AI-Based Digital Therapeutics Platform for Obesity Management

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***Abstract*—Obesity is a global problem that has had a significant impact on society and the economy. The consequences are ominous, with serious health risks. Millions of people are dying every year from complications of obesity and comorbidities. Despite efforts by governments and health agencies, obesity continues to rise. Most of the approaches to management and treat obesity have not been successful because they did not shape people's lifestyle and the solutions that were provided for lifestyle modification are not multidisciplinary, they focus on only specific aspects. Obesity management mandates multidisciplinary approach with effective patient engagement, enhanced patient-healthcare provider communication, better adherence to therapy, minimize therapeutic inertia, motivation, more informed treatment decisions by the healthcare provider, and addressing psychosocial conditions. We designed and developed an AI (artificial intelligence) based digital therapeutics platform (named SureMediks) to the multidisciplinary mandate for obesity management and treatment. We tested the efficacy of our proposed platform (solution) with a 24-week field trial and achieved 13.9% weight loss of the initial weight.**

Keywords- obesity; weight loss; digital therapeutics; artificial intelligence; expert systems.

I. INTRODUCTION

Obesity has matched epidemic proportions, with at least 2.88 million people dying every year [1] as a result of being overweight or obese and a whopping economic and social impact of $1.7 trillion dollars [2]. The costs include $1.24 trillion in lost productivity and $480.7 billion in direct healthcare costs [3]. Once associated with high-income countries, obesity is now also prevalent in low and middle-income countries. Government agencies, non-governmental organizations, and the private sectors have been publishing their expert advice as good practices for a healthy lifestyle, in their research and field trials for decades and acknowledge that this pandemic is ever-increasing.

Despite ubiquitous information about nutrition and exercise, more fitness awareness, and more food and activity tracking devices, over 42% of the US adult population is living with obesity [4]. The world obesity rate grew proportionally as well [5]. The statistics show a significant increase from a decade ago, as depicted in Figure 1. The consequences are ominous; obesity is associated with serious health risks including heart, liver, gallbladder, kidneys, joints, breathing disorders, sleep apnea, diabetes, and several types of cancer [6]. Obesity can disrupt the hormonal balance that regulates ovulation and menstrual cycles, leading to irregular or absent periods and reduced chances of conception in women and can impair the quality and quantity of sperm, as well as cause erectile dysfunction and reduced libido in men [7]. The medical community continues struggling to find successful ways to encourage weight loss and provide effective interventions.

Lifestyle intervention faces challenges like compliance issues making weight loss difficult. Despite this, it continues to be a crucial component of obesity treatment. Digital tools augment lifestyle interventions by offering personalized support catering to the need for continuous interaction and support beyond conventional primary care settings. However, there is a need for a more comprehensive approach in utilizing digital tools to address the multifaceted aspects of obesity treatment effectively.

Traditional digital health methods of lifestyle modification have limited effectiveness in managing obesity as they lack multidisciplinary approach and engagement of HealthCare Provider (HCP). The use of AI health coaching and predictive guidance for weight loss [8-11] is comparable with in-person HCP treatment; however, it lacks patient engagement and treatment adherence.

Studies combining approaches and technologies showed better results. A clinical trial conducted showed that the use of a mobile application that used AI algorithms and gamification techniques to provide personalized feedback led to a significant reduction in body weight, body mass index (BMI), and waist circumference [12]. However, there is a need for effective, holistic, adaptive, cost effective, user-friendly, and integrated digital solution to manage obesity.

In the 21st century, AI and health technological advancement have enabled the development of digital therapeutics. Digital Therapeutics (DTx) are defined as evidence-based therapeutic interventions for patients by means of qualified software programs and medical devices to prevent, manage, or treat medical conditions.

Digital therapeutics can be more flexible than other treatment methods to address patients' individual needs [13]. These technologies employ various techniques, such as mobile applications, wearable devices, and online platforms, to improve the effectiveness of treatment interventions [14].

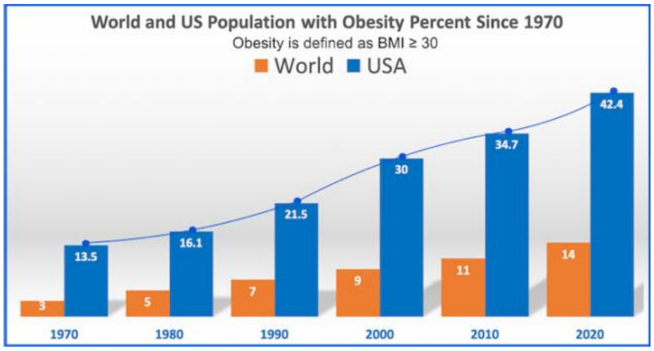

Figure 1: World and US obesity growth in the last six decades.

AI-based DTx would be an ideal complement to the pharmaceutical or even surgical weight loss offerings. AI along with related technologies offer a promising approach for the management of obesity, as they use Machine Learning (ML) algorithms and/or expert systems (ES) to personalize treatment plans for patients. We propose an AI-based DTx integrating all the approaches tried before but individually in a unified single platform, SureMediks. It includes the following approaches and features:

A. Remote monitoring of body weight

Remote monitoring of body weight can help improve weight management outcomes and reduce costs associated with in-person clinic visits. Patients can be provided with digital scales to monitor their weight, which transmits data to a remote monitoring platform such as a mobile app or web portal, allowing healthcare providers to track progress and make necessary adjustments to treatment plans. In a randomized controlled trial (RCT) study conducted among 230 adults, there was a reduction of over 3% BMI among participants who used telemedicine-enabled remote monitoring of body weight compared to the control group [15].

B. Virtual coaching

Virtual coaching can facilitate continuous support and motivation to patients throughout their weight management journey. Healthcare providers can engage with patients through regular phone calls or online messaging using secure platforms. A meta-analysis of 21 RCTs found that by engaging patients in virtual coaching, significant weight loss outcomes could be achieved in a three to six-month period compared to traditional care alone [16].

C. Short-term goals

The weight loss participants who reach their short-term goals have better long-term weight loss [17]. Long-term goals prepare them for a new lifestyle; however, long-term goals are far away and a patient may get lost somewhere in the path in pursuit of the goal far away. It is beneficial to lose weight in a series of smaller short-term goals. The short-term goal achievement effects persist over time, and in fact, induce users to accomplish even more ambitious short-term goals in the future [18]. The successful weight loss, including bariatric Laparoscopic Roux-en-Y gastric bypass operation (LRYGB) conforms to exponential decay [19]. We investigated into mathematical modeling of a successful weight loss behavior and formulated the Khokhar WL Formula [20]. The Khokhar WL formula to generate short-term goals is depicted in the equation below:

$$W_{loss} = \frac{\Delta W}{1-e^{-\frac{r\tau}{10}}}\left(e^{-\frac{rn}{10}} - e^{-\frac{r\tau}{10}}\right);\ r,\tau \neq 0; \qquad (1)$$

Here, $W_{loss}, \Delta W, \tau,$ and r are weight to lose at each short-term goal, total weight loss, time to lose weight in weeks, and r is a special parameter respectively, we called, r, the curve tension. In the formula, n is the week number sequence for short-term weight loss. For example, for n =1, 2, 3, it will determine the required weight loss for the first, second, and third weeks. Figure 2 depicts an example of the short-term weight loss goals for a period of 24 weeks to achieve a long-term goal of 15 Kg. In our implementation, the patient's weight loss curve is dynamically adjusted based on their performance to reinforce their continuous interest and motivation as they see they are achieving their short-term goals. If a patient is struggling with his or her short-term goals, the system detects this and reassigns a different set of short-term goals which are relatively easier to achieve.

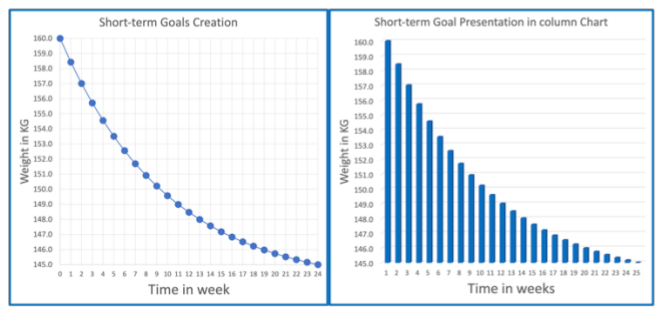

Figure 2: Weekly goals in a curve and columns presentation generated by Khokhar WL formula for 24 weeks period

Conversely, if the short-term goals are too easy for the patients, the system detects this phenomenon and raises the bar a little to keep them motivated and challenged. The SureMediks scale shows the patients their short-term goals on the scale screen along with their overall progress.

D. AI-generated feedback and predictive analyses

Having weight loss tools or platforms available to the patients and the providers to deliver real-time feedback and in-the-moment support may assist the patient with initiating and maintaining changes over the entirety of a day. Technology-based weight loss interventions offer the potential to deliver help at the exact moment necessary to support health behavior change in a way that was never possible before. Frequent and timely feedback to encourage the patients and provide them with support and education shows very productive results and is a key predictor in weight loss [21]. Artificial intelligence offers sophisticated support in weight loss. The intensity of the feedback intervention can be continuously adjusted depending on the patient's weight loss, and it is at a reduced cost compared to a non-optimized intensive intervention [22].

SureMediks, the platform of this study, includes an ES. Expert System is a branch of AI that mimics the decision-making processes of human experts in specific domains. These systems are designed to provide guidance, advice, and recommendations to users based on their input and the knowledge (KB) rules programmed into the system [23]. These rules in KB can be updated as system learns new facts about the patients and their behavior. The integral components of an ES and its operation are depicted in Figure 9. The Knowledge Acquisition System of the ES extracts the expert knowledge and saves (learns) it in Knowledge Base (KB) as rules. Inference Engine (IE) activates these rules based on current and historical data and provides the guidance and education stored and learned in the KB. IE also updates the rules in KB dynamically. Explanatory Systems interprets patient's data and explain to the patients through charts and graphs in the mobile app.

In the context of patients' guidance and education, expert systems can provide personalized and interactive programs for managing and treating various health conditions, including obesity [24] and diabetes [25-26]. These systems can analyze patient data, such as medical history, symptoms, and lifestyle factors, and provide tailored recommendations and interventions to support patients in making informed decisions about their health.

AI feedback system was designed to address the primary barriers to successful weight loss, such as the complexity of dietary information, ineffective motivational strategies, and intermittent physical activity. By delivering real-time personalized feedback, SureMediks helps individuals remain on track, and offer corrective strategies when necessary. Additionally, it offers access to human expert guidance, which can further help individuals develop healthier behaviors that last longer.

E. Guidance through remote interaction and real-time and offline monitoring

The use of remote monitoring, focused on effective guidance, has proved to be a tool to support the care of overweight patients. During the Covid-19 epidemic, remote weight loss patient monitoring has been acceptable to large patients' population [27]. Remote consultation and monitoring, in general, were accepted as an attractive and convenient alternative during the Covid-19 pandemic, not just the weight loss patients, Weight loss behavioral interventions delivered remotely, without face-to-face contact between participants and weight-loss coaches, patients with obesity achieved and sustained clinically significant weight loss over a period of 24 months [28].

With remote guidance and remote monitoring, the weight loss provider imparts a sense of closeness with the patient, which keeps the patient accountable and motivated. This narrative is an integral part of our study and we wanted to have this factor integrated with the other factors for better weight loss results. Our remote guidance and motoring platform (dashboard) were designed to manage, communicate and monitor our participants (patients). The dashboard showed us patients' weight loss progress in real-time or offline. Along with weight loss progress, we could observe the changes in the patients' body metrics such as fats, muscles, metabolic rate, body water, and muscle protein. This gave us insight into how the participants' diet and physical activity are coming along with their weight loss effort. Our coaches then adjusted the relevant guidance for the participants as needed.

F. Motivational and moral support

Motivation is the state of being driven or encouraged to do something or act a certain way. In the context of weight loss, it involves the desire to achieve the desired result, which in our case, is weight loss. Patients' autonomous motivation to participate in a weight-loss program is positively related to their staying in the program and losing weight during the program [29]. Various motivational factors for losing weight may lead to successful weight loss and long-term weight maintenance [30]. Motivational support is such a strong factor in weight loss that a motivation-focused program offers an effective alternative to traditional skill-based programs [31].

The motivation was the center-staged of our program. Each week when the participants fulfilled the weekly target weight the feedback sent by the AI agent had an integrated rewarding and reinforcing motivational message which further strengthened their commitment and motivation. The dynamic and adaptive short-term goals algorithm kept their short-term goals achievable, giving them the sense that they could do it. For those participants who could not achieve their weekly short-term goals, the AI agent sent constructive and supporting motivational messages along with the feedback which held them up and motivated in the weight loss program.

G. Community support and accountability

Numerous studies have indicated that social support can significantly impact weight loss success. The participants who received social support had a greater likelihood of achieving their weight loss goals [32]. Furthermore, the study revealed that participants who received social support experienced a reduced risk of weight regain. In contemporary society, virtual support collaborative communities with common goals and interests flourish. These online communities make salient a context-relevant social identity that motivates behaviors that facilitate compliance to the public commitment, and hence, more effective goal pursuit [33], and play an important role in the participants' weight loss effort [34]. In addition to these studies, another body of research has indicated that individuals who receive support from a group or community are more likely to maintain their weight loss long-term [35]. Accountability can also play a vital role in keeping motivation up in the weight loss journey. Building a support structure around oneself, whether it is through hiring a personal trainer, joining a support group, or seeking advice from friends and family. This will help in holding oneself accountable and keeping them motivated.

Although there is limited research on the effectiveness of a weight loss accountability circle, the available evidence suggests that it is a promising approach for weight management. In a study examining the effectiveness of online weight management communities, participants who received social support and accountability through an online platform were more likely to achieve their weight loss goals than those without support. Another study found that participants who received social support through a mobile phone-based weight management program were more likely to adhere to healthy behaviors and lose weight [36]. Figure 3 depicts SureMediks community support and accountability screenshots.

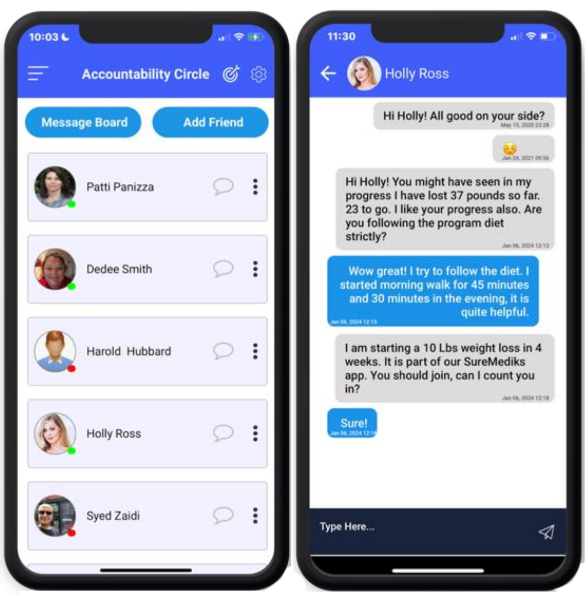

Figure 3: Example of SureMediks accountability circle. The accountability circle members can communicate, see one another progress and engage in gamification challenges.

H. *Instant and interactive communication with weight loss provider*

Several studies have demonstrated the benefits of timely guidance and feedback in weight loss. A meta-analysis of 22 randomized controlled trials found that interventions that included timely feedback were associated with greater weight loss than those without feedback [37]. Timely guidance and feedback help individuals to stay on track with their weight loss goals and to make adjustments as needed. It also provides a sense of accountability, which can be motivating for individuals trying to lose weight. There are several approaches to providing timely guidance and feedback for weight loss. One approach is to use technology-based interventions, such as mobile apps and wearable devices that track physical activity and food intake [38]. Studies have shown that these interventions can be effective in facilitating weight loss and improving adherence to healthy behaviors [39]. Instant communication with patients such as text messages, video consultation, or any other forms of communication as means of behavioral prompting, support, and self-monitoring is more successful in their weight loss [40]. Such instant communication without proper feedback may not be effective [41], which further endorses our idea of providing instant feedback through the providers' guidance as a patient steps on the scale.

I. *Diet and nutrition manager*

The previous studies support the use of managing diet and nutrition as an effective weight loss strategy. Keeping a food journal can increase awareness of eating habits, identify problem areas, and promote accountability. Technology-based approaches to food journaling can make the process more convenient for individuals and may improve adherence. The studies suggest that keeping a food journal is associated with greater weight loss and improved dietary intake. In a randomized controlled trial, participants who kept a food journal lost twice as much weight as those who did not keep a food journal [42]. Similarly, in a study of overweight women, those who kept a food journal lost more weight and consumed fewer calories than those who did not keep a food journal [43]. Technology-based approaches to food journaling, such as mobile phone applications and online websites, have also been found to be effective in promoting weight loss [44]. Consistent tracking is a significant predictor of weight loss, resulting in an additional seven pounds of weight loss over the course of the program suggesting the intervention successfully achieved clinically and significantly long-term weight loss [45].

J. *Physical activity tracker*

Numerous studies have shown a positive correlation between exercise and weight loss. A meta-analysis of randomized control trials conducted [46], found that exercise combined with calorie restriction leads to more weight loss than calorie restriction or exercise alone. Additionally, the American College of Sports Medicine (ACSM) recommends that individuals aiming for weight loss should engage in at least 150-250 minutes of moderate-intensity exercise per week [47]. One effective way to monitor exercise and track weight loss is by keeping a journal. A weight loss and exercise journal can help individuals stick to their goals and track their progress. According to a study [48], participants who kept tracking their physical activity they lose weight and their motivation increases, as they stopped tracking and monitoring, they started gaining weight and their motivation declined. The journaling can also serve as a source of motivation and a reminder of why the individual embarked on the weight loss journey in the first place.

To assess the efficacy of our proposed AI-based DTx platform, SureMediks, we developed a prototype of the platform and set it up for a field trial. The implemented features and expert system's knowledge base were derived from a large research body and field trials mentioned previously in this section. In this paper we report summary of the filed trial and the results.

II. METHOD

This section describes our AI-based platform, SureMediks, field validation covering participants details, procedures and measurements.

A. Platform

The platform, SureMediks, consists of the following key elements: 1) An Internet-connected body composition scale to get patient's weight and related body metrics, 2) A mobile application through which patients receive tailored guidance, education, motivation, communicate with the HCP, interactive with accountability circle members for community support and visually can see the weight loss progress, 3) An AI agent acting as an expert system, 4) Healthcare providers' interaction as an human interface with patients, 5) A dashboard for the HCP to view patients' weight loss progress and interact with the patients, and 6) Optimizing algorithms running in the background.

B. Participants and weight loss goals

A participant sample of 1137 people of age 21 years and older from the USA, Canada, UK, and Australia were invited through emails and a weblink to participate in this field study. They were provided with key screening questions if they were determined and committed to losing weight that year, ready to be strictly focused on weight loss, ready and committed to be on a low-calorie trackable diet with daily trackable physical activity.

Finally, 391 participants took part in the trial from start to end. Of the 391 participants, 59% of the participants were female and 41% were male. Their education level, marital status, and other socioeconomic factors were not part of our selection criterion. However, their current weight, BMI, and age were among the primary concerns as we wanted to have diversity in age and weight buckets. They were diverse in geography and lifestyle; however, these aspects were common; acceptability of using technology in their weight loss effort, determination to lose weight, owning a smart device, phone, or tablet, and having access to the Internet, wired or through cellular data.

Their start (baseline) mean weight, $\boldsymbol{\mu}_{\mathbf{Start}}$, was 124.6 Kg with a standard deviation, $\boldsymbol{\sigma}_{\mathbf{Start}}$, of 31.57 Kg, and a wide range of 65-181 Kg weight distribution as depicted in Table 1. Mean age of the participants, $\boldsymbol{\mu}_{\mathbf{Age}}$, was 43.56 years with a standard deviation, $\boldsymbol{\sigma}_{\mathbf{Age}}$, of 12.60 years, and the range of 21-71 years. Their BMI mean, $\boldsymbol{\mu}_{\mathbf{BMI}}$, was 43.9 Kg/m^2 with SD, $\boldsymbol{\sigma}_{\mathbf{BMI}}$, of 8.5 Kg/m^2 , $30 > \text{BMI} > 25$ was considered overweight and BMI ≥ 30 was considered obesity as per World Health Organization (WHO) generic guidelines. The weight loss goal was 10% of the start weight however we set a stretch goal of 15% as the majority of the participants insisted on raising the bar.

C. Procedure and measures

The participants were provided with a WiFi-enabled smart body composition weighing scale. A mobile app for Apple and Android devices was made available at the Apple App Store and Google Play store which the participants could download free of cost on their respective devices.

The study coordinators and coaches collaborated with the participants through a dashboard. The coaches had their own dashboards which they could log in and manage, communicate, and monitor the participants' progress, food intake, and physical activity. Figure 4 shows the high-level architecture of our implementation. We created six groups of 391 participants with six different weight buckets. Bucket 1 with participants of 65-85kg of weight, Bucket 2 for 86-105kg weight, Bucket 3 for 106-125kg, Bucket 4 for 126-145kg, Bucket 5 for 146-165kg, and Bucket 6 for the participants with the weight of 166-181kg. These six weight buckets had 61, 78, 83, 60, 66, and 43 participants respectively, totaling 391 participants.

The patients' involvement process starts with downloading and installing the app used in this study on their smart devices (phones or tablets). After opening the app, the first step of their setup was to register the smart scale by scanning the scale ID on the back of the scale using the scanning button in the app. Alternatively, they could manually enter the scale ID. Associating the scale ID to each participant's profile is very important as all the key metrics transferred via the Internet from the scale represented the participant's data. Next, they enter their information, including age, height, preferred units (Lbs./inches, Kg/cm), and physical activity level. The desired weight (15% less than the current weight), and duration in which 15% loss to be achieved, i.e., 24 weeks, and their group or bucket number from the list available in the app. After the participants have completed their signup process on their app they are automatically added to their respective coach's dashboard. As they step on the scale the very first time their baseline (weight, BMI, fat mass, muscle mass, and basal metabolic rate) is established automatically, no manual intervention was needed. At that time, the intelligent agent sent them their weekly goals, which they could see in their app and also on the scale. These weekly goals were estimated by the Khokhar WL formula. The curve tension, in the beginning, is moderate, 0.75, and gets adjusted dynamically up and down based on their weight loss performance. Logically one can think of it as hopping from one curve to a more suitable curve dynamically. This is all adjusted by the intelligent agent. If the participants were struggling with one curve, they were moved to the relatively easier curve adaptively. This event was noted in the dashboard as, a sub-goals reassignment. We were interested in the correlation between the percentage of weight loss and the number of sub-goal reassignments.

Each time the participants stepped on the scale they received feedback from the intelligent agent on how they were doing and what they needed to be cautious about. Along with the automatic instant education, guidance, and feedback through AI, their coaches also interacted with them through the text messages which the participants received on their app and could respond back to the coach and video calls through the dashboard. This way the participants had two communication channels with the coach; one through text messages and the other through video calls. Only the coach could initiate the video call. The AI agent had the knowledge base of the weight loss approach. Our objective was to adopt a generic approach to make this study relevant to all types of weight loss approaches. The participants were on a low-calorie diet, designed and supervised by the AI and the coaches. The recommended food items were shown to the participants in the app, they could select the food from that list. If they ate any food out of the list, food library, they could manually enter it in the app. If the participants didn't enter their food in the food journal, they were sent a reminder by the AI agent. Their consumed food got translated into macronutrients, shown to them in the app, and also sent to the dashboard for AI processing and for coaches' records. The participants were guided to a physical activity of their choice from the menu in the app. The physical activity was also tracked by AI and the coach. The participants were asked to step on the scale twice a week; once a week at the least. This was just a guideline; they could step on the scale daily if they wanted. Most participants stepped on the scale two times a week. The participants could view their weight loss progress through charts in their app which included weight loss tracking and key body composition metrics and their coaches could view the same on their dashboards. Based on the information received on the dashboard the coach could send additional informational links on diet and physical activities. The coaches focused on the participants' metabolic rates and weekly weight loss. If the desired weekly goals were not achieved by the participants, the AI agent and the coach sent them strict calorie intake guidelines and instructions.

The participants were encouraged to create their own accountability circle by picking their circle members from any six groups; they were not limited to their own groups. We wanted to record the correlation between the number of accountability members and their weight loss percentage. For each participant, the number of members in their accountability circle was noted by the system automatically. These accountability groups acted as community support groups and proved to be helpful; helping out one another by providing additional moral support. They could interact with one another through an accountability circle and share their progress to keep themselves and the others, motivated.

We set conditions with the AI agent such that if a participant is gaining weight instead of losing, we wanted to be notified by an alert by a text message so that we could intervene timely. This was a great tool to handle unwanted exceptions. The participants were very positive and took immediate measures to correct their diet approach, physical activities, and lifestyle in general.

Through our proposed platform we encouraged participants to take part in the challenges (gamification) which they could initiate within their accountability circle. The app facilitated the challenge creation and follow-up till completion. There were total of six challenges to lose 3% in each challenge. The platform noted how many challenges a participant took part in, as we wanted to see the correlation of these challenges to overall weight loss.

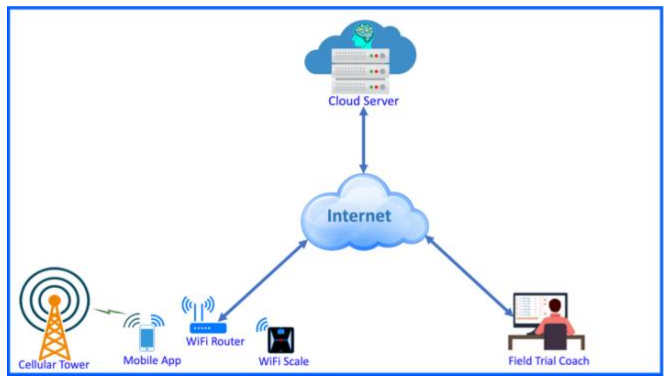

Figure 4: High-level implementation of the architecture: the participants have the scale and app, whereas the coaches have dashboards.

Apart from the community support through the accountability circle, support from the coaches and the AI agent, the participants received a daily motivational quote from the system which would show up on their smart device screen at the scheduled time; different times for the different countries, as we wanted to deliver these quotes in the morning. The quotes were selected by the AI agent based on their progress or the challenges they were facing. This feature of our program was very well received by all participants.

On the completion of 26 weeks of the trial, their weights were noted in the system. The statistics of their weight loss progress are shown in Table 1. In this study, participants received feedback from an intelligent agent (ES) based on their current and historical data, each time they stepped on the scale along with education and guidance through the ES. The flow of ES is depicted in Figure 9. Two sample feedbacks are shown in Figure 5. Coaches also interacted with participants through text messages and video calls. The participants followed a low-calorie diet recommended by AI-based feedback mechanisms and the coaches, with food items shown in the app. Physical activity was chosen from a menu and tracked by AI and coaches. Participants were encouraged to step on the scale at least twice a week and could track their progress through charts in the app. The coaches focused on

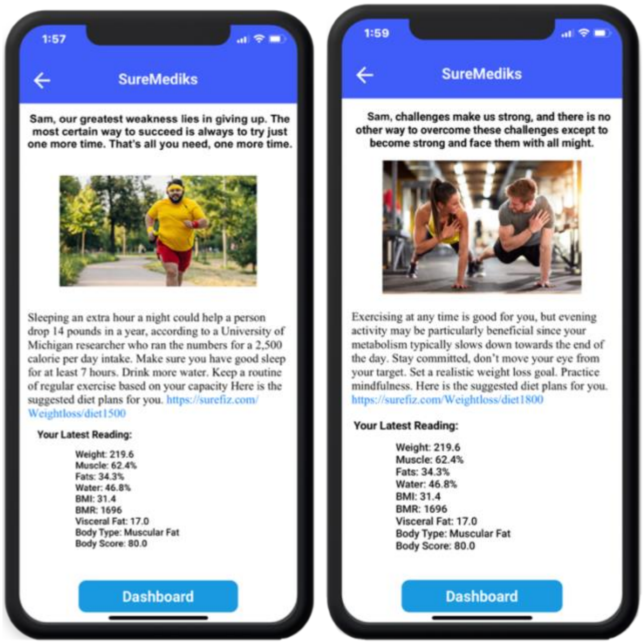

Figure 5: Samples of guidance from the ES, first part is motivational and second part is feedback and guidance.

metabolic rates and weekly weight loss, providing additional guidelines if goals were not achieved. Participants formed accountability circles for support and motivation, and alerts were set up to notify if weight gain occurred. Participants were proactive in making corrections to their diet, physical activities, and lifestyle based on feedback and guidance from the ES.

SureMediks, encouraged participants to engage in challenges within their accountability circle, facilitated by the app. There were six challenges to lose 3% weight each, and the platform tracked the number of challenges participants took part in. In addition to community support, participants received daily motivational quotes selected by the AI agent based on their progress or challenges. After 26 weeks, participants' weekly weights were noted and their weight loss progress statistics were analyzed using MS Excel data analysis tools.

D. Results

The detailed weight loss statistics of each of the six buckets is as follows: For Weight Bucket1, 65-85 Kg, the mean weight loss, μ_{wl1}, was 10.1 kg, standard deviation, σ_{wl1} = 3.4 kg, mean weight loss percentage of 13.3, with a 95% confidence interval (CI) of 12.18% -14.38%, and BMI loss (drop) of 4.3 points. For Weight Bucket2, 86-105 Kg, the mean weight loss, μ_{wl2}, was 13.6 Kg, standard deviation, σ_{wl2} = 4.4 Kg, mean weight loss percentage of 14.2, with a 95% confidence interval (CI), 13.20% -15.19 %, and BMI loss (drop) of 5.2 points. For Weight Bucket3, 106-125 Kg, the mean weight loss, μ_{wl3}, was 15.9 Kg, standard deviation, σ_{wl3} = 5.2 Kg, mean weight loss percentage of 14.0, with a 95% confidence interval (CI), 13.03% - 14.96%, and BMI loss (drop) of 5.9 points. For Weight Bucket4, 126-145 Kg, the mean weight loss, μ_{wl4}, was 19.1 Kg, standard deviation, σ_{wl4} = 5.9 Kg, mean weight loss percentage of 14.5, with a 95% confidence interval (CI), 13.41% - 15.58%, and BMI loss (drop) of 6.8 points. For Weight Bucket5, 146-165 Kg, the mean weight loss, μ_{wl5}, was 19.4 Kg, standard deviation, σ_{wl5} = 6.8 K, mean weight loss percentage of 12.53, with a 95% confidence interval (CI), 11.45% - 13.60%, and BMI loss (drop) of 6.7 points. For Weight Bucket6, 166-181 Kg, the mean weight loss, μ_{wl6}, was 25.5 Kg, standard deviation, σ_{wl6} = 7.3 Kg, mean weight loss percentage of 14.8, with a 95% confidence interval (CI), 13.54% - 16.07% , and BMI loss (drop) of 8.6 points.

Overall, for all 391 participants, 65-181kg, the mean weight loss, μ_{wl}, 17.27 Kg, with standard deviation, σ_{wl6} = 7.0 Kg, mean weight loss percentage of 13.89, with a 95% confidence interval (CI), 13.45% – 14.35%, and BMI loss (drop) of 8.6 points. The p-value was significant, $p < 0.0001$, for all results, confidence interval (CI), 13.54% - 16.07% ,

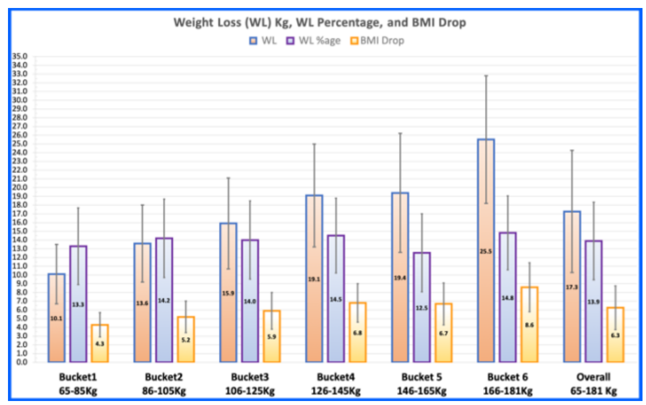

Figure 6: Higher BMI drop with larger weight buckets. the weight loss percentage is similar across all the buckets.

and BMI loss (drop) of 8.6 points. Table 1 shows this data in tabular form. Figure 6 depicts the key results: mean and standard deviation of weight loss, weight loss percentage, and BMI loss (drop).

Figure 7 shows the weekly plotted mean weight loss progress in kilo grams of all the buckets combined (391 participants). In this plot, the Amber curve depicts the weekly weight loss progress for the period of the trial and the Blue line shows the weekly predicted mean weight of the participant per the Khokhar Weight Loss formula (Equation 1). The predicted weight loss curve could serve as the trend curve as well. Figure 8 depicts a typical weight loss progress during the field trial. Both figures demonstrate the predictability and effectiveness of the Khokhar WL Formula as well. The weight loss progress in Amber color line adheres closely with the Blue line, validating the Khokhar WL formula.

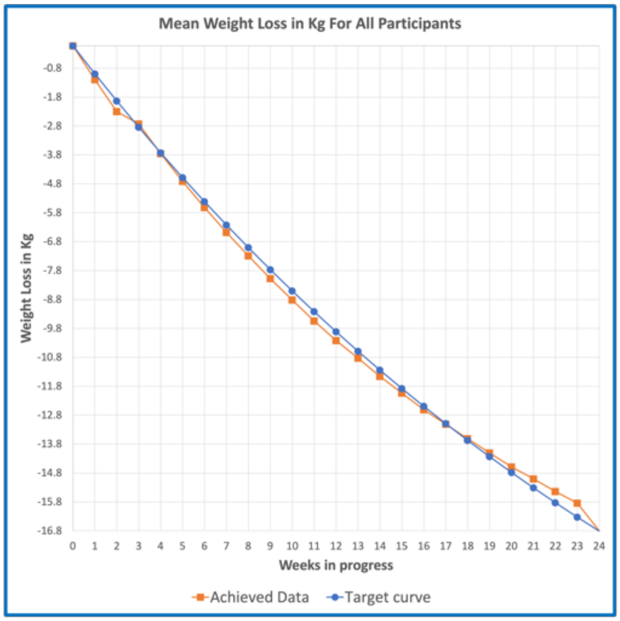

Figure 7: Weekly weight loss progress of all 391 participants. average weekly weight loss was 0.71 Kg.

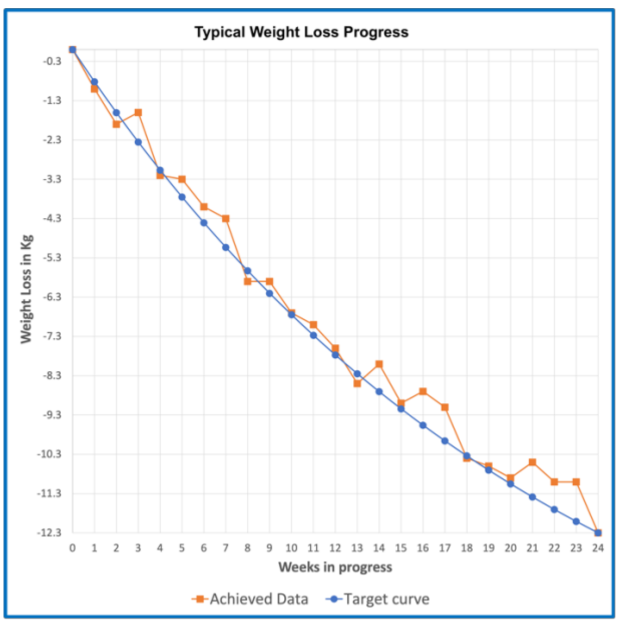

Figure 8: A typical weight loss progress of individual participants.

III. Discussion

This study of digital therapeutics for obesity management in general, and weight loss in particular, suggests that digital platforms are efficient for a weight loss program and can surpass the target of the benchmark of 5%–10% of initial body weight [49-50]. Our goal was to achieve a 10% weight loss of the baseline weight, however, our participants insisted on a higher percentage of weight loss, hence we set a stretch weight loss goal of 15% of the initial weight. Intrinsically the study also manifests that determination plays a vital role in a weight loss effort [51-52]. More significantly, the current study has shown that a bit higher weight loss goal may be beneficial. This is a significant result because there is debate over the wisdom of setting higher weight loss goals [53-54]. However, we agree that the weight loss goals must be reasonable and coherent with the underlying weight loss approach and methodology. There were several driving factors in this study's weight loss outcome: creating short-term weekly goals and dynamically adjusting them, AI guidance, extensive communication and guidance from the coaches, motivation, accountability, and community support, intelligent food journaling, gamification, and physical activity tracking.

Long-term weight loss goals can often seem daunting and overwhelming to individuals seeking to adopt healthier lifestyles. Dividing a large goal into weekly short-term goals made it less overwhelming and increased the participants' sense of control and confidence in the process. Defining the smaller weekly goals resulted in a quick outcome, in a week, precisely. The weekly outcomes helped adaptively adjust diet, physical activity, motivational messaging, and coaches' interaction, which in turn drove a steady weight loss during the study. Additionally, setting smaller goals aided in habit formation. Achieving short-term goals reinforced positive behavior, making it more likely for that behavior to become a habit. Over time, small changes in behavior accumulated and lead to a healthier lifestyle overall [55]. The digital therapeutic platform monitored the short-term goals and accomplishments of the participants. If a participant missed the short-term goals (lagged behind) twice in a row, the short-term goals for that participant were reassigned to a relatively easier set of goals. Table 2 shows a strong negative correlation (-0.679) of weight loss and the number of times sub-goals (short-term goals) were reassigned. It suggests that those participants who missed fewer sub-goals achieved more weight loss.

Every time participants stepped on the scale the AI agent provided them with instant feedback and guidance. Along with other factors, AI's timely guidance played an important role to achieve an overall of 13.9% weight loss. Previous studies [56] support our claim that the implementation of timely guidance and feedback in weight loss interventions leads to better outcomes. Along with the AI guidance and feedback the coaches 'timely and asynchronous guidance further added in achieving the weight loss goal. This body of research further suggests that the use of smartphone applications for weight loss providing frequent guidance (weekly) and feedback lead to greater weight loss than participants without the applications. This is consistent with our study as well. The extensive communication initiated by the coaches kept the diet and physical activity of the participants consistent with their goals and addressed any issues and difficulties they were facing. The key source of success for surpassing the weight loss goal of 10% of initial body weight and approaching 15% weight loss, the stretch goal, is effective communication via AI, text messaging, and video consultation. Such extensive required communication between the healthcare provider and the patient is not in practice, primarily because of the lack of infrastructure or framework needed for this practice.

The motivation was another driving force that directed the participants 'behavior. The motivation to lose weight was derived from various internal and external factors such as achieving better health (this was the case for the majority of the participants), self-esteem, and better physical appearance. Above all, all the participants had been trying to lose weight for a while and had spent a significant amount of money but they did not have a framework to stay motivated and guided. As the participants started seeing weight loss success short-term (weekly), it reinforced their motivation and made a positive impact on their cognitive and emotional well-being [57]. Since the participants had high levels of intrinsic motivation consistently, they got engaged in the required physical activities and initiated healthy social modeling behavior, complied with the diet plans, and exhibited greater levels of peer connectedness using the accountability circle feature in the smartphone app. [58]. Motivation is not a one-and-done incentive; one must stay motivated to reach their desired goals. Regular reinforcement through daily motivational messages, implied motivation in each AI feedback message and guidance, frequent cognitive-behavioral interventions from the coaches, and regular weigh-ins contributed to sustaining motivation leading to their weight loss goal.

Accountability and community support played a significant role for the participants in achieving their weight loss goals with a correlation coefficient of 0.524 ($p < 0.05$) between weight loss percentages and the number of accountability members in the participants 'accountability circle. Accountability means being responsible or answerable for something you do. In the context of this study, this meant that the participants held themselves responsible for their diet, exercise, and staying focused in achieving their weight loss goal. It also meant being accountable to the members of their accountability circle. It kept track of their actions and helped them stay on track. Accountability is one of the most effective ways to achieve desired outcomes [59]. Such support and interventions motivate people to make changes in their diet and physical activity, resulting in a significant role in the process of weight loss. When the participants felt supported, pushing themselves to make lifestyle changes was easier. The impact of accountability circle feedback during a weight-loss competition between men and women played an important role. The study showed that regular behavior feedback led to more significant degrees of weight loss overall. The accountability circle feedback led to a sense of increased stakeholder focus and a notable shift in participants' internal focus resulting in long-term weight loss changes [60]. The participants had agreed during the recruiting and reaffirmed that they would enter the food they consumed in the food journal provided in the mobile app. They adhered to the commitment. Journaling their food assisted them in becoming more mindful of their food habits, reducing their impulsive eating or extreme dieting behaviors, and leading to improvements in healthier food choices. Food intake journaling facilitated weight loss by increasing dietary awareness and reducing caloric intake while increasing physical activity [61]. This approach provided the participants a constant reminder, keeping foodless habitual rather than a source of enjoyment. Journaling has broader use beyond weight loss. Food journals not only positively influenced motives to adhere to healthy food choices, but also supported in identifying dietary triggers [62] and an improved relationship with food. Along with the direct benefits of food journaling to the participants, the reporting of their food consumption to the coaches and the platform further enriched the guidance and feedback delivered to the participants. Similarly, tracking and reporting physical activity played a motivational role in the participants' weight loss [63]. Quantifiable activity tracking data, such as calorie burn or weekly changes in preferred routines resulting from tracking metrics, encouraged the participant's regular self-monitoring behavior adoption [64].

In summary, for weight and obesity management, a comprehensive approach with the optimal use of technology is effective and should be incorporated in weight loss practices and clinics. Inducing motivation and determination into the patients along with frequent and effective communication will keep them in the right direction regardless of the rate at which they lose weight. Technology is the best vehicle to deliver effective and sustained results.

IV. CONCLUSION AND FUTURE WORK

Consistent weight loss needs a multidisciplinary approach. Determination, motivation, effective communication, diet, physical activity, accountability, and tailored guidance and education are vital elements. Digital therapeutics for obesity have the potential to significantly improve patient adherence and treatment outcomes and can deliver a framework where these key elements asynchronously and coherently work for the best patient-HCP engagement and optimal patient outcome. It is a promising way to address the global pandemic of obesity and warrants significant investment for further development. AI plays a vital role in delivering tailored guidance and education to the patient and catalyze the effectiveness of DTx. With a properly designed and operated digital therapeutics platform surpassing the benchmark of 10% weight loss in 24 weeks is feasible with an effective diet and physical plan along with the vital elements of a multidisciplinary approach, which a DTx platform can deliver effectively using ES.

Our future work is focused on studying how SureMediks can effectively complement medical weight loss with Glucagon-Like Peptide (GLP-1) and similar weight loss medication and post metabolic surgery weight loss.

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Table 1: Weight loss statistics of 391 participants in their weight buckets and the overall weight loss. Weight units are in Kg

	Weight Bucket 1 *65-85 Kg*	Weight Bucket 2 *86-105 Kg*	Weight Bucket 3 106-125 Kg	Weight Bucket 4 126-145 Kg	Weight Bucket 5 146-165 Kg	Weight Bucket 6 166-181 Kg	**Overall**
No. of participants	61	78	83	60	66	43	**391**
Start weight mean, μ_{Start}	76.0	95.8	113.5	135.2	154.8	172.1	**124.6**
Start weight SD, σ_{Start}	6.1	3.3	6.1	5.8	5.2	4.5	**31.57**
End weight range	52-79	69-94	85-119	101-131	118-151	132-159	**52-159**
End weight mean, μ_{End}	65.9	82.2	97.6	115.6	135.4	146.6	**107.21**
End weight SD, σ_{End}	6.2	6.6	6.8	7.2	8.6	8.1	**24.7**
Weight loss range	4-18	4-21	5-26	5-29	7-32	7-37	**4-37**
Weight loss mean, $\mu_{Wt.loss}$	10.1	13.6	15.9	19.1	19.4	25.5	**17.27**
Weight loss SD, $\sigma_{Wt.loss}$	3.4	4.4	5.2	5.9	6.8	7.3	**7.0**
Weight loss percentage	13.29	14.20	14.00	14.50	12.53	14.81	**13.89**
%age weight loss 95% CI & p-value	12.18 - 14.38 $p < 0.0001$	13.20 - 15.19 $p < 0.0001$	13.03 – 14.96 $p < 0.0001$	13.41 – 15.58 $p < 0.0001$	11.45 – 13.60 $p < 0.0001$	13.54-16.07 $p < 0.0001$	**13.45-14.33 $p < 0.0001$**
Start BMI mean	31.9	36.7	42.2	48.6	52.6	57.4	**43.9**
Start BMI SD	3.0	4.1	4.7	6.0	6.5	6.2	**8.5**
End BMI mean	27.6	31.5	36.3	41.8	45.9	48.8	**37.6**
End BMI SD	2.7	3.8	4.1	5.8	5.7	5.6	**8.5**
BMI loss	**4.3**	**5.2**	**5.9**	**6.8**	**6.7**	**8.6**	**6.3**

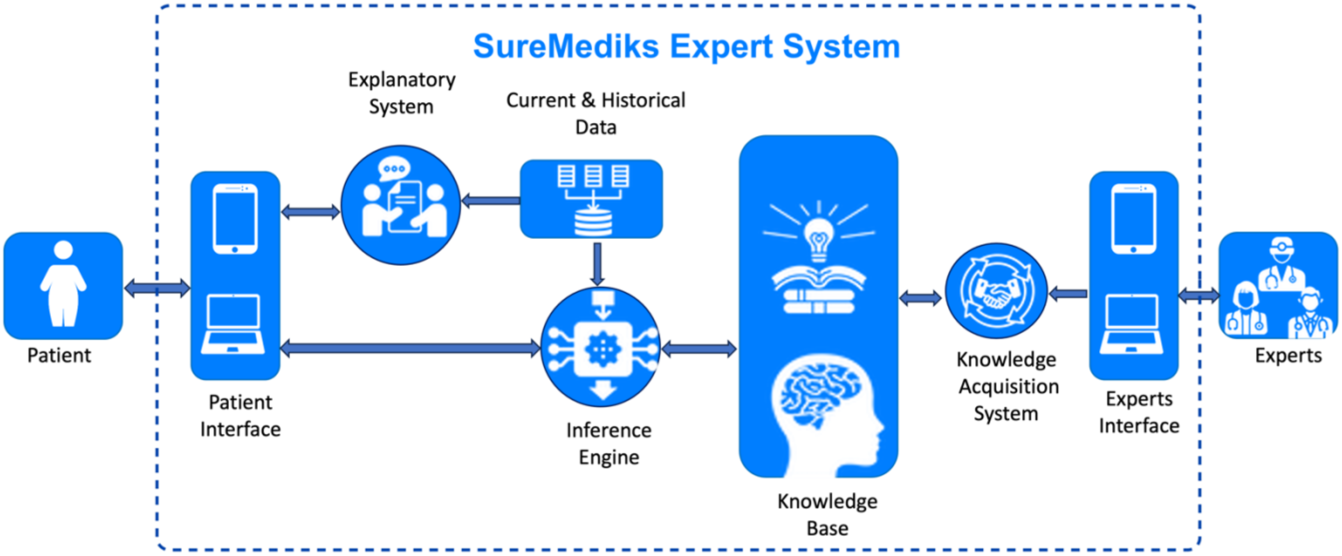

Figure 9: Distributed Architecture and the operation flow of our SureMediks Expert System.

Table 2: Bivariate correlation between study's additional parameters along with p-values

	Weight loss %age	Age	Sub-goals reassignment	Accountability circle members	Challenges participation	**Gender**
Weight loss %age	1					
Age	-0.103 $p < 0.05$	1				
Sub-goals reassignment	-0.679 $p < 0.05$	0.029 $p = 0.56$	1			
Accountability circle members	0.523 $p < 0.05$	-0.050 $p = 0.32$	-0.556 $p < 0.05$	1		
Challenges participation	0.639 $p < 0.05$	-0.125 $p < 0.05$	-0.380 $p < 0.05$	0.348 $p < 0.05$	1	
Gender	0.101 $p < 0.05$	0.039 $p = 0.43$	0.0284 $p = 0.57$	-0.023 $p = 0.64$	0.060 $p = 0.24$	**1**