




BMJ Open Implementation of a Scalable Online Weight Management Programme in Clinical Settings: Protocol for the PROPS 2.0 Programme (Partnerships for Reducing Overweight and Obesity with Patient-Centered Strategies 2.0)

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ABSTRACT

Introduction There is an urgent need for scalable strategies for treating overweight and obesity in clinical settings. PROPS 2.0 (Partnerships for Reducing Overweight and Obesity with Patient-Centered Strategies 2.0) aims to adapt and implement the combined intervention from the PROPS Study at scale, in a diverse cross-section of patients and providers.

Methods and analysis We are implementing PROPS 2.0 across a variety of clinics at Brigham and Women's Hospital, targeting enrolment of 5000 patients. Providers can refer patients or patients can self-refer. Eligible patients must be ≥20 years old and have a body mass index (BMI) of ≥30 kg/m² or a BMI of 25–29.9 kg/m² plus another cardiovascular risk factor or obesity-related condition. After enrolment, patients register for the RestoreHealth online programme/app (HealthFleet Inc.) and participate for 12 months. Patients can engage with the programme and receive personalized feedback from a coach. Patient navigators help to enrol patients, enter updates in the electronic health record, and refer patients to additional resources. The RE-AIM (Reach, Effectiveness, Adoption, Implementation, and Maintenance) framework is guiding the evaluation.

Ethics and dissemination The Mass General Brigham Human Research Committee approved this protocol. An implementation guide will be created and disseminated, to help other sites adopt the intervention in the future.

Trial registration number NCT0555925.

BACKGROUND

Over 70% of US adults have overweight (body mass index (BMI) 25–29.9 kg/m²) or obesity (BMI ≥30 kg/m²).¹ Overweight and obesity are associated with increased morbidity and

STRENGTHS AND LIMITATIONS OF THIS STUDY

- ⇒ The Partnerships for Reducing Overweight and Obesity with Patient-Centered Strategies 2.0 programme is being implemented in a diverse cross-section of patients and providers.
- ⇒ The Best Practice Advisories and internal referral in the electronic health record have made it easy for providers to identify and refer eligible patients to the programme.
- ⇒ The programme is limited to primary care and specialty clinics affiliated with Brigham and Women's Hospital.
- ⇒ There is no external control group.

mortality from many chronic conditions.² Even modest weight loss (3–5% body weight) has important health benefits. Clinical guidelines recommend comprehensive lifestyle intervention for all patients with obesity and for patients with overweight who have cardiovascular risk factors or other obesity-related conditions.³ However, clinicians often do not counsel patients about weight due to limited time, training and resources.^{4–6} Although anti-obesity medications are effective, they may be difficult to access,⁷ and lifestyle intervention is always recommended in addition to medication. There is an urgent need for scalable strategies for treatment of overweight and obesity that are accessible and can be implemented across healthcare systems.

Online programmes that deliver comprehensive lifestyle intervention can help people

achieve and maintain weight loss.^{8–10} Population health management is a team-based approach in which non-clinical staff members identify and reach out to specific groups of patients with unmet preventive and chronic condition care needs, typically outside of face-to-face visits.^{11,12} The original PROPS (Partnerships for Reducing Overweight and Obesity with Patient-Centered Strategies) Study was a cluster-randomised trial that was conducted from 2016 to 2019 among primary care patients. The PROPS Study examined whether integrating an online weight management programme with population health management would lead to greater weight loss at 12 months compared with an online programme alone and with usual care.¹³ The results showed that patients in the combined intervention group (online programme plus population health management) had significantly greater weight loss at 12 months compared with patients in the online only or usual care groups.¹⁴ Although the amount of weight loss in the combined intervention group was modest (average weight loss=3.1 kg),¹⁴ the intervention was designed to be integrated with existing care and delivered by non-clinical staff, minimizing burden to providers. Therefore, it could have a large effect on population health if scalable.

Although the PROPS Study demonstrated that an online programme can be successfully integrated with population health management in primary care, it is critical to appropriately adapt the intervention to maximize its scalability and to implement and evaluate it in a broader population. Therefore, the purpose of PROPS 2.0 is to adapt and implement the combined intervention from the PROPS Study on a larger scale, in a diverse cross-section of patients and providers. The specific aims are as follows:

1. To engage with patients, providers, and other stakeholders to adapt and integrate the PROPS combined intervention in a variety of settings.
2. To implement the intervention in a variety of patients and settings and to evaluate its impact on outcomes, using the RE-AIM (Reach, Effectiveness, Adoption, Implementation, Maintenance) framework.
3. To evaluate maintenance of the intervention six months after formal implementation activities have ended and to prepare a detailed implementation guide to increase future reach and uptake.

In this initial paper, we describe the design and methods of the PROPS 2.0 programme.

METHODS

Design, Setting, and Population

The PROPS 2.0 programme is being offered at no cost as part of standard care to eligible patients from a variety of clinics affiliated with Brigham and Women's Hospital (BWH), including Primary Care, Cardiology, Endocrinology, Orthopedic Surgery, Comprehensive Breast Health, Sleep Medicine, the Center for Weight Management and Wellness, and the Nutrition and Wellness

Service. These clinics are in both urban and suburban locations throughout the greater Boston area and serve a racially and socioeconomically diverse population of patients.

PROPS 2.0 plans to enrol at least 5000 patients over 12–15 months. To be eligible, patients must be at least 20 years old, have a primary care provider, have received care from a provider at BWH in the last two years, and have a BMI of ≥ 30 kg/m² or a BMI of 25–29.9 kg/m² with at least one indicator of increased cardiovascular risk or other obesity-related condition (eg, type 2 diabetes, prediabetes, hypertension, hyperlipidaemia). Because the programme is being integrated as part of standard care, the goal is to offer it to any patients who may benefit from weight loss; therefore, there is no upper BMI limit, which is consistent with current clinical guidelines for recommending comprehensive lifestyle intervention.³ Patients also must speak English or Spanish and have a valid email address and regular Internet access (at least once a week) via a computer, smartphone or other device. Patients who are pregnant, have type 1 diabetes or are taking insulin for treatment of diabetes, or have active cancer or any serious medical condition for which weight loss is not recommended are not eligible. In addition, patients who have had weight loss surgery in the last 12 months are not eligible, due to the need to follow a strict diet for 12 months after surgery. However, patients who are participating in other weight loss programmes or taking anti-obesity medications are still eligible.

Although PROPS 2.0 is being conducted as a clinical implementation project, some components (eg, surveys, interviews) are considered to be research; therefore, we obtained approval from the Mass General Brigham Human Research Committee (HRC) and registered the programme with ClinicalTrials.gov (NCT05553925).

Patient Involvement

We conducted semi-structured interviews with 15 patients and 15 providers to obtain feedback about the programme prior to the beginning of recruitment; the methods and results from these interviews will be described separately. We also formed a Patient and Stakeholder Advisory Committee (PSAC) that includes patients, providers, and stakeholders from within and outside of BWH. The PSAC members provide input on the programme design, evaluation, and other issues related to the adaptation and integration of the intervention (see Aim 1).

Recruitment and Enrolment

Patients are being recruited for the programme through three main pathways, namely: (1) provider referral, (2) self-referral, and (3) identification via the electronic health record (EHR). An overview of the recruitment, enrolment and follow-up process is shown in figure 1.

For the provider referral pathway, we created an internal referral order within the EHR used at BWH (Epic). The referral order (figure 2) can be found with multiple search terms, including 'PROPS', 'overweight',

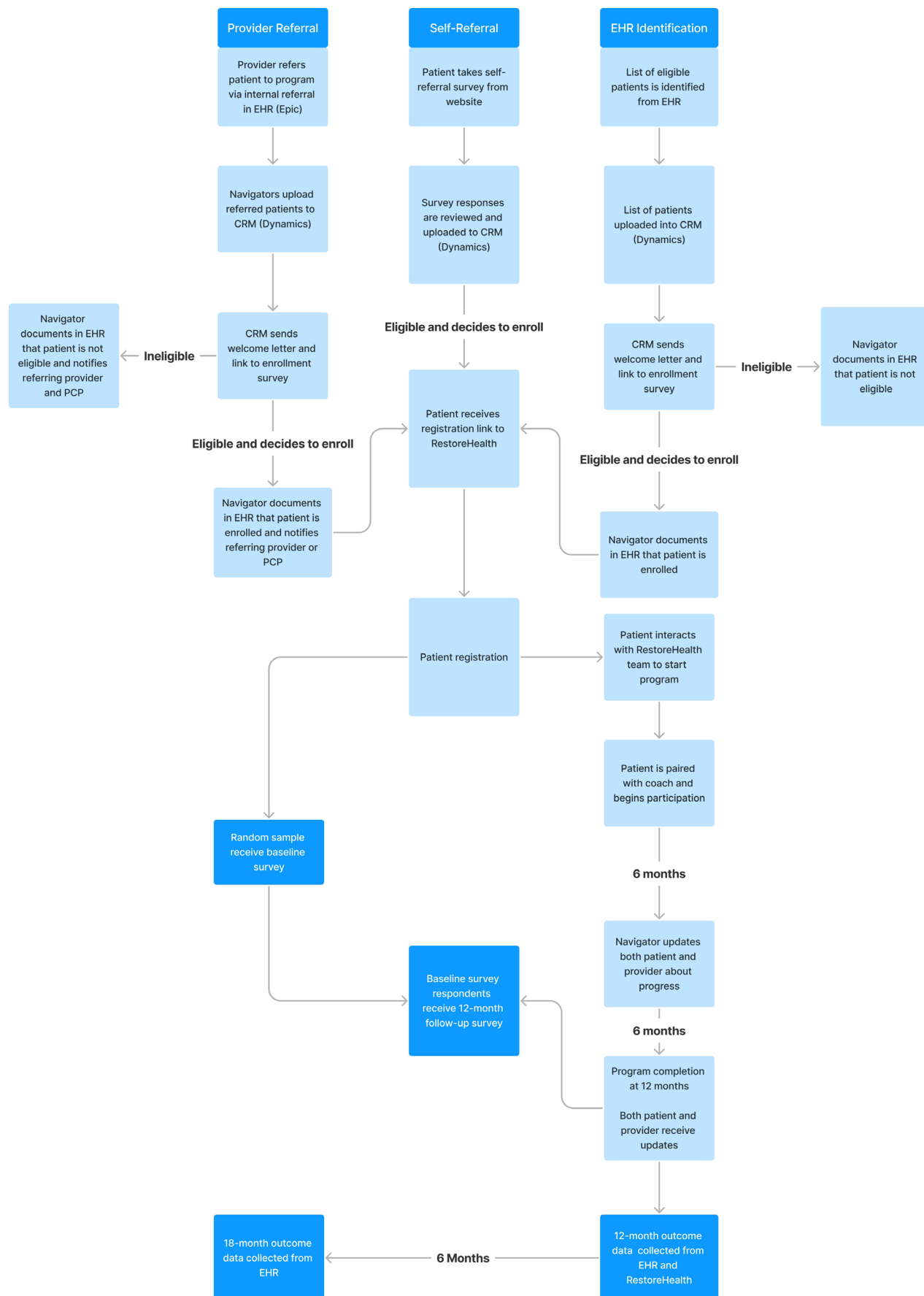


Figure 1 Overview of recruitment, enrolment and follow-up. CRM, customer relationship management; EHR, electronic health record; PCP, primary care provider.

Ambulatory referral to BWH Online Weight Program + Coach ✓ Accept ✗ Cancel

Class: ☐ Internal Ref ☒ Internal Referral

Referral: Priority: Within 3 days (urgent) Within 2 weeks Within 1 month Elective

To provider: 📍

To prov spec: 🔍

Process Inst: PROPS 2.0: Online Program + Coach. A 12-month digital health program that includes an online weight management program/app plus coaching. Patients over 20 years with BMI of at least 30, or with BMI 25 - 30 plus a condition increasing cardiovascular risk (e.g., type 2 diabetes, hypertension, hyperlipidemia) or other obesity-related condition are eligible. [PROPS 2.0: Partnerships for Reducing Overweight and Obesity with Patient-Centered Strategies]

Subspecialty: **PROPS 2.0 Online Program + Coach**

I/referring provider would like to be notified via In Basket in the event an appointment cannot be scheduled for this patient:

☐ Yes ☐ No

Show Additional Order Details ⌵

⚠ Next Required ✓ Accept ✗ Cancel

Important (1) ⌵

⚠ This patient has a BMI 25-29.9

@PHSEXTFEEDBACK@

Based on their BMI (which is between 25 and 29.9) and other medical condition(s), your patient may be eligible for PROPS 2.0 (Partnerships for Reducing Overweight and Obesity with Patient-Centered Strategies 2.0), a 12-month program that includes:

- An online weight management program/app
- Live, personalized coaching

If you'd like to refer your patient, click on the order below.

Order Do Not Order 🏠 Ambulatory referral to BWH Online Weight Program + Coach

Acknowledge Reason

☐ Inaccurate BMI ☐ Pregnancy ☐ Serious Medical Condition ☐ Weight Loss Surgery in Past 12 Months ☐ Patient Declined

☐ Patient Already Enrolled ☐ Other:

✓ Accept Dismiss

Important (1) ⌵

⚠ This patient has a BMI of 30 or greater

@PHSEXTFEEDBACK@

Based on their BMI, which is 30 or greater, your patient may be eligible for PROPS 2.0 (Partnerships for Reducing Overweight and Obesity with Patient-Centered Strategies 2.0), a 12-month program that includes:

- An online weight management program/app
- Live, personalized coaching

If you'd like to refer your patient, click on the order below.

Order Do Not Order 🏠 Ambulatory referral to BWH Online Weight Program + Coach

Acknowledge Reason

☐ Inaccurate BMI ☐ Pregnancy ☐ Serious Medical Condition ☐ Weight Loss Surgery in Past 12 Months ☐ Patient Declined

☐ Patient Already Enrolled ☐ Other:

✓ Accept Dismiss

Figure 2 Internal referral order and Best Practice Advisories in Epic. BMI, body mass index; BWH, Brigham and Women's Hospital.

'online,' and 'online weight'. We also developed two Best Practice Advisories (BPAs) within the EHR, one for patients with BMI ≥ 30 kg/m² and one for patients with BMI 25–29.9 kg/m², to alert providers about patients who may be eligible (figure 2). If one of the BPAs appears for a patient, providers can click on a button to go directly to the referral order. We visited participating clinics to educate providers (e.g., physicians, nurses, physician assistants) about the programme, and we distributed pocket-sized, laminated cards with information for providers about the programme, the eligibility criteria, and referral process. There also are clinician champions at some of the clinics who have helped with distributing materials, answering questions from other providers, and troubleshooting issues.

After patients are referred by their provider, their information is imported from the EHR into a customer relationship management (CRM) platform (Microsoft Dynamics),¹⁵ which was configured for this project. The CRM is used to conduct outreach in bulk, automate and manage tasks, track data, and generate reports. After their data are imported into the CRM, patients are sent a welcome message explaining that their provider referred them, describing the programme, and asking them to complete a brief enrolment survey to verify their eligibility and interest. The welcome message is sent via the secure EHR patient portal (MyChart) to patients with active portal accounts. Patients without an active portal account are initially sent an email message with very limited information about the programme (and no personal health information); this type of message is deemed "low risk" by the healthcare system. Patients must then give consent to use their email address to receive more detailed information about the programme, including the welcome message and enrolment survey. If patients do not complete the enrolment survey after 14 days, the CRM automatically sends a reminder message.

For the self-referral pathway, we developed a website (<https://props2.massgeneralbrigham.org>) with information about the programme for patients, which is available in both English and Spanish. We distributed posters and business cards to all participating clinics with the URL and a QR code to the website and asked staff to display them in exam rooms and/or waiting rooms. From the PROPS 2.0 website, patients can complete the enrolment survey via REDCap (Research Electronic Data Capture) to verify eligibility and to confirm that they want to enrol, if eligible. After patients complete the survey, their information is reviewed and then imported into the CRM.

Finally, in the future, if enrolment targets are not reached from provider referrals and self-referrals, potentially eligible patients will be identified using local EHR data and other clinical systems. Information for these patients will be extracted from the Enterprise Data Warehouse (EDW) and imported into the CRM. An outreach message and link to the enrolment survey will then be sent via the secure EHR patient portal, or the "low-risk"

message will be sent via email for patients who do not have an active portal account.

Independent of specific recruitment/entry mechanisms, if a patient is eligible based on the enrolment survey and decides to enrol, they receive a link to register for the online programme/app. The link is sent via the secure patient portal or email, depending on their communication preference indicated on the enrolment survey. Because the programme is being considered as part of standard care (i.e., offered to all eligible patients in their routine care), the Human Research Committee granted a waiver of the full informed consent form that typically is required for research studies. However, on the enrolment survey, patients still must give their consent to participate and to receive text and email messages from RestoreHealth, the online programme/app being used. They can also withdraw from the programme at any time.

Online Weight Management Programme/App (RestoreHealth)

Because the programme used for the original PROPS Study is no longer available, we chose RestoreHealth as the online programme for PROPS 2.0. RestoreHealth (HealthFleet Inc.) is a 12-month digital health programme that pairs an online programme/app with live one-on-one coaching.¹⁶ The programme is designed to support the behavior modification process via easy and simple interactions, highly personalised coaching, and a holistic curriculum that is based on cognitive behavioral therapy and focuses on overall physical and mental health (rather than focusing strictly on weight loss). It is available in English and Spanish and has interfaces for both patients and coaches.

After patients register for RestoreHealth, they can view brief lessons (a total of 118 lessons, available in written and video format) on specific topics related to weight management, including nutrition, exercise, sleep, and stress. None of the lessons are mandatory. They follow a general path in terms of the sequence, but the curriculum can be personalized for each patient; if a patient is interested in a particular topic, the coach can re-order the lessons to meet that request. Patients also can log their meals, get regular feedback from their coach, and interact with other users via discussion forums.

As part of the programme, RestoreHealth uses data from several connected devices, including scales and sleep/activity trackers, which can be connected to the platform, allowing patients' data to be uploaded automatically and available to their coach. The coaches are behavioral change specialists who are certified through the National Board for Health and Wellness Coaching (NBHWC). After patients are paired with their coach, the coaches monitor patient engagement, weight, diet, physical activity, and stress and give personalized feedback. The coaches primarily correspond with patients via text messaging, but they also can schedule monthly calls with patients who prefer not to use text messaging. Patients can also participate in group coaching to provide additional peer support. The coaches work with patients for

the entire 12 months of the programme. The coaching interactions are personalized, based on the needs of the individual patient, but coaches usually decrease the frequency of communication after the first 4–5 months of the progra, to help patients become more independent. Each patient determines how and how often they would like to interact with their coach and the programme. The patient is always able to engage with their coach via text message, and the coach will always respond. If any medical issues arise, coaches refer patients to their primary care provider.

Patient Navigator Support

Patient navigators, who are non-clinical staff members from the Mass General Brigham Accelerator for Clinical Transformation (ACT) team, are involved in enrolment of patients and provide some monitoring and support during the programme. The ACT team delivers remote care services through a combination of technology, patient navigators, and clinicians; ACT has run entirely remote disease management and drug optimization programmes for over 10,000 patients with hyperlipidaemia and/or hypertension.^{15 17–20} The navigators use the CRM platform to send outreach messages about enrolment to patients who have been referred. Once patients are fully enrolled and registered in the programme, most of their communication is from the RestoreHealth coaches, but the navigators serve as the main connection with the healthcare system. For example, they enter documentation into the EHR at several time points, including when a patient enrolls in the programme, after six months, and at programme completion.

In addition, the navigators monitor patients' weight data throughout the programme and can help connect patients with additional weight management resources, such as through the Center for Weight Management and Wellness. There is a protocol in place for patients who are identified as having "rapid weight loss", which is defined as weight loss >12% over the past 4 weeks or >10% over the past week. If a patient meets these criteria, a patient navigator conducts an outreach call to the patient to ask them a few standard questions about their health status. Depending on the patient's responses, their information is sent to a clinical advisory group, which includes three physicians from the team. One of the physicians reviews the patient's weight and other data and decides about next steps. The physician also notifies the patient's primary care provider about any concerns.

Data Collection and Follow-Up

After patients enrol in PROPS 2.0 and register for RestoreHealth, they participate in the programme for 12 months and engage with the platform and their coach (figure 1). The programme has no in-person visits, other than visits that patients may have with their healthcare provider(s) as part of routine care. During the 12 months of the programme, patients continue to use RestoreHealth and to receive feedback from their coach. Data

on patients' engagement with the programme, as well as their data from the scales and trackers, are collected within the online programme/app. Data on demographic and clinical variables (e.g., weight, blood pressure, and other cardiometabolic measures) are extracted from the EHR. In addition, a sample of patients (50% of English-speaking, 100% of Spanish-speaking) are invited to complete an electronic survey (via REDCap) after registering for the programme and again at 12 months to assess changes in patient-reported outcomes such as diet,²¹ physical activity,²² health status and self-efficacy around weight loss,^{23 24} as well as satisfaction with the programme. Providers within all participating clinics also were invited to complete a brief electronic survey via REDCap before programme implementation, and they will be asked to complete a similar survey after implementation; the purpose of these surveys is to assess their knowledge, attitudes and behaviours about treatment of overweight and obesity and their satisfaction with the programme. In addition to these surveys, we also will conduct semi-structured interviews with patients and providers at the end of the programme to assess their overall experience, satisfaction, and feedback about the programme.

Outcome Measures

The evaluation of the programme will be mixed-methods, incorporating both quantitative and qualitative data, and is guided by the RE-AIM framework. RE-AIM is a well-established framework that was designed to address issues related to the implementation and external validity of health interventions, and it has been applied to questions related to health information technology and overweight and obesity.^{25 26}

To assess reach, we will examine the number and proportion of patients who are referred to the programme by providers, refer themselves, or are identified via the EHR, as well as the number and proportion who are screened, eligible, enrolled, and registered for the programme. To assess effectiveness, we will examine weight change over 12 months (primary outcome), calculated as the difference between each patient's weight at enrolment and 12 months (± 90 days) after enrolment, using weight data from RestoreHealth as well as from the EHR. We also will examine percent weight change, changes in cardiometabolic measures (e.g., blood pressure, haemoglobin A1c), and changes in patient-reported outcomes (e.g., diet, physical activity, health status) over 12 months, using data from the EHR and from patient surveys. To assess adoption at the provider level, we will examine the number and proportion of providers who refer patients to the programme. To assess implementation, we will examine patients' engagement with the RestoreHealth programme (e.g., number of contacts with coaches, number of lessons viewed, number of meals logged). To assess maintenance (post-intervention outcomes), we will examine changes in patients' weight and other outcomes at 18 months, six months after they have finished the programme. Other outcomes and data sources are included in table 1.

Table 1 RE-AIM framework and examples of outcome measures

Dimension	Definition	Outcome measure	Data source
Reach	Absolute number, proportion, and representativeness of individuals willing to participate	Number of patients referred or identified	CRM, EHR
		Number of screened patients	CRM
		Number of eligible patients	CRM
		Number of enrolled patients	CRM
		Number of registered patients	RestoreHealth
Effectiveness	Impact of the intervention on outcomes	Weight change at 12 months	EHR, RestoreHealth
		Change in blood pressure at 12 months	EHR
		Change in haemoglobin A1c (HbA1c) at 12 months	EHR
		Patient satisfaction at 12 months	Patient surveys
		Change in diet at 12 months	Patient surveys
		Change in physical activity at 12 months	Patient surveys
		Change in health status at 12 months	Patient surveys
		Change in self-efficacy around weight loss at 12 months	Patient surveys
		Provider knowledge, attitudes, behaviours, and satisfaction at 12 months	Provider surveys
Adoption (system/setting level)	Absolute number, proportion, and representativeness of setting and agents willing to initiate the programme	Number of providers who refer patients	EHR
		Number of clinician champions involved in implementation	Internal database
		Number of coaches involved in programme	RestoreHealth
		Number of patient navigators involved in programme	CRM
Implementation	Fidelity to the various elements of an intervention's protocol	Number of contacts with coaches	RestoreHealth
		Engagement with RestoreHealth (e.g., completing a lesson, logging a meal, logging weight, etc.)	RestoreHealth
		Number of patients referred to BWH Center for Weight Management and Wellness (CWMW)	EHR
		Number of patients with appointments at CWMW	EHR
Maintenance	Extent to which a programme becomes part of routine practice; long-term effects of a programme on outcomes	Change in weight and other outcomes over 18 months	EHR

BWH, Brigham and Women's Hospital; CRM, customer relationship management; EHR, electronic health record.

Analytical plan

The analyses correspond with the three specific aims, which are included in the Background section. The analyses for Aim 1 will be primarily qualitative, using data from interviews conducted prior to programme implementation; these will be described separately. In addition,

descriptive statistics (e.g., means and standard deviations, percentages and 95% confidence intervals) will be used to summarize results from the provider surveys conducted before implementation.

For Aim 2, we will use descriptive statistics to summarize the reach, adoption, and implementation measures shown

in table 1; we also will examine how these vary by patient characteristics (such as age, sex, race/ethnicity, and language), and we will compare characteristics of patients who enrol to characteristics of the entire BWH patient population. For effectiveness, we will examine changes in patients' weight, cardiometabolic outcomes, and self-reported outcomes over 12 months. We will initially do this using paired t-tests for continuous outcomes (e.g., weight) and McNemar's test for binary outcomes (e.g., excellent/very good health status), but we also will use linear and logistic regression models to examine the impact of patient characteristics on these outcomes. To account for missing data, we will use multiple imputation, in order to include all enrolled patients in the primary analysis. We will use similar methods to examine changes in providers' knowledge, attitudes, and behaviors before and after implementation of the programme.

Because this is a clinical implementation project, there is no true "control group" (i.e., all eligible patients can enrol in the programme). However, we will use a segmented regression model based on a discontinuity design²⁷ to compare measured weight change among patients who enrol in the programme to their weight change projected from a "quasi-control" group of patients from the same practices/clinics. The "quasi-control" patients will be similar to participants in all possible respects, except that their BMIs do not quite reach programme eligibility. For enrolled patients with BMI ≥ 30 kg/m², the quasi-control group will include patients with BMI 25–29.9 kg/m² with no indicators of increased cardiovascular risk or obesity-related conditions. For enrolled patients with BMI 25–29.9 kg/m² with indicators of increased cardiovascular risk or obesity-related conditions, the quasi-control group will include patients with BMI 22–25 kg/m² who have at least one indicator of increased cardiovascular risk or an obesity-related condition. Linear regression models relating weight change to baseline BMI in these quasi-controls will be used to project the amount of weight change that would normally occur (without intervention) in people with higher BMIs. A segmented linear regression model will then be used to compare the actual pattern of weight change among intervention patients (i.e., those who enrol in the programme) to the projected pattern among quasi-control patients; separate models will be run for the two BMI groups, and only weight data from the EHR will be used in these analyses (as control patients will not have weight data from RestoreHealth). In the segmented regression models, the outcome for each patient will be their weight change at 12 months, and the primary predictors will be their initial BMI at enrolment, an indicator for intervention or control group, and an interaction between initial BMI and the indicator for intervention or control group. The models also will adjust for patient characteristics, such as age, sex, and race/ethnicity. Similar models will be run for some of the secondary outcomes (e.g., cardiometabolic measures). We also plan to conduct stratified analyses by age, sex,

BMI, and race/ethnicity to examine whether the impact of the programme may differ within subgroups.

The analyses for Aim 3 will be similar to those for Aim 2, but they will use data collected six months after the end of the implementation period. For example, patients' weight change over 18 months (six months after completion of the programme) will be examined using descriptive statistics, and segmented regression models will be used to compare their actual weight change over 18 months to the projected weight change from the same quasi-control patients described earlier.

DISCUSSION

Implementation of the PROPS 2.0 programme on a large scale, in a diverse cross-section of patients and providers, has the potential to improve weight management and other health outcomes for many patients. Online programmes such as RestoreHealth are generally less expensive and more convenient for patients, compared with traditional in-person programmes. Although this programme is currently being offered at clinics affiliated with BWH, the intervention is versatile and can be expanded to other healthcare systems in the future.

To further implement the programme, we are exploring different options for reimbursement in the future, using RPM (remote patient monitoring) and CCM (chronic care management) billing codes. The workflow is designed to be easily scalable, with many tasks being automated or conducted in bulk. Certain features are integrated with Epic, but they are not dependent on any Epic functionality and could be deployed across other systems. In particular, the BPAs and internal referral within the EHR have raised provider awareness about the programme and made it simple for them to identify and refer eligible patients. The utilization of the CRM platform has helped patient navigators with importing data from the EHR, conducting outreach in bulk, automating patient follow-up, and managing other routine tasks that are not typically performed by EHRs. Most of the outcome data will be extracted from the EHR or collected through devices that can be synced with the online programme, reducing patient burden. The design of the programme is patient-centred, with extensive input and feedback from patients, providers, and other stakeholders at all stages.

During the first four months, we did encounter several challenges with recruitment and enrolment that required us to make modifications in the workflow. For example, some patients who are less comfortable with technology have had difficulty completing the electronic enrolment independently and required a staff member to assist them with completing it by phone. Similarly, some patients also have had trouble registering for RestoreHealth or setting up their devices. RestoreHealth has customer support for patients who are having technical issues or need help with syncing devices, which has improved user experience and accelerated the recruitment and enrolment process. Addressing such challenges can be expected in

an implementation project and will facilitate subsequent scaling.

There also have been challenges with enrolment of Spanish-speaking patients into the programme. Although the programme launched in November 2022, recruitment of Spanish-speaking patients began in late January 2023, to allow for all aspects of the programme to be translated and adapted. Ongoing efforts to boost participation of Spanish-speaking participants have included directly approaching specific clinics and providers working with primarily Spanish-speaking patients, to increase referrals. In addition, we have started calling Spanish-speaking patients after sending them the electronic welcome message, to ensure they received it and to help them complete the enrolment survey by phone, if needed. We also are mailing letters to Spanish-speaking patients who have been referred, in case they do not see the electronic messages.

The PROPS 2.0 programme is limited to primary care and specialty clinics affiliated with BWH, which may reduce the generalizability of the findings. However, the participating clinics represent a broad group of patients from different backgrounds, and the implementation guide that will be developed as part of Aim 3 will describe adaptations that have been made and other adaptations that may be needed to help disseminate the programme in different institutional settings. The implementation guide also will include information about costs and resources that would be necessary to implement the programme at other institutions in the future. As an implementation project, there is no true control group, which makes it difficult to determine whether any effects on weight and other outcomes are attributable to the intervention itself. The use of segmented regression with a quasi-control group will help to address this, although the discontinuity design can fail for lack of a linear relationship between weight change and baseline BMI, which might be induced by unmeasured confounders. In addition, the PROPS 2.0 programme is currently being offered at no cost to patients (including the online programme). Therefore, we are unable to evaluate changes that may occur if there is billing to insurance or if patients are required to cover any costs in the future.

In summary, the implementation of a scalable online weight management programme in a variety of clinical settings has the potential to improve weight loss and other health outcomes for many patients, with no disruption to routine care. The design and results from this programme will be used to create an implementation guide, which should help other sites adopt this intervention in the future.

Ethics and dissemination

The Mass General Brigham HRC approved the protocol and the research components of the evaluation. Because the programme is being offered as part of standard care, we received a waiver of informed consent. Given the low-risk nature of the intervention, a data safety monitoring

board was not required. A manuscript with the main results will be published in a peer-reviewed journal, and separate manuscripts will be published for secondary analyses. In addition, an implementation guide will be created and disseminated, to help other sites adopt the intervention in the future.

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