Stoyanov S, Gravas S, Othman L, de la Rosette J, Albayrak S, Laguna P. Turkish Validation of the User Version of the Mobile Application Rating Scale. Turk J Urol. 2022 May;48(3):236-242. doi: 10.5152/tud.2022.21324. PMID: 35634943; PMCID: PMC9730268.

e) Chasiotis G, Stoyanov SR, Karatzas A, Gravas S. Greek validation of the user version of the Mobile Application Rating Scale (uMARS). J Int Med Res. 2023 Mar;51(3):3000605231161213.

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Greek validation of the user version of the Mobile Application Rating Scale (uMARS)

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Abstract

Objective: The original user version of the Mobile Application Rating Scale (uMARS) is an English-language questionnaire that was designed to allow non-expert app users to assess the quality of health apps. We aimed to translate into the Greek language and validate the uMARS.

Methods: This was a qualitative prospective study. The World Health Organization translation process was followed and a readily available and free-of-charge app was used for the validation process. Internal consistency and reliability were tested twice within one month by 91 Greek medical students.

Results: The total uMARS score showed excellent internal consistency (Cronbach's alpha = 0.86). The internal consistencies of its subscales were also very high (engagement alpha = 0.71; functionality alpha = 0.71; aesthetics alpha = 0.67; information alpha = 0.63), with the notable exception of the satisfaction alpha, which was 0.61. The uMARS total score demonstrated almost perfect agreement levels in most of the subscales according to the r_{WG} index from baseline to 1 month.

Conclusions: The Greek uMARS is a reliable and valid tool for assessing the quality of mobile apps.

Keywords

User version of the Mobile Application Rating Scale, Greek, mobile application, mobile healthcare, translation, validation

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Introduction

Currently, more than seven billion mobile device users exist globally.[1] The use of mobile and wireless technologies to support the achievement of health objectives (mHealth) has the potential to transform the face of health service delivery worldwide. Driving this change is a powerful combination of factors including rapid advances in mobile technologies and applications, a rise in new opportunities for the integration of mobile health into existing eHealth services, and the continued growth in mobile cellular network coverage.[2] Healthcare professionals are increasingly using mHealth apps to source information, provide diagnostic help, monitor patient medication, and manage symptoms. Patients and the general public utilize mHealth apps to communicate and consult with health services and healthcare practitioners, track health symptoms, learn about health conditions, and for many additional uses.[3] The number of mHealth apps is increasing rapidly, inadvertently leading to an overwhelming choice for users and to the risk of the availability of low-quality, ineffective, or even harmful apps. Unregulated health apps may be created by software developers with no health expertise and uploaded to app stores without repercussions to the developer.[4] Interest in mHealth apps for the remote monitoring of patients with chronic diseases has increased in Greece, especially during the coronavirus disease 2019 pandemic. However, knowledge of health app quality is scarce in Greece and consensus is lacking on how to assess quality.[5] In addition, standardized tools in the Greek language for the development, assessment, and appraisal of health apps are lacking. Evaluation of the content and quality of health-related apps for specific health conditions is crucial for providing professionals and end users confidence in the quality and credibility of these apps.[6]

Developed in 2015, the Mobile App Rating Scale (MARS) is an objective, reliable, and easy-to-use tool for the assessment of the quality of health apps.[7] The scale has been translated and validated in several languages,[8–11] but not in Greek. The original MARS was developed for use by professionals including researchers, developers, and clinicians and requires user expertise and training before use. A simplified version was subsequently developed and validated, resulting in the user version of the Mobile Application Rating Scale (uMARS), which can be used in large-scale trials or research with end users.[12] The uMARS was made for mHealth app end users and provides a 20-item measure instead of the 23-item measure of the MARS. An additional subscale was added to measure the perceived impact of the apps evaluated. The important role of the uMARS in the evaluation of mobile apps in clinical studies has recently been demonstrated.[13] To date, the cross-cultural translation and validation of the original English-language uMARS to the Greek language have not been performed. We aimed to translate the uMARS and validate a Greek version of the scale in the context of developing an app for the symptom monitoring and treatment of men with benign prostatic hyperplasia.

Methods

The English-language version of the uMARS

The uMARS provides an evaluation of the quality of an app with a 20-question scale divided into five subscales. Every item is rated on a 5-point Likert scale ranging from 1 (poor) to 5 (excellent). Four subscales—engagement (N = 5), functionality (N = 4), aesthetics (N = 3), and information (N = 4)—are objective and are associated with a quality rating; one subscale (N = 4) is subjective. An additional subscale of six

items measures the perceived impact of the app being evaluated.[12]

Cross-cultural adaptation and translation process

This was a qualitative prospective study. The Greek translation and cross-cultural validation of the English-language uMARS followed the World Health Organization guidelines[14] and consisted of forward and backward translation, pretesting, and cognitive evaluation and production of the final version.

The translation and adaptation processes involved the following steps: (i) The English-language version of uMARS was independently translated into Greek by two native Greek bilingual speakers (one physician and one non-medical professional) who were fluent in English. (ii) The two Greek translations were discussed within the research team to ensure meanings were as close as possible to the original English version. (iii) The Greek version was then back-translated into English by one bilingual researcher (a native Greek with a degree in English literature) and (iv) the result was reviewed and compared with the original English version by the developers of the original questionnaire, who provided feedback on the accuracy of the translation and suggestions for edits. The comments and suggestions from the original developers were discussed within the research group and integrated to develop the final version of the Greek uMARS.

Cultural adaptions were made in every step of the translation by changing the wording of some items to better fit the Greek context. The goals were to adapt uMARS to the Greek culture and language, consider cultural and linguistic differences between English and Greek, identify and resolve inadequate expressions or concepts in the translation, and ensure equivalence.

Selection of the mobile app for validation

When the Greek-language translation was ready, a mobile app was selected according to the following inclusion criteria: available in the Google Play and Apple App stores, free of charge, targeting adults (≥18 years of age) of either sex, containing features that promote interaction, relevant to health management (e.g., questions and answers, the exchange of images, reports, or numerical results).

After discussion and consensus, the research team chose the UTHme app, an accessible and free-of-charge app widely used by students of the University of Thessaly. The app requires the student's academic credentials and is therefore downloadable exclusively for students at the University of Thessaly.

Although emerging, health apps in the Greek language are still scarce. The choice of the UTHme app was appropriate because the app already incorporates many features offered by English-language health apps, some of which are:

- Quick access to students' grades, which are entered by academic personnel—a feature commonly used by various health-tracking apps.
- Use of scores to calculate mean student grades and other statistics—a feature commonly used in health calculator apps (e.g., fitness and nutrition apps).
- Announcements and notifications from the E-class platform of courses in which the user is enrolled—a feature used in health apps that offer services such as communication with health professionals, schedule tracking, and recovery activities.
- View and personalization of lecture schedules, planners, calendars, and notifications—very common features in health-education apps that aim to facilitate recovery through increasing user knowledge of the health aspect addressed.

Further benefits of the UTHme app included: (i) accessibility to all students and used to provide easy, on-the-go access to some University of Thessaly services, (ii) does not store user data, which offered compliance with current GDPR and further convenience to our research, and (iii) availability on Android and iOS devices, with a rating of 4.9/5 stars (1,000+ ratings) and more than 10,000 downloads.

Sample and procedure

All participants were 5th- and 6th-grade medical students at the University of Thessaly. All students were native Greek speakers. A paper version of the Greek translation of the uMARS was distributed on demand to individuals who agreed to participate in the project. The final translated version of the uMARS was hand-distributed to a sample group of 91 medical students from the University of Thessaly.

Each participant completed the uMARS twice—once after using the app for a month and then again 4 to 6 weeks later. If necessary, students were allowed to use the app between the two evaluations. Participants were instructed to complete the questionnaire individually and without assistance. Participants handed in completed questionnaires immediately after completion.

Ethics approval was not required because the study involved the translation and validation of the uMARS questionnaire with the participation of medical students who were informed about the study objective. No patients participated and no form of treatment was used in the study.

Data analysis

The internal consistencies of the uMARS subscales and the total score were calculated using Cronbach's alpha. Test–retest reliabilities were calculated for the subscales and total scores of the uMARS after 1 month of app use post baseline (i.e., a test–retest period of 1 month). Interclass correlation coefficients (ICCs)[15–17] were used because they provide weighted values of agreement and assess proximity rather than equality of ratings. To calculate ICCs, a random-effects average measures model with absolute agreement was used. The r_{WG} index was chosen given the skewness of responses.[15] The r_{WG} index is preferred over ICCs for Likert scale measurements and especially when a single group of participants is used.[18]

Data were analyzed with SPSS version 23 (SPSS Inc., Armonk, NY, USA). The reporting of this study conforms to the Standards for Reporting Qualitative Research guidelines.[19]

Results

All 91 students completed the baseline and one-month follow-up app evaluation (100% follow-up rate). All students were native Greek university medical students. The sex distribution was nearly equal, with 51.6% (47) female and 48.4% (44) male participants, and the median age was 23.5 years (range 22–26 years).

The mean scores for each subscale and item of the uMARS in the first and second rounds of evaluation are presented in detail in Table 1.

Internal consistency of the uMARS

The total uMARS score showed excellent internal consistency (Cronbach's alpha = 0.86). The internal consistency of the subscales was also very high, with Cronbach's alphas of 0.71 for engagement, 0.71 for functionality, 0.67 for aesthetics, 0.63 for information, and 0.61 for subjective satisfaction.

The uMARS total score demonstrated almost perfect agreement levels in most of the subscales according to the r_{WG} index from baseline to 1 month. The r_{WG}s for

Table 1. Test–retest reliability of subscales and total scores of the uMARS.

Subscales/items		r_{WG}	Mean (SD) 1st round	Mean (SD) 2nd round
Engagement		0.97	3.56 (1.02)	3.49 (1.03)
1	Entertainment	0.97	3.48 (0.79)	3.54 (0.73)
2	Interest	0.93	3.85 (0.77)	3.82 (0.77)
3	Customization	0.75	2.88 (1.10)	2.55 (1.07)
4	Interactivity	0.92	3.24 (1.03)	3.27 (0.88)
5	Target group	0.95	4.36 (0.71)	4.24 (0.74)
Functionality		0.98	4.15 (0.75).	4.08 (0.74)
6	Performance	0.96	3.90 (0.70)	3.90 (0.70)
7	Ease of use	0.91	4.35 (0.74)	4.18 (0.77)
8	Navigation	0.93	4.22 (0.70)	4.12 (0.71)
9	Gestural design	0.93	4.13 (0.79)	4.11 (0.75)
Aesthetics		0.98	3.78 (0.73)	3.88 (0.75)
10	Layout	0.91	3.90 (0.72)	4.02 (0.75)
11	Graphics	0.96	3.89 (0.77)	3.93 (0.74)
12	Visual appeal	0.93	3.56 (0.67)	3.70 (0.74)
Information		0.97	4.14 (0.67)	4.09 (0.66)
13	Quality of information	0.93	4.04 (0.63)	4.03 (0.67)
14	Quantity of information	0.95	4.07 (0.65)	4.00 (0.67)
15	Visual information	0.94	3.95 (0.70)	3.97 (0.67)
16	Credibility of source	0.94	4.49 (0.57)	4.36 (0.57)
Total uMARS		0.99	3.91 (0.86)	3.88 (0.87)
Subjective items		0.97	3.71 (1.04)	3.71 (0.92)
17	Would you recommend this app?	0.92	4.36 (0.71)	4.27 (0.62)
18	How many times do you think you will use the app?	0.91	3.62 (0.76)	3.63 (0.71)
19	Would you pay for this app?	0.73	2.89 (1,30)	3.12 (1.13)
20	What is your overall rating of this app?	0.90	3.98 (0.63)	3.82 (0.74)

uMARS: user version of the Mobile Application Rating Scale, r_{WG}: index of interrater agreement within the group, SD: standard deviation.

the engagement, functionality, aesthetics, information, and subjective subscales were 0.97, 0.98, 0.98, 0.97, and 0.97, respectively. The question with the lowest interrater agreement queried the willingness of participants to pay for the app (0.73). Test–retest reliability results are presented in detail in Table 1.

Discussion

The Greek app market is continuously growing, and considerable scope exists for progress and improvement in the future. Currently, Greece must urgently reach international standards for health app development, assessment, and appraisal. Therefore, the ability to access validated and internationally acclaimed evaluation instruments is of paramount importance to researchers, developers, and clinicians.

Overall, the various features of an app (i.e., content, design, navigation, usability, and reliability) should be thoroughly tested before use. In the case of mHealth apps, dissemination without the appropriate evaluation of quality may have serious consequences for patients and medical personnel.[20,21]

Despite the availability of several instruments designed to evaluate the quality of

medical apps, a clear definition of the theoretical framework for testing quality is still lacking, and quality criteria remain widely heterogeneous.[22]

This study illustrates that the linguistic validation of the Greek uMARS is consistent with the cross-sectional validations of other languages.[12,23–25] At present, the Greek version of the uMARS is being tested by end users to evaluate the medical app that prompted this project.

A statistically consistent Greek cross-cultural validation process of the uMARS was achieved using a non-mHealth app. The Greek version of the uMARS is consistent with the original English-language version and is a reliable and valid tool for assessing the quality of mobile apps utilized by Greek users.

Potential limitations of our study include the possible negative effects of a study population limited to medical students and the use of a non-medical app (UTHme). However, a medical app typically relies on reminders and notifications to promote maintaining healthy habits. Similarly, UTHme offers planners and calendars, generates course announcements to retain student engagement with their studies, and provides additional information to students. Importantly, our objective was to perform a cross-cultural and linguistic validation of an existing and validated questionnaire that is designed to assess the quality of mobile apps. Our study was not focused specifically on the application of the scale to mHealth research.

Conclusions

We aimed to develop the uMARS in the Greek language and validate its cross-cultural adaptation. The final translation showed strong overall internal consistency (Cronbach's alpha = 0.86); the internal consistencies of uMARS subscales were also very high. Interrater reliability within the group was equally high for all the questions. The availability of the Greek version of the uMARS to the Greek research community will remove a language barrier for the future evaluation of medical apps by patients.

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Author contributions

G. Chasiotis: data collection and management, manuscript writing. S. Stoyanof: Protocol development and critical revision of the manuscript for important intellectual content. A. Karatzas: critical revision of the manuscript for important intellectual content. S. Gravas: study concept, protocol development, supervision, critical revision of the manuscript for important intellectual content, and manuscript editing.

Declaration of conflicting interests

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