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DreamMapper

White paper

A mobile application and website to engage sleep apnea patients in PAP therapy and improve adherence to treatment

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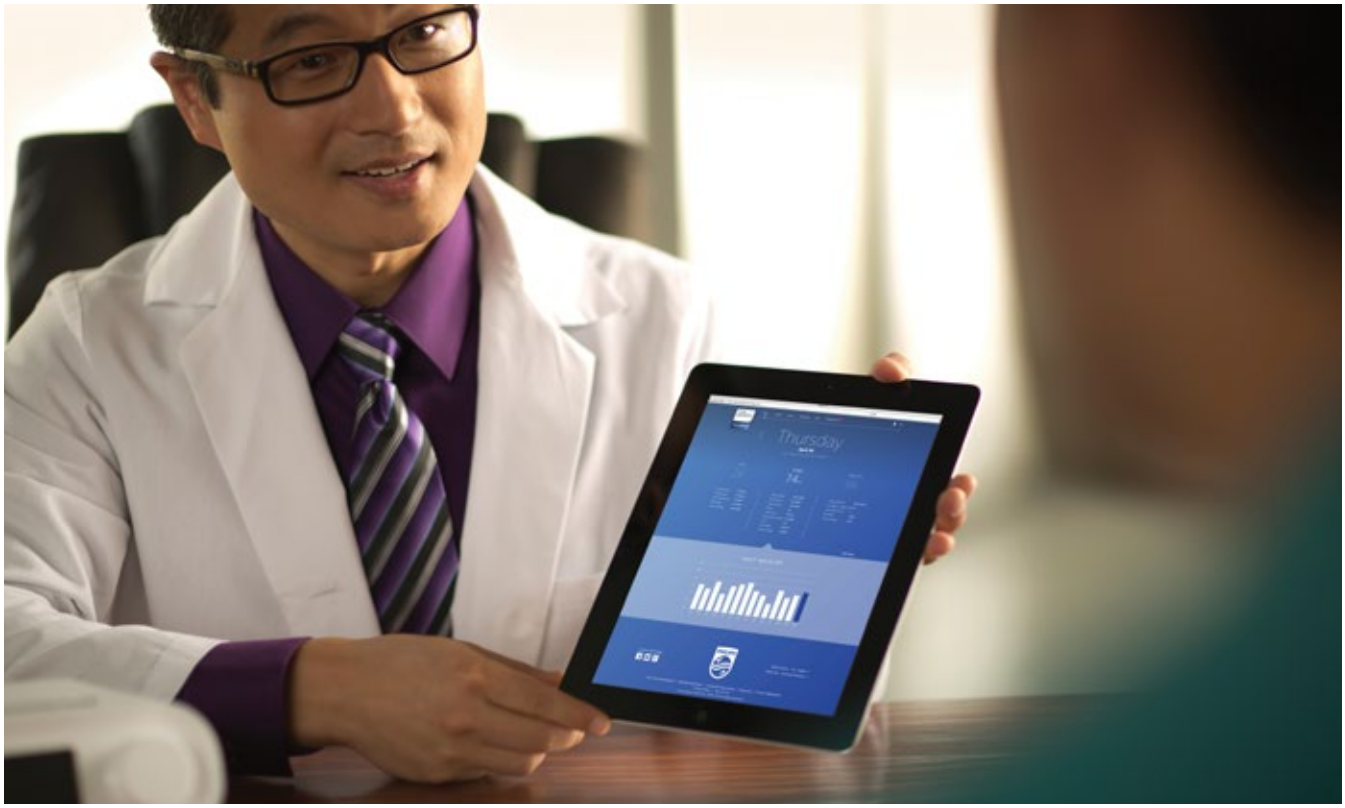
Abstract



Introduction
Sleep Apnea is a serious medical condition with significant health consequences. Treatment with Positive Airway Pressure (PAP) therapy is effective, but adherence to treatment is poor. Lower adherence can result in undertreated patients and, in some cases, may lead to refusal of insurers to pay for therapy. DreamMapper is a mobile application and website that employs theoretically driven and empirically tested interventions designed to improve adherence to PAP therapy.

Methods
In this naturalistic study, we analyzed a retrospective group of slightly fewer than 173,000 patients from the Philips Respironics EncoreAnywhere database to determine whether having the DreamMapper application resulted in any differences in PAP adherence rates compared to patients who did not have DreamMapper.

Results
At 90 days, patients using DreamMapper achieved a 78% adherence rate based upon the CMS adherence requirements, yet patients who did not use DreamMapper demonstrated a 63% rate of adherence. Patients using DreamMapper also used therapy an average of 1.1 hours a night longer than those not using DreamMapper. DreamMapper also helped those patients who struggled early with therapy. Forty-six percent (46%) of those who struggled and had DreamMapper were able to achieve adherence by 90 days compared to only 12% of those who did not have DreamMapper.

Discussion
Patients who engaged with the DreamMapper mobile application and website showed improved adherence rates compared to standard care (defined in this paper). We believe that improvements in adherence are likely related to better patient outcomes and higher patient satisfaction.

Background

Obstructive Sleep Apnea (OSA) is a serious medical illness (1), affecting approximately 13% of men and 6% of women in the US population (2). OSA has concomitant medical comorbidities that can threaten life, but treatment has been shown to effectively improve both medical outcomes and quality of life (3, 4). Positive airway pressure (PAP) therapy is the most commonly prescribed treatment for patients with OSA. To be maximally effective, PAP therapy must be used nightly (5, 6). Recent Medicare guidelines have resulted in denial of reimbursement for PAP therapy if a patient does not demonstrate adequate adherence to treatment (7). Adequate adherence is defined as the use of therapy on at least 70% of nights, for at least 4 hours each night, over a consecutive 30-day period in the first 90 days of treatment (8).

Adherence to treatment has been thought to be influenced by a number of factors, including the severity of symptoms, treatment response, treatment pressure, socioeconomic status and race. However, most of these predictors do not hold up across studies (9, 10). To date, the most significant predictor of adherence to treatment has been patient motivation and one's confidence that s/he can use treatment during times of struggle (11, 12). These two constructs are directly related to psychological theories of how people go about changing their health behaviors. Such theories have been used to develop interventions to improve adherence to treatment (13, 14).

PAP therapy devices are unique because they offer an objective way to account for therapy utilization and provide insight to efficacy. Adherence, determined by the amount of time a patient breathes at the set therapy pressure, can be objectively recorded by PAP devices and reported daily. PAP devices also identify breathing events based on changes in airflow and help identify excessive mask air leaks that could impact therapy use. Data from the PAP device can be downloaded into various software programs that allow the data to be displayed at varying levels of granularity (e.g., hourly, daily, monthly, etc.). The content and presentation of device data vary by the software manufacturer.

One such software program is EncoreAnywhere (Philips Respironics, Murrysville, PA). Device data (adherence and airflow data) are uploaded into a remotely housed, secure server. In addition to device data, additional therapy, health information, healthcare provider and payer information associated with the patient can be entered manually or linked with electronic health records. Device data are uploaded into the database either manually from a data card (SD Card) or automatically through a wireless modem. Data are used to create summary reports with user-selected levels of detail. Currently, there are over 5 million active patients in the EncoreAnywhere database. Only data from Philips Respironics' therapy devices can be loaded into the EncoreAnywhere database.

As an offering to patients, a tool to engage patients with their therapy experience and provide feedback, information and device support tools is available. DreamMapper (Philips Respironics, Murrysville, PA) is a mobile application and website that provides patients with their individual adherence and therapy information and access to information about sleep apnea and therapy equipment. It also gives patients other tools and techniques for dealing with their therapy. The predecessor to DreamMapper was known as SleepMapper. DreamMapper was introduced to support a new family of sleep products and the functionality and content are the same as SleepMapper.

DreamMapper is different from other patient engagement sleep applications in two key ways. First, the content of DreamMapper and its algorithms regarding how it communicates with patients are derived from psychological theories of behavior change and supported by empirical research (15). Second, upon set-up, DreamMapper can be automatically linked to the individual patient's account in EncoreAnywhere and then report individual unique patient data on adherence and airflow data from EncoreAnywhere. DreamMapper has the potential to positively impact patient acceptance of and adherence to PAP therapy.

To date, adherence studies typically involve relatively small numbers of patients and findings may be limited by geographical, socioeconomic or other sources of bias. We undertook an analysis of approximately 173,000 records from the EncoreAnywhere database to compare adherence in patients using DreamMapper to a similar group of patients who did not use it (referred to as Standard Care or SC).

Methods

For this naturalistic, retrospective study the EncoreAnywhere database was queried to produce records based upon a set-up date in EncoreAnywhere between March 1, 2013, and January 1, 2016. All participants had data that were downloaded into EncoreAnywhere either automatically (through the wireless modem), or manually (from the SD card). Automatic downloads occurred regularly, assuring that data were not lost. The manual downloads from SD cards took place at less regular intervals and if the SD card was not downloaded, participant use data would not show up in the EncoreAnywhere database until an SD card download occurred.

Reports were generated with adherence data at 30-day intervals so that adherence was summarized at day 30, 60, and 90 of treatment for each participant.

For this analysis, we matched two groups (DreamMapper and SC) on the percentage of participants with SD cards. Matching on this variable was important to control for motivation, as SD card downloads might represent a level of interest in data only seen in the most motivated users. We could not analyze only those participants with automatic downloads by the wireless modem as this would represent a sampling bias of only those participants who received the type of care that allowed them to receive and keep modems for 90 days. This would likely artificially increase adherence rates. We analyzed the data in three ways.

Conservative Analysis

First, we analyzed all participants who met our criteria. Missing data on any given day were filled in with the number "0" to take the most conservative approach. This approach may underestimate actual use of PAP because there may be use on days where data are not available but therapy was used. 22% of the participants in the DM group had data downloaded from SD cards compared to 21% in the SC group.

High User Analysis

Second, we analyzed only those participants who completed downloaded datasets for the first 90 days, with no blank days. Non-use days would show up as "0," but these numbers could be trusted as accurate. This method artificially overestimates use because it only includes those who receive the special type of care that includes modems for a full 90 days and may represent the most motivated and vigilant users. 19% percent of the participants in the DM group had data downloaded from SD cards compared to 12% in the SC group for this analysis.

Struggling User Analysis

Data were analyzed for participants with less than two hours average usage per night in the first 14 days and who created their DreamMapper account between days 14 and 60. Participants in this category were defined as struggling with therapy.

Records were from active EncoreAnywhere accounts only, to eliminate any accounts established for testing or evaluation purposes. This retrospective data analysis was reviewed and approved by an independent IRB with waiver of consent. All participant records are de-identified in the EncoreAnywhere database to comply with HIPAA requirements.

The initial set of records was then separated into participants who were DreamMapper (DM) users and participants without DreamMapper (SC). The query generated 172,679 records with 85,077 using DM and 87,602 in the SC group. The following primary variables were then determined for each group: percentage of adherent participants defined using CMS guidelines (≥ 4 hours per night over 70% of the nights across a 30-day consecutive period over the first 90 days of treatment) and average use (hours per night) for the first 30, 60 and 90 days.

Statistical Methods

Available demographic data and average adherence metrics were compared between the DreamMapper and Standard of Care groups using an independent-samples t-test. Additionally, adherence was adjusted for age, using analysis of covariance (ANCOVA), among participants with available age data. The Fisher's Exact Test compared the percentage of participants meeting CMS compliance criteria at 90 days. Statistical comparisons were considered significant at $p < 0.05$.

Results

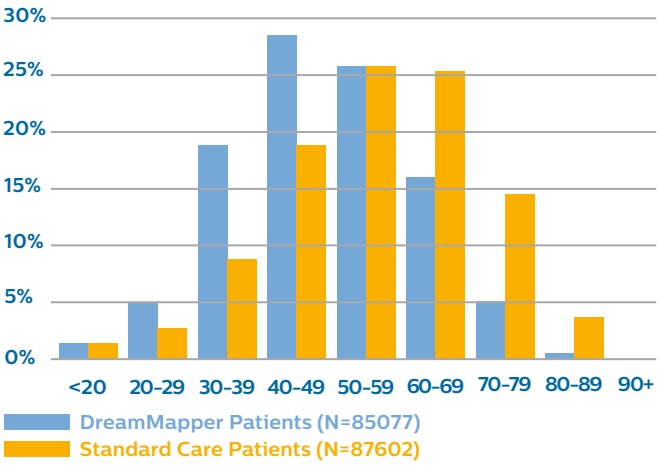
Baseline health characteristics of the participant are not required in the EncoreAnywhere database and are not consistently entered, but some data were available for gender and age. Gender composition is presented in ***Table 1***.

Table 1. Reported Gender Composition (Number, [%])

	DreamMapper	Standard Care
Female	18422 (22%)	21084 (24%)
Male	42337 (50%)	32370 (37%)
Unspecified	24318 (28%)	34148 (39%)
Total	***85077***	***87602***

The DM group was slightly younger than the SC group (DM = 49 ± 13 [N=78,031], SC = 57 ± 15 [N=73,244], p<0.001). The distribution of participants by age are shown in ***Figure 1***. Participants from young adults to octogenarians made use of DreamMapper. We then examined the correlation between age and adherence to determine the degree to which age might serve as a confounder in the subsequent analyses. The correlation was 0.1, p <0.001. Although this correlation is considered small, we analyzed the data with and without age as a covariate to assure none of our findings were related to the slight difference in age.

Figure 1. Age Distribution by Decade



Methods (continued)

Conservative Analysis

The DM group was more adherent to PAP therapy than was the SC group. When considering the conservative analysis, 78% in the DM group met the CMS criteria for adherence compared to only 63% of the SC group (***Figure 2.1***). The DM group also outperformed the SC group in hours of use at 90 days, both before and after age was included as a covariate (unadjusted: DM = 4.9 ±2.4, SC = 3.8 ± 2.8 [t=87.7, p<0.001]; ANCOVA: DM = 5.0 ±2.5, SC = 3.9 ± 2.5 [F=7333.9, p<0.001] ***Table 2***). This increase of 1.1 hours a night by day 90 is quite large compared to clinical trials of interventions to improve adherence to PAP therapy (15).

Participants in the DreamMapper arm of this study had a consistently higher percentage of nights with use (***Table 3***). In the first 30 days of treatment, 84% of DM participants used therapy compared to 72% SC participants. More importantly, 78% DM participants used treatment at 90 days compared to 63% of the participants in the SC group.

High User Analysis

When examining the high-users who had data for a full 90 days, we find the same advantage for DM users. Seventy-five percent (75%) of those in the high-using SC group met criteria for adherence, while 84% of DM users in this analysis met these criteria. The unadjusted average nightly adherence showed a 0.5-hours advantage for DM users over the SC group by day 90 (DreamMapper = 5.5 ± 2.1, Standard of Care = 5.0 ±2.4, [t=35.2, p<0.001]), whereas the age-adjusted adherence showed an advantage of 0.7 hours (SM = 5.6 ±2.2, SC = 4.9 ± 2.2 [F=2265.9, p<0.001]).

84%

84% of the high user analysis DreamMapper users met CMS compliance criteria.

78%

78% of the conservative analysis DreamMapper users met CMS compliance criteria.

Table 2. Adherence at 90 days, Standard Care versus DreamMapper

Conservative Analysis	DM (Mean [± SD]) (N= 85077)	SC (Mean [± SD]) (N= 87602)
Nightly Adherence, All Nights (hrs.)*	4.9 (2.4)	3.8 (2.8)
Nightly Adherence, Nights Used (hrs.)*	5.8 (2.0)	5.1 (2.6)
Percent of Nights Used (%)*	78.5 (28.5)	62.6 (35.9)
Percent of Nights with ≥ 4 hours of Use (%)*	65.9 (31.4)	50.1 (35.8)
High User Analysis	**DM (Mean [± SD]) (N= 71157)**	**SC (Mean [± SD]) (N= 56711)**
Nightly Adherence, All Nights (hrs.)*	5.5 (2.1)	5.0 (2.4)
Nightly Adherence, Nights Used (hrs.)*	6.1 (1.7)	5.8 (2.1)
Percent of Nights Used (%)*	86.8 (19.9)	80.9 (25.6)
Percent of Nights with ≥ 4 hours of Use (%)*	73.3 (26.7)	65.7 (31.4)

Table 3. Percent of Nights with Therapy Use by Time Interval (Conservative Analysis)

Time Period	0-30 days	0-60 days	0-90 days
DreamMapper	84%	81%	78%
Standard Care	72%	67%	63%

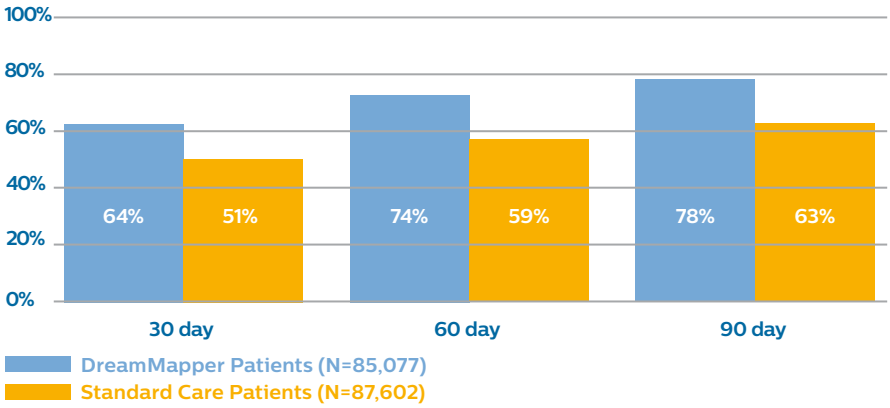
*p < 0.001, Independent Samples t-test
†p < 0.001, ANCOVA

Methods (continued)

Figure 2.1 illustrates the percent of participants satisfying CMS adherence requirements at 30, 60, and 90 days. A significantly higher percentage of participants with DreamMapper met the requirement at 90 days ($p < 0.001$ for each time interval).

Figure 2.1 CMS Criteria for Adherence at 30, 60 and 90 days, Conservative Analysis

% of Participants Satisfying CMS Adherence Requirements; Conservative Analysis ($p < 0.001$ for all time intervals)



Struggling Users Analysis

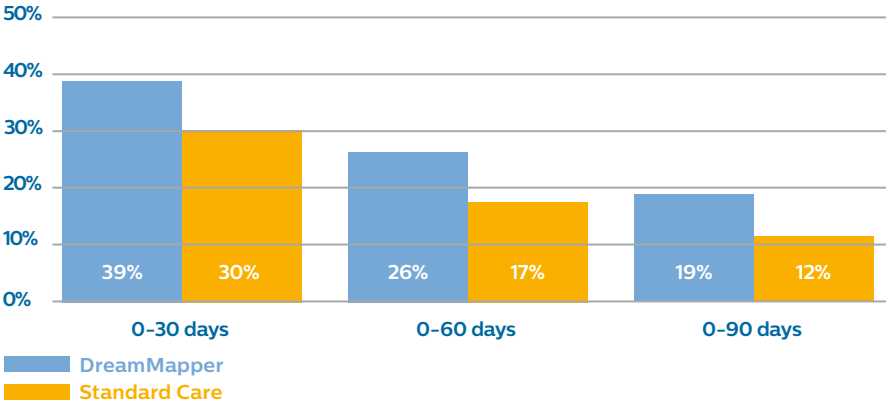
We defined "Struggling Users" as participants who had less than two hours average usage per night for the first 14 days of therapy in the SC group (N = 22,204 [23.5%]), and participants who had fewer than two hours of average usage per night for the first 14 days of therapy and created their DreamMapper account between days 14 and 60 in the DM group (N = 1972 [2.3%]). We analyzed these two groups for meeting CMS adherence requirements. Forty-six percent (46%) of the DreamMapper users who met these criteria went on to achieve adequate adherence with the CMS guidelines at 90 days compared to only 12% of the SC group who met these criteria.

Finally, we looked at participants who used therapy on all (100%) nights (***Figure 3***). In the first 30 days, approximately 1/3 (39% of DM and 30% of SC) of all participants used treatment every night and less than 20% (19% DM and 12% SC) had use documented for all nights over 90 days. A consistently larger percentage of participants with DreamMapper used therapy on 100% of the nights.

58%

58% more people used their therapy every night when they used DreamMapper.

Figure 3. Therapy Use on All Nights



Methods (continued)

Mask Leak and Treatment Efficacy

In both the conservative analysis and the high-user analysis, participants were effectively treated. Mask leak and apnea hypopnea index (AHI) were statistically lower in the DreamMapper groups.

Table 4. Apnea Hypopnea Index and Mask Leak

Conservative Analysis	DM (Mean [± SD]) (N= 85077)	SC (Mean [± SD]) (N= 87602)
Average Mask Leak (l/m)*	32.1 (15.2)	32.6 (21.3)
AHI (Events/Hour)*	3.2 (3.8)	3.7 (5.1)
High User Analysis	**DM (Mean [± SD]) (N= 71157)**	**SC (Mean [± SD]) (N= 56711)**
Average Mask Leak (l/m)*	33.2 (14.1)	35.6 (19.2)
AHI (Events/Hour)*	3.3 (3.7)	3.8 (4.8)

*p < 0.001, Independent Samples t-test

Discussion

PAP adherence has been a consistent problem in assuring that patients and their caregivers reap the full benefits of treatment. Studies have shown that even minimal use of PAP therapy confers benefits (17), but that maximal outcomes are associated with greater long-term use of therapy (5, 6). Advances in device technology have been notable over the past two decades, but these may have begun to plateau in the past few years. Therefore, we need to focus more on the right methods and tools with which the patient can interact to improve their adherence to treatment. These efforts are the purview of the field of health psychology and health behavior change experts.

DreamMapper is designed from prominent theories of health behavior change and empirically tested behavioral PAP adherence interventions. (14, 15) The DreamMapper tool is the culmination of several years of study focused on why patients choose to use PAP therapy and what factors influence patient engagement and motivation. Constructs from social cognitive theory are employed to develop an intervention that guides patients carefully and with regard to their own capabilities. Feedback and goal-setting are used in ways consistent with motivational enhancement techniques (MET) developed by one of the authors (MSA).

The DreamMapper application uses a personal approach, engaging patients in their own therapy and providing information that is relevant to the patient and his/her family to encourage active engagement in therapy. Educational modules are employed but the program operates on the premise that education alone does not change behavior. Finally, specific techniques are employed to enable DreamMapper to provide meaningful information to the users in a timely manner in order to enhance motivation to change. This retrospective study was designed to test the efficacy of DreamMapper on PAP therapy in the real world.

The results from our retrospective analysis suggested that using DreamMapper confers benefit on adherence to treatment. We demonstrated a marked improvement in time on PAP therapy, as well as on the number of participants who met CMS criteria for adherence to treatment in both the conservative analyses and the analyses of high users. There were benefits in adherence to early strugglers as well.

Our analyses demonstrated that 64% of DreamMapper users reached CMS adherence criteria even as early as 30 days into therapy. Comparatively, 51% of Standard Care participants reached this level at 30 days and only 63% at 90 days. CMS criteria for adherence are important, as payers are now implementing similar guidelines across the US and many believe that similar approaches will be taken across the world. Such guidelines require patients to utilize therapy to a set criterion, with proof of adherence, in order to receive reimbursement for their therapy. Our analysis suggests that motivational tools and techniques such as those included in the DreamMapper application and website create a unique opportunity to better engage patients and enable them to help themselves throughout the course of therapy. In fact, when these guidelines are applied to our participants, nearly 26,000 more users achieved CMS adherence criteria.

DreamMapper may also be particularly helpful to those patients who are struggling. We found that individuals who struggle greatly with PAP therapy within the first two weeks adhere to PAP therapy much better when using DreamMapper. ***Forty-six percent (46%) in the DreamMapper group who struggled early in therapy went on to achieve CMS adherence criteria compared to only 12% in Standard Care.*** This suggests that the mobile application is particularly helpful early in therapy when a patient struggles. Even more, this suggests that DreamMapper can help even the most challenged patients.

Some insurance plans require specific therapy adherence levels as a condition of payment. Patients who struggle in the course of treatment may be required to return their therapy device to the DME provider if adherence criteria for insurance payment are not met. This may leave patients with minimal options to treat their apnea. There have been no long-term studies of the outcomes of these patients, but many may go untreated.

The addition of a structured adherence management program appears to have strengthened the benefits of DreamMapper with higher adherence rates and nightly therapy use.

There are many unique aspects to the DreamMapper mobile application. DreamMapper, along with EncoreAnywhere, contains the key elements of telemedicine and mobile application platforms including the use of electronic messaging, remote monitoring, automated care mechanisms and patient self-management platforms (18). Perhaps the most notable is the employment of several empirically tested methods based on theories of behavior change. There are many health behavior applications on the market today but not many studies reporting the outcomes of using these applications. This is largely because changing behavior is more complex than simply providing feedback, educating and letting patients set their own goals (19). Feedback about poor use can lead to feelings of failure and abandonment of therapy. Setting the wrong goals can result in similar outcomes (20). Also, simple education has been demonstrated to work only for motivated patients (15).

The key to successful and lasting behavior change lies in taking an informed approach to patient engagement and activation (21). DreamMapper was created using behavior change models, incorporating tools and techniques developed through decades of research into a single mobile and web application.

We believe that the success of patient engagement applications for health issues will rely mostly on the approach they take to engage and work with patients to help them solve their own problems and to motivate themselves during time of struggle. In this “real world” example, DreamMapper seems to provide this support and motivation for patients with sleep apnea and it does so within relatively short periods of time.

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