A Step Therapy Approach to Diabetes Prevention, Overweight and Obesity Management:

Integrating mHealth Interventions in Clinical Care

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Overweight and Obesity: Impacts and Approaches to Promote Weight Reduction

Excess body fat prevalence rates in the US population remain high and pose a public health threat [1]. Overweight status (BMI ≥ 25 kg/m^2) is found in 71% of the adult population. Obese (BMI ≥ 30 kg/m^2) adults constitute more than 36% of the adult population[2].

The subsequent burden of obesity on medical care is severe [3]. Obesity-related conditions include heart disease, stroke, type 2 diabetes and certain types of cancer, which constitute some of the leading causes of preventable death [4]. The increased consumption of medical services as a result of this sequelae is more than $1,400 per year higher than normal weight (BMI <25-18.5 kg/m^2) adults [3].

A significant segment of the overweight and obese population reports wanting to lose weight [5]. Weight loss of as little as 5% has been observed to ameliorate many adverse health effects of excess body weight [4] including cardiovascular disease [6]. Self-directed attempts and low intensity weight loss programs (e.g., commercial and over the counter programs) dominate the available options for most individuals. The marketplace appears to be dominated by commercial products with little follow-up or maintenance support for participants. High intensity interventions including health professional consultation and readily available meals and meal replacements require time, out of pocket costs and access beyond the reach of many adults. The marketplace also includes some commercial products with little scientific basis and isolated testimonials in advertising.

The updated consensus national guidelines on weight loss and the management of obesity were published in 2013 and have changed little since initially published in 1998 [7-9]. Weight loss through programs that adhere to these guidelines have proven successful in producing 5-10% weight loss or more through individual or group sessions [5, 10, 11]. A meta-analysis and systematic review of 66 studies including behavioral (diet or exercise or lifestyle or combination) approaches, reported on average a 3.13 kg greater weight loss in the intervention group compared to control group participants. A high prevalence of weight re-gain, as behavior changes erode to previous habits, is commonly observed among participants following program completion [12, 13]. An integrated framework including clinical and community systems to combat obesity and related long-term conditions has been suggested as a required innovation for successful long-term weight loss maintenance [14, 15]. A diabetes prevention program (DPP) has been developed and proved successful in reversing participants from a diagnosis of pre-diabetes to normal glycemic control [16]. Recently the Center for Medicaid and Medicare Services (CMS) has approved a 16-week group session format of the DPP for Medicare Beneficiaries with reimbursement to certified providers [17]. Digital health versions of the DPP have been developed and favorable outcomes reported [18].

The high prevalence of Internet and smartphone-based weight management programs creates an opportunity for wide-spread access to interventions. The introduction of mobile health (mHealth) including the use of smartphone/tablet applications (apps) in the scientific literature related to nutrition and weight management first appeared in 2011 and has grown dramatically beginning in 2013 [15]. Apps available through commercial stores such as the Apple Store and Google Play are numerous. More than 30,000 mHealth apps are estimated to be available [19]. The accessibility, low cost, and ease of entry for users to document physical activity, body weight, and record food intake, goals and personal preferences helps drive interest in these types of apps. Recording daily behaviors related to body weight, dietary intake, and intentional physical activity has been associated with increased likelihood to lose and maintain weight loss [20].

The prevalence of adults with overweight and obesity has not declined in the face of this surge in mHealth app availability for weight loss [2]. Few of these apps appear to be based on available scientific principles [21]. A step-therapy approach, common in pharmacologic treatment regimens, has been suggested in the national consensus guidelines to treat overweight and obesity [8]. The recommendation includes matching patient risks with intervention intensities integrated with a strategy to increase program intensities until a healthy body weight is achieved and maintained.

mHealth Weight Management Apps

Comprehensive behavioral weight management programs are typically comprised of several components including: decreased caloric intake, increased physical activity and daily self-monitoring. These components are derived from cognitive behavioral change strategies to shape healthier habits and limit regression to previous behavioral patterns. When in-person group sessions or personal counseling are not available, remote or electronically delivered programs are suggested with professional oversight. The lower intensity of electronically delivered interventions typically resulted in less weight loss than in-person interventions [22].

The advantages of mHealth for weight loss can be leveraged as adjunctive support during face-to-face programs or as a lower intensity option, typically at less cost than in-person interventions. The portability of smartphones/tablets allows mHealth users to access resources, such as restaurant menus, healthy recipes and grocery lists while on the go and at the point of purchase. In addition, the use of mHealth facilitates frequent opportunities for patients to receive feedback from clinicians and experts in weight management (registered dietitians, exercise physiologists, and behavioral specialists) in real time or via asynchronous (i.e., previously recorded) feedback. mHealth affords the expansion of opportunities for patients and clinicians to interact to increase communication and tailored feedback to improve patient diet, activity, and other relevant behaviors for weight loss and weight loss maintenance.

Challenges are present when considering the implementation of mHealth interventions. Methodological issues need to be considered when research is conducted. These challenges are presented below [22].

Study participation
The taxonomy of adherence, engagement and participation poses a threat to the interpretation of results. Erosion occurs in virtually every study. Recording a daily weight may be simple adherence and not necessarily engagement.

Participant Group Diversity
Sample frames of convenience that draw upon users who are more educated and white are not representative of the general US population.

Inaccurate Data Collection
Studies that report outcome variables based on self-reported data is inherently inaccurate. Dietary recall challenges are well documented in nutrition and weight management research. Body weight gathered from home scales lacks standardization and calibration. Accelerometers, pedometers, and activity trackers can vary based on manufacturer and inconsistent use by participants.

Heterogeneity of Technology Components
Many studies will group a series of mHealth features in an intervention set. The literature is not as informative on single individual features such as text messages vs. phone call or Internet content and respective efficacy [23].

Data Security
Although data security may not pose a threat to any single research project, protecting the privacy of participants is a concern. This security aspect is not known or disclosed in the most commercial applications.

Rapid Innovation
The onset of rapid innovation of new mHealth products threatens the deliberate pace of research and scientific discovery. Newer research methodologies may need to become more widespread to keep pace, as technology quickly advances.

The evaluation of mHealth in an implementation research setting is uncommon. The literature is less informative of the generalization of mHealth techniques and applications in practical use across large populations.

The features of mHealth apps (specifically self-monitoring, etc.) have been observed to have a positive impact on nutrition and weight management. The comprehensive evaluation of guideline based mHealth applications in applied settings is not found.

The success of meal replacement diets for short-term weight loss is an example of individuals avoiding the poor choices found in grocery stores, restaurants and fast-food options [24].

Characteristics of mHealth Users and App Features

Weight loss interventions typically target behavior change in specific areas including decreased caloric intake, increased physical activity and daily self-monitoring of diet, weight and activity. Among the US adult population, 64% use a smartphone [19]. A recent survey of mHealth app users reported the following characteristics of this population as: generally younger, more affluent, white, more educated, urban dwellers with a lower prevalence of obesity [25].

< 65 years of age	98%
< 35 years of age	50%
Income > $75,000/year	53%
White Race	71%
Regular Medical Provider	63%
> High School Education	89%
Employed	71%
Urban Resident	90%
< 2 long term conditions	85%
Obese, BMI >30 kg/m^2	9%

A cross-section of 1,600 mobile phone users in 2015 was conducted by Krebs and Duncan. Fifty-eight percent of users had downloaded a health related mobile app. Fitness and nutrition were the most common app types downloaded. Almost one-half of participants who previously downloaded a mHealth app ceased app use at the time of survey completion. Reasons cited for app withdrawal included high data entry burden, loss of interest, and hidden costs (e.g., in-app purchases) [26].

The most commonly reported strategies found in self-help weight loss programs are listed below (from most to least commonly reported) [27]:

- Self-monitoring
- Goal setting
- Motivational support
- Restrictions
- Motivation
- Energy compensation
- Reward
- Rule setting
- Planning content
- Stimulus control
- Imitation
- Allowances
- Scheduling of diet and activity
- Awareness of impulse motives

- Information seeking
- Weight management aids
- Peer support
- Flexible restraint
- Professional support
- Distraction of impulses

An intervention including short message service (SMS) and the Internet was modeled after a successful group-based weight management program. Qualitative research approaches using focus groups, personal interviews, survey and expert opinions were used in this evaluation. Seven common themes emerged in the focus groups [28]:

- Weight management is a roller coaster
- Energy in/out is too simple, there are psychological factors
- Lifestyle change
- Goal setting - set us up for success
- Support us on all levels
- Cultural considerations
- Perceived benefits and barriers of mHealth

The top ten preferences expressed by patients for a weight management toolkit included the following [25]:

- Snacks: cutting down and healthy options
- Healthy, quick and easy recipes
- How to cut down portion sizes and energy intake
- Temptation and how to deal with it
- How to cook and eat healthy when you don't have time
- Exercise, physical activity, TV watching
- Fat, sugar, carbs and protein: understanding the basics
- My personal plan and goals for a healthy life
- Breakfast: fuel yourself of the day
- Drinks: more water and less sugar

A qualitative study with 39 participants in four focus groups of females in a Middle Eastern Country examined preferences for a weight loss mHealth app. Five main features of the app emerged from focus group discussions [29]:

- Language and culturally sensitive
- Motivational tool: positive reinforcement, professional advice, group support
- Dietary and Physical activity tools
- Easy to use, fun and flexible

- Tailored information and feedback

A rating scale for mHealth applications was developed by Stoyanov and colleagues. This scale was based on a review of the literature and a synthesis of themes and criteria. Twenty-three criterion are rated on a 5-point scale [30]. The Mobile App Rating Scale (MARS) includes five primary categories:

- Engagement
- Functionality
- Aesthetics
- Information quality
- Subjective quality.

Evaluation of mHealth Outcomes: A review of the literature

The following 9 studies have been selected from the body of literature to serve as illustrative samples of current insights.

A. 135 participants were randomized into a treatment or control arm. The treatment group received a mHealth app designed to increase vegetable consumption. Features of the app included: goal setting, self-monitoring, behavioral challenges or competition, and push notifications for increased vegetable consumption. The theoretical basis for the behavioral features was guided by Social Cognitive Theory. The mHealth app users increased vegetable consumption by 2 servings per day (p=0.04). Seventy-five percent of treatment arm participants logged into the application daily (0.8 SD=1.1). Logging behavior decreased over time [31].

B. Forty volunteers were randomized into a two-arm treatment and control study over 12 weeks. The treatment arm participants obtained a mHealth app with personalized periodic nutrition and behavioral counseling based on user performance. Weight loss in the treatment group was significantly greater than the control arm 9.4 kg (+/- 0.5%) vs. 0.6 kg (+/- 0.5%) [32].

C. A treatment arm of 25 participants was randomized and compared to a control arm of 26 patients. The intervention evaluated was a mHealth tracking app with podcasts delivered twice per week, push notifications to encourage self-monitoring, a point-based incentive system with social interactions between participants was included. Participation in mHealth app use decreased over time. Points earned through self-monitoring were predictive of weight loss. Treatment group participants lost significantly more weight than control group participants (p=0.02) [33].

D. Participants were randomly placed into one of five diet type regimens. A secure Facebook page for each diet type was created for continued participant support during the maintenance phase of this intervention. The correlation between participation in the Facebook group and weight loss was examined. The greater the number of posts the greater the weight loss observed. A weight loss of 0.43 kg per 10 posts was documented (B= -0.09, P= -0.04). Posts that solicit feedback from participants were

the most engaging, such as polling and suggestions. Counselor initiated posts appear to generate more engagement than peer posts.
Posts that are less engaging such as educational content or informational posts were less effective during the maintenance phase of this weight loss intervention [34].

E. Sixty-one participants were randomized into a treatment or control arm. Treatment arm participants received an intervention designed to mimic a 16 week group session syllabus for the prevention of diabetes mellitus. A mHealth application included self-monitoring, daily reminders to complete self-monitoring, daily messages, video casts and surveys. Six in-person group sessions were included in the intervention group. Participants in the control arm received a digital pedometer with otherwise usual medical care. The intervention group experienced an absolute decrease of 6.2 kg compared to the control group ($p < 0.001$) [35].

F. A worksite health promotion weight management program included 12 sites randomized into the intervention group and 8 sites placed in the control group. Participants self-selected entry into the study. Less than 50% of employees participated (566/1203). 355 employees obtained the Internet and mHealth application intervention. Control group participants were measured at baseline, 16 and 38 weeks without any additional intervention offered. The technology intervention included self-monitoring, suggested activities and social engagement including competitive challenges. The intervention group had a body weight reduction of -1.04 kg ($P=0.03$) compared to the control group, -0.03 kg. Additional outcome measures such as blood pressure or total cholesterol did not differ significantly between the groups [36].

G. A 2014 systematic review and meta-analysis of 33 overweight and obesity behavioral treatment studies was completed. Intervention treatments included any of the following: diet, exercise, lifestyle or behavioral regimen. Pooled analysis examined 6463 experimental group participants and 4366 individuals in the control groups. A mean weight loss of 3.13 kg (SD 0.75) was observed across all intervention types [11].

H. A meta-analysis of self-help programs for weight management was conducted. Twenty-three studies were examined in the analysis. Interventions included Internet and mHealth applications. A pooled analysis of 616 intervention participants and 546 control participants in seven studies resulted in a significant weight loss for intervention participants as compared to control (-1.85 kg, CI = -2.86, $p=0.83$) [27].

I. A three year non-randomized study including 220 participants utilized a digital mHealth equivalent of the in-person group-based Diabetes Prevention Program (DPP). Authors reported a mean weight loss of -3.0% ($p= 0.0009$) when four or more sessions were completed. Eighty percent (n=161) of participants were available at the end of 1-year and a mean weight change of -4.7% body weight ($p< 0.0001$) and a reduction in HbA1c of -0.38 percentage points ($p< 0.0001$) was achieved. Only 46% (n=102) of participants were available at the end of the 3-year DPP .

Discussion

Excess body fat, poor nutritional habits and the resulting sequelae are found in the majority of US adults. Treatments following established guidelines have been successful in obtaining 5% to 10% body weight loss within months of treatment initiation; however, many participants regain lost weight within 2 years of completing treatment [8]. Face to face treatment programs incur high out of pocket costs resulting in limited access for most adults needing treatment.

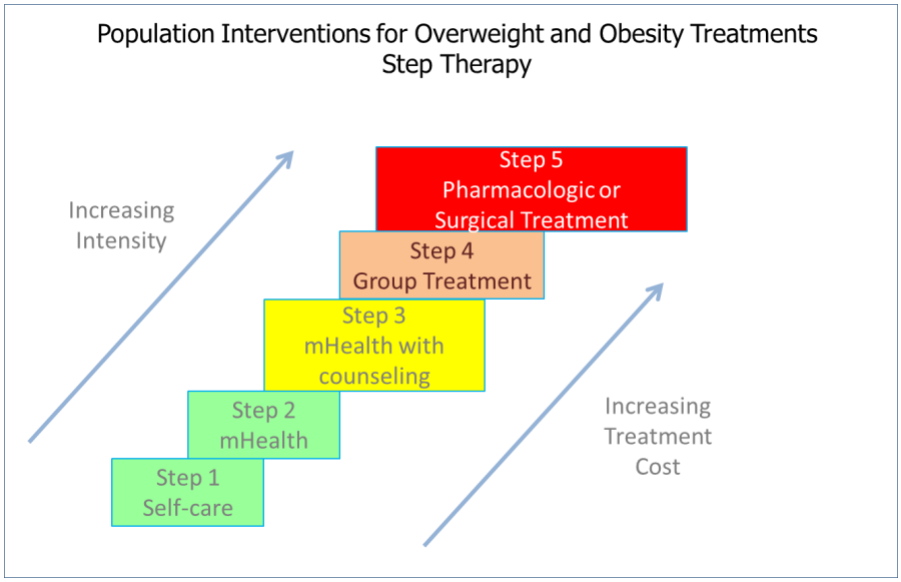
mHealth applications pose tremendous opportunity for widespread, low cost treatments for many US adults. The ability of mHealth applications to deliver tailored content, timely feedback and low effort self-monitoring are factors driving this opportunity for population health improvement. Most mHealth applications available have not been well designed with expert input or adherence to scientific guidelines for nutrition and obesity treatment [21]. Few if any examples are found in the literature to support matched intervention types with risks and treatment costs [14, 15].

Best practices as described by mHealth users are well documented and consistent across multiple methods and rigorous qualitative research methods. A blueprint for mHealth architects is available for intervention and program designs. The efficacy of various mHealth features have not been rigorously studied as discrete intervention types. Thus, the causes of the weight loss effect through specific mHealth features are not well understood. The intensity of interactions and total interaction time between user and mHealth app varies, and is not commonly reported as a mitigation or interaction variable in most research articles reviewed. The ability of any mHealth app to create an environment where the user interacts daily and multiple times each day may be a key factor in mHealth impact on weight management success.

mHealth applications have succeeded in weight loss interventions across numerous studies. Although the weight loss appears to be less than comparable group treatments, significant weight loss has been produced. Digital health interventions for diabetes prevention have shown success at less intervention cost and more convenience for participants than in-person group-based programs [18].

Recommendations and Actions

A review of the literature appears to substantiate the value of mHealth applications in the treatment of pre-diabetes, overweight and obesity. The exclusive use of mHealth applications does not appear to be a panacea for all individuals considering varying health risks, learning styles, personal preferences and access to technology devices. Patients who do not succeed with weight loss through a mHealth application are candidates for higher intensity and more invasive treatments. A suggested step care approach is illustrated below.



mHealth applications for diabetes prevention and weight management should include features to support lifestyle changes including increased physical activity, decreased caloric intake, and behavioral change. Self-monitoring is facilitated through mHealth capabilities and is associated with weight loss success [22]. The various features in an mHealth application must facilitate multiple interactions on a daily basis. Entertainment features such as social support, gamification, and conversational content are desired by users [26]. Practical features for healthy menu access, health food choices, shopping food lists and convenient recommendations for restaurants and prepared meals can increased usability and shape daily habits. The integration of physicians and other health care team members into mHealth prescriptions and step therapy management can stimulate increased interactions and successful treatments for weight reduction. Weight regain may be mitigated with long-term continued use of mHealth applications including periodic communication from a counselor as needed. The influence of the primary care physician can be leveraged for mHealth recommendations and management of the step therapy approach in diabetes prevention and weight management

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