Protocol Title: Facilitating Health System Implementation of Physical Activity Screening and Referral to Community-Based Programs: Exercise is Medicine Greenville

NCT Number: NCT07340580

Document Version and Date: February 27, 2026, V1.0

Protocol Title: Facilitating Health System Implementation of Physical Activity Screening and Referral to Community-Based Programs: Exercise is Medicine Greenville

NCT Number: NCT07340580

Document Version and Date: February 27, 2026, V1.0

Principal Investigator

- Jennifer Trilk, PhD

Funding Sponsor: NHLBI (R01 mechanism)

NIH Grant Number: 1R01HL173601-01A1

IRB Number: [2222165-1] R01 – Implementation/Facilitation of EIMG Program

Abbreviations

ACSM	American College of Sports Medicine
ALC	Administrative Leadership Council
CSG	Clinical Steering Group
DRG	Diagnosis Related Group
DSMB	Data Safety and Monitoring Board
EHR	Electronic Health Record
EIMG	Exercise is Medicine Greenville
GLMM	Generalized Linear Mixed Model
HCPCS	Healthcare Common Procedure Coding System
i-PARIHS	Integrated-Promoting Action on Research Implementation in Health Services
IF	Implementation Facilitation
IV	Instrumental Variable
LISTS	Longitudinal Implementation Strategy Tracking System
NDC	National Drug Codes
ORCA	Organizational Readiness to Change Assessment
PA	Physical Activity
PAVS	Physical Activity Vital Sign
PHQ-9	Patient Health Questionnaire-9
PROMIS	Patient Reported Outcomes Measurement Information System
RE-AIM	Reach, Effectiveness, Adoption, Implementation, Maintenance
REDCap	Research Electronic Data Capture
YMCA	Young Men's Christian Association

Table of Contents

1 Introduction 6

1.1 Background and relevant literature 6

1.2 The Exercise is Medicine Greenville (EIMG) Model 8

1.2.1 EIMG in the Prisma Health-Upstate system 8
1.2.2 Interface between Prisma Health-Upstate and the community PA facilities 9
1.2.3 Evidence-informed PA programming at community PA facilities 9
1.2.4 Closing the loop: interfacing back to Prisma Health-Upstate 9
1.2.5 Program cost and financial assistance 10

1.3 Previous work 10

2 Study design 11

3 Theoretical framework 11

4 Study aims 11

5 Investigational plan and design 11

5.1 Implementation facilitation 11

5.1.1 Baseline Phase 12
5.1.2 Pre-IF Phase 13
5.1.3 IF Phase 14
5.1.4 Post-IF Maintenance Phase 16

5.2 Study outcome measures 16

5.2.1 Aim 1 17
5.2.2 Aim 2 19
5.2.3 Aim 3 21

6 Study population 24

6.1 Eligibility criteria 24

6.1.1 Primary care clinics 24
6.1.2 Primary care clinic staff 24
6.1.3 Patients 24

6.2 Subject recruitment 25

6.2.1 Primary care clinics 26
6.2.2 Primary care clinic staff 26
6.2.3 Patients 26

7 Study procedures 27

7.1 Subject compensation 27

7.2 Subject withdrawal 27

8 Study administration, data handling and record keeping 28

8.1 Study oversight 28

8.2 Confidentiality 28

8.3 Data collection and management 28

8.3.1 Data collection 28
8.3.2 Data management 29
8.4 Risks 29
8.5 Benefits 29
8.6 Informed consent process/HIPAA authorization 29
8.6.1 ORCA Survey 29
8.6.2 Individual interviews with clinic staff and patients 30
8.6.3 Accelerometry 30
9 Study finances 30
10 Dissemination 30
11 Conclusions 31
12 References 32

Synopsis

A public health priority exists for the U.S. healthcare sector to integrate physical activity as part of the patient care model to prevent and treat chronic disease; however, implementation barriers exist, ranging from practice integration to information flow. In 2016, a multi-organizational partnership between a medical school (University of South Carolina School of Medicine Greenville), health care system (Prisma Health-Upstate), and community organization (YMCA), launched Exercise is Medicine Greenville (EIMG), a comprehensive clinic-to-community approach that involves physical activity (PA) assessment, prescription, and referral of patients with chronic diseases to tailored, community-based physical activity programs. Since 2016, EIMG has grown to include 35 Prisma Health-Upstate primary care clinics and 7 community physical activity centers covering >400 miles^2. However, great variability exists in clinic-level implementation and provider-level adoption of EIMG and referral of patients to community-based PA programs. This pragmatic, stepped wedge, cluster randomized trial will examine the impact of implementation facilitation (IF) on the implementation and reach of EIMG with patients visiting EIMG-activated primary care clinics (i.e., provider referral rates). At six-month intervals, 35 randomly selected clinics (Wave 1: 6 clinics, Wave 2: 8 clinics, Wave 3: 10 clinics, Wave 4: 11 clinics) will receive Pre-IF (3 months), active IF (6 months), and Post-IF maintenance (12 months). The specific aims of this study are to: 1) determine differences in the level of implementation (i.e., delivery fidelity) and reach (i.e., number, proportion, and representativeness of patients) at Prisma Health-Upstate clinics before and after IF, 2) assess the level of patient engagement in and the effectiveness of the 12-week, community-based PA programs, and 3) evaluate the costs of IF and the effects of increased EIMG referrals to the community-based PA program on patients costs and clinical outcomes. This mixed methods evaluation approach is guided by the RE-AIM framework to inform the assessment of implementation outcomes, and the i-PARIHS framework to describe contextual factors (i.e., determinants) influencing patient and clinic level outcomes. Through this work, successful IF strategies will be identified across heterogeneous health settings and greater understanding of factors related to patient participation in the community-based PA programs. Results of this study have the potential to provide important information on improving future implementation and scalability of PA integration in large health systems, optimizing clinic-community linkages, and cost savings related to the primary and secondary prevention of cardiovascular disease-related health outcomes in the general patient population.

1 Introduction

1.1 Background and relevant literature

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 a broad array of health conditions [1]. Exercise training is equally (or 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]. PA acutely improves blood pressure [4], glycemic control [5], and inflammation [6]. Regular PA reduces the risk of developing chronic conditions, such as heart disease, stroke, hypertension, type 2 diabetes, and several types of cancer [7, 8]. Given the multiple benefits of PA, it is remarkable that only 54.2% of U.S. adults meet aerobic activity recommendations, while only 24.2% meet both aerobic and strength training recommendations [9]. Engagement of the health sector is essential in increasing population PA levels with strategies well-described in the U.S. National PA Plan [10, 11]. 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 counseling. The Toronto Charter [12], a global call to action for population-based approaches, outlines several strategies for increasing PA in health settings including i) reorienting health services and funding systems, ii) screening of patient PA levels at primary care consultations, and iii) referral to community programs for insufficiently active patients. These overarching guidelines have been supported by calls to action by medical societies [13] and leading health professionals [14, 15]. Yet integration lags because health systems are not properly equipped/designed to promote PA.

Similar to the SBIRT model [16] (Screening, Brief Intervention, and Referral to Treatment), an evidence-based, clinical strategy for addressing substance use disorders, Exercise is Medicine (EIM) [17] is a comprehensive model for integrating PA in clinic workflows. EIM is a framework to improve the identification and referral of physically inactive patients, connecting them to evidence-based PA programs. The individual components of the EIM model include: 1) assessing patient PA levels, 2) providing brief PA counseling or a PA prescription, and 3) referring patients to PA resources for further guidance. In some instances, a 'navigator' is used to increase referred patient engagement (Figure 1).

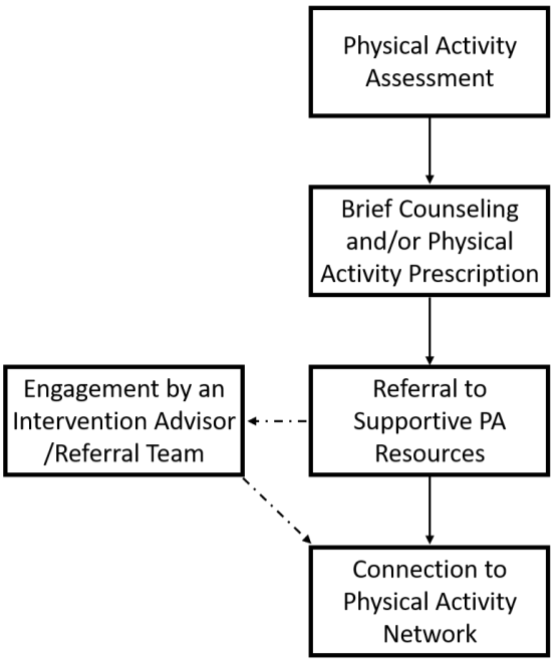

Figure 1. Comprehensive model for physical activity integration into health systems.

Assessing patient PA levels is a catalyst to subsequent prescription and referral [18]. The PA 'Vital Sign' (PAVS) is used by multiple U.S. health systems, demonstrating strong face and discriminant validity in identifying inactive individuals across gender, age groups, and disease conditions [19, 20]. Significant associations exist between PA levels and cardiometabolic risk factors, patient disease burden, and body mass index [21, 22]. PAVS integration into electronic health records (EHR) leads to greater PA progress note documentation, counseling, and referral compared to visits with no PAVS administration [23]. Despite PAVS integration in several U.S. health systems, few have adopted additional steps to address low patient PA levels.

In terms of **PA prescriptions**, The New Zealand Green Prescription is the best-known program involving health professionals giving patients a written/electronic PA prescription, leading to increased PA levels compared to verbal advice alone [24]. Patients receiving a prescription, compared to usual care, were more likely to meet PA guidelines and achieve higher energy expenditure [25] with benefits extending out 2-3 years [26]. Outside of a few small trials, PA prescriptions have not been systematically integrated into U.S. health systems.

The largest **PA referral** or exercise referral schemes exist in the United Kingdom, involving health professionals referring patients to community-based PA programs [27]. Exercise referral schemes increase patient PA levels, lower levels of depression and anxiety, and are moderately cost effective, particularly in older patients and those with greater cardiovascular disease risk factors [28, 29]. However, exercise referral schemes do not often involve a standardized PA assessment. In the U.S., no system-wide PA referral efforts have been established to date. Individual components of the "EIM model" have moderate-to-strong evidence bases. Prisma Health-Upstate is the first major health system in the world to integrate all EIM components into their clinic workflow, connecting patients with chronic diseases to community-based PA programs.

1.2 The Exercise is Medicine Greenville (EIMG) Model

1.2.1 EIMG in the Prisma Health-Upstate system

The innovation under investigation in this study is the Exercise is Medicine Greenville (EIMG) Model, a clinic-to-community model which represents a joint effort across the University of South Carolina School of Medicine Greenville, Prisma Health-Upstate, and the YMCA of Greenville and Oconee counties [30]. EIMG implementation started in 2016 with programming of the PAVS and the electronic referral flow into the EHR, onboarding of two clinics with provider/staff training, and referring patients to community PA facilities. By December 2023, 35 Prisma Health-Upstate primary care clinics had adopted the EIMG model, covering >400 miles^2 in Greenville and Oconee counties. Patients are eligible for an EIMG referral by providers if they are between 18-80 years of age and physically inactive (<150 min/week of moderate intensity aerobic activity), with or without a chronic health condition (i.e., overweight/obese, hypertension, type 2 diabetes, dyslipidemia). Three EIMG Clinician Decision Modules, i.e., 1) PA assessment, 2) PA prescription through patient order sets, and 3) patient referral to a community PA facility, are programmed and integrated into the EHR as part of clinical workflow (Table 1). An EIMG Referral Coordinator (employed by Prisma Health-Upstate) reviews patient eligibility, contacts them via telephone, confirms their interest, identifies their preferred location and ability to pay (or scholarship eligibility), and electronically sends HIPAA-compliant patient information to the YMCA Site Coordinator at the selected community PA facility for a warm "hand off".

Table 1: Exercise is Medicine Greenville clinical referral workflow integrated into electronic health record.

Module 1: PA Assessment	- Front office/nursing staff capture patient PA levels via the EHR-integrated, 3-question PAVS: 1) For an average week in the last 30 days, how many days per week did you engage in moderate to vigorous physical activity (like walking fast, running, jogging, dancing, swimming, biking, or other activities that cause a light or heavy sweat)? 2) On those days that you engage in moderate to vigorous physical activity, how many minutes, on average, do you exercise? 3) During the past month, how many times per week did you do physical activities or exercises to strengthen your muscles? - Best practice alert appears for patients not meeting national PA guidelines of 150 minutes of moderate intensity aerobic activity/week, stating the patient may qualify for EIMG.
Module 2: PA Prescription	- Healthcare providers inform eligible patients about EIMG, review risks, and provide basic PA education through the EIM Rx for Health [31] handouts for exercising with chronic diseases (e.g., diabetes, hypertension) developed by experts in the field. - Healthcare providers electronically start the EIMG Order Set for referral.

Module 3: EIMG Referral	- Healthcare providers send referrals to EIMG Referral Coordinator through a series of EHR prompts. - Patient signs Release of Health Information to proceed with referral (either in clinic or through MyChart).

Prisma Health-Upstate clinics are onboarded following standardized protocols that have been iteratively refined since 2016. Onboard training is provided to all clinic staff and includes a detailed explanation of the EIMG clinic workflow, responsibilities for each part of the EIMG process, and completing the risk severity assessment. After onboard training, access to the EIMG referral process (i.e., activation) in the EHR is 'turned on' allowing clinic staff to electronically identify and engage eligible patients.

1.2.2 Interface between Prisma Health-Upstate and the community PA facilities

The EIMG network includes seven community PA facilities (YMCA sites) across Greenville and Oconee counties (total reach >400 miles^2). All staff undergo standardized EIMG operations training. YMCA Site Coordinators contact referred patients, review logistic and financial needs, and schedule onboarding with EIMG Exercise Professionals (EIMG Pros). The YMCA Site Coordinator is responsible for HIPAA protocols, implementing EIMG protocols, communicating timelines, and audit reporting.

1.2.3 Evidence-informed PA programming at community PA facilities

Referred patients are connected to qualified EIMG Pros, who lead the 12-week PA program over one-hour sessions two times per week. EIMG Pros have an accredited personal training certification, the EIM Credential [32], HIPAA and CITI training for the protection of human subjects, and REDCap database [33, 34] entry training. During onboarding, patients complete: 1) health history forms, 2) pre-participation surveys (i.e., PHQ-9, PROMIS Scale), and 3) measurement of height, body weight, blood pressure, and heart rate. Assessments are completed again at the end of the 12-week program. Rolling enrollment allows patients to onboard in <10 business days to optimize behavior change, with new patients learning from current program participants.

The evidence-informed PA program is based on ACSM Position Stands and scientific evidence on meeting national guidelines of 150 min/week of moderate intensity aerobic activity. Sessions are guided by principles that training: 1) is progressive, 2) includes full body movements, and 3) incorporates active education to promote healthy lifestyle adoption. The sessions are structured to allow for flexible and adaptive delivery by EIMG Pros based on their unique participants and facility resources (i.e., equipment, space), similar to other adaptive and flexible health promotion interventions [35, 36]. EIMG Pros enter session data (i.e., patient attendance, assessments) into REDCap which is accessible to our research team.

1.2.4 Closing the loop: interfacing back to Prisma Health-Upstate

Patient activity (e.g., session completion, adverse events, patient discontinuation) is documented by EIMG Pros and sent by HIPAA-compliant email to the EIMG Referral

Coordinator, who then provides the patient's summary to the healthcare provider through the EHR.

1.2.5 Program cost and financial assistance

Assuring that EIMG is affordable and delivered equitably, YMCA of Greenville earmarks a percentage of their annual giving campaign to EIMG so that no patient is turned away due to their inability to pay. To date, >$350,000 is reserved for patient scholarships with 51% of patients receiving scholarships in the year 2024, a model replicable by community PA facilities across the country.

1.3 Previous work

At the end of 2025, 4204 patients had been properly referred to the EIMG Referral Coordinator (Figure 2) with 974 patients (23.2%) enrolling in the PA program. Analysis of patients (n=196) who participated in the PA program showed that patients experienced significant decreases in bodyweight (1.6±4.4 kg, $p<0.001$). Patients referred for hypertension lost an average of 1.4±4.4 kg ($p=0.002$) and decreased their systolic and diastolic BP by 7±15 ($p<0.001$) and 3±8 ($p<0.0001$) mmHg, respectively. In an exit survey of PA program graduates, all program components and personnel received high satisfaction scores (all provider and patient scores ≥4.75 on a 5-point Likert scale) [37].

Referrals to EIMG Referral Coordinator	Referrals sent to Community PA Facilities	Patients Enrolled in PA Program	Patient Graduation (2016-2025)
4204	1818	974	603
	43.2% referred patients connected to referral coordinator	23.2% of referred patients enrolled in a PA program	14.3% of referred patients graduated from a PA program
61.9% of enrolled patients graduated (603/974)			

Figure 2. Results for EIMG clinic-community referrals, 2016-2025.

Referrals have been consistent over the program's years, demonstrating sustainability of the EIMG model (Figure 2). However, large variations exist in referral patterns between EIMG clinics, and only a small fraction (<1%) of eligible patients receive EIMG referrals. This inefficiency in referral patterns makes it imperative to investigate strategies to optimize clinical implementation of EIMG. Strategies to overcome these contextual barriers could lead to significant advances in PA promotion by improving adoption, implementation, sustainability, and scale-up of efforts to identify, refer, and connect patients to evidence-based PA interventions. Additionally, physical inactivity costs healthcare systems $53.8 billion worldwide, contributing to $13.7 billion in productivity losses [38]. In the U.S., inadequate PA, independent of BMI levels, is associated with 11.1% of direct healthcare expenditures [39]. Conversely, PA interventions are cost-effective in improving population health outcomes [40, 41]. Cost savings have been noted when examining PA interventions introduced in healthcare settings. Linking primary care patients to community PA resources is likely to be cost-effective, but evidence is sparse [42]. To date, no studies have

examined cost and outcome implications of integrating PA into a health system anywhere in the world.

2 Study design

This study will utilize a pragmatic, stepped wedge, cluster randomized design to examine the impact of implementation facilitation on increasing the reach (eligible patients that receive an EIMG referral) at 35 Prisma Health-Upstate primary care clinics where the EIMG model is currently activated.

3 Theoretical framework

The study design is guided by the Implementation Research Logic Model [43], a semi-structured tool designed to integrate conceptual elements and improve the specification and rigor of implementation research. The integrated Promoting Action on Research Implementation in Health Services (i-PARIHS) [44] will be used to explore determinants of implementation while the RE-AIM framework [45], adapted for PA integration in health systems [46], will guide the evaluation of study outcomes.

4 Study aims

This study has three aims:

- Aim 1 (primary aim): To determine clinic-level differences in implementation of EIMG (i.e., delivery fidelity) and reach (i.e., number, proportion, and representativeness) of patients receiving EIMG referrals pre- and post-implementation facilitation.
- Aim 2 (secondary aim): To assess the effectiveness of participating in the community-based, 12-week evidence-informed PA program on patient PA levels and health outcomes (i.e., body weight, blood pressure, hemoglobin A1c, lipid profiles).
- Aim 3 (secondary aim): To evaluate, from the health system perspective, the costs of implementation facilitation and to estimate the effectiveness of increased EIMG referrals to the community-based PA on patient costs.

5 Investigational plan and design

5.1 Implementation facilitation

The study will examine using implementation facilitation (IF) to enhance the implementation and reach of EIMG in real-world settings [47]. As more clinics adopt EIMG, it is essential to have implementation strategies, such as IF, that enhance reach, particularly in lower performing clinics, and improve health equity. IF is widely used to address implementation challenges and increase fidelity to evidence-based practices. IF improves health care capacity, processes, and outcomes through trusting relationships between an external expert and clinic personnel, collaboratively changing care delivery processes [48, 49]. IF involves a set of implementation strategies that are flexibly selected in response to local circumstances at each clinic [50]. Primary care practices are nearly

three times more likely to adopt evidence-based practices when using IF, especially in under-resourced settings [51, 52]. The i-PARIHS framework posits that successful implementation results from the facilitation of an intervention as a function of site characteristics (e.g., clinics), intervention strategies/innovation (e.g., EIMG), and recipients (e.g., clinic staff/patients) [44] (Figure 3).

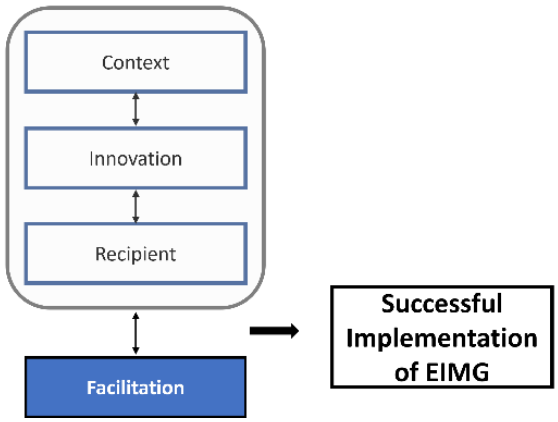

Figure 3. Integrated use of the i-PARIHS framework.

Eligible primary care clinics (Section 6.1) will be randomly assigned to one of the four study waves. Each wave will go through four phases: 1) Baseline, 2) Pre-IF, 3) IF, and 4) Post-IF Maintenance (Figure 4).

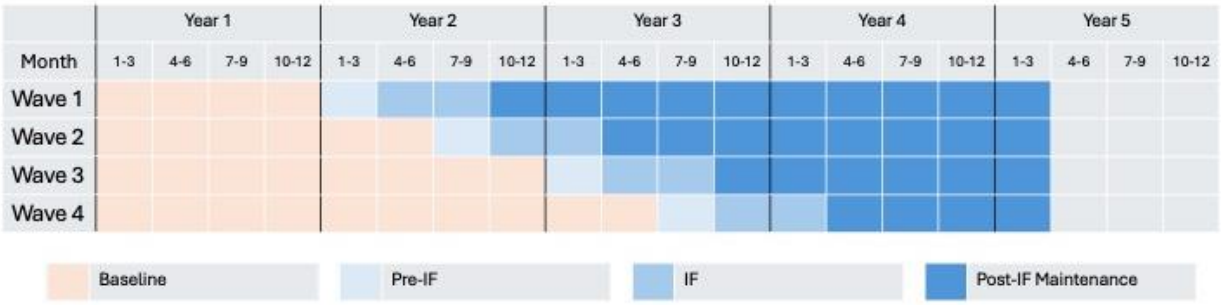

Figure 4. Cluster randomized, stepped wedge study design.

5.1.1 Baseline Phase

5.1.1.1 EHR data extraction

The baseline phase will be used as a run-in period to gather initial data from the EHR, which will be used to establish baseline implementation and reach metrics prior to IF, and to establish profiles of each clinic for use by the internal team. Data to be collected includes clinical data (i.e., patient demographics, patient volume, visits where the PAVS was completed, payer mix, others as needed) and EIMG eligible visit and referral history (i.e., EIMG eligible visits, EIMG referral data, and visits where the PAVS was completed) at clinic level and individual provider level. EIMG referral history will be used to categorize clinics by referral rate. This data will not be shared with clinics but will be used in designing customized IF plans.

5.1.1.2 Patient engagement

Patient engagement in health implementation research can improve research quality, enhance implementation processes, and add the value of lived experience to a study [53]. As such, this study will include patient engagement and feedback to develop and inform tailored IF strategies. Patient engagement will be conducted through the University of South Carolina's Patient Engagement Studio [54], and will be conducted over multiple sessions during the Baseline and Pre-IF Phases. A panel of patient experts has been created through the Patient Engagement Studio, composed of individuals who each manage different chronic conditions as well as some individuals who have participated in the EIMG program before, representing a variety of ages, careers, and racial/ethnic backgrounds that exist in the EIMG service area. The aims of patient engagement are to:

1. Learn about patient experiences to inform IF strategies.
2. Review patient-facing materials to ensure they integrate patient perspectives and improve the clarity, cultural relevance, and motivational appeal of the materials before implementation.
3. Review the referral workflow through the patient lens to better understand how they experience the referral process and the contextual factors in clinic that support or hinder success.

5.1.2 Pre-IF Phase

Pre-IF will occur over three months preceding the IF phase. The phase objectives are split into three activities: (1) introduction and preparation, (2) learning, and (3) planning. Relationship building with clinic staff will be a primary focus throughout the entire phase. This work will be guided by appreciative inquiry [55], such as identifying organizational strengths, focusing on what is working, and reframing inquiries to stimulate positive discussion and reflection regarding system wide change.

1) Introduction and preparation

All clinics in the present study have received EIMG onboarding training; however, many were onboarded as early as 2016 and have since gone through numerous staff changes. The research team will identify the lead physician and the clinic manager for each clinic to (re-)establish contact with each clinic. The research team, led by the study physician, will request times to meet with clinic staff and stakeholders. The purpose of this initial meeting is to introduce EIMG, gather feedback, and outline future involvement in the study.

2) Learning

The research team will review and summarize data collected from the EHR to establish 'profiles' for each clinic at the clinic and provider level, as described in the preceding section (Section 5.1.1). A needs assessment, guided by the i-PARIHS framework, will be conducted to understand the clinic workflow and barriers to EIMG implementation. As part of this needs assessment, the research team will conduct meetings, surveys, and workflow mapping with clinic staff and stakeholders (such as clinic champions (i.e., informal leaders in clinical organizations, highly influential individuals who hold the respect of the clinic [56]), physicians, advanced practice providers, registered nurses, medical assistants, front

office assistants/intake personnel, and clinic leadership/practice managers; hereafter clinic staff). The Organizational Readiness to Change Assessment (ORCA) will be conducted [57] with clinic staff to assess their perceptions of the clinic environment, EIMG implementation barriers, organizational stability, and willingness to change [58]. This will provide a sense of the clinic's culture, an understanding of competing demands (bandwidth), and opportunities for increasing buy-in (i.e., improving intrinsic motivation and trust, navigating organizational stress). A full description of these measures is given in Section 5.2.1. Workflow mapping will be conducted as per Taylor et al. 2025 [59] to develop a clinic-specific EIMG workflow with clinic staff. Facilitator notes will describe variations in EIMG implementation fidelity (e.g., implementation drift over time) and how the clinic workflow might be better adapted for EIMG implementation. Results will be combined with data from the EHR (Section 5.1.1) to inform IF Planning.

3) Planning

The research team will work collaboratively with clinic staff to co-create an ideal EIMG workflow model that maximizes efficiency by enhancing facilitators, overcoming barriers, and identifying peripheral effects of the workflow re-design. Outcomes from the 'Learning ' phase will be mapped to a compilation of implementation strategies [60] and potential clinic-based activities (e.g., training sessions, brochures, working with clinic champions etc.). When selecting IF strategies, the research team will provide clinic staff with a 'toolbox' of adaptive strategies and activities at both the provider- and clinic-level. This work will result in a co-created, tailored IF plan for each site, optimizing the workflow process for enhancing EIMG implementation and increasing overall reach [55]. We will map selected strategies backwards (i.e., examining IF strategies most used by clinics in each category) and forwards (i.e., selecting IF strategies that are most successful for each category) to iteratively refine our IF strategies for subsequent study waves.

4) Relationship building

Relationship building between clinic staff and the research team will be ongoing throughout the process of Pre-IF, IF, and Post-IF. The research team will determine leadership styles within the clinic, attempt to build strong relationships, and learn clinic staff's preferred communication methods to maintain regular communication through check ins, emails, and progress reports. Through this relationship building, the research team will evaluate the vision and direction of the clinic, the commitment to quality improvement, and willingness to redirect resources towards improving EIMG implementation in their clinic.

5.1.3 IF Phase

The IF Phase will consist of a six-month, multilevel process to sustainably improve clinic infrastructure and workflow processes to reduce referral barriers and enhance clinic-community coordination and patient engagement in EIMG. IF will be conducted by two members of the research team (facilitators trained in implementation science approaches), who have clinical backgrounds and experience 'speaking the language' of the practice, better equipping them to understand challenges and build trust among clinic

staff. Relationship building will continue throughout the IF Phase, with the research team engaging with formal and informal leadership within the clinic to direct, motivate, and manage clinic staff engagement in IF activities. Facilitators will aim to build an atmosphere for clinic staff that is open, non-critical, and goal oriented, allowing them to voice feedback on IF activities [61].

As part of a 'co-creation' approach to the IF Phase, clinic staff will work with the research team to implement feasible IF strategies and activities tailored to clinic needs. After collating and analyzing data from the Pre-IF 'Learning 'activities, the research team will present clinic staff with a toolbox of IF strategies matched to every identified barrier or gap in practice, including descriptions of what to expect if the strategy was implemented. Clinic staff will not only select feasible strategies but will also assist with building a timeline for introducing each IF activity, as well as timelines for IF ramp-up and peak IF. Deploying the tailored IF plan developed (Section 5.1.2), we will emphasize the importance of delivery re-design and the potential for EIMG to improve patient health outcomes. IF strategies and activities may be modified during the IF Phase as needed based on clinic staff feedback (Section 5.1.3.2).

5.1.3.1 Toolbox

IF strategies that may be used include changing infrastructure, financial strategies, supporting clinicians, providing interactive assistance, adapting and tailoring to context, training and education for stakeholders, developing stakeholder relationships, using evaluative and iterative strategies, and engaging consumers [60, 62]. IF strategies utilized with clinics will be mapped to later analysis and association with clinic outcomes [60]. One of our overarching aims is to avoid exacerbating health inequalities and inequities (variations in outcomes that are avoidable). Instead of providing the same strategies to all clinics, IF is an inherent process of matching strategies and resources within settings, helping lower resource clinics overcome barriers, and facilitating equitable access to innovations such as EIMG. We will focus on the impact of customized IF across clinics, being mindful that clinics in stronger financial health (e.g., external funding) may be more likely to engage in IF strategies [58]. We will gather information on the heterogeneity of resources across clinics (e.g., staff shortages, turnover, external funding) through the needs assessment conducted during Pre-IF (Section 5.1.2) and examine how this may reduce the impact of IF. We will also examine how power dynamics within a unit might impact communication, trust and respect necessary in IF [63] through mixed methods approaches at the end of the IF Phase.

5.1.3.2 Monitoring and evaluation

An IF fidelity assessment will capture the degree to which facilitation activities influence the implementation of EIMG over time. IF strategies used with clinics will be documented using the Longitudinal Implementation Strategy Tracking System (LISTS) [64]. LISTS allows facilitators to accurately characterize and monitor IF strategies over time, and record modifications or discontinuations. Additionally, facilitators will spend 10-15 minutes a week completing a Time Tracking Log, via Excel, describing the type, frequency, and duration of IF activities at each clinic. The PI will meet weekly with facilitators to debrief,

identify site-specific needs, and review weekly activity logs. The research team will review study progress (e.g., IF strategies) over RE-AIM dimensions to allow for rapid, iterative changes to streamline and improve processes with subsequent study waves. We will operationalize a rapid learning system modifying the example of Glasgow et al. [65]:

1) During regularly scheduled meetings, the research team will review the operationalization of the IF and discuss its impact across RE-AIM dimensions with clinic staff.
2) Clinic staff will be asked to confidentially rate their current perception of the project's importance at their clinic and their level of satisfaction with progress across each RE-AIM dimension using 5-point scales.
3) The research team will review the ratings summarized from the individual rating sheets and engage in a reflective discussion to identify implementation barriers on which to focus and set actionable plans.
4) Follow-up meetings, approximately 6 weeks after step 3, will occur between the facilitators and the clinic staff to discuss integrating the actionable plans as a part of the implementation facilitation process.

The goal of IF is to create a sustainable EIMG model through shared decision-making in which practices choose goals and strategies that work best for them in creating a redefined vision of EIMG implementation. When transitioning to maintenance, this will be augmented by making sure that clinics and clinic staff have access to necessary resources and tools to support ongoing EIMG referrals, incorporating EIMG into the organizational memory, and checking in on clinic progress every 3-4 months. Additionally, the research team will ensure continued support to the clinic champion(s) using active and participatory techniques identified by Ritchie et al [66]. By the end of the IF phase, the research team and clinic staff will co-design a new set of goals, refine process maps, and develop strategies to continue feedback reports. Further, successful IF will lead to the establishment of long-term relationships and the provision of ongoing support as needed.

5.1.4 Post-IF Maintenance Phase

Each wave will have a minimum of 12-months of follow up time to allow for ongoing observation and evaluation of the long-term effects of IF on EIMG referral rates. Data will be extracted from EHRs at selected time points to allow for ongoing estimates of implementation and reach. Twelve months post-IF, we will examine the extent to which: 1) EIMG continues to be implemented at clinics and 2) the fidelity of delivery of the EIMG core components [46, 67]. Individual interviews, informed by the Integrated Sustainability Framework [68], will be conducted with clinic staff to address the sustainability of EIMG at the end of the post-IF Maintenance phase. This data will be integrated with estimates of implementation, reach, and effectiveness to identify factors influencing sustainability at participating clinics.

5.2 Study outcome measures

5.2.1 Aim 1

Patient EHR data will be extracted from the EHR on an ongoing basis to calculate adoption, implementation, and reach before, during, and after IF. **Adoption** will be assessed at the provider level by determining the number, proportion, and representativeness (i.e., sex, age, specialty) of providers that utilize any EIMG component in their practice compared to peers that do not use EIMG. **Implementation** will be assessed by determining the extent to which all three steps of EIMG (i.e., assessment, prescription, patient referral) are conducted with each eligible patient at the provider level, aggregated at the clinic level. Our ultimate measure of implementation is the proportion of steps completed with eligible patients. **Reach,** our primary outcome measure, will be assessed by estimating the number and proportion of eligible patient visits engaged in EIMG by providers. This will be calculated by provider and aggregated at the clinic level. Operationally, a patient's visit will be considered 'engaged' if they receive an EIMG referral. The proportion of patient visits reached is estimated by dividing patient visits with an EIMG referral by all eligible patient visits. An expanded reach indicator will examine the proportion of referred patients that: a) enroll, and b) complete the PA program. Representativeness will be determined by comparing characteristics of patients who participate in the PA programs compared to a) eligible patients who did not receive a referral, and b) eligible patients who received a referral but did not participate in the evidence-informed PA programs.

We will conduct the Organizational Readiness to Change Assessment (**ORCA**) [57] with clinic staff at each participating clinic. The ORCA tool operationalizes constructs defined in the original PARIHS framework to measure organizational readiness to change in clinic settings. The ORCA consists of three major scales that measure the strength of evidence for the proposed innovation, organizational support for change, and organizational capacity to facilitate the change. We will ask clinic staff to complete the ORCA during the Pre-IF phase (to determine baseline levels), at the end of the IF phase (short-term impact of IF), and months 9-12 of the Post-IF Maintenance phase (long-term impact of IF). The ORCA should take no longer than 10 minutes to complete.

In addition to the ORCA survey, we will also conduct semi-structured **meetings and interviews with clinic staff** to gain a more nuanced understanding of EIMG integration across clinics. While self-administered questionnaires or structured interviews cost less and reduce interviewer bias, semi-structured approaches foster rapport and are preferred when seeking information on respondents' attitudes and perceptions on a topic [69]. Semi-structured approaches also allow exploration of issues through extensive probing [70]. Meeting and interview guides will be grounded in the i-PARIHS framework [44] and structured to complement information gained through the ORCA. Semi-structured meetings will take place during the Pre-IF Phase during 'Learning' activities (Section 5.1.2). These meetings will be used to discuss barriers and facilitators in relation to EIMG, and will also explore knowledge and fit of EIMG, EIMG implementation, evaluation capacity, organizational culture, and external factors influencing EIMG adoption. Thus, the meeting guide will be complementary to the topics in the semi-structured interviews, which will be

conducted with individual clinic staff at the end of the IF Phase. Semi-structured meetings will last 15-60 minutes, depending on availability of clinic staff, and the semi-structured interviews should take no longer than 40 minutes to complete.

The impact of IF will be assessed through **process and summative evaluations**. For the *process evaluation,* facilitators will document activities with clinics as detailed summary notes and by completing a Time Tracking Log. Checklists will guide decision-making processes (e.g., implementation processes, staff member roles) and allow documentation of specific action items. After IF sessions, mixed methods data collection will be utilized to determine perceptions of IF, IF quality, length, and utility. After 6 months of IF, a *summative evaluation* will assess the effectiveness of the IF strategies. We will conduct final, semi-structured interviews with clinic staff to gain a nuanced understanding of the impact of IF, triangulating findings with quantitative data (i.e., reach and implementation metrics) collected before, during and after IF. We will track adaptations over all phases of IF (the intervention) pragmatically through all clinics using mixed methods approaches.

5.2.1.1 Sample size

Sample size was established using the swCRTdesign package [71] (R version 4.2.3; R Core Team, 2023) and preliminary data collected from the established 35 primary care clinics. A constrained randomization was applied to eligible clinics, randomly generating 50,000 unique schemes at each of the three randomization phases (a fourth was not needed as all remaining clinics will be randomized in the fourth phase in the stepped-wedge design). At each phase, the limit for usable schemes was set at the 10th percentile of statistical distance, and one scheme was randomly selected. The process was then repeated for each subsequent phase. The clinic characteristics used include:

- Initial EIMG exposure: (1) Pre-Covid, (2) Post-Covid
- Past study involvement[1]: (1) The Duke Endowment, (2) R56, (3) None
- Nearest YMCA Site County: (1) Greenville, (2) Oconee
- Distance to nearest YMCA Site (mean)
- Patient volume per provider (mean)
- 2024 EIMG referrals (mean)
- 2025 EIMG referrals (mean)

We chose to allocate clinics to our four waves as follows: Wave 1 (n=6 clinics), Wave 2 (n=8), Wave 3 (n=10), and Wave 4 (n=11). This was to ensure all 35 Prisma Health-Upstate primary care clinics that have adopted the EIMG model were included in the study, that the anticipated learning curve of IF from wave to wave was considered, and that the anticipated increase in referral rates to the YMCA sites and staff was considered to allow them to adapt to the increase in patient load. We will request clinic staff working in clinics

[1] Our team received an award from The Duke Endowment over a 2-year period (#7058-SP; July ’22 – June ‘24) to retrospectively examine the implementation and cost-effectiveness of EIMG in the 12 original Prisma Health-Upstate primary care clinics. Additionally, we received an NHLBI R56 award (1R56HL157218-01A1; Sept ’22 – Aug ‘23) that assists highly meritorious applications gather data and inform an R01 re-submission.

participating in the study to complete the online ORCA survey. We anticipate a response from 2-3 staff members per clinic at each of our three designated time points: during the Pre-IF phase, at the end of the IF phase, and months 9-12 of the post-IF Maintenance phase. We expect that surveys may be completed by the same individual across the different time points. We will also request clinic staff to complete semi-structured meetings (Pre-IF Phase) and interviews (IF Phase). We anticipate 2-3 staff members per clinic at each of our two designated time points: during the Pre-IF Phase, and at the end of the IF phase.

5.2.1.2 Data analysis

The effect of IF on overall **reach** and **implementation** will be analyzed using separate generalized linear mixed models (GLMM) [72-74]. The use of GLMM will take into account variability between clinics (random intercept), the random effect of time, and the differing effects of intervention vs. non-intervention within clinic. Our experimental units are the clinics themselves with the observational units being EIMG eligible patient visits nested within each clinic. The analytical models will have the following form:

$$logit(Y_{ij}) = \beta_0 + \beta_j + \theta X_{ij} + \beta_1 Z_i + \alpha_i + \gamma_j + u_{Ti} X_{ij} + u_{Ci}(1 - X_{ij})$$

The subscripts i and j refer to clinic, and time, respectively. Y_{ij} is the clinic level referral measure; β_0 is the mean response across clinics; β_j is the effect of time; β_1 is the mean effect of clinic level covariates; θ is the effect of EIMG; X_{ij} is an indicator of intervention; and Z_i is clinic type. The remaining terms in the model represent random variability and are assumed to have an expected value of 0 and associated variance. Specifically, α_i, $\gamma_j, u_{Ti}, and\ u_{Ci}$ are the uncertainty terms associated with clinics, time, and the interaction between clinics and intervention status. Missing data will likely occur due to improper documentation of EIMG steps. Where practical, providers that have utilized, but failed to properly document the utilization of EIMG steps, will be asked to correct the entry. If a provider is unable or unwilling to correct the documentation, the utilization of EIMG step(s) will not be counted, thus generating the most conservative estimate of EIMG implementation and reach. Since all providers are employees of Prisma Health, representativeness variables are required elements of human resources documentation, and we do not anticipate any missingness in the data.

5.2.2 Aim 2

Effectiveness is the degree to which participating in the evidence-informed PA program improves patient PA levels and health outcomes (i.e., changes in cardiometabolic biometric values). Changes in **PA levels** will be evaluated through two strategies. First, patients will be screened for their PA levels during clinic visits using the PAVS. Patients that enroll in the PA program will complete the PAVS (to ensure consistency of assessment) at baseline (week 1), midpoint (week 6), and at program graduation (week 12) with the EIMG Pro, and at 12 weeks after the completion of the PA program via either the EIMG Referral Coordinator or via MyChart. Second, to obtain an objective measure of changes in PA

levels, all participants who enroll in the PA program will be asked to wear an accelerometer to: a) provide an objective measure of PA levels, b) determine agreement between subjective (patient-reported) and objective measures of PA, and c) measure objective changes in PA behavior as a result of participating in the 12-week PA program.

Patients enrolled in the PA program will be asked wear an ActiGraph wGT3X-BT® (Ametris LLC, Pensacola, Florida, USA) accelerometer. Patients will wear the accelerometer for one week at three time points: 1) immediately after orientation (week 0), 2) week 13 (corresponding to the end of the PA program), and 3) week 25 (corresponding to 12 weeks post-PA program). Wrist-worn triaxial accelerometers have proven to be valid and reliable in comparison to hip-worn accelerometers [75-77], to reduce participant burden, increase compliance, and capture upper-body movement. Patients will be asked to keep an activity log tracking non-wear time, time to bed, and time out of bed [78, 79]. We will use established cut points for wrist-worn accelerometers and follow previous analysis guidelines [80].

Primary data for assessing changes in **health outcomes** (i.e., body weight, blood pressure, hemoglobin A1c, lipid profiles) will be extracted from the EHR to allow comparisons between eligible patients that receive an EIMG referral and participate in the PA program and eligible patients that do not receive an EIMG referral. Disease incidence, burden, and complications (i.e., the Charlson Comorbidity Index) will be calculated from extracted data. The Post-IF Maintenance phase will allow us to track patient health outcomes for a minimum of 12 months after PA program participation.

5.2.2.1 Sample size

To assess changes in PA levels, we plan to invite all eligible patients to participate in accelerometry data collection (Section 6.1.3). Based on estimates of EIMG clinic-community referrals in previous years and anticipating an increase in EIMG referrals during Pre-IF and IF activities in primary care clinics, we aim to recruit at a minimum n=70 patients over one year. This sample size will allow us to estimate agreement between patient subjective (i.e., PAVS) and objective (i.e., accelerometry) PA levels. Participants will be asked to complete accelerometry data collection at three distinct time points as described in Section 5.2.2. To assess changes in patient health outcomes, data will be extracted for all patients who are eligible for EIMG (Section 6.1.3).

5.2.2.2 Quantitative analysis

Effectiveness of EIMG relative to improvement in patient-reported PA levels, body weight, blood pressure, hemoglobin A1c, and lipid profiles will be analyzed using separate GLMMs [72-74]. Improvement will be computed for each eligible subject in two ways: 1) [(final – starting) / starting clinical measure], and 2) achieving goal (e.g., 5% weight loss after 12 weeks = 1, otherwise 0). EIMG eligible patients will fall into 1 of 3 categories: not referred; referred but did not participate; and referred and participated. Two measures of effectiveness will be considered: 1) improvement in participants only; and 2) referred patients (participated vs did not participate). Comparisons with non-referred patients may be biased by unmeasured patient- or clinic-level characteristics. For the dichotomized

improvement measures, the model from Aim 1 will be utilized with the addition of $\theta_p X_{ijk}$ and $\beta_2 Z_{ik}$ terms to account for the subject category effect and subject level covariates, respectively. The analytical model for the ratio improvement measure will be:

$$Y_{ijk} = \beta_0 + \beta_j + \beta_1 Z_i + \beta_2 Z_{ik} + \theta X_{ij} + \theta_p X_{ijk} + \alpha_i + \gamma_j + u_{Ti} X_{ij} + u_{Ci}(1 - X_{ij}) + e_{ijk}$$

The subscripts i, j, and k refer to clinic, time, and individual, respectively. Y_{ijk} is the individual outcome; β_0 is the mean response; β_j is the effect of time; β_1 is the effect of clinic level covariates; β_2 is the effect of individual level covariates; θ is the effect of EIMG; θ_p is the effect of participation; X_{ij} is an indicator of intervention; X_{ijk} is an indicator of participation; Z_i is a clinic level covariate; and Z_{ik} is a subject level covariate. The remaining terms in the model represent random variability and are assumed to have an expected value of 0 and associated variance. Specifically, $\alpha_i,\ \gamma_j, u_{Ti}, and\ u_{Ci}$ are the uncertainty terms associated with clinics, time, and the interaction between clinics and intervention status. The e_{ijk} is the un-explained deviance.

5.2.2.3 Qualitative analysis

As part of our mixed methods approach, we will conduct **semi-structured individual interviews** with a randomly selected sample of patients (blocked by gender and race) from each participating clinic (n=35) that receive an EIMG referral during the study period. We anticipate a 20% participation rate in the individual interviews (e.g., 300 patients referred * 20% participation rate = approx. 60 completed interviews), across each of three different groups of patients. Patients will be selected from one of three categories: 1) patients who received an EIMG referral from their provider, but chose not to enroll in the PA program, will be queried about their awareness and reasons for not enrolling (i.e., perceived challenges to participation); 2) patients who received an EIMG referral and enrolled, but dropped out, will be asked about their perceptions and satisfaction with the PA program, motivations for enrolling, and reasons for discontinuation; and 3) patients who enrolled and completed the PA program will be queried about their motivations for enrolling, perceptions of and satisfaction with the program, and challenges encountered. Where possible, responses from the individual interviews will be linked back to our IF strategies, such as clarifying places for additional support and improvements to provider-patient interactions, to add to our comprehensive evaluation of the EIMG referral pathway. Open-ended responses will be uploaded to qualitative analysis software to apply codes developed deductively from the questions posed and inductively from responses [81], developing an initial coding scheme for each question. A coding manual with definitions for each code will ensure that high levels of intercoder reliability (>80%) are achieved throughout the coding process [82, 83]. Analyses will catalogue facilitators, barriers, and challenges receiving EIMG referrals and enrolling in the PA program.

5.2.3 Aim 3

The IRB-approved Prisma Health Data Repository will be used to capture the following information. Patient-level episodes of care for EIMG-eligible patients will be developed for patients across the study period (Figure 5).

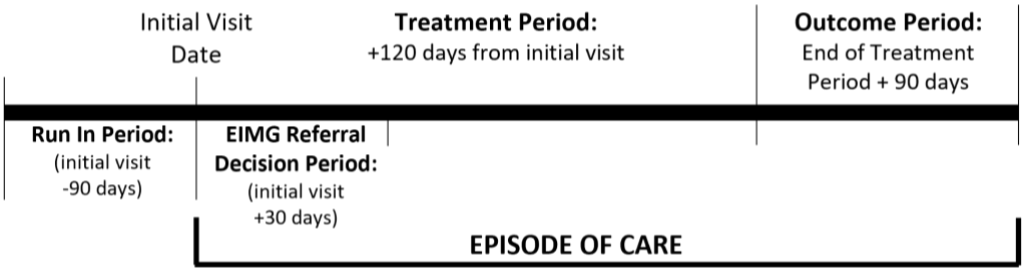

Figure 5. Defining the episode of care.

The ambulatory visit date for each patient with an EIMG eligible diagnosis will be designated as the index visit date for a "candidate" episode of care. To ensure consistent episode definitions across time, candidate episodes will be excluded if the index date is within 90 days of the end of a previous care episode for that patient. Patients will also be excluded if they do not have ambulatory visits with vital statistics and lab results in the episode outcome period of Figure 5. For each patient, a 90-day Run-in-Period prior to the index date will be used to calculate patient baseline covariates at that visit. The Referral Decision Period is the 30 days after the index visit date. The Treatment Period is 120 days from the initial visit date, providing sufficient time for patient referral, entry into and completion of the 12-week PA program. The Outcome Period is the 90 days following the treatment period. Data sources include:

1) Time Tracking Logs: All staff involved in delivering IF will log their time for these activities (Section 5.1.3.2).
2) Program Data: All non-labor resources used to implement IF (e.g., printing of materials).
3) Patient-Specific Healthcare Resources Used: For EIMG eligible patients, we will extract from the EHR during the episode of care: i) all healthcare utilization received by Healthcare Common Procedure Coding System (HCPCS), Diagnosis Related Group (DRG), and National Drug codes (NDC); and ii) the REDCap-based data file used by the EIMG program that captures resources used during the 12-week PA program.
4) Resource Unit Price Data: Medicare standard pricing files for HCPCS, DRG and NDCs, and Prisma Health average wage rates by labor category (i.e., physician, EIMG Referral Coordinator, YMCA Site Coordinator).
5) Patient-Specific Health Outcomes: Blood pressure, body weight, hemoglobin A1c, full lipid profiles, and PA levels will be collected from the EHR at the index visit and visits across the episode of care (Section 5.2.2).

From the perspective of a healthcare system interested in assessing the costs of IF activities, we will calculate: 1) the Total Fixed Cost associated with developing the IF; 2) the Total Variable Cost of providing tailored IF across clinics; and 3) the number of EIMG eligible-patients (N) over the study period across clinics. Implementation costs will be calculating using two sources. First, Time Tracking Logs filled out by those devoted to conducting IF activities will assess resource use. Then, labor costs will be calculated using

average wage rates based on the relevant types of job titles conducting IF (e.g., program manager). Second, program data will be used for estimating non-labor related costs of IF (e.g. printing). We will calculate the total costs of providing tailored IF across both clinics and patients as follows: (1) total implementation cost per clinic calculated as

$$EIMG\ IF\ Costs\ per\ Clinic = \frac{Total\ Implementation\ Costs\ (labor + non\ labor\ costs)}{Number\ of\ clinics}$$

and (2) cost per EIMG eligible patients (N) over the study period across clinics. Total implementation costs include labor and non-labor costs and will be allocated across the number of eligible patients (N) to calculate:

$$EIMG\ IF\ Costs\ Per\ Eligible\ Patient = \frac{Total\ Implementation\ Costs\ (labor+non\ labor\ costs)}{N}$$

To assess the estimate of effects of IF on EIMG referral rates and patient level healthcare costs and health outcomes, we will use data at the episode of care level. Outcomes will include *Episode Healthcare Costs* (the price-weighted sum of all healthcare resources used by patient "i" during the episode of care) and *Episode-Specific Clinical Outcomes* (change in clinical outcomes (blood pressure; body weight; hemoglobin A1c; full lipid profile and PA for patient "i")) between the index visit and the first provider visit in the episode in the Outcome Period (Figure 5) in which this information is collected.

5.2.3.1 Data analysis

We will regress whether eligible patients were referred to EIMG during their index provider visit on variables representing: 1) whether the clinic providing the visit had received IF, 2) baseline patient clinical and demographic characteristics, 3) time trends, and 4) clinic-specific fixed effects using a GLMM [84]. The parameter estimate of the effect of IF in this model will equal the effect of IF on the probability of a patient being referred to EIMG. The specification of clinic-specific binary variables (L_j) and time trends (M_k) will enable us to control for unmeasured clinic specific factors affecting referral and any global secular trends in EIMG referral patterns (e.g., stemming from new scientific findings reported during the study period) [85]. We will then estimate the effects of increases in EIMG referrals induced by IF by exploiting the stepped wedge rollout of IF across practices using instrumental variable (IV) estimation methods. The IV in this study will be a binary variable indicating whether the patient's index visit within a care episode occurs after the clinic received EIMG IF. The IV estimation will yield unbiased estimates of the effect of EIMG referral on outcomes for the subset of patients whose referrals were a result of IF. This is known as the Complier Average Causal Effect [86-96]. Because our specified IV will be based on the randomized stepped wedge clinic rollout, the EIMG referral variation stemming from this instrument will be independent of unmeasured confounding variables. Combining estimates of IF costs per eligible patient with our IV estimates will enable us to estimate cost-effectiveness ratios summarizing the impacts of the IF. Estimated cost-effectiveness ratios will equal the incremental cost per change patient clinical outcome for those patients whose EIMG referrals were induced by IF.

6 Study population

There are three groups of participants in this study i) primary care clinics (which will be the unit of randomization in the stepped wedge design), ii) primary care clinic staff, iii) primary care clinic patients.

6.1 Eligibility criteria

6.1.1 Primary care clinics

Inclusion criteria:

a) Currently EIMG-activated Prisma Health-Upstate Primary Care clinics (family or internal medicine)
b) Adopted EIMG ≥6 months prior to the beginning of this study

Exclusion criteria:

a) Not EIMG-activated
b) Adopted EIMG < 6 months prior to the beginning of this study
c) Greater than 15 miles from the nearest community PA facility (YMCA site)

6.1.2 Primary care clinic staff

Inclusion criteria:

a) ≥18 years of age
b) Has worked at the Prisma Health-Upstate clinic since the start date of the intervention in the respective wave, i.e., Pre-IF start date for each wave
c) Has clinical encounters with a minimum of 25 patients per month
d) Study clinic is their primary clinic (>50% of their working time)
e) Able to understand and communicate in English

Exclusion criteria:

a) <18 years of age
b) Work at the Prisma Health-Upstate clinic started after the Pre-IF phase began
c) Has clinical encounters with <25 patients per month
d) Unable to speak or understand English
e) Adults unable to provide consent

6.1.3 Patients

Inclusion criteria (must meet all the below):

a) Age ≥18 and ≤80 years
b) Clinically eligible (diagnosis of hypertension, dyslipidemia, obesity, diabetes, or physical inactivity) to receive an EIMG referral
c) A healthcare visit with an eligible encounter type (evaluation, telemedicine, consult, office visit, e-visit, follow-up, appointment, education, multidisciplinary visit, nutrition, occupational medicine-office visit)
d) A healthcare visit at a participating clinic

Exclusion criteria

a) Age < 18 or > 80 years
b) Current referral to physical therapy or occupational therapy

c) Current referral to cardiac, pulmonary, or oncology rehab
d) One of the following visit diagnoses: Alzheimer's disease, amyotrophic lateral sclerosis, angina or chest pain, congenital stenosis of aortic valve, congenital insufficiency of aortic valve, moderate or severe persistent asthma, typical or atypical atrial flutter, autonomic dysreflexia, acute bronchitis, cerebral infarction, encounter for chemotherapy, chronic kidney disease (stage 3-5), end stage renal disease, coma, acute chronic obstructive pulmonary disease, unspecified dementia, dependence on renal dialysis, trisomy 21, pulmonary embolism, venous embolism and thrombosis, history of falling, acute fracture, left ventricular failure, congestive heart failure, hypertensive urgency, emergency or crisis, diabetes with ketoacidosis, chronic respiratory failure, dependence on supplemental oxygen, myocardial infarction, osteoporosis with current fracture, encounter for palliative care, paraplegia or quadriplegia, Parkinson's disease, pneumonia, encounter for supervision of pregnancy, encounter for radiation therapy, serious mental illness (schizophrenia, psychotic disorder), homicidal or suicidal ideations, sepsis, injury of spinal cord, presence of coronary stent, dependence on wheelchair or ambulatory aid

For patients completing **accelerometry** data collection, the additional inclusion/exclusion criteria apply:

Inclusion criteria:

a) Received an EIMG referral and scheduled for orientation
b) Attending orientation at two pre-determined community PA facilities (these sites were selected due to each being the largest urban and rural YMCA referral sites in the study)

Exclusion criteria

a) Unable to provide verbal informed consent
b) Planning on travel or vacation during data collection, as patient PA behavior is anticipated to differ from 'everyday' PA behavior at home
c) Unable to wear a watch during work hours due to employment restrictions e.g., food service, healthcare, operating heavy machinery/construction, laboratory-based work etc.

In addition, for patients completing **interviews**, the additional inclusion/exclusion criteria apply:

Inclusion criteria:

a) Received an EIMG referral

Exclusion criteria

a) Unable to provide verbal informed consent
b) Unable to speak or understand English
c) <18 years of age

6.2 Subject recruitment

6.2.1 Primary care clinics

Currently, 35 of 43 eligible Prisma Health-Upstate primary care clinics have received EIMG onboard training and activation and are thus eligible to participate in this study. The research team will begin contacting primary care clinics three to four weeks before the Pre-IF Phase (Section 5.1.2) begins in their respective study wave. The purpose of this contact will be to briefly introduce the study activities from a clinical perspective and request time in a future meeting with clinic staff.

6.2.2 Primary care clinic staff

After (re-)establishing contact with each clinic in each wave, the research team will arrange time to meet with respective clinic staff during a large provider meeting. Clinic staff will be recruited at these and subsequent meetings, as well as through lead physicians and clinic managers, to complete the ORCA survey and semi-structured interviews. The research team will attempt to ensure a broad, representative sample of clinic staff. Completion of surveys or interviews does not obligate clinic staff to complete additional study activities. Once recruited for the ORCA survey, clinic staff will have the option to complete a paper copy of the survey, use a QR code to access an online version, or an email will be sent out to clinic staff that includes a link to the online survey. Additionally, our research team will follow up directly with providers (e.g., advanced practice providers, physicians). For clinic staff who elect to participate in interviews, these will be conducted during non-work hours. No more than four communication attempts will be made when recruiting participants to complete any of the above.

6.2.3 Patients

There are four distinct groups of patient participants in this study; 1) eligible patients (Section 6.1.3) who did not receive an EIMG referral during the study period, 2) eligible patients who received an EIMG referral during the study period but chose not to enroll in the PA program, 3) patients who received an EIMG referral during the study period, enrolled, but then dropped out, and 4) patients who enrolled during the study period and completed the PA program. Our research team will attempt to ensure a broad, representative sample of patients from diverse subgroups and social dimensions. Completion of interview or accelerometry data collection does not obligate patients to complete additional study activities. Group 1) will be obtained from de-identified EHR data collected as part of routine clinical practice and will be used to explore implementation and cost outcomes.

To recruit patients for **interviews** (i.e., Groups 2-4), the research team will obtain a list of patients with an EIMG referral documented by the EIMG Referral Coordinator, who is both an employee of Prisma Health and a member of the study team. This list will be transferred to members of the research team who have permission to access identifiable Prisma Health-Upstate patient information. We will begin contacting EIMG-referred patients in months 1-6 of the second year of this study (Figure 4), and the process will be repeated with each subsequent wave every six months over years 2-4. Patients will be sent informational letters (on Prisma Health-Upstate letterhead) through the US postal service

to alert them of the research study and that they may be contacted by a member of our research team. Approximately two to three weeks after the delivery of the letter, a member of the research team will attempt to contact patients via the phone to assess their interest in participating in an individual interview. Patients may also receive a text message in conjunction with the phone call, as we have found that many individuals do not respond to phone calls from unknown numbers. No more than three attempts (call + text is equivalent to one attempt, as persons may prefer one communication style over the other) will be made to contact. Patients that agree to participate in a phone interview will then select a future date and time that is convenient for them.

The EIMG Referral Coordinator will recruit patients for **accelerometry** data collection (i.e., Groups 3 & 4). After receiving a complete referral, the Referral Coordinator contacts the patient via phone within three business days to discuss details of EIMG participation and arrange an orientation at the YMCA site of their choice. After assessing eligibility during this call, the Referral Coordinator will inform patients verbally about the opportunity to participate in accelerometry data collection. Patients will provide verbal informed consent to participate in accelerometry data collection to the Referral Coordinator and will be sent additional study information through electronic channels (i.e. email, text message link, etc.). The Referral Coordinator will transfer a list of patients who have provided verbal informed consent, as well as the date, time and location of their orientation (when available) to research team members who have permission to access identifiable Prisma Health patient information. The research team will then arrange distribution of accelerometers to the relevant community PA facilities, and patients will be fitted with the accelerometer by the EIMG Pros, who will also provide guidance on how to wear the device, at the orientation session (week 0) and at the end of the PA program (week 13). Patients will be contacted via phone by the EIMG Referral Coordinator at week 25 to arrange distribution of accelerometers, as the patient will have completed the PA program.

7 Study procedures

7.1 Subject compensation

Clinic staff will receive a $50 gift card for completing the ORCA survey or individual interview to compensate them for their time and effort outside of their business hours, a value partially commensurate with their current salary. Patients will receive a $25 gift card for completing individual interviews, and $10 gift card per accelerometry data collection time point to compensate them for their time and effort.

7.2 Subject withdrawal

All potential participants will be informed that their employment standing/status (clinic staff), participation in the PA program, or health care (patients) will not be affected in any way based on their decision to participate in the study as noted on the informed consent forms. Participants may decide to end their study participation at any point throughout the study.

8 Study administration, data handling and record keeping

8.1 Study oversight

Oversight to this study is provided by three separate committees: the Administrative Leadership Council (ALC), the Clinical Steering Group (CSG), and the Data Safety and Monitoring Board (DSMB). The ALC is designed to provide high level input to the study design to ensure the research fits with the mission, vision, and goals of both Prisma Health and University of South Carolina School of Medicine Greenville. The ALC will work closely with the PI to align the research with the function and operations of the Prisma Health system. The CSG is developed to pragmatically align the research with clinical practice. The CSG provides valuable input from front-line providers and leaders in the Prisma Health-Upstate primary care system to ensure smooth involvement of the primary care clinics in the implementation facilitation process. The DSMB will safeguard the interests of study participants and protect the integrity and credibility of the study. The DSMB will meet at minimum, every six months during the study period. The DSMB will convene urgently or hold ad hoc meetings to review any unexpected, serious, or high-volume adverse events to ensure participant safety.

8.2 Confidentiality

We will apply standard methods for protecting the confidentiality of participants by using a personal ID number on all study documents, storing data on password-protected computer data files, and storing physical forms (e.g., signed informed consent forms, notes from interviews) in locked file cabinets in locked offices belonging to the PI. Other than the ID number, names and any other personal identifying information will not be recorded on any study documentation other than one electronic linking document that will be stored on in a password protected electronic file. Only the PI and research team members conducting data collection will have access to the document linking participant identifying information and their study ID number. No protected health information will be collected or disclosed in this research study. No individual data will be shared with anyone outside of the research team. Participant responses will be aggregated and presented as summary findings so that no individuals can be personally identified.

8.3 Data collection and management

8.3.1 Data collection

Research activities will be carried out by trained members of the research team. Patient-level data will be extracted from the EHR for eligible patients in Prisma Health-Upstate primary care clinics participating in the research study via the Prisma Health Data Repository methods described in Section 5.2.3. Other research activities will be carried out in-person, virtually (i.e., the electronic survey), through an online platform (e.g., individual interviews with clinic staff using Teams), or over the telephone (e.g., individual interviews with patients). While in-person activities will be scheduled to take place in clinic or community PA facility settings, staff or patients may request to meet in other locations (e.g., outdoors, in research office) to complete study assessments. Regardless of the

location or modality, all study activities will take place in quiet, private settings to ensure privacy and confidentiality of responses.

8.3.2 Data management

The PI will develop a Data Management Plan to describe how data will be handled during and after the study in accordance with institutional guidelines. A Data Sharing Plan will be developed by the PI to ensure that appropriate study data will be made accessible, no later than the time of publication or the end of performance period. The plan will outline policies for the storage and public accessibility of data beyond the life of the project. Data sharing agreements will be developed with Prisma Health-Upstate for any external investigators needing identifiable patient data (e.g., patient contact information to conduct individual interviews). In addition, the DMSB will provide independent oversight to data management and sharing. Data will be made available to outside investigators upon written request.

8.4 Risks

There may be minor risks to participating in this study associated with:

- *Information risks due to a loss of privacy and/or breach of confidentiality*. To minimize this risk, a participant ID will be used on all study documents and securely stored in password-protected electronic files to ensure confidentiality. Further, responses will be aggregated across all individuals interviewed and/or who engage in accelerometry data collection, and no potentially identifiable information will be reported. The research team will ensure that all study participants are interviewed in a quiet, private setting where their responses are not heard by anyone else.
- *Psychological or emotional risks*. There is a small chance that study participants may experience fear, stress, guilt, loss of self-esteem, or a triggering of past emotional experiences. Participants will be informed that they do not have to answer questions and can stop the interview at any time.
- *Discomfort with accelerometer*. There is a small chance that patients may experience discomfort or skin irritation from wearing the accelerometer. Patients will be informed of this risk and asked to record periods of non-wear in the activity log. Patients will also be informed that they can stop participating at any time.

8.5 Benefits

Study participants will receive no direct benefit from participating in this research study. However, findings from our research will be used to increase the efficiency of incorporating EIMG into the patient workflow and improve the connection of patients to supportive PA resources.

8.6 Informed consent process/HIPAA authorization

Informed consent will be obtained prior to any participation in the study.

8.6.1 ORCA Survey

The first page of the online/paper survey will be a consent form providing a detailed explanation of the study and potential risks of participation. At the bottom of the page,

participants will be asked to provide their consent to participate in the study before continuing to the survey. Individuals that do not agree to participate in the study will be thanked for their time and exited from the survey (online).

8.6.2 Individual interviews with clinic staff and patients

Participants will be notified prior to completing the informed consent that the interviews will be recorded to allow for accurate transcription in the future. All clinic staff who choose to participate in the individual interviews will receive an electronic version of the consent form prior to the individual interview. For patients, during the initial recruitment call, the research team will ask patients if they would like a copy of the informed consent form emailed or mailed to them ahead of their individual interview appointment. At the beginning of the individual interview appointment, clinic staff will take part in the informed consent process to obtain either their written (for in-person interviews) or verbal (for virtual interviews) consent. Patients will undergo the informed consent process virtually (over the phone) to obtain their verbal consent immediately prior to conducting the phone interview. Verbal consent to participate in the study will be documented by the research team.

8.6.3 Accelerometry

The EIMG Referral Coordinator will inform eligible patients about accelerometry data collection and send additional study information to patients who provide verbal informed consent to participate. Patients will have time to consider this information prior to their orientation. They will be offered the opportunity to participate in accelerometry data collection at their orientation session (week 0), at the end of the PA program (week 13), and 12-weeks post-PA program (week 25). Verbal consent will be obtained via the EIMG Referral Coordinator, who is also a study team member, to participate at each time point and will be documented. If the patient attends orientation, consents to accelerometry data collection, but does not complete the PA program, they will not be contacted to complete subsequent accelerometry data collection time points.

9 Study finances

This study is financed through an R01 grant from the U.S. National Heart, Lung, and Blood Institute. No investigators have any conflicts of interest.

10 Dissemination

Based on initial deployment, an EIMG toolkit was developed and made available for health systems on a limited basis. In 2022, the EIMG toolkit was formally recognized at the White House Conference on Hunger, Nutrition and Health as a population health strategy and subsequently made freely available to >600 health systems, >750 YMCA associations, and CDC-funded state health departments focused on arthritis interventions. We will revise the toolkit, guided by the i-PARIHS framework, to incorporate Page 30 of 35information on clinic adoption (context), the intervention (EIMG), recipients (clinic staff and patients) and the overall impact of IF on increasing EIMG implementation. The updated toolkit will be made freely available to the CDC, DHHS, and all U.S. health systems for integrating PA referral pathways in primary care settings. The toolkit will also be disseminated through the EIM

Global Network to leaders integrating PA into their regional/national health systems in >35 countries around the world.

11 Conclusions

This study has the potential to significantly advance our understanding of optimally integrating a PA pathway that involves the prescription, referral, and engagement of patients in community-based PA programs. Integrating the EIM model in health systems to connect patients to available community resources has the potential to significantly alter clinical practice and improve population health outcomes. Information gained from this study will lead to the refinement of a generalizable approach that will inform future implementation strategies on optimizing and scaling up the integration of comprehensive PA models in Prisma Health systems in South Carolina, and U.S. health systems generally. Study findings will also provide cost estimates of potential savings to health systems comprehensively integrating PA as a population health management tool using clinical-community linkages. Study findings and developed resources will be made available to health systems for broad scale-up with the goal of increasing patient engagement in community-based PA programs as an extension of health care.

12 References

1. Fiuza-Luces, C., et al., *Exercise is the real polypill.* Physiology (Bethesda), 2013. **28**(5): p. 330–58.
2. Naci, H. and J.P. Ioannidis, *Comparative effectiveness of exercise and drug interventions on mortality outcomes: metaepidemiological study.* Br J Sports Med, 2015. **49**(21): p. 1414–22.
3. Lee, I.-M., et al., *Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy.* The Lancet, 2012. **380**(9838): p. 219–229.
4. Casonatto, J., et al., *The blood pressure-lowering effect of a single bout of resistance exercise: A systematic review and meta-analysis of randomised controlled trials.* Eur J Prev Cardiol, 2016. **23**(16): p. 1700–1714.
5. Colberg, S.R., et al., *Physical Activity/Exercise and Diabetes: A Position Statement of the American Diabetes Association.* Diabetes Care, 2016. **39**(11): p. 2065–2079.
6. Wolff-Hughes, D.L., et al., *Total Activity Counts and Bouted Minutes of Moderate-to-Vigorous Physical Activity: Relationships With Cardiometabolic Biomarkers Using 2003-2006 NHANES.* J Phys Act Health, 2015. **12**(5): p. 694–700.
7. 2018 Physical Activity Guidelines Advisory Committee, *2018 Physical Activity Guidelines Advisory Committee Scientific Report*. 2018, US Department of Health and Human Services: Washington, DC. p. 779.
8. Durstine, J.L., et al., *Chronic disease and the link to physical activity.* Journal of Sport and Health Science, 2013. **2**(1): p. 3–11.
9. Elgaddal, N., E.A. Kramarow, and C. Reuben, *Physical Activity Among Adults Aged 18 and Over: United States, 2020.* NCHS Data Brief, 2022(443): p. 1–8.
10. Physical Activity Alliance. *National Physical Activity Plan*. 2026 [cited 2026 9 January].
11. Patrick, K., M. Pratt, and R.E. Sallis, *The healthcare sector's role in the U.S. national physical activity plan.* J Phys Act Health, 2009. **6 Suppl 2**: p. S211–9.
12. Bull, F.C., et al., *The Toronto Charter for Physical Activity: a global call for action.* J Phys Act Health, 2010. **7**(4): p. 421–2.
13. Jacobson, D.M., et al., *Physical activity counseling in the adult primary care setting: position statement of the American College of Preventive Medicine.* Am J Prev Med, 2005. **29**(2): p. 158–62.
14. Vuori, I.M., C.J. Lavie, and S.N. Blair, *Physical Activity Promotion in the Health Care System.* Mayo Clinic Proceedings, 2013. **88**(12): p. 1446–1461.
15. Sallis, R.E., et al., *Call to Action on Making Physical Activity Assessment and Prescription a Medical Standard of Care.* Curr Sports Med Rep, 2016. **15**(3): p. 207–14.
16. Saitz, R., *Screening and brief intervention enter their 5th decade.* Subst Abus, 2007. **28**(3): p. 3–6.
17. Lobelo, F., M. Stoutenberg, and A. Hutber, *The Exercise is Medicine Global Health Initiative: a 2014 update.* Br J Sports Med, 2014. **48**(22): p. 1627–33.
18. Strath, S.J., et al., *Guide to the assessment of physical activity: Clinical and research applications: a scientific statement from the American Heart Association.* Circulation, 2013. **128**(20): p. 2259–79.
19. Coleman, K.J., et al., *Initial validation of an exercise "vital sign" in electronic medical records.* Med Sci Sports Exerc, 2012. **44**(11): p. 2071–6.
20. Greenwood, J.L., E.A. Joy, and J.B. Stanford, *The Physical Activity Vital Sign: a primary care tool to guide counseling for obesity.* J Phys Act Health, 2010. **7**(5): p. 571–6.
21. Ball, T.J., et al., *Predictive Validity of an Adult Physical Activity "Vital Sign" Recorded in Electronic Health Records.* J Phys Act Health, 2016. **13**(4): p. 403–8.
22. Young, D.R., et al., *Associations between physical activity and cardiometabolic risk factors assessed in a Southern California health care system, 2010-2012.* Prev Chronic Dis, 2014. **11**: p. E219.
23. Grant, R.W., et al., *Exercise as a vital sign: a quasi-experimental analysis of a health system intervention to collect patient-reported exercise levels.* J Gen Intern Med, 2014. **29**(2): p. 341–8.
24. Swinburn, B.A., et al., *The green prescription study: a randomized controlled trial of written exercise advice provided by general practitioners.* Am J Public Health, 1998. **88**(2): p. 288–91.
25. Elley, C.R., et al., *Effectiveness of counselling patients on physical activity in general practice: cluster randomised controlled trial.* Bmj, 2003. **326**(7393): p. 793.
26. Hamlin, M.J., et al., *Long-term effectiveness of the New Zealand Green Prescription primary health care exercise initiative.* Public Health, 2016. **140**: p. 102–108.
27. Pavey, T.G., et al., *Effect of exercise referral schemes in primary care on physical activity and improving health outcomes: systematic review and meta-analysis.* Bmj, 2011. **343**: p. d6462.

28. Murphy, S.M., et al., *An evaluation of the effectiveness and cost effectiveness of the National Exercise Referral Scheme in Wales, UK: a randomised controlled trial of a public health policy initiative*. J Epidemiol Community Health, 2012. **66**(8): p. 745–53.
29. Campbell, F., et al., *A systematic review and economic evaluation of exercise referral schemes in primary care: a short report.* Health Technology Assessment, 2015. **19**(60): p. 1–110.
30. Exercise is Medicine Greenville. *Exercise is Medicine Greenville®*. 2018 [cited 2026 09 January]; Available from: https://eimgreenville.org.
31. American College of Sports Medicine. *Rx for Health Series*. 2021 [cited 2026 09 January]; Available from: https://www.exerciseismedicine.org/eim-in-action/health-care/resources/rx-for-health-series/.
32. American College of Sports Medicine. *Specialty Certificate Programs*. 2026 [cited 2026 09 January]; Available from: https://www.acsm.org/certification/specialized.
33. Harris, P.A., et al., *The REDCap consortium: Building an international community of software platform partners*. Journal of Biomedical Informatics, 2019. **95**: p. 103208.
34. Harris, P.A., et al., *Research electronic data capture (REDCap)—A metadata-driven methodology and workflow process for providing translational research informatics support.* Journal of Biomedical Informatics, 2009. **42**(2): p. 377–381.
35. Saunders, R.P., et al., *Conceptualizing, implementing, and monitoring a structural health promotion intervention in an organizational setting.* Health Promot Pract, 2013. **14**(3): p. 343–53.
36. Howie, E.K., et al., *The 3-year evolution of a preschool physical activity intervention through a collaborative partnership between research interventionists and preschool teachers.* Health Educ Res, 2014. **29**(3): p. 491–502.
37. Porter, R.R., et al., *Design and implementation of a clinic-to-community, physical activity health promotion model for healthcare providers.* Preventive Medicine Reports, 2022. **26**: p. 101697.
38. Ding, D., et al., *The economic burden of physical inactivity: a global analysis of major non-communicable diseases.* The Lancet, 2016. **388**(10051): p. 1311–1324.
39. Carlson, S.A., et al., *Inadequate physical activity and health care expenditures in the United States.* Prog Cardiovasc Dis, 2015. **57**(4): p. 315–23.
40. Laine, J., et al., *Cost-effectiveness of population-level physical activity interventions: a systematic review.* Am J Health Promot, 2014. **29**(2): p. 71–80.
41. Wu, S., et al., *Economic analysis of physical activity interventions.* Am J Prev Med, 2011. **40**(2): p. 149–58.
42. GC, V., et al., *Are brief interventions to increase physical activity cost-effective? A systematic review.* British Journal of Sports Medicine, 2016. **50**(7): p. 408–417.
43. Smith, J.D., D.H. Li, and M.R. Rafferty, *The Implementation Research Logic Model: a method for planning, executing, reporting, and synthesizing implementation projects*. Implementation Science, 2020. **15**(1): p. 84.
44. Harvey, G. and A. Kitson, *PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice.* Implementation Science, 2016. **11**(1): p. 33.
45. Glasgow, R.E., et al., *RE-AIM Planning and Evaluation Framework: Adapting to New Science and Practice With a 20-Year Review.* Front Public Health, 2019. **7**: p. 64.
46. Stoutenberg, M., et al., *A Pragmatic Application of the RE-AIM Framework for Evaluating the Implementation of Physical Activity as a Standard of Care in Health Systems.* Prev Chronic Dis, 2018. **15**: p. E54.
47. Curran, G.M., et al., *Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact.* Med Care, 2012. **50**(3): p. 217–26.
48. Parchman, M.L., et al., *A Randomized Trial of External Practice Support to Improve Cardiovascular Risk Factors in Primary Care.* Ann Fam Med, 2019. **17**(Suppl 1): p. S40–s49.
49. Taylor, E.F., et al., *Enhancing the primary care team to provide redesigned care: the roles of practice facilitators and care managers.* Ann Fam Med, 2013. **11**(1): p. 80–3.
50. Ritchie, M.J., et al., *Evaluation of an implementation facilitation strategy for settings that experience significant implementation barriers.* Implementation Science, 2015. **10**(Suppl 1): p. A46.
51. Ritchie, M.J., et al., *Using implementation facilitation to foster clinical practice quality and adherence to evidence in challenged settings: a qualitative study.* BMC Health Serv Res, 2017. **17**(1): p. 294.
52. Baskerville, N.B., C. Liddy, and W. Hogg, *Systematic review and meta-analysis of practice facilitation within primary care settings.* Ann Fam Med, 2012. **10**(1): p. 63–74.
53. Bisson, M., et al., *Patient engagement in health implementation research: A logic model.* Health Expectations, 2023. **26**(5): p. 1854–1862.
54. University of South Carolina. *Patient Engagement Studio*. [cited 2026 09 January]; Available from: https://sc.edu/about/centers_institutes/patient_engagement_studio/.
55. Knox, L., et al., *Primary Care Practice Facilitation Curriculum (Module 9)*. 2015, Agency for Healthcare Research and Quality: Rockville, MD.

56. Miech, E.J., et al., *Inside help: An integrative review of champions in healthcare-related implementation*. SAGE Open Med, 2018. **6**: p. 2050312118773261.
57. Helfrich, C.D., et al., *Organizational readiness to change assessment (ORCA): development of an instrument based on the Promoting Action on Research in Health Services (PARIHS) framework*. Implement Sci, 2009. **4**: p. 38.
58. Geonnotti, K., et al., *Engaging Primary Care Practices in Quality Improvement: Strategies for Practice Facilitators*. 2015, Agency for Healthcare Research and Quality: Rockville, MD.
59. Taylor, N., et al., *Advancing the Speed and Science of Implementation Using Mixed-Methods Process Mapping – Best Practice Recommendations*. International Journal of Qualitative Methods, 2025. **24**: p. 16094069251340908.
60. Powell, B.J., et al., *A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project*. Implement Sci, 2015. **10**: p. 21.
61. Ritchie, M.J., et al., *Using Implementation Facilitation to Improve Healthcare Implementation Facilitation Training Manual (Version 3)*. 2020, Veterans Health Administration, Behavioral Health Quality Enhancement Research Initiative (QUERI).
62. Yakovchenko, V., et al., *Refining Expert Recommendations for Implementing Change (ERIC) strategy surveys using cognitive interviews with frontline providers*. Implement Sci Commun, 2023. **4**(1): p. 42.
63. Morena, A.L., L.M. Gaias, and C. Larkin, *Understanding the Role of Clinical Champions and Their Impact on Clinician Behavior Change: The Need for Causal Pathway Mechanisms*. Front Health Serv, 2022. **2**: p. 896885.
64. Smith, J.D., et al., *The Longitudinal Implementation Strategy Tracking System (LISTS): feasibility, usability, and pilot testing of a novel method*. Implement Sci Commun, 2023. **4**(1): p. 153.
65. Glasgow, R.E., et al., *Making Implementation Science More Rapid: Use of the RE-AIM Framework for Mid-Course Adaptations Across Five Health Services Research Projects in the Veterans Health Administration*. Front Public Health, 2020. **8**: p. 194.
66. Ritchie, M.J., L.E. Parker, and J.E. Kirchner, *From novice to expert: methods for transferring implementation facilitation skills to improve healthcare delivery*. Implement Sci Commun, 2021. **2**(1): p. 39.
67. Shelton, R.C., D.A. Chambers, and R.E. Glasgow, *An Extension of RE-AIM to Enhance Sustainability: Addressing Dynamic Context and Promoting Health Equity Over Time*. Front Public Health, 2020. **8**: p. 134.
68. Shelton, R.C., B.R. Cooper, and S.W. Stirman, *The Sustainability of Evidence-Based Interventions and Practices in Public Health and Health Care*. Annu Rev Public Health, 2018. **39**: p. 55–76.
69. Strauss, A. and J.M. Corbin, *Basics of qualitative research: Grounded theory procedures and techniques*. 1990: Sage Publications, Inc. .
70. Berg, B.L., *Qualitative Research Methods for the Social Sciences*. 6th ed. 2001: Allyn and Bacon.
71. Hughes, J., et al. *Stepped Wedge Cluster Randomized Trial (SW CRT) Design. Published online October 14, 2022*. 2022 [cited 2026 12 January]; Available from: https://cran.r-project.org/web/packages/swCRTdesign/swCRTdesign.pdf.
72. Hussey, M.A. and J.P. Hughes, *Design and analysis of stepped wedge cluster randomized trials*. Contemp Clin Trials, 2007. **28**(2): p. 182–91.
73. Hemming, K., M. Taljaard, and A. Forbes, *Analysis of cluster randomised stepped wedge trials with repeated cross-sectional samples*. Trials, 2017. **18**(1): p. 101.
74. Nickless, A., et al., *Mixed effects approach to the analysis of the stepped wedge cluster randomised trial—Investigating the confounding effect of time through simulation*. PLOS ONE, 2018. **13**(12): p. e0208876.
75. Clevenger, K.A., K.A. Pfeiffer, and A.H.K. Montoye, *Cross-generational comparability of hip- and wrist-worn ActiGraph GT3X+, wGT3X-BT, and GT9X accelerometers during free-living in adults*. J Sports Sci, 2020. **38**(24): p. 2794–2802.
76. Liu, F., A.A. Wanigatunga, and J.A. Schrack, *Assessment of Physical Activity in Adults Using Wrist Accelerometers*. Epidemiol Rev, 2022. **43**(1): p. 65–93.
77. Ozemek, C., et al., *Intermonitor reliability of the GT3X+ accelerometer at hip, wrist and ankle sites during activities of daily living*. Physiol Meas, 2014. **35**(2): p. 129–38.
78. Evenson, K.R., et al., *Historical development of accelerometry measures and methods for physical activity and sedentary behavior research worldwide: A scoping review of observational studies of adults*. PLoS One, 2022. **17**(11): p. e0276890.
79. Matthews, C.E., et al., *Best practices for using physical activity monitors in population-based research*. Med Sci Sports Exerc, 2012. **44**(1 Suppl 1): p. S68–76.
80. Gao, Z., et al., *The Dilemma of Analyzing Physical Activity and Sedentary Behavior with Wrist Accelerometer Data: Challenges and Opportunities*. J Clin Med, 2021. **10**(24).
81. Neuendorf, K.A., *The Content Analysis Guidebook*. 2017, SAGE Publications, Inc: Thousand Oaks, California.

82. Syed, M. and S.C. Nelson, *Guidelines for Establishing Reliability When Coding Narrative Data*. Emerging Adulthood, 2015. **3**(6): p. 375–387.
83. Mays, N. and C. Pope, *Quality in Qualitative Research*, in *Qualitative Research in Health Care*. 2020. p. 211–233.
84. Breslow, N.E. and D.G. Clayton, *Approximate Inference in Generalized Linear Mixed Models*. Journal of the American Statistical Association, 1993. **88**(421): p. 9–25.
85. Greene, W.H., *Econometric Analysis*. 7th ed. 2012: Pearson.
86. Liang, Y., et al., *Behavioral support intervention for uncontrolled hypertension: a complier average causal effect (CACE) analysis*. Med Care, 2015. **53**(2): p. e9–e15.
87. Peugh, J.L., et al., *Beyond intent to treat (ITT): A complier average causal effect (CACE) estimation primer*. J Sch Psychol, 2017. **60**: p. 7–24.
88. Knox, C.R., et al., *Treatment compliance and effectiveness of a cognitive behavioural intervention for low back pain: a complier average causal effect approach to the BeST data set*. BMC Musculoskelet Disord, 2014. **15**: p. 17.
89. Berg, J.K., et al., *Using Complier Average Causal Effect Estimation to Determine the Impacts of the Good Behavior Game Preventive Intervention on Teacher Implementers*. Adm Policy Ment Health, 2017. **44**(4): p. 558–571.
90. Gruber, J.S., et al., *Estimation of treatment efficacy with complier average causal effects (CACE) in a randomized stepped wedge trial*. Am J Epidemiol, 2014. **179**(9): p. 1134–42.
91. Connell, A.M., *Employing complier average causal effect analytic methods to examine effects of randomized encouragement trials*. Am J Drug Alcohol Abuse, 2009. **35**(4): p. 253–9.
92. Ashworth, E., et al., *Game On-Complier Average Causal Effect Estimation Reveals Sleeper Effects on Academic Attainment in a Randomized Trial of the Good Behavior Game*. Prev Sci, 2020. **21**(2): p. 222–233.
93. Panayiotou, M., N. Humphrey, and A. Hennessey, *Implementation matters: Using complier average causal effect estimation to determine the impact of the Promoting Alternative Thinking Strategies (PATHS) curriculum on children's quality of life*. Journal of Educational Psychology, 2020. **112**(2): p. 236.
94. Carmody, T., et al., *A Complier Average Causal Effect Analysis of the Stimulant Reduction Intervention using Dosed Exercise Study*. Contemp Clin Trials Commun, 2018. **10**: p. 1–8.
95. Huang, S., et al., *An application of the Complier Average Causal Effect analysis to examine the effects of a family intervention in reducing illicit drug use among high-risk Hispanic adolescents*. Fam Process, 2014. **53**(2): p. 336–47.
96. Cowen, J.M., *School Choice as a Latent Variable: Estimating the "Complier Average Causal Effect" of Vouchers in Charlotte*. Policy Studies Journal, 2008. **36**(2): p. 301–315.