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Bridging the Gap: Community Pharmacists' Burgeoning Role as Point-Of-Care Providers During the COVID-19 Pandemic Through the Integration of Emerging Technologies

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Abstract

Community pharmacies are an under-utilized setting for the provision of primary and preventative care measures, especially the provision of clinical dietary care. The SARS-CoV-2 pandemic presented a unique opportunity to study pharmacist-based nutritional counseling in the absence of ready access to primary nutritional care. In the present interventional pilot study, we analyzed the efficacy of a Clinical Decision Support System (CDSS) for community pharmacy integration on patient weight management, monitoring, and goal setting over a 4-week period. 57 Greek adult patients (16 males and 41 females) of a community pharmacy in the greater Athens area were enrolled in the intervention and subsequently assigned a hypo- or iso-caloric diet according to baseline anthropometric measurements, total daily energy expenditure, medical history, and drug treatment status as assessed by the CDSS. At the end of the intervention period participant weight (kg) and corresponding Body Mass Index (BMI) (kg/m^2) calculations were recorded to gauge sample diet and CDSS recommendation efficacy. Among patients who remained diet compliant to study completion, body weight and BMI were significantly decreased in the hypo-caloric diet group compared to baseline (n=13) (mean difference = -2.685 kg, $p = 0.004$; mean difference = -1.112 kg/m^2, p = 0.004, respectively). No significant change in body weight nor BMI from baseline of iso-caloric diet compliant patients was registered (n=9) ($p=0.273$; $p=0.320$, respectively), succeeding in the purported goal of weight maintenance. This study provides preliminary evidence for the efficacy of a CDSS in assisting pharmacists with nutritional assessment, screening, and sample diet counselling concordant with patient dietary and weight-loss requirements. This trial also builds on emerging research into the broadening purview of traditional pharmacy services in primary care settings.

Introduction

Nutritional and dietary education for medical personnel and clinical providers is woefully lacking globally. Despite the emerging medical consensus that health-aligned nutritional and dietary habits are a sine que non for robust health, disease prevention, and indeed even disease treatment, widespread adoption of nutrition education for healthcare practitioners remains inadequate and misaligned with evidence [1]. An amalgam of factors has been documented as contributing to the relative paucity of nutritional education for clinical use: practicality issues with large-scale diet-based randomized control trials, conflict of interest and lobbying from food manufacturers, scientific disagreement over optimal dietary patterns, contradictory research findings across varying populations and age cohorts, accuracy and verifiability issues with self-reported and memory-based food survey data, intra-foodstuff nutrient profile differences, non-extrapolatable patient-specific nutritional needs, and palatability and preference considerations all contribute to stymie progress in the adoption of nutritional interventions in a clinical setting [2,3]. Further, a clinical paradigm of retroactive pharmacological treatment as opposed to prospective and non-pharmacological preventative treatment has long been the standard of care. Notwithstanding, educating healthcare professionals on evidence-based nutritional counselling has an appreciably positive effect on patient disease outcomes that are comparable and, in some cases, superior to pharmacological intervention without the associated side effect risk profile [4,5].

Overweight and obese status is a major global public health issue associated with significantly increased morbidity and mortality risks [6]. In 2016, the World Health Organization (WHO) estimated that approximately 1.9 billion adults aged 18 years or older were overweight, while 650 million were obese. This 2016 report further reported 41 million children under the age of 5 years as overweight or obese, with over 340 million children and adolescents aged between 5 and 19 years as such [6-8]. In the context of the ongoing Covid-19 pandemic, it is well documented that obesity is associated with a strong increased mortality risk and negative disease prognosis [9-12] while tripling the risk of hospitalization [13,14].

Disease-related malnutrition is a serious challenge in treating patients with chronic or severe illness such as obesity; eventual hospitalization occurs at rates between 30-50% in populations of malnourished patients suffering from both hypo- and hypercaloric nutritional indispositions [6,7]. Many malnourished

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patients with attendant chronic illness are largely underserved by traditional channels of first-line healthcare professionals such as family doctors and general practitioners due to time-constraints, tendencies toward strict diagnostic care, and institutional inadequacies in addressing nutrition-based needs [15]. A gap-bridging role in a patient's nutrition-based healthcare is that of the community pharmacist, a provider considered to be one of the most accessible and trusted of all healthcare professionals [15]. The role of a community pharmacist not only includes the dispensation of prescription medicines and auxiliary medicinal products, but also the provision of services that adapt to their patients' needs, such as nutritional counselling to improve quality of life outcomes [15]. According to the Royal Pharmaceutical Society of Great Britain, the holistic promotion of healthy lifestyles is listed as a primary goal of a pharmacy practice; this belies the traditional view that pharmacists operate strictly within the realm of drug dispensation and safe-use counsel [16].

Relatedly, Clinical Decision Support Systems (CDSS) are computer-based information and data aggregation systems designed to assist clinicians like community pharmacists in implementing clinical guidelines, evidence-based practices related to screening and other preventive services, clinical tests, and treatment at the point of care [17-19]. Patient information is entered manually or automatically through an Electronic Health Record (EHR) system, and CDSSs provide personalized patient assessments and treatment recommendations pursuant to the patient input data.

Manifold applications of CDSSs at varying levels of sophistication exist as an adjuvant for clinical care strategies. At the community pharmacy stratum, CDSSs represent propitious tools for effectively and efficiently improving patient outcomes with empirical and generalizable treatment recommendations. In Greece, community pharmacies are comprised of an interconnected and extensive communication network, an ideal setting for CDSS cross-adoption for health promotion and disease prevention.

During inchoate wave of the Covid-19 pandemic in Greece (between March and June of 2020), certified dietician and nutritionist services remained closed due to the then-urgent restrictive measures taken by the state in conjunction with the ad hoc scientific committee assembled for the management of the health crisis. Pharmacies, guided by the Panhellenic Pharmaceutical Association, remained open throughout and at the height of the pandemic. This unique circumstance accorded an auspicious opportunity to utilize a CDSS that provided nutritional assessment, screening, and a comprehensive dietary plan to evaluate its impact on patient BMI outcomes in the absence of confounding nutrition-based care access to patients. Our pharmacy practice located in Athens, Greece utilized a propriety food database CDSS to input patient data and to provide patients with an evidence-based sample diet according to CDSS output for the respective intervention arm. Our research objective was to evaluate the effectiveness of a CDSS on weight management as well as on weight-related goal setting and monitoring for a community pharmacy patient population.

Materials and Methods

Study Design

Our study utilized a proprietary CDSS called Nutrient® and accompanying food database with the capability to provide a personalized nutritional and physical activity plan as well as lifestyle counseling. It was originally designed and developed by a multidisciplinary team of scientistspharmacists, dieticians, and marketing communication consultantsat the IASO Maternity Hospital for Obstetrics and Gynecology in Athens, Greece in 2018. The CDSS was first used to assist nutritional counseling to oncology patients with breast cancer on an outpatient basis with promising results [20].

In the present study, the neoteric CDSS was introduced to adult volunteers (males and females) in a community pharmacy situated in the southern suburbs of Athens, Greece from April of 2020 to June of 2020. The inclusion criteria were twofold: (i) study participants of ≥18 years of age, and (ii) completion of a 4-week follow up appointment in the pharmacy setting. The community pharmacist who administered the CDSS patient input data of anthropometric measurements, total daily energy expenditure, medical history, and drug treatment was previously trained in the use of CDSS.

The CDSS output provided the following services on individual basis: (1) a nutritional, medical, and physical screening as a generalized patient health assessment; (2) information on potential drug interactions; (3) a weight-goal monitoring and setting program; (4) a calculation of daily nutritional and caloric needs; and (5) the provision of a sample diet according to assigned intervention arm. Weight goals were automatically set pursuant to the CDSS proprietary software recommendations, and the enrolled participants were divided into three diet groups according to CDSS-recommended nutritional needs: DIET-A group, a hypocaloric diet for weight loss; DIET-B group, an isocaloric diet for maintenance of a healthy body weight; and DIET-C group, a hypercaloric diet for restoration of a healthy body weight.

At baseline, each enrolled participant completed an interview with the community pharmacist who recorded anthropometric measurements [body weight (kg), height (cm), and waist circumference (cm)], medical history, age (years), metabolic blood panel measurements at last check-up, physical activity, smoking status, and alcohol consumption patterns. Body weight was measured in the community pharmacy on a standing scale calibrated to 0.1kg of accuracy. Height was measured with a standard stadiometer to the nearest millimeter. Waist circumference was measured with a standard measuring tape to the nearest millimeter. All measurements were performed in duplicate by a single community pharmacist, and the average value was recorded. The community pharmacist also collected information on concurrent medication treatment and the use of nutritional supplements. These data were then registered in the CDSS.

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Drug-Drug and Drug-Nutrient interactions were assessed by the CDSS. The pharmacist provided advice on non-pharmacological nutritional supplements to all participants according to individual need. Personalized advice was also administered on potential drug-herbal-nutrient interactions as necessary [21]. Participant Body Mass Index (BMI) was calculated by the CDSS, as the ratio of average weight (kg) to the square of average height (m2), and was subsequently taxonomized as underweight, normal weight, overweight or obese according to the "WHO, Global Database on Body Mass Index (BMI)" for adults [22]. The CDSS calculated daily nutritional requirements (kcal/day) based upon the recorded Total daily Energy Expenditure (TEE) after incorporating the physical activity factor [23,24] multiplied by the Resting Energy Expenditure (REE) [25]. To calculate REE, participants were provided an opportunity to obtain a recent (within 2 weeks of study participant uptake) measurement of indirect calorimetry [26] performed in a private or public clinic. For those participants who did not perform a recent indirect calorimetry measurement, the CDSS used a proprietary equation to estimate individuals' REE [27-30].

The CDSS lifestyle output section disaggregated physical activity status into the following categories: Limitation of physical activities due to disability, Low Activity, Moderately Active, Active, and Vigorously Active. The CDSS output detailed the metes and bounds of each activity category so as to disambiguate self-reported status for study participants, with comprehensive descriptions of exercise type, time, and intensity as well as sedentary timescales to instantiate proper allocation into physical activity level categories.

Two additional imputation tools were incorporated to approximate participant nutritional status at baseline; (i) the Malnutrition Universal Screening Tool (MUST), a screening tool to identify adults, who are malnourished, at risk of malnutrition (undernutrition), or obese; and (ii) MNA®, a validated nutrition screening and assessment tool that can identify geriatric patients age 65 and above who are malnourished or at risk of malnutrition.

Participants assigned to DIET-A received a hypocaloric sample diet in which daily energy intake was less than TEE, at approximately net -500 kcal/day [31]. Participants assigned to DIET-B received an isocaloric balanced sample diet in which daily energy intake was equal with the TEE in order to maintain body weight. Participants assigned to DIET-C received a hypercaloric sample diet in which daily energy intake was increased by 250 kcal/day based upon participant-specific TEE in order to achieve the ideal body weight for height and age. In accordance with the Hippocratic imperatives of beneficence and autonomy for healthcare providers, participants' health and weight-goal preferences were onboarded by the community pharmacist administrator in intervention placement. Thus, random intervention allocation was not feasible in the present study.

All sample diets were in line with Mediterranean dietary patterns [32-35]. The distribution of nutrients in relation to the total caloric value for each sample diet was as follows: 30% of total energy as fat (<10% as saturated fatty acids, ~10% as monounsaturated fatty acids, and ~10% as polyunsaturated fatty acids), 20% of total energy as protein, and 50% of total energy as carbohydrate. Each sample diet had approximately 300 milligram of dietary cholesterol per diem and 20-30 grams of fiber per diem. Macromolecule proportions remained commensurate between DIET-A, DIET-B, and DIET-C and only varied in total caloric value according to weightgoal intervention placement.

Endpoint body weight measurements (kg) of each enrolled participant was registered in the CDSS at a follow-up appointment after the 4-week intervention period. Weight was recorded in the community pharmacy setting on the same scale on which baseline were recorded, calibrated to .1 kg of accuracy. At follow-up, all participants adhering to their respective sample diet also completed a questionnaire assessing overall subjective results of the CDSS-based dietary recommendations. The structured questionnaire was developed by our research team based on a comprehensive literature review and extensive qualitative research as prior research on subject-perceived efficacy of CDSS-based dietary interventions is nonexistent to our current knowledge [36]. To ensure reliability in the developed questionnaire, we utilized items randomly selected from all factors in the validated USE (Usefulness, Satisfaction, Ease of use) questionnaire developed by Lund (2001) [37] and which was also adapted by Yu and Qian (2018) [38].

Statistical Analysis

All analyses were conducted by applying the Statistical Package for the Social Sciences (SPSS 21.0 for Windows, Chicago, IL, USA). The primary hypothesis was tested with a significance level of 0.05. The Shapiro-Wilk test, Skewness, Kurtosis and histograms were applied for all continuous variables for testing normality. Descriptive statistics were performed, and values are presented as mean plus standard deviation of the mean (SD). A Paired sample t-test was carried out to estimate the mean differences in body weight (kg) and BMI of participants of each group who completed the trial. The Wilcoxon rank test was used for non-parametric continuous variables.

Ethics Approval

The Scientific and Ethical Committee of "IASO Maternity Hospital, Obstetrics - Gynecology" approved the study protocol (approval code: 31052019b). The trial was performed according to the principles of Helsinki Declaration in accordance with the terms of Good Clinical Practice.

Patient Consent Statement

Adult volunteers who agreed to participate in the study were provided with a detailed information leaflet describing the aims, methods, benefits, and potential hazards of the study to establish participatory informed consent. In addition, each recruited participant provided a written informed consent agreement of which participants were instructed to retain a copy.

Results

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At baseline, 57 adult participants (16 males and 41 females), aged between 20 and 86 years, met the inclusion criteria and were included in the study divided into the following groups: DIET-A: losing weight (N=41); DIET-B, maintaining a healthy weight (N=15); DIET-C, restoring weight (N=1). Descriptive characteristics of the enrolled participants at baseline are presented in (Table 1). Twelve participants were under concurrent medication treatment (5 for hypertension, 1 for psychosis, 2 for hyperlipidemia, 1 for diabetes type II, 1 for ulcers in the duodenum, 1 for hyperuricemia, and 1 for angina). All twelve participants under concurrent medication treatment were also taking natural product supplements. All were advised to stop supplementation due to drug interactions as assessed by the nutrient-drug interaction software in CDSS [21,39].

Finally, 22 participants (4 males and 18 females) completed the trial: N=13, DIET-A and N=9, DIET-B. Characteristics of the final sample size at baseline and follow up (4 weeks) are presented in (Table 2).

At the end of the 4-week intervention period, participants (N=22) completed the CDCC assessment questionnaire to evaluate the subject-perceived results of the intervention. To ensure questionnaire reliability, line items were randomly selected from all factors of the validated Usefulness, Satisfaction, and Ease of Use (USE) questionnaire developed by Lund (2001) for integration into the participant outcome survey [37]. The questionnaire was then pretested and subsequently retested to a sample group of 17 people, which demonstrated consistent survey results. All items were measured on a 7-point Likert scale anchored by 1- strongly disagree to 7 –strongly agree (Table 3).

Table 4 shows mean differences in body weight and BMI at baseline before the start of the trial and at the end of the intervention period (4 weeks). The Diet-A group registered a significant decrease in average body weight and BMI as compared to baseline by 2.68 kg (*p=0.004*) and by 1.11 kg/m^2 (*p=0.004*), respectively. Participants in Diet-B registered no statistically significant change in average body weight (*p=0.273*) and BMI (*p=0.320*) at follow up.

Table 1: Descriptive statistics of enrolled participants at baseline

		N (%)	Mean ± SD	Minimum	Maximum
Males		16 (28.1%)	-	-	-
Females		41 (71.9%)	-	-	-
Age (years)		57	51.0 ± 17.0	20.0	86.0
Body weight (kg)		57	78.4 ± 21.2	47.6	183.0
Minimum IBW (kg)		57	53.6 ± 10.4	33.9	78.6
Maximum IBW (kg)		57	65.6 ± 12.5	46.4	96.0
Height (cm)		57	165.8 ± 10.1	144.0	189.0
BMI (kg/m^2)		57	28.6 ± 7.4	17.5	54.6
BMI categories [N (%)]	Underweight	4 (7.0%)			
	Normal weight	21 (36.8%)			
	Overweight	20 (35.1%)			
	Obese class I	8 (14.0%)			
	Obese class II	1 (1.8%)			
	Obese class III	3 (5.3%)			
Intervention groups [N (%)]	DIET-A	41 (71.9%)			
	DIET-B	15 (26.3%)			
	DIET-C	1 (1.8%)			
Total daily energy needs (kcal/day)		53	2645.0 ± 639.5	1454.2	3780.0
Total daily energy intake from sample diet (kcal/day)		53	2234.6 ± 665.3	954.2	3330.0
Total daily energy intake from proteins (%)		53	21.4 ± 2.6	17.0	23.0

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Total daily energy intake from carbohydrates (%)	53	44.4 ± 4.0	42.0	51.0
Total daily energy intake from fats (%)	53	34.2 ± 1.3	32.0	35.0
Physical activity level categories [N (%)]	Disability	3 (6.0%)		
	Low	15 (30.0%)		
	Moderate	22 (44.0%)		
	Active	9 (18.0%)		
	Vigorous	1 (2.0%)		
Nutritional assessment [N (%)]	At risk for Malnutrition	8 (14.0%)		
	At no risk - healthy eating	35 (61.4%)		
	Overnutrition	14 (24.6%)		

Data are expressed as N (%) or mean values ± standard deviation of mean (SD). BMI, body mass index; IBW, ideal body weight.

Table 2: Descriptive charcteristics of the final sample size (22 participants) at baseline and follow up (4 weeks)

	N (%)	Mean ± SD	Minimum	Maximum
Males	4 (18.2%)			
Females	18 (81.8%)			
Age (years)	22	59.7 ± 16.8	34.0	86.0
Body weight at baseline (kg)	22	74.6 ± 15.8	49.0	120.0
Minimum IBW at baseline (kg)	22	49.5 ± 7.9	33.9	67.1
Maximum IBW at baseline (kg)	22	60.8 ± 9.2	47.5	82.0
Height (cm)	22	161.8 ± 8.0	147.0	177.0
BMI at baseline (kg/m2)	22	28.7 ± 6.5		
BMI categories at baseline [N (%)]	Underweight	1 (4.5%)	17.5	41.6
	Normal weight			
	Overweight	7 (31.8%)		
	Obese class I	2 (9.1%)		
	Obese class II	1 (4.5%)		
	Obese class III	1 (4.5%)		
Intervention groups [N (%)]	DIET-A	13 (59.1%)		
	DIET-B	9 (40.9%)		
Total daily energy needs (kcal/day)	20	2363.5 ± 667.0	1454.2	3780.0
Total daily energy intake from sample diet (kcal/day)	20	2013.5 ± 740.9	954.2	3280.0
Total daily energy intake from proteins (%)	20	20.6 ± 3.0	17.0	23.0
Total daily energy intake from carbohydrates (%)	20	45.6 ± 4.5	42.0	51.0
Total daily energy intake from fats (%)	20	33.8 ± 1.5		35.0
Physical activity level categories at baseline [N (%)]	Disability	2 (9.5%)		
	Low	4 (19.0%)		
	Moderate	10 (47.6%)		
	Active	4 (19.0%)		
	Vigorous	1 (4.8%)		
Nutritional Assessment	At risk for Malnutrition	4 (18.2%)		
	At no risk – healthy eating	15 (68.2%)		
	Overnutrition	3 (13.6%)	32.0	

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Body weight at follow up (kg)	22	72.8 ± 14.6	49.0	117.0
BMI at follow up (kg/m2)	22	27.9 ± 5.8	17.5	39.0
BMI categories at follow up	Underweight	1 (4.5%)		
	Normal weight	10 (45.5%)		
	Overweight	8 (36.4%)		
	Obese class I	1 (4.5%)		
	Obese class II	2 (9.1%)		
	Obese class III	0 (0.0%)		
Data are expressed as N (%) or mean values ± standard deviation of mean (SD). BMI, body mass index; IBW, ideal body weight.				

Table 3: Outcomes of the CDSS assessment questionnaire in participants who completed the trial

Question	N	Mean
1. The nutritional education provided to me, helps me to adopt a healthier nutrition diet	22	5.5 ± 1.4
2. The nutritional education provided to me, helps me to adopt a healthier behavior	22	5.0 ± 2.0
3. The nutritional education program provided meets my performance needs	22	4.8 ± 1.8
4. The nutritional education program is easy to follow	22	4.6 ± 1.7
5. The nutritional education helps me to easily understand my clinical condition	22	6.0 ± 1.4
6. It is easy to learn to use the nutritional education system	22	4.8 ± 1.6
7. Overall, I am satisfied with the nutritional education system	22	5.3 ± 1.6

Table 4: Mean differences of body weight and BMI in the final sample size (22 participants) at baseline (time 0) and follow up (4 weeks)

			N	Mean ± SD	Mean Difference	95% Confidence Interval	*P*
Group A	**Weight (kg)**	At baseline	13	81.4 ± 16.5	-2.685	-4.351, -1.019	0.004
		At follow up	13	78.7 ± 15.4			
	BMI (kg/m²)	At baseline	13	32.5 ± 5.3	-1.112	-1.806, -0.417	0.004
		At follow up	13	31.3 ± 4.7			
Group B	**Weight (kg)**	At baseline	9	64.7 ± 8.0	-0.500	-1.480, +0.480	0.273
		At follow up	9	64.2 ± 7.9			
	BMI (kg/m²)	At baseline	9	23.2 ± 3.5	-0.167	-0.530, +0.197	0.320
		At follow up	9	23.1 ± 3.4			

Data are expressed as N or mean values ± standard deviation of mean (SD). BMI, body mass index. *P*: comparison with the baseline values by the paired samples *t*-test or the Wilcoxon test, where applicable; difference was considered significant at $P < 0.05$.

Discussion

Existing literature on the implementation of patient facing CDSSs for nutrition and medication counselling in a community pharmacy setting is limited but compelling at present. Although there remains limited evaluation on CDSS use for weight management in a pharmacy practice setting, several independent reviews have noted improved prescriber practice and patient outcomes by using CDSS-assisted diagnostic and treatment procedures across other various healthcare sectors [17,43].

Recently, Schüttler et al. (2017) found that electronic CDSS implementation for artificial nutrition management is beneficial for the critically ill and greatly reduces the likelihood of medication dosing errors [40]. Similarly, Nije et al. (2015) showed that electronic CDSSs are effective in improving clinician practices related to screening and other preventive care services, clinical tests, and treatments, especially in the assessment and

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management of cardiovascular disease and its associated risk factors in pharmacy [41]. In a 2014 pilot study conducted by the French National Nutrition and Health Program (PNNS), the implementation of a CDSS tool for dispensing nutrition advice to pharmacy patients proved beneficial and was positively reviewed by a cohort of surveyed patients [42]. A systematic literature review on the efficacy of computerized CDSSs on medicine prescribing outcomes by Robertson et al. (2010) showed significant salutary benefits of utilizing a pharmacist assisted CDSS to mitigate medicine safety issues [43]. To reify such benefits, Calloway et al. (2013) provided a case study on CDSS adoption for a large clinical pharmacy practice, finding that computerized CDSS implementation greatly augmented communication and knowledge among pharmacy staff and improved relationships with associated medical staff, nursing, and case management professionals [44].

A limited number of studies have focused on the contribution of community pharmacy interventions to weight management generally [45]. A recent systematic review evaluated ten studies on community pharmacybased weight management interventions, which were conducted in the United States of America (USA), United Kingdom (UK), Switzerland, Spain, and Denmark. The authors concluded that pharmacy-based weight management interventions can produce modest weight loss outcomes in overweight and obese populations [16]. In Australia particularly, the community pharmacy seems to be an ideal setting to aid in obesity management and prevention [15].

Plainly, socio-cultural mores, population health status, legacy healthcare infrastructure, and political climate all conspire inform community pharmacy-based intervention efficacy and its apposite application. In Greece, the community pharmacy holds a number of benefits as a setting for public health intervention. Greece contains the highest number pharmacies per capita in the European Union (97 per 100.000 inhabitants). Greek community pharmacies operate with extended opening hours and without requisite appointment scheduling for medication dispensation service and health consultation. As such, community pharmacy can be more accessible than other comparable healthcare service sectors.

To our knowledge, our pilot study is the first intervention to evaluate an advanced integration of a CDSS that utilizes structured data to forecast optimal nutritional support for patients within the community pharmacy setting. Not only did this intervention result in a significant and robust increase in the nutritional awareness of community pharmacy patients assigned to CDSS-based dietary interventions, but it also demonstrated the efficacy of specific CDSS-generated sample diets for weight loss and weight maintenance within a community pharmacy patient population in Athens, Greece. All adult participants achieved their intervention-directed primary goal of weight loss (DIET-A) or weight maintenance (DIET-B) after the 4week CDSS-assisted nutritional intervention. As operated by a community pharmacist, a CDSS-directed dietary program represents an effective and easy-to-use tool for obesity prevention and management for pharmacy patients and patrons.

Further, our interventional study included a thorough nutrition screening and assessment. Drug interaction and food-drug interaction assessments are vital components of the comprehensive implementation of a safe and effective dietary intervention. In a previous study, our research team evaluated the implementation of a Web-based approach to pharmaceutical care in Greece. We observed that a significant proportion of Greek pharmacists reported that the use of a Web-based drug-food interaction software enhanced their role as health consultants and helped them to improve the quality of services provided [21]. In the present study, 12 participants who were prescribed therapeutic drug medication and were concurrently supplementing with natural products were advised to stop supplementation due to drug interactions as assessed by the CDSS. A CDSS such as the one used in the present study incorporates a Web-based system for detecting potentially hazardous drug interactions in consilience with its patient-specific dietary recommendations, allowing the pharmacist to provide a more fulsome standard of care to the patient.

Study Limitations

Our study had several significant limitations. The initial sample size of 57 study participants is manifestly small, and participant gender parity was not achieved with 16 males and 41 females in the study population at trial outset. Furthermore, a comparatively high attrition rate resulted in only 22 adult participants (4 males and 18 females) completing the trial at the 4-week followup appointment, with 13 and 9 participants in the DIET-A and DIET-B cohorts, respectively. As 4week trial, our study was also not able to capture the efficacy of CDSS-based dietary recommendations for sustained weight management. Participant allocation into dietary intervention arms was not random but rather assigned by CDSS output according to net caloric energy requirements for weight management; participants in the DIET-A and DIET-B cohort may have possessed significant differences in propensity for weight loss and in non-dietary lifestyle patterns not captured by BMI outcome data. Moreover, sample diet adherence was not monitored over the 4week intervention period.

Our study design included the provision of a DIET-C cohort, which provided a hypercaloric sample diet for the purpose of weight gain, however only 1 study participant was assigned to this dietary intervention, and this participant subsequently discontinued study participation. Further exploration on the efficacy of CDSS-recommended hypercaloric dietary patterns is warranted. An additional DIET-D cohort that recommended no change in dietary patterns for the 4-week intervention period to control for potential situational confounders such as ubiquitously reduced access restaurant dining due to state-level lockdown restrictions would have been an ideal inclusion in the trial but was infeasible due to clinical equipoise considerations and financial constraints. Furthermore, it is well documented that BMI can be an imprecise proxy for salubriousness in certain populations [46]. Future study

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should take into account more comprehensive anthropometric measurement and metabolic blood panels at followup.

Finally, the intervention took place in a single community pharmacy setting. Geographic and population selection effects are relevant given that all study participants were prior community pharmacy patients. Our research team has forwarded a future proposal to conduct a similar intervention across several community pharmacy patient populations in Athens, Greece. Further exploration with larger study populations and more robust confounder controls is warranted.

Conclusion

Our findings provide preliminary evidence that use of a computerized CDSS can assist pharmacists in the provision of clinical pharmaceutical and nutritional care in a patient accessible setting, especially in the absence of ready patient access to primary care and nutritionist care as was the case during the early aughts of the SARS-CoV-2 pandemic. These results suggest that a software-based CDSS can serve as a clinically effective tool to detect, evaluate, and ameliorate nutritional health and weight-related problems with the provision of sample hypo-caloric and iso-caloric dietary recommendations pursuant to patient need as assessed by a CDSS. Moreover, CDSS-assisted care can broaden the range of traditional pharmacy service offerings. Adoption of burgeoning clinical care technologies like CDSSs by community pharmacists will benefit both the pharmacy profession and its patients, especially during emergency health situations. We recommend that future research focus on the longer-term efficacy of CDSS-assisted dietary counseling in larger community pharmacy study populations. Further work on the efficacy of nutrition-based CDSSs in ameliorating undernutrition and underweight states via hyper-caloric dietary recommendations is also warranted.

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