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A MIXED RESEARCH STUDY ON THE USERS-CENTERED M-HEALTH MOBILE APPLICATION DESIGN, DEVELOPMENT & SUS EVALUATION ON UTILITY AND USABILITY FOR SELF-CARE MANAGEMENT OF TYPE-2 DIABETES IN URBAN HOME SETTINGS

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Abstract

The m-health application was designed for self-care management of type 2 diabetes and keeping the patient at the core, the application was designed, human-centered focusing on comprehensive self-care management, which included, daily dairy, nutrition, food update, exercise, medicine intake, and nutrition informatics to support for improving self-care management adherence to self-care activities. A mixed research study both qualitative and quantitative exploratory sequential study in an urban population of 18-75 years with type-2 diabetes patients recruited from urban clinics and those who have access to Android mobile. A Sample of N=275 patients was recruited over the telephone, and from health apps, and n=250 was retained in this study. All of them went through self-assessment of Diabetes Based Management System Questionnaires (DBMS) and filled out daily diaries, tracked exercise, food, and nutrition, and were followed up on health applications. The usability and utility of this application were tested and scored using qualitative methods in a sample n=55 using the system usability scale (SUS)global tool and the application was evaluated using 10 points scale of SUS. The study shows overall, the combined improvements in these factors resulted in a substantial 5.1% enhancement in self-care management, highlighting the potential benefits of addressing multiple aspects of Type 2 diabetes self-care management led to an increase in HbA1c improvement by 14.2% of the sample, indicating a positive impact on diabetes management. significant variation ($p < 0.0000$) with a mean square (MS) of 428.2. The Intercept also showed significant variation ($p < 0.0000$) with an MS of 5412. The Gender factor had a significant but relatively smaller impact ($p = 0.0042$, MS = 1250). The final SUS score on the utility and usability of this designed application. X = 5 - the total points for all questions with an odd number. The sum of the points for all even-numbered questions equals Y = 25, or 25. SUS Score = 2.5 times (X + Y). X= 16.6 + Y+ 17.1= 33.7 * 2.5 = 84.25 total score is achieved findings on SUS qualitative assessment, that users find health applications designed useful, easy to use, and helpful for them, therefore utility and usability scores >80 scores in the scale. The Hb1AC improvement reporting had a highly significant effect ($p < 0.0000$, MS = 64.5). reporting of the results will is done at 95% CIs and *P=.0.05*. In n=55 respondents tested with the SUS questionnaire.

Key Words: ***Self-care management, T2DM, Human-centered designs, self-care-oriented mobile apps***

Introduction

One of the most common and chronic diseases in the world, diabetes mellitus type 2 (T2DM) affects people in both industrialized and developing nations. About 95% of diabetic patients have insulin resistance diabetes mellitus (T2DM), which has several risk factors associated with it. Although there is no cure, the disease can be better controlled and managed with adequate self-care management, lifestyle change, dietary intake, and nutrition management along with prescribed medicines. Healthcare systems struggle to deliver high-quality care in the face of a constantly growing population. It is now more crucial than ever to concentrate on self-care management to deal with T2DM problems because of the nature of the disease and the setting of the healthcare system. With more than 537 million cases and a predicted increase to 783 million by 2045 [1, 3], diabetes mellitus (DM), a chronic metabolic condition characterized by persistent hyperglycemia, is one of the top global health problems of the twenty-first century. The illness is divided into T1DM and T2DM, respectively, based on the underlying pathophysiological pathways, decreased insulin production, or insulin resistance by the peripheral tissues. Double diabetes is a condition where both disorders coexist in a person in particular circumstances [1, 2]. T2DM is the most prevalent and rapidly expanding worldwide and in India [3]. Due to the disease's progressive nature, if not appropriately monitored and managed, the condition worsens over time, impacting various organs, developing neuropathy, cardiovascular disease, and retinopathy [3,4]. T2DM is more common in the Middle Ages, although it is also becoming increasingly common in persons over the age of 20. People under the age of 40 tend to experience the disease's early onset. Along with a few other risk factors, environment, and genetics play a major influence in the development of T2DM [5]. People with T2MD, with regular glucose monitoring, and blood pressure monitoring equipment have all shown their importance in the diagnosis, prevention, and treatment of T2MD. Adopting a human-centered strategy also helps the healthcare system, which is already struggling to deal with the demands of a constantly expanding population [4, 6].

One of the most challenging problems for healthcare providers today is meeting the continual demands and needs of persons with chronic diseases like diabetes which is increasing at an alarming rate [6]. Regular follow-ups for diabetic patients are far more crucial and important to prevent long-term problems [6]. Numerous scientific studies have shown that good metabolic control can halt or stop the progression of diabetes problems [5]. Regarding the needs of diabetes patients, these go beyond just keeping blood sugar levels stable to include things like support, rehabilitation, and, changes in lifestyle that can improve and can reverse diabetes [4]. Strong scientific data shows that the general public's lack of health literacy and poor attitude is compromising the treatment's effectiveness. Since there is no permanent cure for DM, it is always crucial to manage the condition efficiently and effectively [5,6,7]. Patients with diabetes can manage their illness on their own for the whole of their lives because it is practically impossible for them to visit medical facilities frequently [7]. Both the American Diabetes Association and The European Association for Diabetes Study support the self-centered care management strategy, which involves regular medication use, sufficient nutrition, physical activity, foot care, and self-monitoring of glycemia levels. People need the necessary knowledge, confidence, and abilities to accomplish this. The major goal of Self-center management is to promote a healthy lifestyle to manage T2DM [5,6].

Self-care management & Nutrition informatics

Type-2 diabetes risk can be significantly reduced in those who followed a balanced diet pattern, which has been shown to have a positive influence on glucose metabolism and diabetes mellitus in general [8]. Fruits, low-fat dairy products, vegetables, and whole grains are recommended daily, but eating less poultry, fish, legumes red meat, and tree nuts is also emphasized [7]. Self-care or self-care management in Chronic Care Management (CCM) can improve health outcomes and it has the potential to reduce the risk of diabetic complications. Use of Mobile phone-based technology or m-health interventions for various global programs focusing on self-care management in cardiovascular

diseases. [7]. Numerous studies are focusing on improving self-efficacy, self-care activities, health-related quality of life, and clinical outcomes for patients. However, m-health applications developed are mostly clinical and do not focus on self-care aspects such as nutrition, diet, exercise testing of blood glucose levels, and tracking of medicines.
The m-health application has the potential to improve support for patients with type 2 diabetes mellitus and it is important to improve patient outcomes by improving self-care, comprehensive self-care management, and incorporating nutrition informatics, and psychological support can assist patients to cope with diabetes and adhering to self-care activities. Most studies addressed healthy lifestyle behaviors like physical activity and testing of glucose. However, integrated management of diabetes with self-care management and following food intake, and nutrition regime can improve health outcomes. [9]. The mobile phone presence has a huge penetration across different socioeconomic groups and ages and provides wider scope in health care, leveraging technology can be useful for self-care management of type 2 diabetes in home settings.

The future appears to be more relying on mobile health interventions (mHealth) that utilize entrenched technology to highlight enhanced utilization of smartphones to help in preventing and managing chronic conditions. which can play an important role. In self-care management. food consumption and nutrition have the potential to reduce glucose levels 9]. Dietary strategies, however, have evolved with the passage of time and the advancement of scientific research [8, 9]. Traditionally nutritional management was involved in restricting high sugar containing foods-fruits, starch, bread, and refined carbohydrates [10]. With fewer carbs, the diet may include an unhealthy quantity of protein and fat. But now the focus remains on a diet with minimum lipids, particularly saturated fats, which can boost cholesterol levels, as well as minimize the protein for those with renal impairment [10]. The new method places a greater emphasis on fat as diabetes patients struggle more with fat [11]. High-fat levels impair the function of insulin, making it difficult for glucose to get into the cells, leading to hyperglycemia. Conversely, lowering body fat and limiting fat consumption let insulin perform its function in a better way [12].

Mobile Health App design and development- Human-centered design of health app

Human-centered designs (HCD) emerged as a powerful configuration to develop satisfying and easy-to-use mobile health (mHealth) applications [15]. Both quantitative and qualitative methods are used for a specific design to provide optimized self-centered care [15]. Although different mobile apps work on different mechanisms the main principle remains the same for all; utilizing patient-generated data to monitor ongoing health conditions through the empowerment of the patients, they are providing the possibilities to promote patient self-care management [13]. Understanding the needs and requirements from both the health care provider's and patient's perspectives, human-centered design applications on mobile are proving more effective [14]. The mHealth app is available on personal mobile devices and usually is patient-facing. The use of such apps is growing with time and is now the second most used app just behind mental health-related mobile apps [16]. The health apps can play a multifunctional role including tracking physical activities, measurement of carbohydrates and nutrition database, weight tracking, sharing data with peers or clinicians, reminders, messaging, and social support. The most important feature which makes it distinct from traditional monitoring devices is having the ability to make the connection between health care provider and patient without the physical presence [16].
Different apps use different reporting formats which may be in the form of graphs, comprehensive reports, or text data which may display the daily sugar level or another important physiological parameter [18]. As these apps keep the individual updated with the current physiological parameters, they assist the patient to adhere to exercise, diet, management plans, and medications which ultimately yield positive outcomes in terms of improving diabetes conditions through self-care management. It is important to mention that mobile app application development testing with users on utility and usability can be beneficial for the ease of use, and features purposes, the user choice whether they

require an app multifunction depending on self-care management required for managing the ailments [18].

The m-health application's human-centered design with testing features, usability, and utility of self-care management of type 2 diabetes in an urban setting, age 20-75 years self-care management in a home setting. The qualitative aspect of the app needs to have various features like tracking of self-diary in which nutrition, physical exercise medicines can be tracked daily. Self-assessment questions DBMS integrated, with features embedded such as rewards, goal setting, chat with FAQs, and WhatsApp group was developed, below is the screenshot from the mobile.

Screenshot 1-7 m-health app HCD Design (Swayam Diabetes)

Diabetes education is an integral part of self-management as per the international clinical guidelines [15]. It is a vital component of diabetes treatment, but most diabetic self-management programs that attempt to aid self-management actions do not provide educational content. Many studies manifested that diabetes education is strongly related to good self-management in individuals with T2DM leading to achieving the HbA1c goal. The T2DM self-care mobile apps also assist the individual with their educational requirements, such as nutritional information, diabetes care guidelines, and solutions to user inquiries from experts. These characteristics can be upgraded in more advanced apps [15, 19].

The feature of mutual communication is the most important way through which apps provide useful information to the health care provider [19]. Based on the provided physiological data, important decisions can by diabetic patients. Recently the complete feedback loop between health care providers and participants can help in reducing the HbA1c at a significant level. Many studies proved that two-

way communication yielded better results. Moreover, the developer and health care provider work mutually to maximize the functionality of the app. For instance, useful information obtained through the medical or specialist team is utilized in an effective way to improve the design of the app and to make it more user-friendly [19, 18]. The traditional way of sharing information always produces artifacts as environmental factors and personal circumstances influence physiological information, but through this feature, these issues can be avoided. Mobile applications are specifically designed to monitor physical activity and measure physiological changing because of an exercise which includes measuring the oxygen saturation level, recording the activity, and grading it into slow, moderate, and high levels. Based on the given data, these are also able to set the goals for the patient and send the alerts according to the set goals. Exercise is the most beneficial activity to control diabetes [20]. Exercise, specifically in T2DM, leads to enhancing the sensitivity of insulin. Importantly, the activity has an immediate effect, leading to a decrease in the glucose level in the blood. Moreover, many studies suggested that during fasting, blood glucose concentration remains constant after exercise, but blood glucose levels decreased in the patient who exercised after taking a meal [20]. Currently, about 9% to 17% of the apps contain personalized data, and a further improvement in upcoming years could result in more positive outcomes [19, 18, 17].

Mixed research study design

A mixed research design both qualitative and quantitative sequential study in an urban population of 20-78 years with type-2 diabetes patients from urban clinics and access to Android mobile. A Sample of N=275 patients recruited from online, clinics and health apps and n=250 was retained in this study. All of them went through self-assessment of Diabetes Based Management System Questionnaires (DBMS) and filled out daily diaries, tracked exercise, food, and nutrition, and followed up on health applications. The usability and utility of this application were tested using qualitative methods in a sample n=55 using the system usability scale (SUS)global tool and the application was evaluated using 10 points scale of SUS. Mixed-methods research employs both approaches that are quantitative and qualitative. exploratory, and sequential use of both methods is used for this mixed research study [15]. The use of mixed approaches would provide both "what?", "why," and from the viewpoint of diabetes and its challenges on self-care management at home using health apps. In this study, the qualitative and quantitative elements are independent of one another, and the data of each component would be investigated individually. The informed consent form was duly used in the study and also data protection norms are followed as per the study protocol. Both the finding of quantitative using SPSS's latest version and qualitative analysis using NVIVO.

SUS evaluation- Qualitative Assessments and Findings

The system Usability Scale (SUS), a tool that has undergone extensive testing worldwide, was used to evaluate the application. Any system or software can be tested with SUS applications, such as mobile apps, websites, digital kiosks, laptops, and equipment [16]. An overall SUS score can be given based on performance in terms of effectiveness and usability [17]. SUS tools as per the research design used qualitative methods to assess the effectiveness of nutrition and mobile health informatics interventions for self-care and at-home care of type 2 diabetes. For data collection FGDs and IDIs, or in-depth interviews, were used in the study along with SUS tool testing. To analyze the findings, utility, and usability of the designed health app for self-care management of type 2 diabetes in a home setting. SUS is a Likert scale., the 10-item System Usability Scale (SUS) is a straightforward scale. In n=55 respondents tested with the SUS questionnaire. The finding is below on the final SUS score on the utility and usability of this designed application. X = 5 - the total points for all questions with an odd number. The sum of the points for all even-numbered questions equals Y = 25, or 25. SUS Score = 2.5 times (X + Y). X= 16.6 + Y+ 17.1= 33.7 * 2.5 = 84.25 total score is achieved stands in grade A and excellent score and findings on SUS qualitative assessment tells that users find health applications designed useful, easy to use, and helpful for them and therefore utility and usability scores >80 scores in the scale.

Study survey- Quantitative method

A Sample of N=275 patients recruited from online, clinics and health apps and n=250 was retained in this study. All of them went through self-assessment of Diabetes Based Management System Questionnaires (DBMS) and filled out daily diaries, tracked exercise, food, and nutrition, and followed up on health applications. To evaluate the effectiveness and usefulness of the built mobile health SUS application and feedback from users. The study also covers the demographic traits of people living in Delhi (NCR) and India, and their relationships to several health-related factors. Age, gender, diabetes status, marital status, the presence of diabetes in other household members, work hours, highest educational level, preferred religion, special dietary preferences, preferred language, the presence of any chronic complications, diabetes health attitude, medical history, diabetes in the family, healthy eating practices, and follow-up procedures are among the variables under investigation. This study aims to find trends and connections between these factors through extensive surveying and data analysis. The study also followed up with users n=55 samples for 4 months period and evaluated whether the use of health apps has any improvement in self-care management of type 2 diabetes and improvement in Hb1AC. The two-way ANOVA results of testing the improvement in HB1AC through two factors: Gender and Hb1AC improvement.

Table 1.1 Frequency of the sample

Components	Variable	Frequency	Percent	Valid Percent
Healthy Eating	No	17	6.2	6.2
	Yes	258	93.8	93.8
Language Preference	Hindi	252	91.2	91.2
	Other	23	8.4	8.4
Religion Preference	Christian	3	1.1	1.1
	Other	51	18.5	18.5
	Hindu	209	76.0	76.0
	Muslim	11	4.0	4.0
	Panjabi	1	0.4	0.4
Marital Status	married	256	93.1	93.1
	Single	8	2.9	2.9
	Unmarried	11	4.0	4.0
Medical History	NO	69	25.1	25.1
	YES	206	74.9	74.9
Diabetes Health Attitude	NO	17	6.2	6.2
	YES	258	93.8	93.8

Information about the distribution of answers for various variables in the dataset is available from the interpretation frequency distribution. It shows how many people responded to each category of the supplied variables. Most participants practice a healthy diet, as evidenced by the fact that 93.8% of respondents who were asked about the "Health Eating" category chose "Yes," while just 6.2% chose "No." 91.2% of respondents in the "Language Preference" field selected Hindi, while 8.4% selected other languages. In terms of "Religion Preference," 76% of respondents said that they were Hindu, making it the most popular option, followed by 18.5% of respondents who specifically indicated "Hindu." Muslim, Christian, and Panjabi religious inclinations all had lower rates, ranging from 0.4% to 4.0%. In terms of "Marital Status," the majority (93.1%) of respondents were married, while 4.0% and 2.9% of them were single. Regarding "Medical History," 74.9% of respondents said "YES," while 25.1% said "NO." In the last category, "Diabetes Health Attitude," 93.8% of respondents indicated a good attitude (YES), whereas 6.2% indicated a negative attitude (NO).

Table 1.2 The testing of the variables

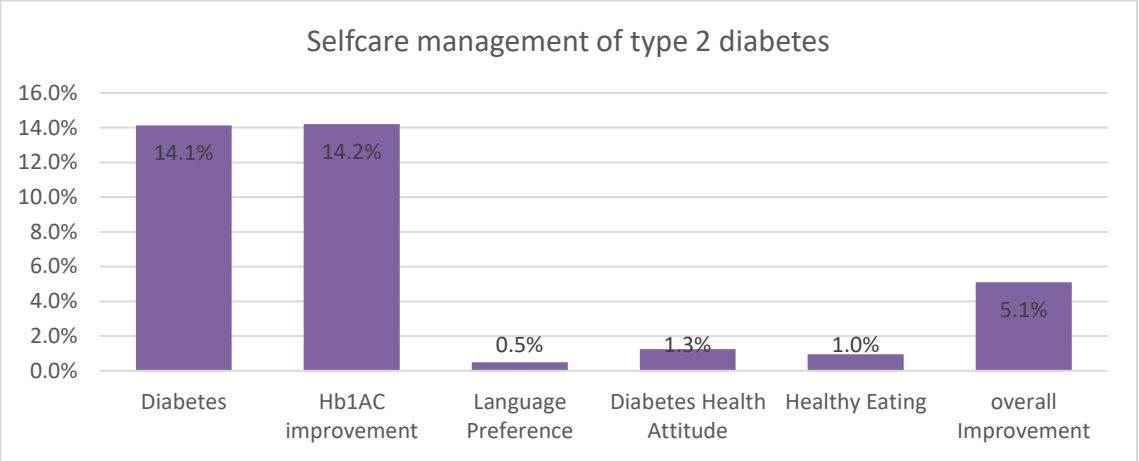
Variable	Subgroup	Mean	SD	95% CI	Testing Value
Religion Preference	Christion	0.8451	0.0070	0.062±0.082	chi-value = 2.0145, p-value =0.0001
	Other	0.1452	0.0058	0.068±0.084	
	Hindu	0.1254	0.0086	0.063±0.082	
	Muslim	0.0114	0.0058	0.073±0.082	
	Punjabi	0.1433	0.0058	0.073±0.082	
Medical History	NO	0.89741	0.0063	0.058±0.082	chi-value = 21.1105, p-value =0.0000
	YES	0.1236	0.0093	0.073±0.080	
Diabetes Health Attitude	NO	0.8974	0.0070	0.062±0.085	chi-value = 4.0744, p-value =0.0052
	YES	0.1423	0.0062	0.067±0.078	
Healthy Eating	No	0.7856	0.0086	0.063±0.079	chi-value = 3.0145, p-value =0.0012
	Yes	0.1483	0.0058	0.073±0.079	
Language Preference	Hindi	0.1447	0.0056	0.058±0.080	chi-value = 2.0145, p-value =0.0012
	Other	0.1483	0.0087	0.064±0.082	
Age	20 TO 35	0.5741	0.0078	0.058±0.080	chi-value = 6.1452, p-value =0.0001
	36 TO 50	0.4571	0.0095	0.056±0.081	
	51 TO 65	0.2631	0.0062	0.056±0.083	
	66 TO 80	0.124	0.0063	0.062±0.084	

According to the chi-square test discussed above, those who identify as Christians have the highest level of religious preference (mean = 0.8451), followed by those who identify as Hindus (mean = 0.1452) and Muslims (mean = 0.0114). The preference of those without a medical history is higher (mean = 0.89741) than that of those with a medical history (mean = 0.1236). Respondents without a positive attitude towards their diabetes health often have a greater preference (mean = 0.8974) than those who have (mean = 0.1423). People who practice healthy eating habits have a higher preference (mean = 0.1483) than people who don't (mean = 0.7856). Both Hindi speakers and those who prefer other languages scored similarly (mean = 0.1483). Preference ratings are greater for younger age groups (20 to 35) and 36 to 50 (mean = 0.5741 and 0.4571, respectively).

Table 1.3 is the testing of the two-way HB1AC improvement.

Item	DF	SS	MS	T-test	P-value
correct Model	5	2141	428.2	78.53	< 0000
Intercept	1	5412	5412	9145.25	< 0000
Gender	1	1250	1250	0.582	0.0042
Hb1AC improvement	2	129	64.5	18952	< 0000
Gender*Hb1AC improvement	2	1464	732	7.264	< 0000
Error	263	7812	29.70342		
Total	274	18208			

The two-way ANOVA table (Table 1.3) presents the results of testing the improvement in HB1AC through two factors: Gender and Hb1AC improvement. The correct model exhibited significant variation ($p < 0.0000$) with a mean square (MS) of 428.2. The Intercept also showed significant variation ($p < 0.0000$) with an MS of 5412. The Gender factor had a significant but relatively smaller impact ($p = 0.0042$, MS = 1250). The Hb1AC improvement factor had a highly significant effect ($p < 0.0000$, MS = 64.5). Additionally, the interaction between Gender and Hb1AC improvement was significant ($p < 0.0000$, MS = 732). The error term had an MS of 29.70342. Overall, the analysis involved 274 degrees of freedom, with a total sum of squares of 18208. The majority of participants practice a healthy diet, as evidenced by the fact that 93.8% of respondents who were asked about the "Health Eating" category chose "Yes," while just 6.2% chose "No." 91.2% of respondents in the "Language Preference" field selected Hindi, while 8.4% selected other languages. In terms of "Religion Preference," 76% of respondents said that they were Hindu, making it the most popular option, followed by 18.5% of respondents who specifically indicated "Hindu." Muslim, Christian, and Punjabi religious inclinations all had lower rates, ranging from 0.4% to 4.0%. In terms of "Marital Status," the majority (93.1%) of respondents were married, while 4.0% and 2.9% of them were single. Regarding "Medical History," 74.9% of respondents gave a response.



Graph 1- Self-care management using a health app designed.

The interpretation of the improvements in various factors related to diabetes, self-care management, and overall health can be summarized as follows.

The study shows a significant increase in HbA1c improvement by 14.2%, indicating a positive impact on type 2 diabetes self-care management. There are also noteworthy improvements in Diabetes Health Attitude (1.3%) and Healthy Eating (1.0%) which may have contributed to better outcomes. Language Preference (0.5%) showed a minor influence. The Hb1AC improvement reporting had a highly significant effect ($p < 0.0000$, MS = 64.5). reporting of the results will is done at 95% CIs and *P=.0.05.* Overall, the combined improvements in these factors resulted in a substantial 5.1% enhancement in overall health, highlighting the potential benefits of addressing multiple aspects of diabetes care and lifestyle.

Conclusion

Self-care management with the assistance of human-centered or user-centered design applications can be an effective way to manage the complications of T2DM. Living a healthy lifestyle physically and through a balanced diet & nutrition is the key to managing complications. The perspective of balanced nutrition and knowledge of self-care management through health application can be very beneficial. Human-centered designed mobile applications, keeping the users at the center can improve the usability and utility features of the application. Self-care management features like a daily diary on food, nutrition, glucose level, physical exercise, and tracking of daily intake of medicines can improve daily tracking, reminding of self-care management goals for a healthy lifestyle. This study can be done in varied populations such as Rural and other demography to understand better self-care management of diabetes and overall health outcomes on the demographic characteristics and health-related variables. This study addresses diabetes self-care management in an urban context and is beneficial for future application and research in this area. Health practitioners might benefit greatly from the research's findings.

Abbreviations-

- *T1DM- Type 1 Diabetes management*
- *T2DM- Type 2 Diabetes Management*
- *HbA1C--Haemolobin A1C test*
- *HCD- Human-Centred Design*
- *Mhealth-Mobile Health*
- *SUS- System Usability scale*

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Authors' Contributions

All authors have contributed to the design of the study, the development of the questionnaire, and the preparation of the manuscript, and have approved the manuscript for publication.

Conflicts of Interest

None declared

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