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Implementing and evaluating the comprehensive integration of physical activity into a major health system: study design and protocol

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ABSTRACT

Introduction The healthcare sector has great potential for promoting physical activity (PA) for chronic disease prevention, treatment and management; however, multiple adoption and implementation barriers exist, ranging from practice integration to information flow. In 2016, Exercise is Medicine Greenville (EIMG), a comprehensive clinic-to-community approach that involves PA assessment, recommendation and/or prescription and provider-based referral of patients to community-based PA programmes, was launched by Prisma Health in Greenville, South Carolina, USA. Since inception, variability has emerged in adoption and implementation, impacting patient reach, referral rates and engagement in the community-based PA programmes, highlighting the need for closer evaluation and refinement of strategies to maximise programme impact.

Methods and analysis This pragmatic study will examine the adoption, implementation and reach of EIMG. 20 Prisma Health primary care clinics will be invited to adopt EIMG. In Phase I, adopting clinics will receive a standardised EIMG instructional video followed by EIMG activation, allowing providers to refer eligible patients to a 12-week evidence-informed PA programme offered at local community facilities. In Phase II, adopting clinics will receive a more in-depth EIMG onboard training. At adopting clinics, referral rates of eligible patients will be tracked over both phases (each lasting 4 months). A mixed-methods approach will explore factors related to EIMG adoption, achieving optimal implementation and reach, and patient enrolment in the PA programmes. The Reach, Effectiveness, Adoption, Implementation and Maintenance framework will inform the assessment of implementation outcomes, while the integrated Promoting Action on Research Implementation in Health Services framework will be used to explore contextual factors influencing patient-level and clinic-level outcomes.

Ethics and dissemination We received ethical approval to conduct this study from the Prisma Health IRB Committee A (#1963762). The results of this study have the potential to significantly enhance clinical practice and improve health outcomes related to integrating a clinic-to-community PA model in health systems to connect patients with community-based PA resources. Information gained from this study will lead to the refinement of a generalisable approach to inform future implementation strategies on optimising and scaling up the integration of comprehensive PA models in US health systems and be disseminated through conference presentations, publication in peer-reviewed journals and direct work with health systems.

Trial registration number NCT06073041.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ This study will evaluate the scaling up of an existing physical activity (PA) referral pathway to additional clinical sites in a major US health system.
⇒ Primary care clinics will have the opportunity to adopt the PA referral pathway, followed by a mixed-methods evaluation of factors influencing the decision-making process.
⇒ Provider-level adoption (engaging at least one patient in the PA referral pathway) will also be evaluated through a mixed-methods approach using the integrated Promoting Action on Research Implementation in Health Services framework.
⇒ One potential limitation is our ability to engage non-adopting clinics and providers in obtaining their insight into the adoption and utilisation of the PA referral pathway.

INTRODUCTION

The evidence around the benefits of physical activity (PA) is irrefutable; PA is unquestionably a 'best buy' for overall health and is effective in reducing the incidence, severity and/or impact of a broad array of health conditions.[1] Exercise is equally (and sometimes more) effective as drug therapy on mortality outcomes, secondary prevention of coronary heart disease, treatment of heart failure and diabetes prevention.[2] Globally, physical inactivity causes 6%–10%

of all major non-communicable diseases and is responsible for 9% of premature deaths, rates similar to other established cardiovascular disease risk factors, such as smoking and obesity.[3] Conversely, PA acutely improves blood pressure,[4] glycaemic control[5] and inflammation.[6] Regular PA reduces the risk of developing chronic conditions, such as stroke, hypertension, heart disease, type 2 diabetes and several types of cancer.[7 8] Given the benefits of PA, it is remarkable that only 46.9% of US adults meet aerobic activity recommendations, while only 24.2% meet both aerobic and strength training recommendations.[9] This level of physical inactivity costs healthcare systems $53.8 billion worldwide and contributes to $13.7 billion in productivity losses.[10] In the US, inadequate PA, independent of body mass index, is associated with 11.1% of aggregated, direct healthcare expenditures.[11]

Engagement of the healthcare sector, through strategies described in the US National PA Plan,[12 13] is essential for increasing population PA levels. Healthcare providers see a large portion of the general population, often several times a year. These ongoing, multiple contacts offer the ideal opportunity to provide brief, impactful PA counselling. The Toronto Charter[14] outlines several strategies for increasing PA in health settings including: reorienting health services and funding systems, screening of patient PA levels at primary care consultations and referral to community programmes for insufficiently active patients. These overarching guidelines have been supported by calls to action by medical societies[15] and leading health professionals[16 17]; yet, integration lags because health systems are not properly equipped/designed to promote PA.

Similar to the SBIRT model[18] (Screening, Brief Intervention and Referral to Treatment), an evidence-based, clinical strategy for addressing substance use disorders, Exercise is Medicine (EIM)[19] is a comprehensive model for integrating PA in the clinic workflow. EIM is not a PA intervention, but a framework to improve the reach of evidence-based PA interventions by identifying and engaging patients that would benefit from increased PA (see figure 1). The components of the EIM model include: (1) assessing patient PA levels, (2) providing brief PA recommendation and/or a PA prescription and (3) referring patients to PA resources for further guidance. In some instances, a 'navigator' or referral team is involved to increase referred patient engagement levels. Initial evaluations of EIM have been limited to assessments of one or two components and demonstrated positive results when considering cardiometabolic health. Until the past decade, no major health system in the US had attempted to systematically integrate all EIM components into their clinic workflow, connecting at-risk patients to community-based PA programmes.

The use of dissemination and implementation science methods and models has been proposed to accelerate the scale up and scale out of EIM within and across healthcare settings.[20 21] Frameworks, such as the Reach, Effectiveness, Adoption, Implementation and Maintenance

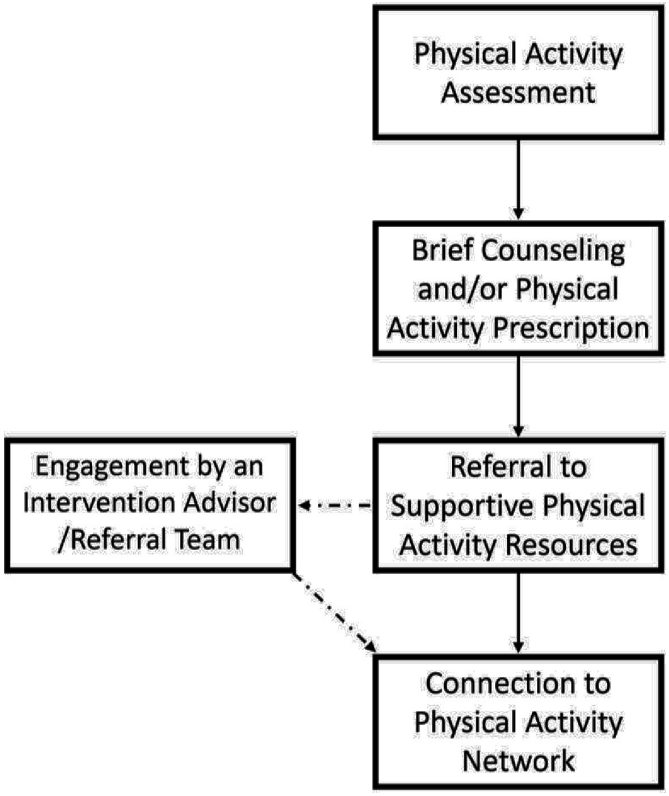

Figure 1 Comprehensive model for physical activity integration into health systems.

(RE-AIM) and integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) frameworks, have been used to provide guidance for moving implementation strategies, such as EIM, into sustained clinical practice.[22 23] RE-AIM encourages a broad focus on both dissemination (ie, reach into the patient population; adoption by clinics and providers) and implementation outcomes (ie, implementation fidelity; strategy maintenance), while also addressing effectiveness (ie, changes in patient health outcomes).[24] The i-PARIHS framework addresses factors related to the: (1) strategy characteristics (ie, the innovation; EIM), (2) context (eg, healthcare system infrastructure), (3) recipients of the EIM strategy (ie, patients and clinical staff implementers) and (4) internal or external facilitation processes and structures.[25] By combining the RE-AIM and i-PARIHS frameworks, investigators can document changes in effectiveness, dissemination and implementation, while also providing information on the potential mechanisms by which outcome changes are produced.[26 27]

Exercise is Medicine Greenville (EIMG)

In 2016, Prisma Health (formerly named Greenville Health System) began the process of integrating a PA referral pathway in their health system, connecting patients to community PA facilities that offer an evidence-informed PA programme tailored for patients with chronic diseases. Prisma Health was the first large health system committed to a multilevel process of promoting PA with patients through a model called EIMG,[28] a joint

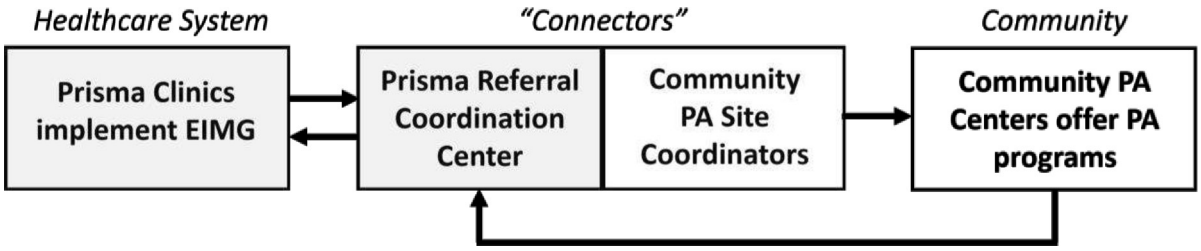

Figure 2 Schematic of the EIMG clinic-to-community linkage model (*Image reproduced with permission from work by Porter *et al*[29]). EIMG, Exercise is Medicine Greenville; PA, physical activity.

effort in partnership with the University of South Carolina School of Medicine Greenville (USC SOM Greenville) and the YMCA of Greenville and Oconee counties.

A description of EIMG (see figure 2) and outcomes from an initial pilot study have been previously published.[29] In brief, eligible patients between the ages of 18–80, who are physically inactive with or without a chronic condition (ie, overweight/obese, hypertension, type 2 diabetes), are engaged in EIMG by their healthcare team during an ambulatory visit at the Prisma Health clinics participating in EIMG. Front office or nursing staff capture patient current PA levels via the physical activity vital sign (PAVS), which is programmed into the electronic health records (EHRs) to identify 'eligible' patients. This prompts a best practice alert that the patient may qualify for EIMG. The healthcare provider informs eligible patients about EIMG, reviews risks and provides basic PA counselling (eg, using EIM Rx for Health handouts[30]). The healthcare provider then electronically completes an 'EIMG Order Set' that includes patient referral to a Prisma Health EIMG nurse navigator who reviews the patient's EHR for initial eligibility (see online supplemental file 1), contacts them via telephone, confirms their interest and identifies their preferred location and ability to pay (eg, scholarship eligibility). The EIMG nurse navigator then electronically sends Health Insurance Portability and Accountability Act (HIPAA) compliant patient information to the EIMG site coordinator at the patient's preferred community PA facility. EIMG site coordinators contact patients, review logistic and financial needs and schedule them for onboarding with an EIMG exercise professional (EIMG Pro), who leads referred patients through a 12-week evidence-informed PA programme over 1 hour sessions, two times per week.

From its launch in 2016, EIMG expanded to 18 Prisma Health practices and six community PA facilities across Greenville County by 2019. Over time, referral numbers have been consistent within a clinic, demonstrating the initial sustainability of the EIMG model. Despite the existence of a standardised framework for integrating EIM in Prisma Health clinics, variability in EIMG adoption and implementation fidelity has emerged over the initial years of the EIMG programme, underscoring the need to understand the contextual factors and processes at both clinic-level and provider-level to enhance adoption and implementation. This study will evaluate the adoption and initial implementation of EIMG at Prisma Health primary care clinics, which will generate vital information on optimising the onboarding process, the referral pathway and developing clinic-to-community linkages to engage patients in the community-based PA programme to inform subsequent dissemination in other health systems.

Study aims

Primary aim

To determine differences in clinic-level and provider-level adoption (ie, proportion and characteristics of clinics that adopt and initiate use of EIMG), implementation (ie, delivery fidelity) and reach (ie, number, proportion and representativeness of patients) before and after EIMG integration at newly adopting Prisma Health primary care clinics.

Secondary aim 1

To assess contextual factors (recipient, context, innovation and facilitation efforts) impacting the adoption and implementation of EIMG at newly adopting Prisma Health primary care clinics.

Secondary aim 2

To assess the effectiveness of participating in the evidence-informed, 12-week PA programme at the community PA facilities on patient health outcomes (ie, body weight, blood pressure, haemoglobin A1c, lipid profiles) captured in their EHRs.

METHODS AND ANALYSIS

Overview of study design

This pragmatic quasi-observational study, guided by the RE-AIM and i-PARIHS frameworks, will examine the adoption, implementation and reach of EIMG across Prisma Health primary care clinics. Study activities will commence in August 2023, participant enrolment between September 2023 and August 2024, and data cleaning, analysis and publication being completed by May 2025. 20 novel (eg, not already participating) Prisma Health primary care clinics will have the opportunity to adopt EIMG beginning in August 2023. Adopting clinics will receive a standardised instructional video and have the EIMG referral process activated (phase I), allowing providers to refer eligible patients to the 12-week evidence-informed PA programme. In January 2024,

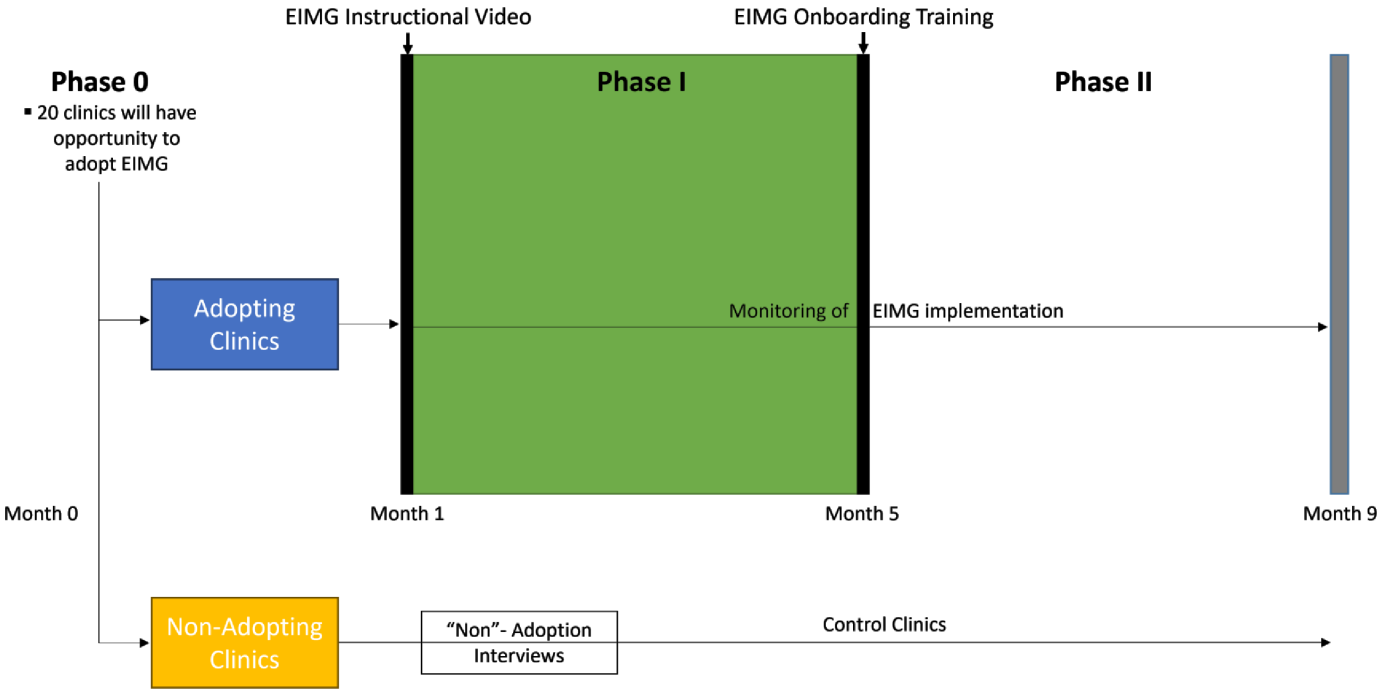

Figure 3 Overall schematic study design. EIMG, Exercise is Medicine Greenville.

adopting clinics will receive in-depth, semi-tailored EIMG onboard training (phase II). At adopting clinics, referral rates of eligible patients will be tracked over a total of 8 months (months 1–4 after instructional video, months 5–8 after semi-tailored, onboard training). A mixed-methods approach will explore factors related to EIMG adoption (eg, characteristics of adopting vs non-adopting clinics and providers), implementation fidelity (eg, clinic workflow, referral process), reach (ie, proportion of eligible patients receiving a referral, characteristics of referred vs non-referred patients) and patient enrolment in evidence-informed PA programmes at participating community PA facilities. See figure 3 for the overall schematic study design.

Setting

This study will occur in Prisma Health primary care clinics located in upstate South Carolina, USA. Prisma Health consists of 18 hospitals with >2900 licensed beds, >300 physician practice sites, reaching 1.2 million patients annually (220 000 patients with Medicaid) through a network of 4700 providers and 750 employee health business partners. Prisma Health is committed to the communities it serves within a 21-county service area with approximately 45% of South Carolina's population within 15 min of a health facility. Prisma Health strives to meet the quadruple aims of optimising patient experience, addressing population health, increasing the well-being of the care team and reducing costs. Under this mission, Prisma Health is committed to using information gained through the evaluation of EIMG implementation in Prisma Health–Upstate primary care settings to effectively scale the programme across remaining Upstate clinics.

Primary care settings, as opposed to acute and urgent care centres or specialty clinics, were selected for this study. The primary care setting is often the first point of contact (and sometimes the only point of contact) for patient populations (eg, patients with diabetes, hypertension, obesity) requiring primary and/or secondary disease prevention, such as PA promotion and counselling. Primary care practices are tasked with providing high quality care for patients on a long-term basis, many of them with co-morbid conditions that could be positively impacted by greater PA levels. Further, the primary care setting allows for the ongoing observation of the trajectory of chronic diseases through multiple visits over time.[31] Lastly, the patients seen in primary care settings are representative of the surrounding population, allowing for a greater examination of interventions that reduce health disparities and improve health equity.

The department chairs of Internal and Family Medicine at Prisma Health serve as co-medical directors on the EIMG Advisory Board and provide consulting, clinical interpretation of programme outcomes and communication on the growth and sustainability of the programme to their respective departments. They will facilitate communication and recruitment of internal and family medicine primary care clinics within Prisma Health during the study to increase patient reach of participation.

Study eligibility

Our study population will consist of: (1) clinic staff at participating Prisma Health primary care clinics and (2) all patients eligible to receive an EIMG referral to participate in the evidence-informed PA programme at local community PA facilities.

Table 1 Determining the proportion of patients eligible to receive an EIMG referral

	Definition	Description
Numerator	# of eligible patients who receive an EIMG referral	► Determined via real-time patient workflow process in Prisma Health primary care clinics participating in the study.
Denominator	# of patients who were eligible to have received an EIMG referral	► Retrospective extraction from the Prisma Health EHR. ► Determine eligible patients based on ICD-10 inclusion criteria. ► Remove ineligible patients based on ICD-10 exclusion criteria.

EHR, electronic health record; EIMG, Exercise is Medicine Greenville; ICD-10, International Classification of Disease, Tenth Revision.

Clinic level

As the unit of randomisation, 20 Prisma Health primary care clinics that have not yet implemented EIMG will have the opportunity to adopt EIMG. Eligibility criteria for clinics to participate in the study include:

- Prisma Health primary care clinics (ie, family or internal medicine) located in upstate South Carolina.
- Have not received EIMG onboarding or activation in the past.
- Consist of at least two attending providers.
- Located 15 miles or less from a participating community PA facility.

All potentially eligible Prisma Health primary care clinics will be geographically coded to determine the distance to the nearest participating community PA facility. Clinics >15 miles from a participating PA facility will be ineligible for study participation, as previous research demonstrates that engagement in leisure time PA and enrolment in fitness centres is negatively correlated with distance to PA destinations.[32 33]

Patient level

Adult patients (≥18 years of age) will be deemed eligible to receive an EIMG referral (criteria 1) and participate in the study (criteria 2) as summarised below (see table 1).

1. Patient eligibility to receive an EIMG referral is determined in real time through the decision of healthcare providers at adopting Prisma Health primary care clinics through a series of steps integrated in the patient workflow process. During EIMG onboard training, healthcare providers receive guidance on general eligibility criteria; however, the final decision on the provision of an EIMG referral is at the discretion of the provider. Once the provider has deemed that a patient will benefit from participating in a PA programme as an appropriate part of their patient care programme, they initiate the EIMG referral process. The following must be completed by the provider or another member of the clinic staff:
   a. Completing the PAVS.
   b. Completing a Risk Severity Assessment to ensure that participating in an exercise training programme will be safe and appropriate for their patients.
   c. Uploading the consent and release of information forms signed by the patient (either electronically or written) to allow the transfer of limited HIPAA-protected patient health information to the site coordinator at the community PA facility.

   If patients do not meet or have all three of these steps completed, they will be considered ineligible to continue with the EIMG referral process. The EIMG referral is then electronically sent to the EIMG nurse navigator, who checks for completeness, ensures patient eligibility to participate in the PA programme and contacts referring clinicians for any missing information or to clarify safety concerns. Patients receiving an EIMG referral will have the opportunity to enrol in the community-based PA programmes and will be considered as the numerator in our 'reach' calculations.
2. After the study period, we will identify adult patients who should have received an EIMG referral (whether they received one or not) at participating clinics through retrospective data extraction from the Prisma Health EHR applying the following criteria that have been developed a priori. This broader sample of patients who were eligible for an EIMG referral will be considered as the denominator in our 'reach' calculations. The process of retrospective identifying potentially eligible patients is described in the subsection 'Exclusion criteria for EHR data extraction'.

Inclusion criteria for EHR data extraction

As part of the study protocol, a list of International Classification of Disease, Tenth Revision (ICD-10) codes will be developed via expert consensus to identify all patients who were potentially eligible for an EIMG referral. The inclusion criteria will be based on priority health conditions identified by Prisma Health leadership in partnership with the EIMG Advisory Board. These criteria will be emphasised in the EIMG introductory video and the EIMG onboard training with adopting clinics to guide providers in identifying eligible patients. Broadly, these conditions include patients who are: (1) physically inactive, and/or who have (2) obesity, (3) diabetes, (4) hypertension or (5) dyslipidaemia. The list of ICD-10 codes was first selected by the research team and later verified by the EIMG Advisory Board and a sample of Prisma Health primary care clinicians not involved in the research study.

Exclusion criteria for EHR data extraction

A list of ICD-10 codes will be developed to exclude potentially eligible patients during the final EHR data extraction who may meet the inclusion criteria, but for

whom an EIMG referral is not appropriate. Patients seeking medical assistance with any of these criteria will be deemed ineligible to receive an EIMG referral and removed from the denominator during implementation, reach and effectiveness analyses. The list of exclusionary criteria will be developed through a multistep process that includes searching published, existing tools for PA contraindications and seeking input from a representative sample of primary care and sports medicine physicians to develop a final list of ICD-10 codes to serve as exclusionary criteria for which an EIMG referral is either inappropriate or contraindicated.

The inclusion/exclusion criteria for EHR data extraction will be completed during the study period, prior to EHR data extraction, which will occur after the end of phase II.

Intervention

Phase 0—initial EIMG adoption

The initial 'phase' of this study will involve a three-step approach inviting all eligible Prisma Health primary care clinics to adopt EIMG. First, practice managers and physicians at eligible clinics will receive an email introducing EIMG and how adopting it may benefit their clinic, as well as a link to the EIMG website. Physicians who respond to the initial email will be encouraged to reach out to their practice manager to be jointly involved in the EIMG adoption process. The practice managers were chosen as the focal point in the adoption process as they are most likely to broadly disseminate information and materials to the entire clinic staff. Practice managers at non-responsive clinics will receive two follow-up emails, spaced 1 week apart. If a practice manager expresses that their clinic is not interested in adopting EIMG, the clinic will be considered a 'non-adopter'. Practice managers who express interest in adopting EIMG will be invited to a brief introductory meeting, during which the study coordinator will provide an overview of the adoption process (phases I and II), discuss the EIMG introductory video, the timeline for its dissemination and EIMG activation at the clinic, explain the optional research components accompanying EIMG adoption and answer any questions.

Phase I—EIMG instructional video

Phase I will start with disseminating the EIMG instructional video to adopting clinics, followed by EIMG activation. The EIMG instructional video is intended to be a light touch strategy, similar to the current standard of practice in Prisma Health, for disseminating information and introducing new programmes into clinical practice. The EIMG instructional video is a brief (approximately 12 min), voice-over PowerPoint presentation that provides information on: (a) the origins of EIMG, (b) the 12-week, community-based PA programme, (c) initial patient effectiveness results and (d) process for placing an EIMG referral. The EIMG instructional video will be sent to the practice managers at EIMG-adopting clinics for broader dissemination to all clinic staff. After delivery of the video, access to the EIMG referral process in the EHR will be 'turned on' (EIMG activation) allowing clinic staff to electronically identify and refer eligible patients. Due to current information technology configurations at Prisma Health, the EIMG activation in the EHR occurs at a clinic level, providing access to all healthcare providers in that clinic once they have received the EIMG introductory video. From previous experience, most providers will be either unaware or unable to complete the EIMG patient referral process without first viewing the EIMG introductory video.

Phase II—EIMG onboard training

Phase II will consist of an in-depth EIMG onboard training (eg, initial external facilitation) that will take place with EIMG-adopting primary clinics. The EIMG onboard training will be scheduled in collaboration with the clinic practice manager at a time most convenient for the clinic staff. The scheduling of the EIMG onboard training will occur during the second half of month 4, with trainings taking place during the first half of month 5. The training will follow an established, semistructured protocol that has been iteratively developed and refined from lessons learnt through the onboarding of previous EIMG clinics. The standardised yet flexible and adaptable training will be targeted to practice managers, physicians, nurses and front-office staff at clinics. The training will include a review of the EIMG Clinical Education Workflow, a breakdown of responsibilities for each part of the EIMG process (ie, conducting the PAVS, obtaining the consent and release of information forms) and completing the risk severity assessment. Strategies used in the EIMG onboard training will be mapped to implementation strategies compiled as a part of the Expert Recommendations for Implementing Change.[34]

Data collection and outcomes

An overall summary of the data collection plan, outcomes and timeline can be found in online supplemental file 2. This study will examine the adoption, implementation and effectiveness across three different groups of individuals:

- Practice managers at Prisma Health primary care clinics that are eligible to adopt EIMG.
- Clinic staff at Prisma Health primary care clinics implementing EIMG.
- Patients at primary care clinics that receive an EIMG referral.

All individuals who agree to participate in research activities will go through an informed consent process.

Adoption—clinic level

The adoption of EIMG at eligible Prisma Health primary care clinics will be examined through two strategies. First, we will compare key characteristics (eg, proximity to the PA facilities, number of patient clinic visits, patient insurance distribution, number and type of providers) between adopting and non-adopting clinics. Second, at the end

of the first month of Phase I, we will conduct semistructured, individual interviews with practice managers from Prisma Health primary care clinics, regardless of whether their clinic decided to adopt EIMG. The development of the interview script will be guided by the i-PAHRIS framework.[25] To maximise the engagement of clinic managers, particularly those from non-adopting clinics, we will develop operating procedures (eg, number and types of communications, support of Prisma Health leadership) to maximise participation and anticipate challenges engaging clinic managers, particularly at non-adopting clinics.

Adoption and implementation—provider level

Two assessments will be used to examine contextual factors influencing the adoption and implementation of EIMG by clinic staff. First, we will conduct the Organisational Readiness to Change Assessment (ORCA), which operationalises constructs defined in the original PARIHS framework to measure organisational readiness to change in clinic settings.[35] The ORCA consists of three major scales that measure the strength of evidence for the proposed innovation, organisational support for change and organisational capacity to facilitate the change. In previous work, we adapted and pilot-tested the ORCA as an online questionnaire with Prisma Health primary care clinics to assess contextual factors related to EIMG implementation. In the current study, we will conduct the ORCA as an online questionnaire with a representative sample of clinic staff from each clinic after the dissemination of the EIMG instructional video (month 2) and again after the EIMG onboard training (month 6). We will also conduct brief (~30 min), semistructured interviews with clinic staff to gain a more nuanced understanding of EIMG adoption and implementation within each clinic by the providers and staff. The interview scripts will be mapped to the i-PAHRIS framework[25] and structured to complement data gained through the ORCA. We will attempt to conduct interviews with a representative sample of staff (eg, administrative staff, two clinicians) at one time point, approximately 2–3 months after the EIMG onboard training (months 7–8). Similar to the recruitment of clinic managers at non-adopting clinics, we will develop operating procedures for the recruitment of clinic staff and healthcare providers, with a focus on the recruitment of healthcare providers who do not individually adopt the EIMG referral process with their patients.

Evaluating the effectiveness of the 12-week, community-based PA program

Changes in patient PA levels will be evaluated through two strategies. First, patients will be screened for their PA levels during clinic visits using the PAVS. Patients who enrol in the 12-week PA programme will continue to complete the PAVS (to ensure consistency of assessment) at baseline (week 1), midpoint (week 6), conclusion (week 12) and 12 weeks after the completion of the PA programme by the EIMG Pros. As a secondary data source, we will extract patient PAVS data from the Prisma Health EHR. We will use this data to monitor patient PA levels prior to receiving the EIMG referral through 6 months after completing the PA programme.

Changes in patient health outcomes will be evaluated using primary data (eg, body weight, blood pressure, haemoglobin A1c, lipid profiles) extracted from the Prisma Health EHR to allow comparisons between eligible patients who received an EIMG referral and participated in the PA programme and eligible patients who do not receive an EIMG referral. Disease incidence, burden and complications (ie, the Charlson Comorbidity Index) will be calculated from extracted data.

Individual surveys with patients will be conducted, based on the COM-B (Capability, Opportunity, Motivation—Behaviour) framework, with patients receiving an EIMG referral. Patients from each of the following three categories will be interviewed:

1. Patients who received a referral from their provider, but chose not to enrol in the evidence-informed PA programme, will be queried about their awareness of and reasons for not enrolling (ie, perceived challenges to participation).
2. Patients who received a referral and enrolled, but dropped out of the evidence-informed PA programme, will be asked about their perceptions of and satisfaction with the programme, motivations for enrolling and reasons for discontinuation.
3. Patients who enrol and complete the programme will be queried about their motivations for enrolling, perceptions of and satisfaction with the programme, and challenges encountered.

Similar to the recruitment of clinic managers at non-adopting clinics and non-adopting healthcare providers, we will develop operating procedures for recruiting patients from each of these three sections with a focus on patients who do not enrol in the PA programme and those who enrol, but drop out of the PA programme.

Wherever possible, responses from the patient surveys will be linked to EIMG implementation strategies, such as clarifying steps for additional support and improvements to provider-patient interactions. We will contact and invite all patients to participate in the individual interviews who received an EIMG referral during both Phase I (EIMG introductory video) and Phase II (EIMG onboard training).

Patient and public involvement

The EIMG programme has been iteratively refined since 2017 through the participation and feedback of Prisma Health clinical staff. Additionally, the EIMG programme is guided by an advisory board consisting of health system leadership, department chairs and representatives from the community PA facilities. For this study, which focuses on the adoption and implementation of EIMG into primary healthcare clinics, clinic staff (eg, clinic managers), nurses, physicians and health system administrators were involved in all steps of the study design.

Statistical analyses

Analysis of primary aim

Clinic level nominal characteristics will be summarised as count and proportion; quantitative characteristics (eg, patient census, provider census) will be summarised as using the median and IQR. Patient level data will be summarised monthly by clinic using count and proportions for categorical data and mean (SD) or median (IQR) as appropriate. Clinic level characteristics will be compared between adopting and non-adopting clinics to look for indicators that may be leveraged to improve the adoption of EIMG into the patient care workflow. Similarly, there may be providers within participating clinics that choose not to adopt EIMG (refer eligible patients to the PA programme); characteristics of the providers will be compared with look for ways to improve EIMG referral adoption and implementation.

The primary endpoint will be analysed on an intent-to-treat basis. This means that clinics will be analysed according to their agreement to adopt regardless of their subsequent participation. For analyses at the patient level, patients within EIMG-adopting clinics who receive referrals will be analysed as EIMG participants regardless of their subsequent actions/participation. Referred patients will be considered as part of the 'EIMG group' even though they may not be perfectly compliant or follow the prescribed dose of exercise in the PA programme.

The effect of EIMG on outcomes for overall reach will be analysed using generalised linear mixed models (GLMM). The use of the GLMM accounts for the variability between clinics (random intercept) and the random effect of time within each clinic. The right-hand side of the model will have the same form. The left-hand side of the model may require the use of different link functions. Our experimental units are the clinics themselves with the observational units being the EIMG eligible patients nested within each clinic. The analytical models will have the following form:

$$g\left(Y_{ijk}\right) = \left(\beta_0 + \mu_{0i}\right) + \beta_1 EIMG_j + \left(\beta_2 + \mu_{2i}\right) X_i + \left(\beta_3 + \mu_{3k}\right) T_k + \left(\beta_4 + \mu_{4jk}\right) EIMG_j T_k + e_{ijk}$$

The subscripts i, j and k refer to clinic, EIMG status and time (monthly), respectively. Y_{ijk} is the clinic level outcome measure; $g\left(Y_{ijk}\right)$ is the link function; β_0 is the mean response across clinics; β_1 is the effect of EIMG; β_2 is the mean effect of clinic level covariates controlling for EIMG status; β_3 is the effect of time; β_4 is the effect of the interaction between EIMG status and time. The remaining terms in the model represent random variability and are assumed to have an expected value of 0 and associated non-zero variance. Specifically, μ_{0i} is the uncertainty term for the intercepts between clusters; μ_{2i} is the uncertainty term for clinic level covariate slopes between clusters; μ_{3k} is the uncertainty term for the effect of time; μ_{4ijk} is the uncertainty term for EIMG by time interaction between clusters and e_{ijk} is the unexplained residual.

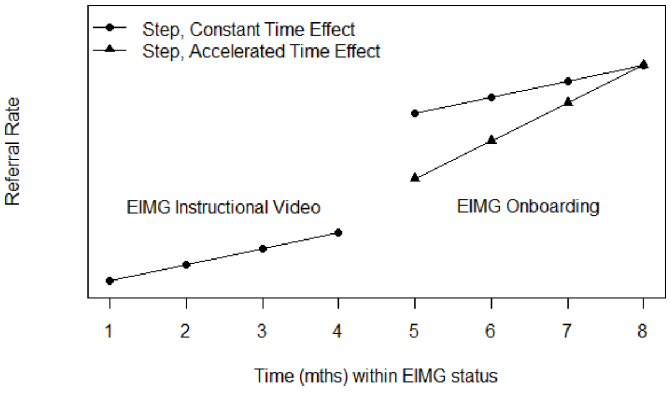

Figure 4 Referral rate profiles considered in sample size analysis. EIMG, Exercise is Medicine Greenville.

Rationale for sample size and statistical power

Sample size was established via simulation in R V.4.2.3 (R Core Team, 2023) using preliminary data from clinics participating in a pilot study. This analysis is based on a within clinics, repeated measures design with two levels of EIMG exposure: instructional video and onboard training. The outcomes (eg, referral rates) will be measured four times (once per month) under each level of EIMG, for a total of eight observations per outcome per clinic. Two marginal referral rate profiles were considered in determining the sample size: a step effect of EIMG onboarding with parallel time effect (main effects model) and a step plus accelerated time effect. A generic plot showing the two marginal rate profiles considered is presented in figure 4.

Pilot data from 12 previously onboarded EIMG-clinics indicated that the marginal referral rate (reach with eligible patients) prior to onboarding to EIMG was approximately 0.01 (unpublished data). The following assumptions were then made for both referral rate profiles. The SD for the random effect of clinic, and random deviation is 0.01, the significance level for each comparison is 0.05. For the step with constant time effect, it was assumed that there was a linear change from 0.001 to 0.01 over the 4 months following the EIMG instructional video, a step-jump of 0.02, followed by a linear and parallel time effect achieving 0.04 (4%) referral rate at 8 months. For the step with accelerated time effect profile, the profile for the first 4 months was assumed to be the same as for EIMG instructional video with a step-jump of 0.01 followed by a linear increase to 0.04. Simulations (n=100) under each profile were conducted to compute a single empirical power, this was repeated 100 times. The power reported corresponds to the minimum empirical power observed. For a step with constant time effect, a total of 10 clinics are needed to achieve a power of 92% to detect the EIMG onboarding effect of 0.02. For the step plus accelerated time effect profile, a total of 20 clinics achieves 78% power to detect the time by EIMG status interaction when using a significance level of 0.05. 10 clinics provide 40% power to detect the step plus accelerated time effect profile.

Analyses of secondary aim

Effectiveness is the degree to which participating in the evidence-informed PA programmes improves patient PA levels and health outcomes (ie, changes in cardiometabolic biometric values). Primary data for assessing effectiveness will be extracted from the Prisma Health EHR to allow comparisons between patients who are engaged in EIMG and participate in the evidence-informed PA programmes and patients who do not participate (either those who are not engaged in EIMG by their providers or those who choose not to participate). Disease incidence, burden and complications (ie, the Charlson Comorbidity Index) may also be calculated from data captured in the EHR. Secondary assessment of patient-level effectiveness (eg, blood pressure, blood glucose, cholesterol concentrations) will be collected by the EIMG Ex Pros at the community PA facilities for EIMG-referred patients who consented to participate in the research study.

Analysis of qualitative data

A rigorous approach will be employed in the analysis of the qualitative data. Open-ended responses will be uploaded to a qualitative software programme (eg, Dedoose) to create and apply codes to textual data, write analytic memos and conduct analyses by question and respondent. Individual responses will be analysed as follows: responses will be reviewed to develop an initial coding scheme for each question. Codes will be developed deductively from the questions posed and inductively from responses.[36] As new codes emerge, they will be incorporated into the schemes for each question. A coding manual with definitions for each code will ensure high levels of intercoder reliability (>80%) are achieved throughout the coding process.[37 38] Disagreements in the application of codes will be resolved by a third member of the research team. The analyses will catalogue facilitators, barriers and challenges to EIMG implementation in each phase, as well as strategies for overcoming those barriers.

Poolability of data

We intend to perform the primary treatment effect analysis by pooling data from all clinics. It is possible that the treatment effect will differ across clinics, and this will be investigated. We will fit a model with site by treatment interaction and if significant (at 0.05 level), we will present treatment effects by clinic. Although the study is not powered for the detection of different treatment effects across clinics, this analysis will provide insight into possible varied treatment effects across sites or reassure that data can reasonably be pooled over sites with respect to the treatment effect.

ETHICS AND DISSEMINATION

We received ethical approval to conduct this study from the Prisma Health Institutioanl Review Board (IRB) Committee A (#1963762). All requirements related to obtaining IRB review and approval, as well as informed consent, will be met. Written informed consent will be obtained from each study participant using the local IRB-approved informed consent form (see online supplemental file 3). Appropriate research personnel will explain all aspects of the study to each participant, answering all questions and ensuring that all basic elements of the informed consent process are covered. All study personnel will be required to complete Human Subject Protection, Good Clinical Practice and HIPAA training (as applicable) and will be instructed to act under those guidelines at all times when working with participants, participant data or protected participant health information.

Defining EIMG research participants

EIMG (the process of identifying and referring patients to the community-based PA programme) is part of a clinical workflow process that is not considered a part of the research study. The research study itself consists of gathering data from surveys, conducting individual interviews with clinic staff and patients who have been referred to EIMG and evaluating the effectiveness of the PA programme (using data that are already collected in the EHR or through the community-based PA programme). There will be minimal risk to the participants with study activities, and all available measures will be taken to protect the privacy of participant responses. Patients enrolling in the community-based PA programme will have the option of participating in the research study via the informed consent process. Those who do not consent to participate in the study will be provided with the same opportunity to enrol and complete the PA programme as patients who do consent to participate in the research study.

The informed consent process

Prior to consenting to participate in the study, a copy of the informed consent will be mailed or emailed (as appropriate) to prospective participants to review ahead of the consent process and to keep as a reference. At a scheduled study meeting, a member of the research staff will explain the study to the potential participant, reviewing all sections of the informed consent in detail and answering any of the participant's questions. During the informed consent process, details of the study will be explained, including participant burden, potential risks and benefits, names and contact information for the study prinicipal investigators and other local individuals (ie, IRB staff) who can be contacted for additional study details. There will be no coercion to participate or prejudice against those who choose not to take part in the study, and potential participants will be encouraged to ask any questions they have regarding study procedures. Informed consent will be obtained prior to any data collection. Proxy consent will not be accepted as we anticipate that all individuals eligible to participate in the study will be able to provide their own informed consent.

Verbal informed consent

Individuals conducting virtual study activities (ie, telephone or virtual interviews) will be asked to provide

their verbal consent to participate in the study. The research team member will follow the same informed consent process as with the written informed consent process. However, the participant will not be asked to sign a consent form, only to verbally agree to participate in the study after the informed consent process. The final page of the informed consent form will have a page for documentation of verbal consent that the research team member will check off (if provided) and date.

Participant remuneration

Participants (practice managers, clinic staff, and patients) will receive monetary remuneration (gift cards) for participating in the individual interviews to compensate them for their time, travel and burden of participation. Recruitment materials will mention that both adopting and non-adopting clinic managers and healthcare providers are eligible to participate in the study and receive remuneration for their efforts. Clinic staff will not be compensated for completing the online ORCA questionnaire and patients will not be compensated for participating in the 12-week, community-based PA programme or any of the programme assessments.

Data management and access

Data monitoring and the data management plans for the study can be found in sections 15.9 (Data Safety and Monitoring Board) and 16.0 (Data Management and Procedures) of the study protocol located in the ClinicalTrials.gov registry. The data sharing plan was directly entered into a field within our protocol registry within ClinicalTrials.gov.

Participant confidentiality

Information on how participant data will be collected, shared and maintained to protect their confidentiality can be found in sections 15.7 (Participant Confidentiality/Privacy) and 15.8 (Confidentiality Breach) of the study protocol located in the ClinicalTrials.gov registry.

Protocol registration and amendments

This trial was registered with ClinicalTrials.gov. Any modifications to the study protocol and/or materials will be shared with the entire research team and subsequently updated in the trial registration in ClinicalTrials.gov.

Dissemination of study findings

In addition to traditional routes of disseminating study findings (eg, publication, conference presentations), findings from this study will be disseminated more broadly through several methods. Study findings will be shared with Prisma Health leadership (eg, the Chief Scientific Officer, department chairs), participating clinics (via clinic managers) and the EIMG Advisory Board Team. Further, findings will be shared with the leadership of YMCA of Greenville (eg, the CEO) and the USC SOM Greenville (eg, Dean). Finally, we will share study findings with the US Center for Disease Control and Prevention for dissemination through their website, newsletters and outreach activities (eg, county grantees).

DISCUSSION

The completion of this study and achievement of our study aims have the potential to significantly advance understanding of how to optimally integrate a PA referral pathway into clinical settings involving the prescription, referral and engagement of patients in community-based PA programmes. It will also advance dissemination and implementation science by providing information on factors that are more likely to lead to successful adoption, implementation and reach. Finally, this study will enhance the operationalisation of future, large-scale PA models in health systems that have diverse policies, practices, and patients.

Strengths and limitations

The strengths of this study come from the real-world implementation and dissemination of a PA referral pathway in a major US health system using dissemination and implementation science models and methods. The referral pathway is not a research artefact depending on grant funding, but an accepted standard of patient care in the Prisma Health system. This study will explore, as part of a natural experiment, the dissemination, adoption (or non-adoption) and implementation of EIMG by additional Prisma Health primary care clinics. Further, we will use a stepped approach to examine the level of effort necessary to fully onboard and engage clinics and providers in referring their eligible patients, comparing a 'light touch' (eg, dissemination via a brief introductory video) onboarding to a subsequent more time-intensive, real-time onboarding. A limitation of this work is that the research team has no control over how many clinics and providers will choose to adopt and implement the EIMG model. We expect challenges engaging non-adopting clinic managers, medical staff and healthcare providers, limiting insight into the barriers and challenges faced by clinics and practitioners in greatest need of implementing the EIMG model. Further, as currently designed, we are unable to link healthcare provider engagement with the EIMG introductory video or participation at the EIMG onboard training with their ability to provide their patients with EIMG referrals.

Dissemination and implementation of study findings

Study findings and resources will be made available to health systems for broad scale-up with the goal of increasing patient engagement in community-based PA programmes as an extension of healthcare systems. Finally, the achievement of our study aims will provide an economic evaluation that has the potential to impact coverage decisions made by insurance companies and

adoption/implementation decisions made by health systems when determining the design and uptake of clinical/community health promotion programmes.

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