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A Nurse-Led Omaha System-Based MHealth App in Managing Symptoms and Improving QoL in Patients with COVID-19: Study Protocol of RCT

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ABSTRACT

Timely management of COVID-19 symptoms at the primary care level is critical. Several mobile health applications have been developed, but they face limitations in data collection, transmission to healthcare professionals, and patient feedback systems. This study outlines a protocol for a RCT to assess a nurse-led mobile app based on the Omaha System in reducing symptoms and improving quality of life in home-monitored COVID-19 patients. Conducted in Kocaeli, Türkiye, 60 participants aged 18-64 will be randomly assigned to groups (intervention=30, control=30). The intervention group will use the nurse-led Omaha System-based app; the control group will receive usual care. Study outcomes include physical, psychosocial, and cognitive symptoms and quality of life in home-monitored COVID-19 patients. The "Problem Rating Scale for Outcome" of the Omaha System will assess status parameters. The SF-12 will assess quality of life, and the System Usability Scale will assess app usability. Data will be collected at baseline, 1st month, 2nd month, and 3rd month follow-up. In conclusion, structured, technology-enabled care models with standardized health terminology are important for improving patient outcomes during public health crises like COVID-19. For the first time, a mobile health app based on the nurse-led Omaha System will be developed to improve symptom management and quality of life in home-monitored COVID-19 patients. The study will provide insight for the implementation of the app in the community.

Keywords: COVID-19, Omaha System, Nursing Informatics, Quality of Life, Symptom Management.

INTRODUCTION

Coronoviruses (CoVs) constitute a diverse group of viruses that are responsible for a range of diseases, from the common cold to more severe conditions [1]. In December 2019, the World Health Organization (WHO) announced unidentified pneumonia cases in Wuhan, China. Researchers soon discovered these were caused by a new coronavirus strain, 2019-nCoV, not previously seen in humans, which led to a swift international spread, resulting in an epidemic of viral pneumonia. In response to the escalating situation, the WHO declared to a "public health emergency of international concern" in January 2020, then to a pandemic status in March 2020 [2].

The Centers for Disease Control and Prevention (CDC) advises that people who test positive for COVID-19, as well as those who might have been exposed to the virus, should self-isolate and monitor any developing symptoms related to COVID-19. This strategy aims to safeguard public health, effectively control the pandemic, and minimize its spread [3]. Additionally, a guideline for managing COVID-19's long-term effects has been internationally published, detailing the infection's prevalent signs and symptoms [4]. According to this guideline, signs/symptoms of acute COVID-19 infection last up to 4 weeks, signs/symptoms of infection in the ongoing prolonged symptomatic period last up to 4-12 weeks, and signs/symptoms of infection in post COVID-19 syndrome last longer than 12 weeks [4]. It has been reported in the literature that the common physical signs/symptoms of COVID-19 are fever, fatigue, dyspnea, cough, chest pain, chest tightness, palpitations, sleep disturbances, headache, abdominal pain, nausea,

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diarrhea, loss of appetite, muscle/joint pain, ear/throat pain, loss of taste/smell; psychosocial signs/symptoms are depression, anxiety, stress, and cognitive signs/symptoms are memory problems and difficulty concentrating [4]-[7]. A multicenter study (2020) found that physical and psychosocial signs/symptoms of patients diagnosed with COVID-19 were common in the acute phase and their quality of life was low [8]. A meta-analysis study (2021) found that 80% of patients diagnosed with COVID-19 had at least one signs/symptoms during the ongoing prolonged symptomatic period [7]. Therefore, it is important to effectively manage the signs/symptoms associated with COVID-19 infection in the community with appropriate interventions in both the early, ongoing and prolonged periods [7]-[9].

Mobile health applications (mhealth apps) have been used in recent years to manage various diseases and their signs/symptoms, and several applications have been developed and rapidly implemented in many countries to manage the COVID-19 pandemic process. The first mhealth app developed were contact tracing applications in Singapore, Italy and South Korea, which inform users about contact with a person infected with COVID-19 [10]-[12]. However, in addition to contact tracing apps, COVID-19 symptom monitoring apps have also been developed in countries such as Spain, the United Kingdom and the Netherlands [10], [13]-[15]. These apps include a series of questions aimed at identifying signs/symptoms of COVID-19, collecting information about the health of individuals, and making differential diagnoses based on the data collected [10], [13]. The primary limitations of these applications are the inability to share collected data with healthcare professionals, their design solely for data collection purposes, and the lack of provision for healthcare professionals to offer feedback to patients [13]. This gap became particularly critical during the COVID-19 pandemic, highlighting the urgent need for comprehensive health data collection and the efficient remote monitoring of patients, enabling timely feedback based on their health condition.

The Omaha System (OS) is a terminology that defines health problems, interventions, and outcomes of care with simple codes, is well suited for documentation of health services, and is used in mhealth apps in several countries [16]. In addition, the system adheres to a structure recognized by HL7 (Health Level Seven), a prominent organization that develops standards in the field of health informatics, accredited by the American National Standards Institute, and is compatible with the JCI (Joint Commission International) accreditation standard [16]. The system is applicable to all healthcare professionals across various patient-centered and community-based settings, incorporates an international health terminology, and possesses the capability to integrate with other software utilized in healthcare facilities. Since the 1980s, the Omaha System has been used in many countries such as Denmark, the Netherlands, New Zealand, Japan, China and Sweden, especially in the USA, to document health problems with a standardized health terminology. In our country, the Omaha System has been used since 2000 in the documentation of the practice of undergraduate and graduate students in various nursing faculties [17]. However, the lack of a mhealth app based on the Omaha System for managing health information in public health institutions in our country is an important deficiency.

OBJECTIVES

The objective of this RCT focus on the usefulness of the proposed nurse-led Omaha System-based mhealth app intervention for decreasing symptoms and enhancing quality of life compared to a control group.

METHODS

Design and Setting:

This research utilized a randomized controlled trial (RCT) framework, deploying a two-arm, parallel-group structure. It involved the recruitment of 60 participants, who were COVID-19 positive individuals receiving outpatient care from a community health facility in Türkiye. These individuals were selected based on predefined eligibility criteria.

The determination of the sample size was facilitated by the GPower 3.1 software [19]. Drawing from a preceding study [20], it was established that a cohort of 30 individuals for each group would suffice to achieve a power of at least 82%, with a significance threshold of 0.05, to discern a minimal effect size of 0.68.

Criteria for inclusion encompassed: (a) being aged 18 to 64, (b) Positive PCR within 24-48 hours, (c) emergence of symptoms within the last 48 hours, (d) exhibiting at least one symptom of COVID-19, (e) undergoing home-based follow-up for COVID-19, (f) ability to read and write, (g) own to a smartphone, and (h) agreement to participate

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expressed through written consent. Exclusion criteria eliminated individuals with: (a) history of COVID-19 infection, (b) vision and hearing impairments, (c) chronic health conditions, (d) mental health disorders, (e) pregnancy and postpartum status, and (f) refusal participate.

Allocation and Randomization:

Participants who met the inclusion criteria were initially contacted by the researcher via telephone. During the telephone conversation, they were informed about the study. Participants were required to confirm their intention to participate in the study during the telephone interview, and the researcher subsequently scheduled an appointment for a home visit. During this visit, detailed information regarding the study's aims and processes was shared, and informed consent was secured from individuals assigned to both the intervention and control groups.

For the allocation of participants, a stratified randomization approach was employed, dividing individuals equally into either the intervention or control group, based on age, educational attainment, and vaccination status against COVID-19 (Figure 1). This process was carried out by an independent statistician not involved in the study.

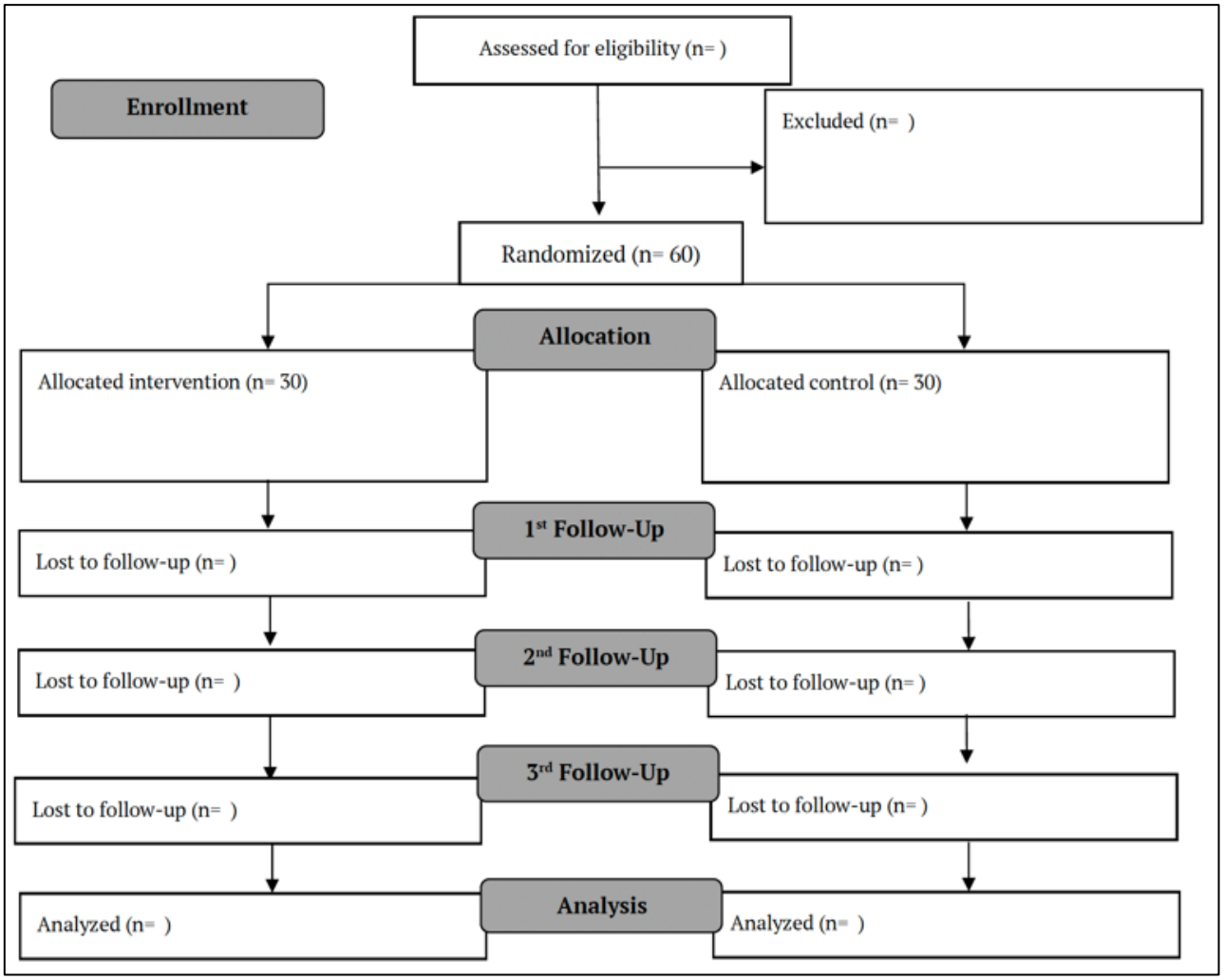

Figure 1. CONSORT Flowchart

Withdrawn Criteria:

Participants were considered withdrawn if any of the following occurred: (1) the participant elected to withdraw from the study at any time, (2) adverse effects were experienced, and (3) significant violations of the study protocol were observed. The reasons for withdrawal and the corresponding date were documented by the researcher.

Strategies for Tracking and Strengthening Intervention Protocol Adherence:

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All participants were invited to contact the researchers when necessary. The contact section in the developed mhealth app was introduced to communicate any problems experienced by the participants in the intervention group to the researchers. Researchers were monitor compliance with the intervention by providing remote access to the research data set via the admin panel. On the dates when the research data should be filled in, a notification was sent via the mhealth app and people was asked to fill it in. In addition, reminder messages were sent to participants in the intervention group who did not fill in the research data on the planned dates and did not watch the videos they were supposed to watch. Participants who do not complete the research data at the scheduled times were contacted via phone call.

Intervention:

The COVOS mobile health application, developed under the guidance of the nurse-led Omaha System, was designed to improve the care of COVID-19 patients at home by addressing their physical, psychosocial, and cognitive symptoms, thereby enhancing their overall quality of life. This study involved a three-month nursing intervention utilizing the COVOS app, with a focus on (1) monitoring the various symptoms experienced by patients, (2) employing the four categories of the Omaha System "Intervention Scheme" for symptom management, and (3) evaluating the outcomes of the intervention.

Conceptual Framework of COVOS:

The development of the COVOS mhealth application is based on the principles of the OS, a globally recognized framework in nursing that provides a structured approach for problem identification across environmental, psychosocial, physiological, and health behavior domains. This system facilitates the creation of targeted interventions and the assessment of their effectiveness [21], [22]. It comprises three main components: the Problem Classification Scheme (PCS) for diagnosing issues, the "Intervention Scheme (IS)" for planning actions, and the "Problem Rating Scale for Outcomes (PRSO)" for evaluating progress. The PCS catalogs potential or existing health concerns, the IS outlines intervention strategies, and the PRSO assesses changes in knowledge, behavior, and status related to health issues. [23].

During the study, the three-month nursing intervention through the COVOS app included (1) monitoring symptoms associated with COVID-19, (2) applying the Omaha System's four IS categories to manage these symptoms, and (3) using the app to evaluate intervention results. The identification of COVID-19 symptoms and the formulation of nursing interventions adhered to global COVID-19 guidelines, incorporating strategies recommended in the "COVID-19 Response Guidelines" by an international research group of Omaha System users [24].

For this project, nursing interventions were categorized into "Education, Guidance and Counselling (EGC)", "Treatment and Procedures (TP)", "Case Management (CM)", and "Surveillance (S)", in accordance with the Omaha System's "Intervention Scheme". The COVOS app included 19 short videos, each lasting between 1 to 3 minutes, tailored to address specific needs within the EGC and TP categories of the Omaha System. For instance, if a patient reported dyspnea, educational content and exercises for managing dyspnea were automatically offered on the app's management interface for COVID-19 symptoms, as depicted in Figure 2. These videos covered various topics, including home care guidelines for patients, medication management, daily life activities, and handling COVID-19 symptoms.

Preparation of Videos

The preparation stages of the videos to be integrated into the COVOS mhealth application are shown in Figure 2. To prepare the videos to be integrated into the mhealth application, current literature on the subject and reports from expert institutions (Ministry of Health, WHO, CDC) are reviewed and video content was prepared. The voice-over program named 'Voicer' was used to voice the content texts of all prepared videos. A paid subscription was created by the researcher for the use of the relevant program. Photographs/videos taken by the researcher and copyright-free images were used in all prepared videos. Animation videos were created using the video preparation program named "Animaker". In this context, a total of 3 videos

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were prepared under the title of "Home Patient Follow-up Rules", 1 video under the title of "Medication Use", 1 video under the title of "Daily Activities" and a total of 14 videos under the title of "COVID-19 Sign and Symptoms Management". A paid subscription was created for the use of the video preparation program.

In the CM category of the OS "Intervention Scheme", an information message was prepared to summarize the situations in which they should contact the health facility.

In the "Surveillance" category of the OS "Intervention Scheme", patients received daily notifications for the initial 10 days, followed by monthly notifications for a period of three months. These alerts served to track COVID-19 related symptoms, with tailored nursing interventions to these symptoms being directly sent to the individuals via the COVOS app. The effectiveness of these interventions was assessed by using the "Problem Rating Scale for Outcomes" status parameter.

For the purpose of evaluation, the videos underwent scrutiny by experts for both their design and informational content. This panel of experts comprised professionals from various nursing disciplines such as public health, mental health, and nursing fundamentals, in addition to community-based nurse and physicians. These experts provided their critical feedback and suggestions on the videos, which were then revised accordingly.

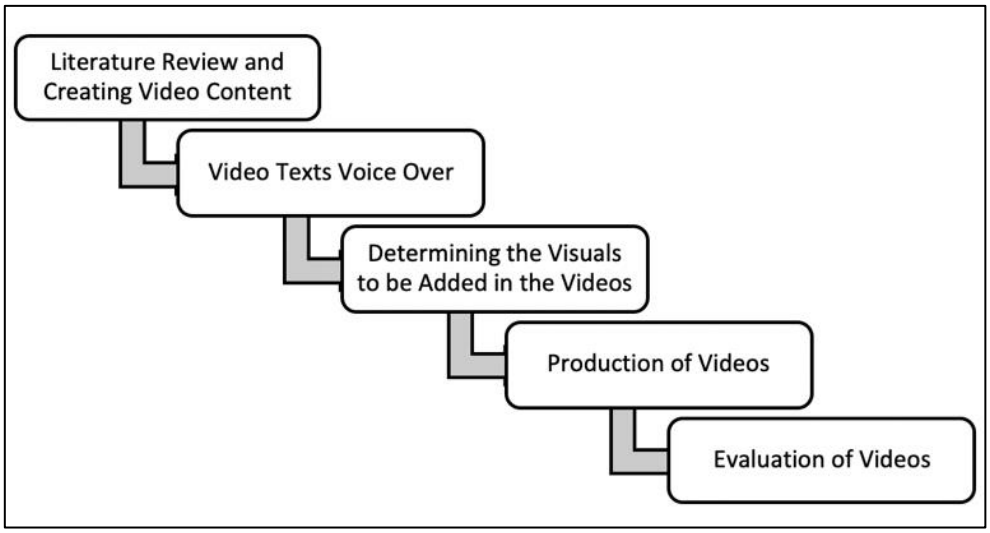

Figure 2. Video Preparation Steps

Development of COVOS:

The creation of the COVOS application was a collaborative effort involving a diverse team of professionals including public health nurses, a user experience (UX) designer, and software engineers. The mhealth app was developed to include all components of the Omaha System. In the study, the list of requirements for the design of the mhealth app was presented to the computer engineer who is develop the mhealth app and the expectations about interfaces and transitions were shared.

The mhealth app (COVOS) to be developed in this study was developed using the Flutter development framework developed by Google and Dart language. The application was developed as distributable on Web, Android and IOS platforms. A web-based management panel was developed for the services (Management, Reporting and Analysis) of the mhealth app. This panel was create the necessary web service infrastructure for the mhealth application to save, update, create and delete data. Web service infrastructure was realized with RESTFul architecture. Web management panel and web services were developed in PHP (Personal Home Page) language using Yii2 development framework. MariaDB server was used as the database of the web management panel. Web management panel and web services were designed with MVC (Model-View-Controller) layered architecture. Traditional waterfall management methodology was utilized throughout the project. Git system and github platform were used for version management in coding and testing processes. User acceptance tests, availability tests, load tests, user experience tests, unit tests

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and system tests were performed. The success results of the tests were evaluated and reporting was made. In this context, the following processes were followed:

Identification of Requirements: The data required for the project was determined and the relevant technologies for development was determined by considering the technological infrastructure and needs.

Analysis: The identified requirements and the suitability and adequacy of the existing infrastructure for the realization of the project was analyzed.

Design: The architectural design of the mhealth application, web management panel and web services were realized. In addition, draft interfaces (wireframes) were designed and user interface designs were made. A User Experience Designer (UX designer) was hired to design the user interfaces. In addition to the interface design, the UX designer was design a unique logo for the application.

Coding: Mhealth application, web management panel and web services were coded in the specified languages.

Testing: External application developers, not affiliated with the study, evaluated the COVOS content, examining its interface design, functionality, interactivity, and privacy features. The study's internal application developer conducted a series of tests, including interaction, accessibility, user acceptance, and system usability assessments, to ensure the application's quality and performance. The content of COVOS was also sent to experts for further evaluation. The experts were academicians working in the field of public health nursing, mental health nursing and nursing principles, and nurses and doctors working in the community. In addition, COVID-19 patients participated in the assessment of the COVOS application's content to verify its accessibility to the intended audience. Based on feedback from application developers, subject specialists, and the target population, appropriate revisions were implemented to enhance the application's effectiveness.

Deployment / Maintenance: Applications were published on Google Play (Android), IOS (App Store) and Web platform. Maintenance was carried out according to the reported errors and update requests, and the previous processes were re-operated and the distributions were re-published.

Procedure:

Patients who meet the inclusion criteria was contacted by telephone and discuss about the study details and schedule a home visit. During this visit, the aims and procedures of the study were thoroughly explained and participants who were willing to participate in the study were asked to sign the informed consent form. Home visits was last an average of 15-20 minutes and the researcher was use personal protective equipment and comply with social distancing rules during the home visit.

Intervention Group:

COVOS application was introduced to the patients included in the intervention group during the home visit and was downloaded from the virtual market (App Store or Google Play) to the patients' phones. Each participant received unique login credentials for the app. They were guided through the initial login process and introduced to the app's functionalities. The screen features in the application was explained to the patient and an information brochure about the use of the application was given. The patient's questions about the application was answered. The patient was then be asked to fill in the data collection forms on the 'Patient Profile' screen in the application. In addition, a kit containing a digital thermometer, saturation device and triflo were given to the patients during the home visit so that the patients can perform self-monitoring, and the usage features were shared in writing and verbally. During the study, the participants were asked to measure their body temperature and blood saturation levels and use the triflo for a total of 13 times, daily for the first 10 days and once in the 1st month, 2nd month and 3rd month. They were asked to record the obtained values on the mhealth app screen.

Patients in the intervention group were asked to watch a total of 5 videos in the categories of 'Home Patient Follow-up Rules', 'Medication Use' and 'Daily Activities' in the mhealth app. After the home visit, outcome variables were assessed at the 1st, 2nd, and 3rd month. In this process, individual-specific interventions (training and exercise videos, reminder messages) for the signs/symptoms reported by the patients in the COVOS application was also made with the COVOS application. According to the signs/symptoms experienced by the patient, the appropriate videos

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from the 'COVID-19 Sign and Symptoms Management' category were shared with the patient and asked to watch. For example, when a participant reports dyspnea, dyspnea management education and exercise videos were automatically posted on the interface of COVID-19 Sign and Symptoms Management.

Control Group:

Data collection forms were filled in during the home visit with the patients included in the control group. A kit containing a digital thermometer, saturation device and triflo were given to the patients during the home visit so that the patients can perform self-monitoring, and the usage features were shared in writing and verbally. During the study period, the participants were asked to measure their body temperature and blood saturation levels and use the triflo daily for the first 10 days and once in the 1st month, 2nd month and 3rd month, totaling 13 times. The obtained values were shared with the researcher during the follow-up by telephone. No intervention was made to the patients in the control group, and the usual follow-up and health services provided by the community health center were continue. Outcome variables were assessed from the patients in the control group at the 1st, 2nd and 3rd month.

Outcome Variables:

COVID-19-Specific Problem Rating Scale for Outcomes (COV-PRSO)

The COV-PRSO was developed based on the PRSO, a component of the OS, which has been validated for use in Turkish (κ = 0.72–0.83) [25]. This scale employs a Likert-type approach, allowing for each issue to be scored from 1 to 5 across knowledge, behavior, and status dimensions [23]. In this study, the Status parameter was used to assess physical and cognitive symptoms. Physical Sign/Symptom Status: Higher scores indicate fewer and less severe physical symptoms. Cognitive Sign/Symptom Status: Higher scores indicate fewer and less severe cognitive symptoms.

Depression Anxiety Stress Scale (DASS-21)

The assessment of psychosocial symptoms status were conducted through the DASS-21 Scale. This tool is divided into three sections, each with seven queries dedicated to evaluating the presence and intensity of depression, anxiety, and stress symptoms respectively. It employs a 4-point Likert scale for responses, ranging from 0 (indicating no applicability) to 3 (indicating high applicability) [26]. The Turkish version demonstrated Cronbach's alpha coefficients: 0.86 for depression, 0.67 for anxiety, and 0.79 for stress [27].

Short Form Health Survey (SF-12)

To evaluate participants' quality of life, the study was utilized the Short-Form Health Survey (SF-12). SF-12, which evaluates eight health dimensions and are compiled into Physical and Mental Component Summary (PCS and MCS), each scored between 0 and 100 [28]. The Turkish version showed Cronbach's alpha of 0.73 (PCS) and 0.72 (MCS) [29].

System Usability Scale (SUS)

The usability of the COVOS application was assessed utilizing the System Usability Scale (SUS). This scale consists of 10 items rated on a 5-point Likert scale from 0 (strongly disagree) to 4 (strongly agree) [30]. The Turkish adaptation demonstrated Cronbach's alpha of 0.78 [31].

Data Analysis:

SPSS (version 20.0) statistical package program was utilized for data analysis, and G Power program (version 3.1) was employed for power analysis. In this study, the intention-to-treat (ITT) approach was implemented, incorporating baseline data for every participant and using mean values to substitute any missing information. The significance level was established at $p< 0.05$. Data were presented as frequencies for categorical variables, means and standard deviations for continuous variables. The Shapiro-Wilk test was employed to analyze conformity with the normal distribution. Fisher's exact test, Yates correction, Mann-Whitney U test and Pearson chi-squared test were utilized to compare categorical data according to groups, and multiple comparisons were conducted using the Bonferroni corrected Z-test. The Independent Samples t-test was employed to compare data that conformed to the

normal distribution according to groups, and the Mann-Whitney U test was utilized to compare data that did not conform to the normal distribution.

Ethical Consideration:

The study was conducted in compliance with the ethical guidelines of the Declaration of Helsinki and also received approval from the Ministry of Health's Scientific COVID-19 Research Platform in the Republic of Türkiye. Furthermore, authorization to carry out the study within a community health center was granted by the Kocaeli Provincial Health Directorate. Ethical approval was obtained by a clinical research ethical committee of an university prior to conducting the trial (August 5, 2021). Registration of this study was cataloged on ClinicalTrials.gov under the identifier NCT 05258734 (February 25, 2022). Prior to their inclusion in the study, all participants were thoroughly briefed on its objectives and methodologies. Written informed consent was obtained from patients who agreed to participate in the study. Measures were taken to anonymize and safeguard the confidentiality of the collected data, with re-identification possible only by the research team members.

DISCUSSION

Addressing the symptoms of COVID-19 promptly and effectively is crucial at the primary healthcare level. To this end, innovative forms of primary care delivery, including digital health solutions, are proposed for the management of COVID-19. Specifically, mhealth applications have proven useful in disseminating information, evaluating patients, and overseeing COVID-19 cases in self-quarantine, adapting to various contexts. Such applications also play a role in decreasing the interaction between healthcare workers and COVID-19 patients, thereby lowering the risk of spreading the virus [32]. Developments in mhealth, including apps for contact tracing, quarantine management, information dissemination, and symptom monitoring of COVID-19, aim to enhance the timely and efficient control of the disease [10], [13]. Nonetheless, these applications face challenges like the collection of structured and standardized data, transmission of this data to healthcare professionals, and a deficiency in feedback mechanisms for healthcare workers to communicate with patients [13]. Therefore, future app designs are advised to monitor COVID-19 symptoms over short and long terms, include evidence-based educational content, and improve the reporting of symptoms to healthcare providers. [9]. In this point, the use of standardized consumer facing health technologies is important in the development on mhealth apps. The use of Omaha System terms seamlessly integrates consumer-generated health data within mhealth apps to reveal the consumer's health perspective [21], [22].

The mhealth application developed in this research, named as COVOS, is a nurse-led, Omaha System-based application designed for the monitoring of COVID-19 symptoms over both short and long terms, inclusion of evidence-based interventions, and enhancement of communication between patients and healthcare providers regarding symptoms. The Omaha System offers a standardized language for identifying health issues, interventions, and care outcomes through straightforward coding [17], [33]. The COVOS application incorporates all components of the Omaha System. The COVID-19 Response Guideline, a global evidence-based guideline developed by the Omaha System International Community during the COVID-19 pandemic, was used to develop nursing interventions within the intervention scheme [24], [34]. The findings from this study will shed light on the management of physical, psychosocial, and cognitive symptoms through the COVOS application and contribute to enhancing the quality of life for patients with COVID-19 being monitored at home.

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