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## Physical Activity Promotion, Assessment, and Engagement in Clinical Settings in the United States

Kristin A. Grogg

West Virginia University, [kristin.grogg@mail.wvu.edu](mailto:kristin.grogg@mail.wvu.edu)

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**Physical Activity Promotion, Assessment, and Engagement in Clinical Settings in the United States**

**Kristin A. Grogg, MPH**

Dissertation submitted  
to the **School of Medicine**  
at West Virginia University

In partial fulfillment of the requirement for the degree of

**Doctor of Philosophy in  
Clinical & Translational Science**

Peter Giacobbi, MS, PhD, Co-Chair  
Trea Haggerty, MD, MS Co-Chair  
George Kelley, MS, DA  
Christa Lilly, MS, PhD  
Carena Winters, MPH, PhD

West Virginia Clinical & Translational Science Institute  
Morgantown, West Virginia  
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**Keywords: Physical Activity, Clinical Setting, Promotion, Scoping Review, Wearable Technology,  
Systematic Review, Patient Activation**

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## ABSTRACT

### **Physical Activity Promotion, Assessment, and Engagement in Clinical Settings in the United States**

Kristin A Grogg, MPH

Physical inactivity is an important contributor to morbidity and all-cause mortality and the 2018 Physical Activity Guidelines Advisory Committee recommended that physicians increase their role in physical activity assessment and promotion to combat physical inactivity and related comorbidities. Healthcare providers are increasingly called upon to initiate physical activity promotion with their patients to manage conditions like obesity, diabetes, and cardiovascular diseases. Still, recent reports indicate that less than half of primary care visits include some type of physical activity promotion. Although the National Physical Activity Plan includes some recommendations for clinicians and the healthcare sector on physical activity promotion, it does not include a detailed assessment of the evidence and the processes for standardizing physical activity-related care in the clinical setting. The presented dissertation expands our understanding of exercise promotion in the clinical setting by having: 1) closely examined published studies with focus on how physical activity promotion is conducted, by whom, and under what circumstances in the clinical setting; 2) evaluating the effectiveness of physical activity promotion in the clinical setting, and 3) piloting a weight management tablet application developed to increase patient activation and engagement in the clinic setting at West Virginia University (WVU) Medicine. This dissertation contributes to the evolving field of physical activity assessment, promotion, and counseling in clinical settings. The findings emphasize the importance of integrating physical activity as a standard of care, leveraging technology to enhance assessment and promotion, and the potential of specialized personnel in delivering interventions. The use of theoretical frameworks and interdisciplinary collaboration can further enhance the effectiveness of these interventions. This work sets the stage for future research that can advance healthcare practices, improve patient outcomes, and address the growing burden of chronic diseases associated with physical inactivity.

## **DEDICATION**

To my family, all of you.

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## TABLE OF CONTENTS

|   |           |
|---|-----------|
| List of Figures .....   | vii       |
| List of Tables .....  | viii      |
| List of Appendices .....  | ix        |
| <b>1 Introduction .....</b>   | <b>1</b>  |
| <b>1.1 Background and Significance .....</b>  | <b>1</b>  |
| <b>1.2 Specific Aims.....</b>   | <b>2</b>  |
| <b>1.3 Overview of Methodological Approach .....</b>  | <b>3</b>  |
| <b>2 Physical Activity Assessment and Promotion in Clinical Settings in the United States: A Scoping Review .....</b>   | <b>6</b>  |
| <b>2.1 Abstract.....</b>  | <b>6</b>  |
| <b>2.2 Introduction.....</b>  | <b>7</b>  |
| <b>2.3 Methods.....</b>   | <b>10</b> |
| <b>2.4 Results .....</b>  | <b>13</b> |
| <b>2.5 Discussion.....</b>  | <b>16</b> |
| <b>2.6 Strengths and Limitations .....</b>  | <b>21</b> |
| <b>2.7 Tables and Figures .....</b>   | <b>22</b> |
| <b>3 Physical Activity Assessment and Promotion Using Activity Monitors in Clinical Settings: A Systematic Review of Randomized Controlled Trials in the United States.....</b> | <b>38</b> |
| <b>3.1 Abstract.....</b>  | <b>38</b> |
| <b>3.2 Introduction.....</b>  | <b>39</b> |
| <b>3.3 Methods.....</b>   | <b>44</b> |
| <b>3.4 Results .....</b>  | <b>47</b> |
| <b>3.5 Discussion.....</b>  | <b>50</b> |
| <b>3.6 Strengths and Limitations.....</b>   | <b>53</b> |
| <b>3.7 Tables and Figures .....</b>   | <b>55</b> |
| <b>4 Patient Acceptability and Usability of an Electronic Health Application for Patient Engagement and Activation in Weight Management .....</b>                               | <b>62</b> |
| <b>4.1 Abstract.....</b>  | <b>62</b> |
| <b>4.1 Introduction.....</b>  | <b>63</b> |
| <b>4.2 Methods.....</b>   | <b>65</b> |
| <b>4.3 Results .....</b>  | <b>68</b> |
| <b>4.4 Discussion.....</b>  | <b>70</b> |
| <b>4.5 Strengths and Limitations.....</b>   | <b>71</b> |

|   |           |
|---|-----------|
| <b>4.6 Tables and Figures .....</b>       | <b>71</b> |
| 5 Summary and Conclusion .....            | 74        |
| <b>5.1 Summary of Key Findings .....</b>  | <b>74</b> |
| <b>5.2 Significance.....</b>              | <b>74</b> |
| <b>5.3 Strengths and Limitations.....</b> | <b>75</b> |
| <b>5.4 Future Research .....</b>          | <b>75</b> |
| <b>5.5 Conclusions.....</b>               | <b>76</b> |
| 6 References.....                         | 78        |
| 7 Appendices.....                         | 89        |

## LIST OF FIGURES

|  |    |
|--|----|
| Figure 2.1: PRISMA Flow Diagram .....  | 24 |
| Figure 2.2: Word cloud depicting outcome measures for included studies .....   | 37 |
| Figure 3.1: Number of PubMed-referenced articles published between 2008 and 2022 concerning 'physical activity' and 'primary care' ..... | 57 |
| Figure 3.2: PRISMA Flow Diagram .....  | 58 |
| Figure 3.3: Cochrane Risk of Bias (v 2.0) assessment results .....   | 61 |



## LIST OF TABLES

|   |    |
|---|----|
| Table 2.1: Study characteristics, study designs, and patient demographics (Total N= 78) .....           | 25 |
| Table 2.1: Study characteristics, study designs, and patient demographics (Total N= 78) (cont.).....    | 26 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies .....         | 27 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 28 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 29 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 30 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 31 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 32 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 33 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 34 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 35 |
| Table 2.2: Study design, setting, delivery agent and results reported from all 78 studies (cont.) ..... | 36 |
| Table 3.1: Characteristics and results reported by study (N=11).....                                    | 59 |
| Table 3.1: Characteristics and results reported by study (N=11) (cont.) .....                           | 60 |
| Table 4.1: Characteristics of Participants (N=32*).....   | 73 |

## LIST OF APPENDICES

|  |     |
|--|-----|
| Appendix A: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist..... | 91  |
| Appendix B: Scoping Review Search Strategy .....   | 93  |
| Appendix C: Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) Checklist .....                                  | 94  |
| Appendix D: PROSPERO Protocol.....   | 98  |
| Appendix E: Systematic Review Search Strategy .....  | 105 |
| Appendix F: mWRAPPED Usability Study Protocol Document (Protocol #: 180290671).....  | 108 |

## CHAPTER 1

### 1 Introduction

#### 1.1 Background and Significance

Eighty percent of American adults do not meet the government's national physical activity recommendations for aerobic activity and muscle strengthening.<sup>1</sup> While over 30% of U.S. adults are inactive, approximately 20% of those who do participate in physical activity are not sufficiently active to achieve health benefits.<sup>2</sup> This is problematic given that a sedentary lifestyle contributes to nearly 70% of deaths in the United States, doubles the risk of cardiovascular diseases, diabetes and obesity, and increases the risk of colon cancer, high blood pressure, osteoporosis, lipid disorders, depression and anxiety.<sup>2</sup> Recent data from a national survey on health care expenditures has estimated that nearly 150 million Americans are living with at least one chronic condition, contributing to almost 90% of healthcare spending. Not surprisingly, an estimated \$117 billion in healthcare costs have been shown to be associated with inadequate physical activity.<sup>3</sup> Recent reports from the Centers for Disease Control and Prevention revealed that 11.1% of total healthcare expenditures are associated with inadequate levels of physical activity.<sup>4</sup> In addition, it is expected that the prevalence of cardiovascular disease will increase by 10% and direct medical costs will triple by 2030.<sup>5</sup> To address this health and financial crisis, population-based efforts in advancing cardiovascular health include national initiatives such as the physical activity advisory committee report released in February 2018.<sup>6</sup> The report summarizes the scientific evidence on physical activity and health, and the government used it to develop the second edition of the Physical Activity Guidelines for Americans.<sup>1</sup> These strategies endorse that any physical activity is better than none and additional benefits occur as the amount of physical activity increases through higher intensity, greater frequency, and/or longer duration, especially with regard to cardiovascular health.

The national physical activity plan highlights the important health benefits from regular physical activity for adults with chronic conditions. The plan also highlights the important role that healthcare

providers have in physical activity assessment and prescription. Still, reports indicate that less than one third of primary care visits include some type of physical activity counseling.<sup>7-9</sup> Reported barriers include competing health demands, time for counseling, as well as a perceived lack of knowledge regarding physical activity programming, counseling, and guidelines.<sup>5</sup> Given the former, the purpose of this current project is to expand our understanding of exercise promotion in the clinical setting by: 1) closely examining the extent, range, and nature of studies in the clinical setting; 2) evaluating the effectiveness of physical activity promotion in the clinical setting, and 3) piloting the use of a weight management tablet-based application during clinic visit wait time.

## **1.2 Specific Aims**

*Aim 1:* Evaluate published studies that focused on physical activity promotion in the clinical setting by describing who conducts physical activity promotion, how it is conducted, and under what circumstances (annual wellness visit versus acute event).

*Objective 1.1:* Provide a descriptive review of the language and procedures used when describing or evaluating physical activity promotion in the clinical setting.

*Objective 1.2:* Ascertain the knowledge, characteristics, and qualifications of clinical personnel responsible for physical activity promotion and evaluation.

*Objective 1.3:* Identify potential knowledge gaps in the literature related to physical activity promotion in the clinical setting.

*Aim 2:* Determine the effectiveness of physical activity promotion delivered in the clinical setting by conducting a systematic literature review, with or without, meta-analysis.

*Objective 2.1:* Assess heterogeneity of methods, procedures, risk of bias, and outcome measures in published studies on physical activity promotion in the clinical setting.

*Objective 2.2:* Determine the feasibility of conducting a meta-analysis as informed by Objective 2.1.

*Aim 3:* Determine the acceptability and usability of a tablet-based application for weight management to annual and routine follow-up clinic visits by conducting a cross-sectional study.

*Objective 3.1:* Establish a baseline knowledge/understanding of technology usage in the patient population.

*Objective 3.2:* Determine the overall acceptability and usability of the mWRAPPED app in the clinic patient population.

### **1.3 Overview of Methodological Approach**

#### *Aim 1 Scoping Review*

The scoping review was intended to provide an assessment of the potential size and scope of the available research literature. Scoping reviews follow many of the same methodological steps as systematic reviews. These include rigorous and transparent methods for data collection and reporting of results, robust analysis, and appropriate interpretation. These steps are essential for reliability of results and the potential for replication. The release of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) 20-item Checklist (Appendix A) is intended to serve as the guiding document for this review.<sup>10</sup> These guidelines lead this project aim by utilizing the following overarching steps: 1) identify the research question; 2) identify relevant studies; 3) detail study selection; 4) chart the data; 5) collate, summarize, and report results, all while completing the necessary reporting steps identified in the PRISMA-ScR Guidelines.<sup>10</sup> These steps included giving the number of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, using the PRISMA flow diagram.<sup>10-13</sup> A strength of scoping studies includes their breadth, depth, and comprehensiveness of evidence covered in a given field. This was found to be most appropriate for understanding the various conceptual and operational terms, methods, and approaches for physical activity assessment, prescription, and promotion in primary care settings. This method was also able to account for a diversity of relevant literature and studies using different

methodologies and measurement approaches, something that is usually not feasible in a more focused systematic review.

### *Aim 2 Systematic Review*

Systematic reviews and meta-analysis are essential tools for summarizing evidence accurately and reliably. They help clinicians keep up to date; provide evidence for policy makers to judge risks, benefits, and harms of healthcare behaviors and interventions; gather together and summarize related research for patients and their caregivers; provide a starting point for clinical practice guideline developers; provide summaries of previous research for funders wishing to support new research; and help editors judge the merits of publishing reports of new studies.<sup>11,13</sup> A systematic review was conducted (without meta-analysis) because it is a structured process with gold standards for this method developed by the Cochrane Collaboration, a global network of professionals dedicated to using high-quality, timely research evidence to advance healthcare decision making.<sup>14</sup> Like the aforementioned scoping review, the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines lead this project aim by utilizing the following overarching steps: 1) identify the research question; 2) identify relevant studies; 3) detail study selection; 4) abstract the data; 5) collate, summarize, and report results, all while completing the necessary reporting steps identified in the PRISMA Guidelines.<sup>15</sup> These steps included giving the number of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, using the PRISMA flow diagram.<sup>15</sup>

### *Aim 3 Cross-Sectional Study*

A cross-sectional, convenience sample study with patients seen during their regularly scheduled clinic visits to the WVU Medicine University Town Center Family Medicine Clinic was conducted. The study took place during the Wednesday evening clinic hours throughout March 2018. A tablet device (a Samsung tablet) containing the mWRAPPED application was used. The application asked the participant their age, height, and weight. From the provided information the application calculated the

participants BMI. The application then used the calculated BMI to offer information regarding cardiovascular risk, as well as information on managing/controlling their risk. The application also provided patient participants with additional information and resources tailored to their identified interests and needs.

## CHAPTER 2

### **2 Physical Activity Assessment and Promotion in Clinical Settings in the United States: A Scoping Review**

#### **2.1 Abstract**

*Objective:* The purpose of this scoping review was to systematically examine interventions that focused on physical activity assessment and promotion in clinical settings in the United States.

*Data Sources:* A literature search was performed in six major databases to extract published peer-reviewed studies from 2008 to 2019.

*Inclusion and Exclusion Criteria:* Interventions with practicing health professionals in the United States who performed physical activity assessment and promotion with adult patients 18 years of age and older. Studies were excluded if they were published in non-English, observational or case study designs, or gray literature.

*Data Extraction:* Studies were screened and coded based on the population, intervention, comparison, outcomes and study setting for scoping reviews (PRISMA-ScR) framework. Of 654 studies that were identified and screened for eligibility, 78 met eligibility criteria and were independently coded by two coders.

*Data Synthesis:* Data were synthesized using qualitative and descriptive methods.

*Results:* Forty-three of the included studies were randomized controlled trials with a majority being delivered by physicians and nurses in primary care settings. Fifty-six studies reported statistically significant findings in outcome measures such as anthropometrics and chronic disease risk factors, with 17 demonstrating improvements in physical activity levels as a result of the interventions.

*Conclusion:* The assessment and promotion of physical activity in clinical settings appears to be effective but warrants continued research.

*Keywords:* Health Promotion, Physical Activity Assessment, Health Care Setting, Physician Counseling, Lifestyle, Scoping Review



## 2.2 Introduction

### *Objective*

National Physical Activity Guidelines (2018) in the United States (US) recommend that adults limit sedentary time and participate in 150 minutes of moderate-intensity aerobic physical activity each week, 75 minutes of vigorous aerobic physical activity per week, or some combination of the two.<sup>1</sup> In addition, muscle strengthening exercises should also be conducted two or more days a week for substantial health benefits.<sup>1</sup> Unfortunately, 80% of American adults do not currently meet the government's recommendations for aerobic activity and muscle strengthening.<sup>16</sup> While nearly 30% of US adults are inactive, approximately 20% of those who do participate in physical activity are not sufficiently active to achieve health benefits.<sup>2</sup> This is problematic since a sedentary lifestyle has been shown to contribute to nearly 70% of all deaths in the US, doubles the risk of cardiovascular diseases, diabetes and obesity, and increases the risk of colon cancer, high blood pressure, osteoporosis, lipid disorders, depression and anxiety.<sup>17</sup> In terms of healthcare expenditures, physical inactivity has been estimated to cost approximately \$117 billion per year, or roughly 8.4 percent of US health care expenditures.<sup>3</sup>

Primary care providers are increasingly called upon to initiate physical activity counseling with their patients to manage conditions such as obesity, diabetes, and cardiovascular disease.<sup>18</sup> The National Physical Activity Plan (NPAP) highlights the important health benefits from regular physical activity for adults with chronic conditions under the supervision of a healthcare provider to consult on the types and amounts of appropriate physical activity.<sup>19</sup> Unfortunately, reports indicate that less than one third of primary care visits include some type of physical activity counseling, suggesting a need to be more strategic in discussing and promoting physical activity to the general population.<sup>20</sup> Barriers include, but are not limited to, financial support, competing health demands, time for counseling, as well as a perceived lack of knowledge regarding physical activity programming and counseling.<sup>21</sup> Furthermore,

the US Preventive Services Task Force recommends that primary care providers offer physical activity counseling for cardiovascular disease prevention.<sup>22</sup> Given the importance of this issue, it is not surprising that the number of articles examining physical activity counseling within the primary care setting doubled between 2012 to 2014.<sup>23</sup> This observation demonstrates a growing interest in the topic, including the identification of factors that lead to successful adoption and implementation of interventions in clinical settings.

While the NPAP includes selected recommendations for clinicians and the healthcare sector on physical activity promotion, it does not include a detailed assessment of the evidence as well as challenges of physical activity assessment, promotion, and counseling in clinical settings.<sup>19</sup> While several approaches to physical activity promotion in clinical settings have shown effectiveness in modifying negative health behaviors and improving health outcomes, the intervention approaches are inconsistent across settings.<sup>24</sup> More specifically, the terms physical activity assessment, prescription, promotion, and counseling are often used interchangeably even though they suggest distinct practices.<sup>25</sup> A recent scientific statement from the American Heart Association set out to increase the adoption of routine physical activity assessment and promotion, identifying health promotion as physical activity counseling and referral, and assessment as a detailed measure of physical activity.<sup>18</sup> Along those lines, Kaiser Permanente in Southern California<sup>26</sup> and the Greenville Health System in South Carolina<sup>27</sup> have both adopted the Exercise Is Medicine® (EIM) initiative,<sup>28</sup> including the implementation of consistent physical activity assessment as an additional vital sign during clinic visits.<sup>29</sup> This initiative assesses the amount of moderate physical activity per week as a standard of care for use in current and future clinic visits. Other approaches to exercise promotion in clinical settings either do not assess measurable physical activity or use different measures in exercise assessment,<sup>30-32</sup> making comparison of effective interventions challenging for both clinicians and researchers. In addition, intervention studies in clinical settings employ varied methods to measure and report physical activity levels. These include numerous

self-report surveys (e.g. minutes of activity, meeting guideline thresholds),<sup>33-35</sup> electronic devices (e.g., pedometers and accelerometers measuring physical exertion),<sup>36-38</sup> as well as reporting physical activity levels in either number of minutes per week or as a categorical assessment of meeting physical activity recommendations. Another observable inconsistency is in who delivers the physical activity recommendations. These include, but are not necessarily limited to, health care providers (e.g., physicians and nurses),<sup>39-41</sup> certified diabetes educators,<sup>42</sup> and physical activity coaches or health educators.<sup>40,43</sup> With respect to observed outcomes, previous studies have reported physical activity interventions that focused on reductions in cardiovascular and metabolic risk factors.<sup>33,35,44,45</sup> improvements in physical functioning,<sup>36,46,47</sup> mental health outcomes,<sup>37,48,49</sup> and feasibility or impact of the intervention itself.<sup>50-53</sup>

Many reviews have focused on the implementation of physical activity assessment and promotion interventions in clinical settings and the effectiveness of those programs. One recent study found that while primary care providers are receptive to promoting physical activity, many individual and organizational barriers exist that make effective counseling difficult.<sup>21</sup> Several systematic reviews that have explored the effectiveness of physical activity assessment, promotion, and/or counselling in primary care settings demonstrated the effectiveness of both exercise referral schemes and counselling interventions.<sup>25,54-56</sup> In addition, studies that examined the cost and economic benefit of physical activity interventions in primary care settings reported no negative impact on cost.<sup>57,58</sup> Another recent systematic review endorsed by the Centers for Disease Control and Prevention (CDC) and which focused on incorporating the physical activity vital sign into the clinical workflow found the quick assessment tool to be promising.<sup>59</sup> Other research on the use of brief physical activity interventions in specific patient populations throughout primary care concluded that a need exists for the development and evaluation of brief tools deliverable in a primary care consultation.<sup>60</sup> Similarly, a scoping review related to physical activity promotion in clinical settings reported the need for broader training and

systematic change before widespread adoption into standard of care.<sup>61</sup> However, to the best of the authors' knowledge, there have been no reviews examining physical activity assessment, promotion, and/or counseling across multiple clinical settings. By conducting a scoping review, our hope is to facilitate physical activity assessment, promotion, and/or counseling to become a standard of care in various clinical settings, as well as provide direction for future research.<sup>6</sup> Given the former, a need exists to map the literature with respect to physical activity promotion in the clinical setting, including the identification of major concepts, gaps in the literature, and types and sources of evidence needed to inform practice, policymaking, and research. Scoping reviews are ideally suited to map the scope and range of methods and outcomes reported for research on a topic area and can provide justification and guidance for systematic reviews with or without meta-analyses.<sup>62</sup> Using this approach, we critically examined physical activity assessment and promotion interventions in clinical settings. More specifically, we reviewed study designs, nature of the clinical setting, type of healthcare professionals who conducted the interventions, funding sources and registration in clinicaltrials.gov, theoretical influences, and keywords that characterize these studies. We also examined the outcomes measured, the measurement approaches used, and reported results.

### **2.3 Methods**

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis extension for Scoping Reviews (PRISMA-ScR), including the PRISMA-ScR checklist (Appendix A) and flow diagram.<sup>10</sup> The protocol for this study was not registered in the systematic review trial registry PROSPERO because PROSPERO does not allow for the registration of scoping reviews.<sup>63</sup>

#### *Data Sources*

A search was conducted by KG and PG in EbscoHost, where citations were retrieved from six electronic bibliographic databases: 1) PubMed (MEDLINE), 2) Academic Search Complete, 3) PsycINFO, 4) Cumulative Index to Nursing and Allied Health Literature (CINAHL), 5) SPORTDiscus,

and 6) Health Source. Keywords included physical activity, exercise, promotion, counseling, prescription, referral, clinical setting, and primary care. Relevant Medical Subject Headings (MeSH) terms identified by the U.S. National Library of Medicine's thesaurus were also considered when identifying the final search strings.<sup>64</sup> The final search included: (physical activity OR exercise OR fitness OR physical exercise) AND (counseling OR counselling OR health promotion OR health education OR patient education) AND (primary care OR primary health care OR primary healthcare OR family practice OR community care OR general practitioner OR generalists OR clinical setting OR clinical practice). (Appendix B) In addition, the reference lists from these publications and any systematic reviews located were scanned to identify any studies that had not been previously identified and appeared to contain information on the topic of interest. To avoid multiple publication bias, all included studies were examined to ensure that each study was independent of all others. Multiple publication bias was addressed by including the most recent/relevant study from multiple studies using data from the same cohort. Each search was conducted separately and downloaded as a separate file using Endnote X8.<sup>65</sup>

### *Inclusion/Exclusion Criteria*

Eligibility criteria included the following: 1) studies involving practicing health professionals (licensed, allied, and non-medical health professionals) in the US, except if it was only by referral; 2) assessment, promotion, and/or counseling of physical activity practices reported; 3) adult humans ages 18 years and older as research participants; 4) peer-reviewed studies published in English; 5) studies published and indexed between 2008 and 2019. The rationale for the search dates are based on the release of EIM<sup>®</sup> by the American College of Sports Medicine (ACSM) in late 2007,<sup>28</sup> the initial release of the National Physical Activity Guidelines in 2008,<sup>66</sup> and the release of the 2<sup>nd</sup> Edition of the National Physical Activity Guidelines in late 2018.<sup>67</sup> Study designs included experimental/intervention trials, feasibility studies, and those that included randomized and non-randomized trials with single or multiple

arms. Exclusion criteria included the following: 1) observational study designs (case reports, prospective and retrospective cohort, cross-sectional studies, etc.), 2) commentaries, 3) letters to the editor, 4) animal studies, 5) studies published in non-English languages, 6) presentations from conference meetings, and 7) unpublished studies (abstracts, master theses, dissertations, etc.).

While the exclusion on non-English language studies may present a risk for language bias, it is important to note that while some studies have reported that excluding studies reported in languages other than English may bias results,<sup>68,69</sup> others have shown that it has little to no effect on overall findings.<sup>70</sup> In addition, the impact of language bias may be decreasing given the shift towards publication of studies in English-language journals.<sup>71</sup> Our rationale for the exclusion of unpublished studies was based on the work of van Driel et al., who concluded that the difficulty in retrieving unpublished work could lead to selection bias, that many unpublished trials are eventually published, that the methodological quality of such studies are poorer than those that are published, and that the effort and resources required to obtain unpublished work may not be warranted.<sup>72</sup>

### *Data Extraction*

Independent, dual selection of studies and data abstraction was performed in this review. This process included two phases; 1) an initial screening phase to review titles, abstracts, and keywords, followed by 2) full-text eligibility screening for inclusion in the subsequent analysis. The initial screening process was conducted by KG and PG, both independently, who identified those articles for inclusion by reviewing the titles, abstracts, and keywords for all articles generated through the database searches. After removing duplicate articles, KG and EB read the full-length manuscripts included, screened them for eligibility, and selected those that met the inclusion criteria for this scoping review. They then met to review their selections. Disagreements were resolved by consensus.

A codebook was developed by KG to extract the following characteristics: participant attributes, methodological features, intervention details (i.e., length and delivery agent), outcome measures, and

study results. Types of information coded included continuous and categorical variables as well as free text information. The final codebook was confirmed once an entire article was coded without any additions needed to the codebook categories. After identifying eligible studies, KG and EB independently coded the selected studies to address the research questions. They then met to review their coding. Disagreements were resolved by consensus.

### *Data Synthesis*

Since this was a scoping review, data were not synthesized quantitatively, i.e., meta-analyzed. Rather, results were synthesized qualitatively, with statistics limited to descriptive statistics, i.e., frequencies and percentages.

## **2.4 Results**

A total of 654 articles were initially identified and screened for eligibility (Figure 1). An additional four articles were identified during the initial screening process. Supplemental File 1 contains the full list of all studies identified during the initial screening, reasons for exclusion, and identification of those retained for further analysis. Following the initial title and abstract screening, 558 articles were excluded using the PICOS (Population, Intervention, Comparison, Outcomes, and Study Design/Setting) framework.<sup>73</sup> Of these, 100 articles met the inclusion criteria and were considered for full-text eligibility screening. Following our reading of the full text articles, 78 articles met the inclusion criteria and were selected for further analysis (Supplemental File 2). Study characteristics are organized and presented in Table 1, while study design and results are shown in Table 2. Major findings across studies are summarized below. All percentages were calculated from the 78 articles included in our review.

**[INSERT FIGURE 2.1]**

### *Study Characteristics and Results*

Tables 1 and 2 show the major findings of this scoping review. Of the 78 included studies, 43 (55%) were randomized controlled trials (RCTs)<sup>30-38,42-44,49,53,74-101</sup> while the remaining trials involved a

variety of study design types. Sixteen studies (21%) were characterized as feasibility trials by the study authors as a sub-set of the major design types reported.<sup>39,41-43,46,51-53,75,77,102-107</sup> Only 28 of the studies (36%) were registered through the U.S. National Library of Medicine on [clinicaltrials.gov](http://clinicaltrials.gov).<sup>31-33,36-38,43,44,53,76,79,82,83,85,86,90,91,93-96,98,100,101,107-110</sup> The clinical settings where these interventions took place revealed that the majority were in primary care or family medicine clinics (42%)<sup>31-33,35,37,38,41,43,45,48,49,52,75,79,84,85,89,93,94,96,101-103,106-115</sup> followed by community clinics and hospitals (23%),<sup>30,42,50,53,76,78,81,82,88,90,98,104,109,116-120</sup> and specialty clinics (23%).<sup>43,47,53,75,83,92,96,97,99,104,110,111,117,120-124</sup> More than half of the studies used a health care provider to deliver the intervention (62%), with physicians (27%),<sup>35,40,41,45,49,76,79,81,85,89,93,94,104,108-113,122,124</sup> nurses (17%),<sup>32,39,76,77,81,82,92,105,111,115,116,119,122</sup> and nurse practitioners (10%)<sup>39,41,47,52,90,102,122,125</sup> utilized the most. Registered dietitians (6%)<sup>32,48,101,119,124</sup> and physical therapists (1%)<sup>36</sup> were also among those health care providers who delivered interventions. Exercise/health coaches and counselors (22%),<sup>34,35,40,43,44,50,75,79,84,95-97,99,107-109,117</sup> research staff (18%),<sup>31,37,46,76,81,87,90,94,100,101,103,104,110,126</sup> trained health practitioners (15%)<sup>33,51,83,85,86,91,99,111,121-124</sup> (e.g., medical assistants), and trained/certified health educators (13%)<sup>30,38,41,42,86,110,117,119,120,124</sup> (e.g., diabetes educators) made up almost the same proportion of interventionists as physicians and nurses.

In terms of funding, 40 studies (51%) were funded by a government agency with 36 studies (46%) funded by the National Institutes of Health (NIH) and/or the CDC<sup>31,32,34,35,37,38,43,44,49,53,75,76,78-86,88,90-94,96,98,102,107,108,110,117,121</sup> and nine (12%) by the Department of Veterans Affairs (VA) or another military grant.<sup>75,95,100,101,108,110,114,121</sup> Eleven studies (14%) were supported by academic institutions<sup>30,38,39,42,79,82,92,94,121,124,127</sup> while nine studies (12%) were corporate funded.<sup>39,48,50,74,91,109,111,113,119</sup> Of those studies receiving corporate funds, four studies (5%) were funded by major pharmaceutical companies that included Pfizer,<sup>91,111</sup> Sanofi-Aventis,<sup>119</sup> Bayer<sup>74</sup> and Pepsi, Inc.<sup>113</sup> The majority of the studies were not guided by a theoretical framework. Those studies that were theory-based used Social



Cognitive Theory (22%),<sup>30,34,39,42,43,48,50,80,95,97,103,107,110,115,118-120</sup> the Transtheoretical Model (10%),<sup>31,34,41-43,80,110,113</sup> or Health Belief Model (6%)<sup>33,41,52,99,120</sup> most frequently. Interestingly, only five studies (6%) adopted technology (tablets, automated phone calls, etc.) to deliver the interventions as reported by the authors.<sup>31,49,89,114,126</sup>

### [INSERT TABLE 2.1 & 2.2]

A word cloud that highlights the frequency of the measured outcomes reported in the studies reviewed is shown in Figure 2. Outcome measures for “physical activity” were reported by 25 studies (32%).<sup>30,31,34,35,37,38,40-43,50,53,75,76,78,80,81,83,86,94,104,108,121,122,126</sup> Other commonly reported outcomes measures included “body weight” (40%),<sup>30,32,35,38,39,44,45,48,49,51,52,76,78,79,85,87,97,100-103,105-107,111-113,115,119,120,124,125</sup> “body mass index” (26%),<sup>30,32,39,45,48,49,52,76,85,87,101,103,106,107,111,113,115,119,124,125</sup> “behavior” (13%),<sup>33,37,78,84,95,99,107,109,116,123</sup> and “health” (9%).<sup>48,78,100,107,113,114,116</sup>

### [INSERT FIGURE 2.2]

Self-report measures were the most common method to measure physical activity. Of the 27 studies that used self-report, 16 (21%) used previously validated measures,<sup>31,33,35,37,42,49,76,80,81,83,86,89,104,108</sup> while 11 (14%) used study-specific physical activity self-report questions.<sup>43,53,75,77,95,96,101,108,110,113,126</sup> Quality-of-life was measured in seven studies (9%),<sup>34,48,75,83,104,120</sup> and other disease specific measures were used in 10 studies (13%).<sup>43,46,51,77,94,96,99,106,109,118</sup> Six studies (8%) included participant physical activity diaries or logs.<sup>92,97,99,104,121,123</sup> Seven studies (9%) incorporated various forms of activity monitors, including pedometers,<sup>30,36,39,46,85,92,103</sup> while six (8%) used accelerometers.<sup>38,40,80,82,83,121</sup> Two other studies (3%) that used commercial activity tracking technology to record participant data did not report major findings from the collected information.<sup>97,120</sup> Physical activity was also assessed in two studies (3%) by direct observation through attendance in meetings and participation in physical assessments throughout the intervention period(s).<sup>39,120</sup> Seven

studies (9%) used other, more unique measures to assess physical function, including timed and distance walking tests<sup>40,43,46,86,98,121</sup> and balance scales.<sup>36</sup>

In terms of reported findings, 57 studies (73%)<sup>30-32,34,35,37,39,40,45-53,74,75,77-83,85,86,88,92,94,95,97-104,106-109,112,114,117-126</sup> reported significant changes in primary outcome measures pre- to post-intervention while 21 studies (27%)<sup>33,36,38,41-44,76,84,87,89-91,93,96,105,110,111,113,116,127</sup> reported non-significant changes (Table 2). Of the 25 studies (32%) that identified physical activity as a primary outcome measure, 17 (22%) reported statistically significant improvements,<sup>30,34,35,37,40,50,53,78,80,81,83,86,95,104,108,121,122</sup> with two (3%) identifying physical activity as a significant predictor of other outcome measures.<sup>75,126</sup> Non-significant improvements in physical activity were observed in six studies (8%),<sup>31,38,41-43,84</sup> with one study identifying no difference between intervention groups.<sup>76</sup> Five additional studies (6%) identified significant changes in physical activity behaviors as a secondary outcome measure,<sup>51,52,89,93,111</sup> with one study (1%) identifying physical activity as a significant predictor of other outcome measures.<sup>98</sup>

Other outcome measures included changes in anthropometrics, cardiovascular and diabetes risk reduction, and behavior change. Anthropometric outcomes included changes in body weight,<sup>30,35,44,45,79,85,97,100-102,105,107,111,112,124</sup> decreases in waist circumference,<sup>32,45,87,88,107,112</sup> and reductions in body mass index,<sup>32,39,45,115,124</sup> Results related to cardiovascular risk factors included changes in blood lipid levels<sup>87,112</sup> and improved blood pressure.<sup>95,112</sup> Diabetes risk reduction was observed through glycemic control biomarkers,<sup>82,110,112,119</sup> improved diet and nutrition,<sup>32,37,52,76,84,87,102,111,117,118,124,125</sup> and diabetes knowledge.<sup>117</sup> Several studies reported psychosocial results, including increased self-efficacy,<sup>115</sup> decreased depressive symptoms,<sup>46,49,51,77,82</sup> or reduction in anxiety,<sup>46,48,51,52,103</sup> and improved mood or behavior.<sup>45,52,53,78,103,116-118,123</sup>

## 2.5 Discussion

The overall results of this scoping review demonstrate that many of the studies were RCTs, funded by US government agencies, had interventions implemented by physicians and nursing staff, and

used self-report measures of physical activity. Randomized controlled trials were the most common study design utilized in the 78 included studies, followed by pre- and post-intervention designs with or without randomization. It is also important to note that many of the RCTs were feasibility trials to determine preliminary efficacy with small sample sizes in order to justify future trials with larger samples. This is not surprising given the practical constraints (i.e., time) of adding more demands, particularly using RCTs, on physicians.<sup>18</sup> Although RCTs are often viewed as the “gold standard” for determining efficacy and reducing bias, this study design is not always possible, and, in some instances, may not be the most appropriate approach.<sup>128</sup>

A closer look at Table 2 reveals that only twenty five of the 43 reported RCTs were registered in [clinicaltrials.gov](http://clinicaltrials.gov). Although not required, 10 studies that identified as RCTs and reported funding from at least one government agency were not registered through [clinicaltrials.gov](http://clinicaltrials.gov). The importance of registering on [clinicaltrials.gov](http://clinicaltrials.gov) is to uphold a scientific, ethical, and moral responsibility to ensure the public has information about ongoing and previously conducted trials to provide information to potential participants and referring clinicians, reduce publication bias, and promote a more efficient allocation of research funds.<sup>129</sup> The current pool of medical literature is large, and it is often difficult to keep up to date with all relevant research. This review identified several gaps in reporting clinical trials that could limit the access or reach of relevant information to patients, their family members, health care professionals, researchers, policymakers, and the general public.

The majority of studies were conducted in primary care or family medicine clinical settings, followed by community clinics and hospitals. Physical activity assessment and promotion fall into the scope of practice for many primary care and family medicine providers, and it is no surprise that many studies were conducted in these settings.<sup>130</sup> In 2011, the Centers for Medicare & Medicaid Services (CMS) passed a decision to reimburse primary care providers (PCP) for delivering intensive behavioral therapy to treat patients with obesity, further emphasizing the importance of physical activity assessment

and promotion in primary care.<sup>131</sup> It is possible that other specialties (e.g., cardiology, endocrinology, or oncology) also adopt health behavior promotion, including physical activity assessment and promotion, into their plan of care for patients.<sup>132</sup> However, positive effects were observed in other settings such as Federally Qualified Health Centers (FQHCs), Veterans Administration hospitals, and other free clinics. Federally Qualified Health Centers provide comprehensive primary and preventative care to underserved or vulnerable populations. We also found 11 studies working with military populations in primary care clinical settings, the majority of which were funded through government agencies and/or the U.S. Department of Veterans Affairs (VA). This follows the increasing emphasis on preventative care in medicine and the role of a primary care provider (e.g., physicians, nurse practitioners, and physicians' assistants) in the health of various patient populations.

Physicians were the most common program delivery agent in this review, followed by nurses and nurse practitioners. Both trained and untrained health educators and/or coaches also made up a strong portion of program delivery agents, demonstrating an increase in the utilization of additional resources for program delivery along the training spectrum. With the growing demand put on primary care providers to cover more and more topics during their short patient visits, this review demonstrates that nurses and other trained health practitioners and educators are intervention delivery agents for physical activity assessment and promotion in clinical settings. For example, given the lack of training that clinicians and other health care personnel receive in exercise programming,<sup>133-135</sup> increasing physical activity in patients may best be achieved by the clinician or other relevant healthcare personnel referring the patient to a certified exercise program professional which is then appropriately reimbursed for their services. Implementation of a physical activity vital sign has been shown to promote favorable changes, with patients 14% more likely to report having discussed exercise with their primary care physician and a 14% increase in providing referrals and resources to patients.<sup>136</sup> Unfortunately, poor reimbursement

for physical activity counseling in the US healthcare system continues to present challenges to health care providers.<sup>18,137</sup>

A majority of the reviewed studies assessed physical activity using self-report measures, including surveys and questionnaires. A limited number of studies in this review utilized various technology, including pedometers, accelerometers, and other wearable activity monitors (e.g., FitBit<sup>®</sup> or Garmin vívofit<sup>®</sup>). The inconsistency in reporting accurate measures of physical activity (e.g., self-report and wearable activity trackers) provides a challenge for researchers to collate information to create a unified approach to promotion. Activity monitors are not without limitations but may provide a more objective measure of physical activity levels in participants and can remove those biases associated with self-report measures.<sup>138</sup> Consumer physical activity monitors are becoming increasingly more affordable and enable researchers to continuously monitor physical activity, allowing investigators to assess physical activity in new ways.<sup>139</sup> The need for standardized physical activity assessment and promotion to ensure replication and success in future studies is evident in this review.

It is encouraging that a majority of the reviewed studies were funded. Funding for clinical research for physical activity assessment and promotion is important because it shows the U.S. federal government, along with researchers and clinicians from around the country, value this line of inquiry. Table 2 identifies each study that received funding from a government agency, including grants from many of the offices under the NIH, CDC, and the US VA. This supports the numerous initiatives taken by many government supported organizations promoting the implementation of regular physical activity assessment, promotion, and counseling in the US today, including the USPSTF aimed at reviewing the evidence and effectiveness of research in primary care and prevention and developing recommendations for clinical action.<sup>140</sup> Another popular source of funding for many of the reviewed studies were from private organizations, public foundations, and other invested groups supporting the research. One major contributor was the Robert Wood Johnson Foundation, the US's largest philanthropy focused solely on

health.<sup>141</sup> Surprisingly, corporate funds were also a notable contributor in financial support for nine studies (12%) in this review. Another interesting observation was that the Bayer Pharmaceutical Corporation provided funding for the design and implementation of an intervention study conducted in VA medical clinics looking at physician and patient communication.<sup>74</sup> Many studies were supported by more than one source of funding; however, 15 of the included studies (nearly 20%) did not specify a source of funding or did not acknowledge any financial support for their study. Finally, the fact that many of the RCTs included in this study received financial support from various government organizations demonstrates a viable interest in moving forward with research on this topic, including support for future initiatives using more robust methods.

It is important to note that 31 (40%) of the 78 studies (less than half) were guided by a theoretical framework. Theories offer researchers and clinicians guidance about program planning, implementation, and suggestions towards evaluation.<sup>142</sup> They provide behavioral targets, a better understanding of the context of behavior change, and information about measurement strategies.<sup>143</sup> Future research should consider theoretical frameworks to guide work in clinical settings, including a comparison of theoretical versus atheoretical approaches.

The findings reported here support the wide range of physical activity research being conducted in clinical settings and the need for more consistency in reporting results. This reinforces the need for standardized definitions and processes of physical activity assessment and promotion. The ACSM has offered one solution through their EIM<sup>®</sup> initiative that encourages primary care providers to consider physical activity as a “5<sup>th</sup> vital sign,” including the provision of resources for the consistent reporting and documentation of physical activity levels in patients.<sup>28,144</sup> This initiative was first released in 2007 and has expanded significantly in recent years. Several observational studies have been conducted to assess barriers and facilitators to the implementation of exercise and physical activity assessment, promotion, and counseling by healthcare providers, identifying similar responses, including lack of

knowledge and time, lack of incentives or reimbursement, and competing priorities.<sup>18</sup> The results of our current review reinforces the successful delegation of physical activity promotion to other healthcare practitioners within clinical settings in the US, including trained health educators and coaches available for referral, thereby alleviating many of the burdens identified by healthcare providers. Additionally, a study conducted by Asiamah et al (2021) supports the usefulness of nurse consultants to primary care practices supporting improved preventative care delivery, including physical activity.<sup>25</sup> These findings and initiatives set in place by the American Heart Association Scientific Statements<sup>18</sup> – together with global initiatives like EIM<sup>®28</sup> have the ability make consistent physical activity assessment and promotion a standard of practice across clinical settings.

## **2.6 Strengths and limitations**

In general, the heterogeneity in the outcome variables posed a challenge when comparing results, making a quantitative analysis of study results difficult unless a significant narrowing occurs. For example, and as previously mentioned, 25 studies (32% of total studies included) directly observed physical activity as a primary outcome measure. Twenty one of those studies reported measurable physical activity,<sup>30,31,34,35,37,38,40-43,50,53,75,76,80,81,83,86,104,108,121</sup> including seven studies that used wearable technology in addition to other self-report measures for more accurate reporting.<sup>30,38,40,80,83,104,121</sup> This indicates a need for a closer examination at these detailed studies to provide more robust information regarding physical activity assessment, promotion, and counseling in clinical settings. This may best be achieved by narrowing the focus and conducting either a systematic review or systematic review with meta-analysis.

From the investigator's perspective, the major strengths of this study was that this was the first scoping review that the authors are aware of to map the literature on physical activity assessment and promotion in clinical settings, identifying key concepts, gaps in the research, and types and sources of evidence that could inform research, practice and policymaking. In addition to strengths, there are

several potential limitations. First, this study was a qualitative synthesis rather than a quantitative review. Thus, no further analysis was performed because of the diverse outcomes examined and methodological heterogeneity between studies. Second, this study did not search the grey literature, including dissertations, conference proceedings, and recommendation reports, etc., thus possibly biasing the findings. Third, given that this review only included studies conducted in the US, the generalizability of results may be limited. However, given between-country differences in healthcare systems, an *a priori* decision was made to limit our review to US studies. The former notwithstanding, this offers an area of comparison for future studies between countries. Fourth, this study was limited by what the authors of the included studies reported. For instance, we were unable to report sample sizes because some authors reported only those enrolled while others reported study completers. Additionally, we were unable to report on any identified barriers to adoption of the physical activity interventions in the included studies, an area in need for future research. It is also possible that other findings, particularly null findings, were not reported by the authors. Finally, while we did not formally assess the quality, potential bias, or credibility of the published studies included in this review, it is important to note that quality appraisal of studies is not mandated by the PRISMA guidelines for scoping reviews.<sup>10</sup> Nevertheless, future researchers may want use some type of formal risk of bias assessment instrument, although this may be challenging given the nature of scoping reviews versus systematic reviews, with or without meta-analysis.

## **2.7 Conclusions**

*What is already known on this subject?*

There has been increased public health interest and scientific inquiry in physical activity assessment, promotion, and counseling in clinical settings. Physical activity promotion by healthcare providers in primary care has been shown to be effective in increasing physical activity and reducing other comorbidities in patients.



*What does this article add?*

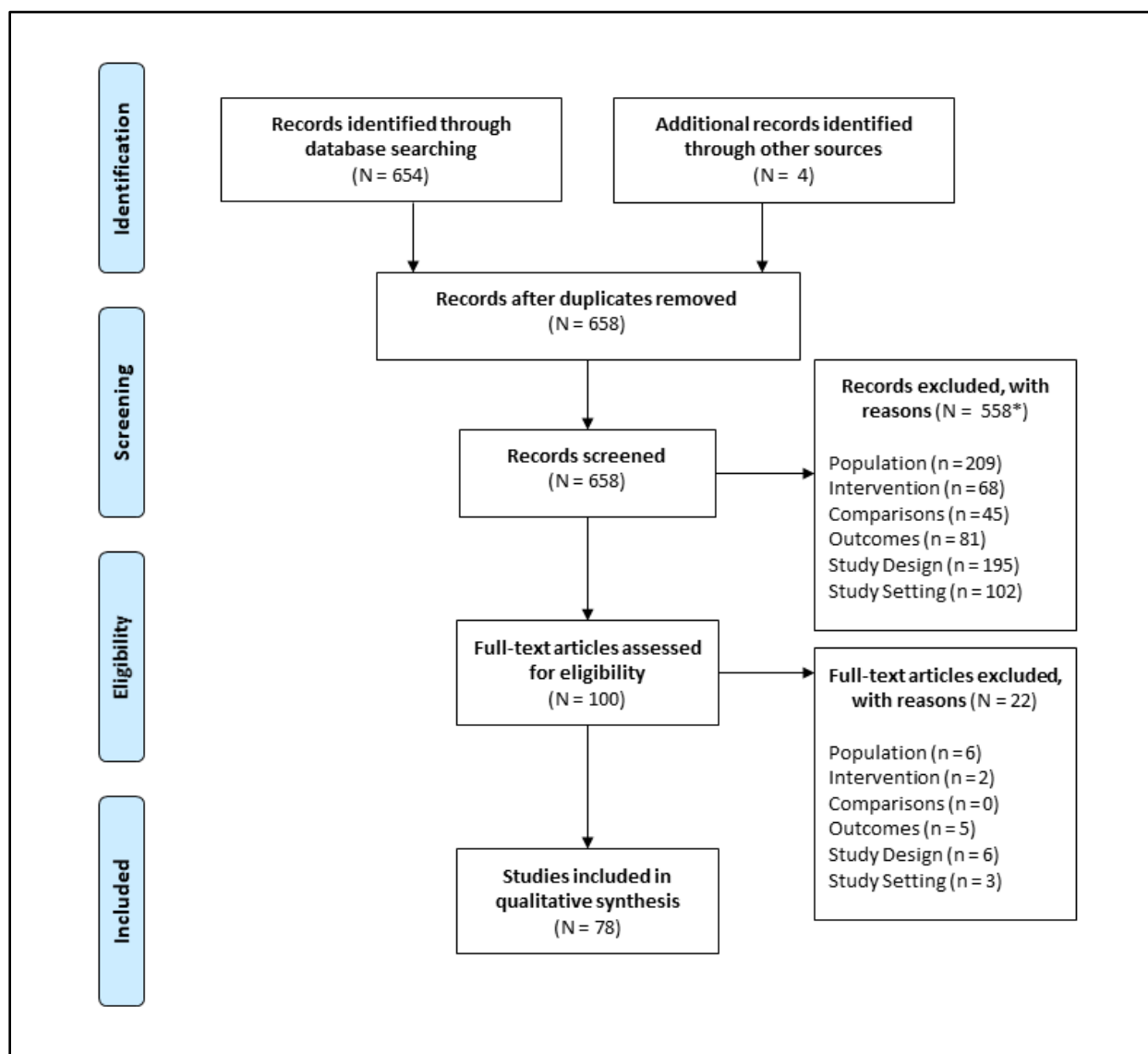
This study supports the use of physical activity assessment, promotion, and counseling across various clinical settings. This review also showed that diverse members of the healthcare team can be utilized in the delivery of physical activity interventions to assist physicians in clinical settings to help overcome common barriers in practice.

*What are the implications for promoting practice health or research?*

This review supports the need for physical activity assessment, promotion, and counseling as a standard of care across clinical disciplines. This study also identified the need for more accurate measures of activity through the adoption of electronic activity monitors and more accurate and consistent physical activity reporting.

## 2.7 Tables & Figures

Figure 2.1



**Figure 2.1** PRISMA Flow Diagram. \*Studies excluded during screening may have been excluded for multiple reasons, therefore the sum of the PICOS will not equal 558.

**Table 2.1:** Study characteristics, study designs, and patient demographics (Total N= 78).

| <b>Study Characteristics</b>                                | <b>Frequency n (%)</b> |
|---|------------------------|
| <b>Study Design</b>   |                        |
| Randomized Control Trial (RCT)                              | 43 (55.13%)            |
| Cluster Randomized Control Trial                            | 2 (2.56% of N)         |
| Crossover Randomized Control Trial                          | 1 (1.28% of N)         |
| Pre-Post Intervention Study                                 | 14 (17.95%)            |
| Randomized Trial  | 5 (6.41%)              |
| Controlled Clinical Trial                                   | 3 (3.84%)              |
| Quasi-Experimental Study                                    | 3 (3.84%)              |
| Clinical Trial  | 2 (2.56%)              |
| Mixed Methods Study   | 2 (2.56%)              |
| Practical Clinical Trial                                    | 1 (1.28%)              |
| Practical Controlled Trial                                  | 1 (1.28%)              |
| Pragmatic Clinical Trial                                    | 1 (1.28%)              |
| Repeated Measures Intervention Study                        | 1 (1.28%)              |
| Evidence-Based Behavioral Intervention Study                | 1 (1.28%)              |
| Evidence-Based Practice Change Study                        | 1 (1.28%)              |
| <b>Registered Trials (clinicaltrials.gov)</b>               |                        |
| No  | 50 (64.10%)            |
| Yes   | 28 (35.89%)            |
| <b>Clinical Settings*, **</b>                               |                        |
| Primary Care/Family Medicine Practices/Clinics              | 33 (42.31%)            |
| Community Clinics/Hospitals                                 | 18 (23.08%)            |
| Specialty Practices/Clinics                                 | 18 (23.08%)            |
| Veterans Affairs /Military Clinic                           | 11 (14.10%)            |
| Federally Qualified Health Center/Free Clinics              | 9 (11.54%)             |
| Academic Medical Center                                     | 5 (6.41%)              |
| Unknown   | 3 (3.84%)              |
| Medicare-Certified Home Facility/Homecare                   | 2 (2.56%)              |
| Recruitment Only – No Clinical Involvement for Intervention | 2 (2.56%)              |
| Physical Therapy  | 1 (1.28%)              |
| <b>Program Delivery Agent **</b>                            |                        |
| Health Care Provider  | 48 (61.54%)            |
| Physician   | 21 (26.92% of N)       |
| Nurse   | 13 (16.67% of N)       |
| Nurse Practitioner  | 8 (10.26% of N)        |
| Registered Dietitian  | 5 (6.41% of N)         |
| Physical Therapist  | 1 (1.28% of N)         |
| Exercise/Health Coach or Counselor (training not specified) | 17 (21.79%)            |
| Research Staff  | 14 (17.95%)            |
| Trained Health Practitioner (Medical Assistants, etc.)      | 12 (15.38%)            |
| Trained/Certified Health Educator (Diabetes, etc.)          | 10 (12.82%)            |
| Trained Clinic Staff  | 7 (8.97%)              |
| Technology (Internet, Tablet, Automated Phone calls, etc.)  | 5 (6.41%)              |

|   |           |
|---|-----------|
| Trained Volunteer/Staff                           | 4 (5.13%) |
| Qualified Instructor (exercise, yoga, chef, etc.) | 3 (3.85%) |
| Unknown   | 2 (2.56%) |

**Funding Sources\*\***

|  |                  |
|--|------------------|
| Government Agency                                | 40 (51.28%)      |
| NIH/CDC  | 36 (46.15% of N) |
| Veterans Affairs/Military                        | 9 (11.54% of N)  |
| Not Specified                                    | 16 (20.51%)      |
| Other (Private Organizations, Foundations, etc.) | 15 (19.23%)      |
| Academic/University                              | 11 (14.10%)      |
| Corporate Funding                                | 9 (11.54%)       |

**Theory-Based/ Driven:**

|                         |                  |
|-------------------------|------------------|
| No or Not Reported      | 47 (60.26%)      |
| Yes                     | 31 (39.74%)      |
| Social Cognitive Theory | 17 (21.79% of N) |
| Transtheoretical Model  | 8 (10.26% of N)  |
| Health Belief Model     | 5 (6.41% of N)   |

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\*Percentages rounded to nearest whole number and thus, may not equal 100;

\*\*Multiple clinical settings, program delivery agents, and/or funding sources reported for some studies; Numbers do not sum to 78 and percentages do not equal 100.

**Table 2.2:** Study design, setting, delivery agent and results reported from all 78 studies.

| <b>Author, Year</b>                 | <b>Study Design</b> | <b>Study Setting</b>                                | <b>Program Delivery Agent</b>   | <b>Primary Outcomes Measured (Intended)</b>  | <b>Reported Results</b>  |
|-------------------------------------|---------------------|---|---|--|--|
| <b>Dutton, 2008</b> <sup>42</sup>   | RCT                 | Community Health Center                             | Trained/Certified Health Educator   | Minutes of Physical Activity and State of Change   | Weekly increase in physical activity after one month in intervention group compared to control.  |
| <b>Haskard, 2008</b> <sup>74</sup>  | RCT                 | Veterans Affairs Clinic and Academic Medical Center | Trained Volunteer/Staff   | Physician and Patient Communication  | Patient satisfaction increased significantly when physicians were trained, while physician satisfaction increased when patients were trained. †  |
| <b>Kerr, 2008*</b> <sup>49</sup>    | RCT                 | Primary Care Clinic                                 | Physician and Technology  | Depressive Symptoms and Body Mass Index  | Intervention group significantly decreased their depression scores compared to standard care group. †  |
| <b>Morey, 2008*</b> <sup>75</sup>   | RCT                 | Primary Care Clinic and Specialty Clinic            | Exercise/Health Coach or Counselor  | Self-Reported Physical Activity and Physical Function  | Individuals meeting physical activity guidelines had mean physical function scores significantly higher than those who did not. †  |
| <b>Nies, 2008*</b> <sup>126</sup>   | RCT                 | Unknown   | Research Staff and Technology   | Physical Activity and Mood   | Restructuring plans, physical activity status, and percentage body fat were significant in predicting responder and non-responder sedentary women, as well as perceived benefits of walking, number of children in household, and having a child to walk with. † |
| <b>Steele, 2008*</b> <sup>121</sup> | Randomized Trial    | Specialty Clinic                                    | Trained Health Practitioner   | Physical Activity, Exercise Adherence, and Exercise Capacity   | The intervention group showed a significantly longer distance walked compared to the control group. †  |
| <b>Tosi, 2008</b> <sup>122</sup>    | Pre-Post            | Specialty Clinic                                    | Nurse, Nurse Practitioner, Physician, Trained Health Practitioner, and Trained Clinic Staff | Counseling on Supplementation, Physical Activity, Smoking, and Fall Prevention, Bone Mineral Density, and Medication | Significant improvements were shown in patient counseling on supplementation, physical activity, fall prevention, and communication providers and patients. †  |

|  |                            |   |  |  |  |
|--|----------------------------|---|--|--|--|
| <b>Ferrer, 2009</b> <sup>33</sup>        | RCT**                      | Primary Care Clinic                             | Trained Health Practitioner                      | Risk Behaviors and Participation   | Medical assistant referrals were greater but did not achieve a higher success rate.  |
| <b>Holtrop, 2009</b> <sup>116</sup>      | Pre-Post                   | Community Health Center                         | Nurse  | Health Behavior Documentation  | Eighty five percent (85%) of practices saw improved delivery of target behaviors.  |
| <b>Morey, 2009*</b> <sup>108</sup>       | RCT**                      | Primary Care Clinic and Veterans Affairs Clinic | Physician and Exercise/Health Coach or Counselor | Gait Speed, Physical Activity, Function and Disability   | Multicomponent physical activity significantly improved rapid gait and physical activity and integration with primary care was successful. †               |
| <b>Parra-Medina, 2009*</b> <sup>76</sup> | RCT**                      | Community Health Center and FQHC                | Physician, Nurse, and Research Staff             | Changes in Physical Activity and Dietary Fat Consumption   | Standard care and intervention participants did not differ in primary outcome measures.  |
| <b>Schillinger, 2009</b> <sup>109</sup>  | Practical Clinical Trial** | Primary Care Clinic and Community Health Center | Physician and Exercise/Health Coach or Counselor | Change in Self-Management Behavior, Patient Perspectives of Care, and HbA1c  | Compared with the usual care group, both intervention groups showed statistically significant improvements in outcome measures. †                          |
| <b>Vincent, 2009</b> <sup>30</sup>       | RCT                        | Community Health Center                         | Trained/Certified Health Educator                | Physical Activity, Weight, and Body Mass Index   | Intervention participants had a statistically significant increase in the number of steps walked per day and mean weight loss of five pounds. †            |
| <b>Whittemore, 2009*</b> <sup>102</sup>  | Mixed Methods              | Primary Care Clinic                             | Nurse Practitioner                               | Reach (demographic and clinical data), Implementation (attendance, attrition, satisfaction), and Efficacy (weight loss, waist circumference, insulin resistance, and lipid profiles) | Increase in program reach was achieved and preliminary efficacy results of the program indicate modest improvements on clinical and behavioral outcomes. † |
| <b>Carroll, 2010*</b> <sup>31</sup>      | RCT**                      | Primary Care Clinic                             | Technology and Research Staff                    | Duration of Physical Activity  | The intervention group showed an increase (approaching significance) in minutes of physical activity at follow-up compared to the control group.           |

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| <b>Delaney, 2010</b> <sup>77</sup>       | Quasi-   | Medicare-Certified Home-Care Facility    | Nurse  | Quality of Life, Depressive Symptoms, and Hospitalizations   | The intervention group showed a significant increased quality of life (QOL) and decrease in depressive symptoms. †   |
| <b>Hall, 2010*</b> <sup>34</sup>         | RCT      | Veterans Affairs Clinic                  | Exercise/Health Coach or Counselor                                       | Self-Efficacy and Physical Activity Adherence  | The intervention group showed a significantly larger initial increase in health goal status at the 6-month mark, and a smaller increase at 12-months. †  |
| <b>Hayashi, 2010*</b> <sup>78</sup>      | RCT      | Community Health Center and Hospital     | Trained Volunteer/Staff  | Changes in Health Behaviors (Physical Activity) and Changes in the Cardiovascular Disease Risk Profile | Women in the intervention experienced more improvements in health behaviors, both eating habits and physical activity compared to usual care. †  |
| <b>Izquierdo, 2010*</b> <sup>32</sup>    | RCT**    | Primary Care Clinic                      | Nurse and Registered Dietitian   | Waist Circumference and Body Mass Index  | The telemedicine participants had a statistically significant increase in diet and exercise knowledge over time. Women in the telemedicine group were significantly more likely to decrease waist circumference but not body mass index over time compared to usual care. There were no significant effects for men. † |
| <b>Kruse, 2010</b> <sup>36</sup>         | RCT**    | Physical Therapy Clinic                  | Physical Therapist   | Balance, Strength, and Patient Reported Falls  | No significant differences in number of falls between groups.  |
| <b>Snow, 2010</b> <sup>111</sup>         | Pre-Post | Primary Care Clinic and Specialty Clinic | Physician, Nurse, Trained Health Practitioner, and Trained Clinic Staff  | Impact on Cardiovascular Disease Risk Profile  | Practices showed significant improvement in counseling for diet, exercise, and weight loss. †  |
| <b>Villablanca, 2010*</b> <sup>117</sup> | Pre-Post | Specialty Clinic and Hospital            | Trained/Certified Health Educator and Exercise/Health Coach or Counselor | Improve Knowledge, Reduce Cardiovascular Disease Risk Profile and Meet Healthy People 2020 Objectives  | Statistically significant improvements in knowledge, risk awareness, and clinical outcomes at 6 months, and significant increases in health behavior counseling for physical activity, diet, and diabetes. †   |

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| <b>Appel, 2011*</b><br>79                | RCT**                      | Primary Care Clinic  | Physician and Exercise/Health Coach or Counselor     | Percent Body Fat   | The in-person intervention group had the highest percentage of patients with significant weight loss. †  |
| <b>Castro, 2011*</b><br>80               | RCT                        | Recruitment Only (by telephone)                                  | Trained Volunteer/Staff and Trained Clinic Staff     | Moderate Intensity Physical Activity Capability  | Both intervention groups significantly increased physical activity capability at 6- and 12-month compared to the control group. †  |
| <b>Estabrooks, 2011</b> <sup>50</sup>    | Practical Controlled Trial | Community Health Center  | Exercise/Health Coach or Counselor                   | Minutes of Physical Activity Per Week and Self-Efficacy                                      | The intervention group showed sustained or increased physical activity compared to standard care. †  |
| <b>Evans, 2011</b> <sup>127</sup>        | Pre-Post                   | Academic Medical Center  | Trained Clinic Staff                                 | Patient Engagement   | Patients had a 3% satisfaction increase after the interns had the education.   |
| <b>Parra-Medina, 2011*</b> <sup>81</sup> | RCT                        | Community Health Center and FQHC                                 | Physician, Nurse, Research Staff                     | Level of Physical Activity and Dietary Fat Intake  | Comprehensive patients were significantly more likely to decrease total physical activity, but also more likely to improve in leisure-time physical activity than standard care. †       |
| <b>Piette, 2011*</b> <sup>82</sup>       | RCT**                      | Community Health Center and Hospital and Veterans Affairs Clinic | Nurse  | Glycemic Measures  | Intervention patients had significantly greater increases in step-counts and greater reductions in depressive symptoms with little change in glycemic measures. †                        |
| <b>Pinto, 2011*</b> <sup>83</sup>        | RCT**                      | Specialty Clinic   | Trained Health Practitioner and Trained Clinic Staff | Physical Activity Assessment, Motivational Readiness, Lipid Levels, and Physical Functioning | The maintenance group reported significantly higher exercise participation, probability of exercising at or above physical activity guidelines and self-reported physical functioning. † |
| <b>Ricanati, 2011</b><br>112             | Pre-Post                   | Primary Care Clinic  | Physician  | Changes in Cardiovascular and Glycemic Control Variables                                     | There was a statistically significant reduction in weight, waist circumference, cardiovascular and   |



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|                              |                           |  |  |  | glycemic control biomarkers, as well as a decreased use of medications. †   |
| <b>Ruffin, 2011*</b><br>84   | Cluster-RCT               | Primary Care Clinic  | Exercise/Health Coach or Counselor                   | Lifestyle Behaviors and Biomarkers                               | Intervention participants were more likely to increase daily fruit and vegetable consumption and increase physical activity per week.                                   |
| <b>Wadden, 2011*</b> 85      | RCT**                     | Primary Care Clinic  | Trained Healthcare Practitioner                      | Body Weight  | Intervention group showed significantly greater weight loss than did usual care. †  |
| <b>Buchholz, 2012</b> 39     | Controlled Clinical Trial | Free Clinic  | Nurse Practitioner and Nurse                         | Weight Loss and Program Compliance                               | A significant decrease in body mass index in 6-month completers was observed. †   |
| <b>Feinglass, 2012</b><br>40 | Clinical Trial            | Academic Medical Center  | Physician and Exercise/Health Coach or Counselor     | Minutes of Physical Activity                                     | The lowest functioning patients saw the largest relative increases in function regardless of intervention group. †  |
| <b>Gregg, 2012*</b><br>44    | RCT**                     | Unknown  | Exercise/Health Coach or Counselor                   | Remission of Diabetes  | Intensive lifestyle intervention group lost significantly more weight and had greater fitness increases.  |
| <b>Jacobson, 2012</b><br>103 | Pre-Post                  | Primary Care Clinic  | Research Staff                                       | Weight Loss and Program Compliance                               | Adults in the intervention group showed significant increase in mean beliefs with positive effects on increased knowledge, beliefs, behaviors, and decreased anxiety. † |
| <b>Migneault, 2012*</b> 37   | RCT**                     | Military Treatment Facility and Primary Care Clinic                | Research Staff                                       | Adherence to Medication, Dietary Behavior, and Physical Activity | The intervention showed significant improvements in a measure of overall diet quality and in energy expenditure. †  |
| <b>Morey, 2012*</b><br>110   | RCT**                     | Veterans Affairs Clinic, Primary Care Clinic, and Specialty Clinic | Research Staff and Trained/Certified Health Educator | Glycemic Control Indicators                                      | There were no significant differences between intervention and control group glycemic indicators.   |

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| <b>Ang, 2013*</b> <sup>86</sup>      | RCT**            | Recruitment Only            | Trained Health Practitioner and Trained/Certified Health Educator    | Frequency and Duration of Physical Activity and Pain    | Motivational interviewing patients achieved a meaningful improvement in fibromyalgia score and increased physical activity levels. †                                  |
| <b>Beebe, 2013</b> <sup>87</sup>     | RCT              | Academic Medical Center     | Research Staff   | Low-Density Lipoprotein – Cholesterol (LCL-C)           | LDL-C nor apolipoprotein B improved in either group.  |
| <b>Chang, 2013*</b> <sup>88</sup>    | RCT              | Community Health Center     | Unknown  | Urinary Albumin Excretion                               | Decreases in waist circumference, 24-hour urine phosphorus excretion, and protein intake were associated significantly with reduction in urinary albumin excretion. † |
| <b>Dickinson, 2013</b> <sup>89</sup> | RCT              | Primary Care Clinic         | Technology and Physician   | Use of Website  | Both normal and enhanced website users reported increases in physical activity.   |
| <b>Josyula, 2013</b> <sup>41</sup>   | Randomized Trial | Primary Care Clinic         | Physician, Nurse Practitioner, and Trained/Certified Health Educator | Changes in Physical Activity Level                      | Among completers, physical activity increased, but not significantly.   |
| <b>McPherson, 2013</b> <sup>46</sup> | Pre-Post         | Military Clinic             | Research Staff   | Reduction in Anxiety                                    | Significant reductions in anxiety pre- and posttest were observed, as well as overall and individual subscale reductions on depression and anxiety scores. †          |
| <b>Nguyen, 2013*</b> <sup>90</sup>   | RCT**            | Hospital                    | Nurse Practitioner and Research Staff                                | Dyspnea with Activities                                 | No differences in dyspnea with activities, exercise behavior, performance, or health related quality of life across groups was observed.                              |
| <b>Owsley, 2013*</b> <sup>91</sup>   | RCT**            | Free Clinic (Senior Center) | Trained Health Practitioner  | Attitudes about Eye Care and Eye Care Utilization       | There were no group differences 6 months post-event.  |
| <b>Pace, 2013</b> <sup>113</sup>     | Randomized Trial | Family Medicine Clinic      | Physician and Trained Clinic Staff                                   | Body Mass Index, Fitness Level, and Mental Health Score | Regardless of patient group, no significant before and after improvements were observed in selected patient-level outcomes.   |
| <b>Pinto, 2013</b> <sup>104</sup>    | Randomized Trial | Community Health Center,    | Physician and Research Staff   | Stage of Motivational Readiness for Physical            | Telephone counseling was significantly more effective than  |

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|                                       |                           | Hospital, and Specialty Clinic       |                                    | Activity, Overall Wellbeing, and Physical Activity Level  | contact control in increasing motivational readiness for physical activity at all follow-ups. †   |
| <b>Wenzel, 2013*</b><br>92            | RCT                       | Specialty Clinic                     | Nurse                              | Sleep Quality, Distress, and Fatigue  | The exercise group reported significantly more vigor, less fatigue, and less emotional distress than control group participants. †  |
| <b>Carroll, 2014*</b><br>93           | RCT**                     | FQHC and Primary Care Clinic         | Physician                          | Clinicians Use of "5A's"  | Physical activity scores for both groups increased, but the score decreased at 6-month follow-up.   |
| <b>Collins, 2014</b> <sup>51</sup>    | Controlled Clinical Trial | Veterans Affairs Clinic              | Trained Health Practitioner        | Feasibility and Patient Satisfaction  | Participants reported a statistically significant increase in exercise behaviors and health eating from pre-to post-intervention. †   |
| <b>Delaney, 2014</b><br>105           | RCT                       | Homecare                             | Nurse                              | Quality of Life   | Quality of life scores improved but not significantly.  |
| <b>Hackley, 2014</b><br>118           | Mixed Methods             | Community Health Center and Hospital | Trained Volunteer/Staff            | Nutrition and Exercise Knowledge  | Nutritional knowledge was poor and significantly lower among nonpregnant nulliparous women. Women felt sure they could engage in health behaviors (e.g., physical activity), but few did. † |
| <b>Jarl, 2014</b> <sup>125</sup>      | Pre-Post                  | Unknown                              | Nurse Practitioner(s)              | Diet, Lifestyle Factors, and Body Mass Index  | Patients had significant increases on the rapid eating assessment for patients and partners in health scores after the intervention. †  |
| <b>Keeley, 2014*</b><br>94            | Cluster-RCT**             | Primary Care Clinic                  | Research Staff and Physician       | Motivational Interviewing, Primary Care Provider Physical Activity Recommendation, and Medication | Primary care providers with motivational interviewing training scored significantly higher motivational interviewing treatment integrity scores than untrained. †                           |
| <b>Friedberg, 2015*</b> <sup>95</sup> | RCT**                     | Veterans Affairs Clinic              | Exercise/Health Coach or Counselor | Adherence to Healthy Behaviors, and Blood Pressure  | Stage-matched intervention led to a significantly lower systolic blood pressure and better blood pressure control than usual care group. †  |

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| <b>Groh, 2015</b> <sup>48</sup>     | Repeated Measures Intervention         | Primary Care Clinic and Free Clinics     | Qualified Instructor and Registered Dietitian    | Changes in Mental Health and Lifestyle, Blood Pressure, Body Mass Index, Blood Glucose, and Blood Lipids | Mental health scores increased significantly in first 12 weeks but decreased in 2nd half when women were "on their own". †   |
| <b>Murrock, 2015</b> <sup>106</sup> | Pre-Post                               | Primary Care Clinic                      | Qualified Instructor                             | Physical Function of Upper and Lower Extremities   | Significant improvements in upper and lower extremity activities were noted at 12 weeks and maintained at 18 weeks. †  |
| <b>Coultas, 2016*</b> <sup>96</sup> | RCT**                                  | Primary Care Clinic and Specialty Clinic | Exercise/Health Coach or Counselor               | Change in Dyspnea Score and Aerobic Capacity   | No improvements in dyspnea score or aerobic capacity after 18-month intervention.  |
| <b>Diaz, 2016*</b> <sup>114</sup>   | Quasi-                                 | FQHC and Primary Care Clinic             | Technology                                       | Conversation with Primary Care Provider about Health Risks/Habits  | Intervention group was significantly more likely to discuss results of questionnaire and their health risks with the primary care provider. †  |
| <b>Eaton, 2016*</b> <sup>35</sup>   | RCT                                    | Primary Care Clinic                      | Physician and Exercise/Health Coach or Counselor | Anthropometrics, Resting Heart Rate, Blood Pressure, and Physical Activity                               | Significantly more enhanced intervention participants showed clinically significant weight loss from baseline and reported significantly more minutes of moderate to vigorous physical activity over time. † |
| <b>Hartman, 2016</b> <sup>97</sup>  | RCT                                    | Specialty Clinic                         | Exercise/Health Coach or Counselor               | Weight Loss  | Intervention group lost significantly more weight than usual care group. †   |
| <b>Hays, 2016*</b> <sup>38</sup>    | RCT**                                  | Primary Care Clinic                      | Trained/Certified Health Educator                | Minutes of Physical Activity and Weight Loss   | The YMCA adaptation of the U.S. Diabetes Prevention Program did not cause a significant increase in physical activity.   |
| <b>Ritten, 2016</b> <sup>52</sup>   | Evidence Based Behavioral Intervention | Primary Care Clinic                      | Nurse Practitioner                               | Feasibility of Nurse Practitioner Delivering Intervention and Physiological Outcomes of Participants     | Participants reported significant improvement in health responsibility, physical activity, diastolic blood pressure, nutrition, spiritual growth, stress management and motivation for health living. †      |

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| <b>Rotberg, 2016</b><br>119  | Quasi-          | Community Health Center                             | Nurse, Registered Dietitian, or Trained/Certified Health Educator | Improvements in Clinical Indicators of Care, Risk Reduction, and Diabetes Measures | Glycemic measures were lowered significantly from baseline to follow up. †  |
| <b>Botosaneanu, 2017*</b> 98 | RCT**           | Community Health Center                             | Unknown   | Incidents and Persistent Major Mobility Disability                                 | Moderate intensity physical activity significantly reduced the frequency of MMD in patients with metabolic syndrome, but not in patients without metabolic syndrome. †          |
| <b>Katz, 2017</b> 99         | RCT             | Specialty Clinic                                    | Trained Health Practitioner or Exercise/Health Coach or Counselor | Behavior Change  | In both treatment arms there showed a significant difference in perceived benefits and increased readiness to changes dietary and physical activity behavior at follow-up. †    |
| <b>Tessier, 2017*</b> 100    | Crossover-RCT** | Veterans Affairs Clinic                             | Research Staff  | Overall Health and Weight  | With each therapeutic lifestyle change (TLC) practiced, a reduction of weight was observed. †   |
| <b>Voils, 2017*</b> 101      | RCT**           | Veterans Affairs Clinic and Primary Care Clinic     | Research Staff and Registered Dietitian                           | Weight Regain  | Mean weight regain was statistically significantly lower in the intervention group compared to the usual care group. †  |
| <b>Celano, 2018*</b> 53      | RCT**           | Hospital and Specialty Clinic                       | Trained Clinic Staff  | Feasibility, Acceptability, Impact of Intervention, and Physical Activity          | The intervention was well accepted, with significant improvements in behavioral and psychological outcomes, and improved adherence in moderate to vigorous physical activity. † |
| <b>Coultas, 2018*</b> 43     | RCT**           | Primary Care Clinic and Specialty Clinic            | Exercise/Health Coach or Counselor                                | Physical Activity and Health Care Utilization                                      | All intervention patients reported more consistent physical activity over the follow-up period compared to the usual care group.  |
| <b>Driver, 2018</b> 120      | Pre-Post        | Specialty Clinic, Hospital, Academic Medical Center | Trained/Certified Health Educator                                 | Adherence, Physiologic Changes, Quality of Life                                    | Average participant attendance and self-monitoring were high, with significant decreases in blood pressure and waist/arm circumference post intervention. †                     |

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| <b>Golubić, 2018</b><br>45    | Pre-Post                             | Primary Care Clinic                 | Physician   | Changes in Biometric Measures and Laboratory Variables           | Participants lost a statistically significant amount of weight and inches off their waist, body mass index decreased significantly, while changes in psychosocial variables included significant improvements in perceived stress and quality of life. † |
| <b>Haire-Joshu, 2018*</b> 107 | Pragmatic Clinical Trial**           | Primary Care Clinic and Free Clinic | Exercise/Health Coach or Counselor  | Weight Loss and Health Behavior                                  | Significant differences in weight and waist circumference between groups at 12 months was shown. †   |
| <b>Johnson, 2018</b><br>123   | Clinical Trial                       | Specialty Clinic                    | Trained Health Practitioner   | Change in Couples' Behavior                                      | Both partners in a couple tried something from therapy. †  |
| <b>Wilson, 2018</b><br>115    | Evidence Based Practice Change Study | Primary Care Clinic and Free Clinic | Nurse   | Self-Efficacy and Weight Loss                                    | Most participants met the benchmark for an increase in self-efficacy and body mass index reduction. Pre- and posttest self-efficacy, as well as body mass index reduction showed a statistically significant increase. †                                 |
| <b>Frith, 2019</b> 47         | Repeated Measures Intervention       | Specialty Clinic                    | Nurse Practitioner  | Gait and Balance Scores, Number of Falls, and Knowledge          | Participants had a significant improvement in the fourth position of the 4-Stage Balance test and the 30-Second Chair Stand, as well as a reduced number of falls. †   |
| <b>Schneeberger, 2019</b> 124 | Pre-Post                             | Specialty Clinic                    | Physician, Trained Health Practitioner, Qualified Instructor, Registered Dietitian, and Trained/Certified Health Educator | Participant Biometrics, Psychosocial Factors, and Dietary Habits | Statistically significant decreases in weight and body mass index were observed from, as well as a significant decrease in average weekly fat consumption. †   |

\*Funded by Government Agency (e.g., NIH, CDC, VA/Military, etc.); \*\*Registered through clinicaltrials.gov; † Statistically significant results reported for primary outcome measures

Figure 2.2



Figure 2.2 Word cloud depicting outcome measures for included studies.

## CHAPTER 3

### 3 Physical Activity Assessment and Promotion Using Activity Monitors in Clinical Settings: A Systematic Review of Randomized Controlled Trials in the United States

#### 3.1 Abstract

*Objective:* The primary purpose of this systematic review was to evaluate the impact of physical activity assessment and promotion in clinical settings from published reports of randomized controlled trials (RCTs) that used physical activity monitors as primary outcome measures. A secondary objective was to evaluate the potential differential impacts of physical activity assessment and promotion based on study length and who delivered the intervention (e.g., nurses, medical doctors, etc.).

*Methods:* The systematic review has been registered through PROSPERO (CRD42021270852). English-language-only studies were included if they were RCTs, involved physical activity interventions implemented by practicing health professionals in clinical settings, and used activity monitors.

Potentially eligible studies were retrieved from a literature search of nine major databases to extract published peer-reviewed studies from January 1, 2008, to July 15, 2023. Additionally, reference lists from these publications and systematic reviews were reviewed to identify studies that had not been previously identified. Risk of bias was assessed using the Cochrane Risk of Bias instrument for RCTs (v 2.0). Data were synthesized using qualitative and descriptive analyses.

*Results:* Eleven studies were included in the final analysis. Overall, findings demonstrated that objectively measured physical activity interventions in clinical settings had a positive impact on participants' physical activity levels. Six studies reported statistically significant increases in physical activity among intervention groups compared to control groups, while two studies also favored the intervention group.

*Discussion:* The findings demonstrate qualified support for the continuation of utilizing wearable technology to assess physical activity levels of patients in clinical settings. The review reveals that physical activity interventions in clinical settings can lead to statistically significant improvements in



patients' physical activity levels, physical function, and various clinical measures. Notably, studies using accelerometers showed promising results. These interventions show potential benefits in reducing the risk of chronic diseases, improving mental health, and enhancing overall well-being.

*Keywords:* Physical Activity, Assessment, Promotion, Activity Monitor, Systematic Review, Wearable Technology

### **3.2 Introduction**

Physical inactivity is the fourth leading contributor of mortality and a major risk factor for chronic disease.<sup>2</sup> In addition, a sedentary lifestyle contributes to nearly 70% of deaths in the United States (US), and doubles the risk for cardiovascular diseases, diabetes, and obesity, as well as increases the risks for colon cancer, high blood pressure, osteoporosis, lipid disorders, depression, and anxiety.<sup>4,17,145-147</sup> The National Physical Activity Guidelines Advisory Committee (2018) recommends that adults participate in 150 minutes of moderate-intensity aerobic physical activity each week, 75 minutes of vigorous aerobic physical activity per week, or some combination of the two, as well as muscle strengthening exercises two or more days a week.<sup>19</sup> Unfortunately, 80% of American adults do not meet the government's recommendations for aerobic activity and muscle strengthening.<sup>16,148,149</sup> While more than 30% of US adults are inactive, approximately 20% of those who do participate in any physical activity are not sufficiently active to achieve health benefits.<sup>2,67,148</sup>

Physical activity assessment and promotion in clinical settings has been shown to be effective for modifying negative health behaviors and improving health outcomes.<sup>150</sup> Healthcare providers are increasingly called upon to initiate physical activity counseling with their patients to manage conditions such as obesity, diabetes, and cardiovascular disease.<sup>150</sup> The National Physical Activity Plan (NPAP) highlights the potential role and benefits that healthcare providers can provide in assessing and promoting physical activity.<sup>19</sup> Furthermore, the United States Preventive Services Task Force (USPSTF)

recommends that primary care providers offer physical activity counseling for cardiovascular disease prevention during clinical visits.<sup>151</sup>

**[INSERT FIGURE 3.1]**

Given the importance of this issue, it is not surprising that the number of articles examining physical activity within primary care settings has more than tripled from 2008 to 2020 (Figure 1). This demonstrates a growing interest in the topic, including the identification of factors that lead to successful adoption and implementation of physical activity interventions in clinical settings.

While the NPAP includes several recommendations for clinicians and the healthcare sector on physical activity promotion, it does not include any detailed assessment or guidance on overcoming the challenges of physical activity assessment, counselling, and promotion in clinical settings.<sup>19</sup> As patients routinely visit their primary care providers for wellness visits or continued care, the support and adoption of a Patient-Centered Medical Home (PCMH)<sup>152</sup> could provide a more comprehensive, team-based approach that will allow providers to incorporate more detailed physical activity assessment and promotion in their clinical workflow. Similar approaches have been recommended by organizations such as the American College of Sports Medicine (ACSM) through their Exercise is Medicine® initiative. This program encourages physicians to adopt the Physical Activity Vital Sign (PAVS) into clinical practice to increase the assessment and maintenance of physical activity for reducing the health risks associated with a sedentary lifestyle.<sup>153</sup> Unfortunately, reports indicate that less than one third of primary care visits include some type of physical activity assessment.<sup>8,9</sup> Reported barriers from providers include financial support, competing health demands, time during patient visits, as well as a perceived lack of knowledge regarding physical activity promotion and counseling.<sup>21,55,60,61,154,155</sup> While health care providers understand the importance of physical activity promotion and their role in promoting physical activity, they also report that non-physician members of the clinical team may help in facilitating physical activity promotion independently or in conjunction with physicians.<sup>21</sup> Similarly, a recent

scoping review related to physical activity promotion in clinical settings reported the need for broader training and systematic change before widespread adoption into standard of care.<sup>61</sup> Notably, the use and evaluation of non-physician members of the clinical team in the assessment and promotion of physical activity in clinical settings has largely been unexplored.

Several approaches to physical activity assessment, prescription, and promotion have been shown to be effective in modifying negative health behaviors and improving health outcomes.<sup>55,60,154,155</sup> Systematic reviews with and without meta-analyses have analyzed the effectiveness of various physical activity assessment and promotion interventions in clinical settings, demonstrating the effectiveness of both exercise referral schemes and counselling interventions.<sup>24,55,155-157</sup> For example, Orrow et al. (2012) assessed randomized controlled trials (RCTs) of physical activity promotion in sedentary adults who received physical activity counseling during their primary care visits.<sup>55</sup> They found that promotion of physical activity with sedentary adults identified through primary care resulted in small to medium improvements in self-reported physical activity at 12 months (odds ratio = 1.42, 95% confidence interval, 1.17 to 1.73).<sup>55</sup> Additionally, Sanchez et al. (2015) conducted a review of reviews that examined interventions in the primary care setting aimed at increasing physical activity levels in insufficiently active or sedentary adults. They found that interventions in primary care resulted in small to moderate increases in physical activity levels.<sup>155</sup> They also reported additional benefit when the intervention included multiple behavioral change techniques.<sup>155</sup> A systematic review of reviews by Lamming et al. (2017) assessed the effectiveness of brief interventions (verbal advice, discussion, or encouragement with or without written or other support or follow-up) aimed at promoting physical activity in adults delivered in primary care settings.<sup>60</sup> Although the review's conclusions were uncertain about the effectiveness, feasibility, and acceptability of brief interventions in primary care consultation, the authors identified the need for long-term studies to investigate intervention effects on objectively measured and self-reported physical activity.<sup>60</sup>

Several researchers examined the literature surrounding physical activity interventions using objectively measured physical activity monitors. A systematic review by de Vries et al. (2016) assessed RCTs with behavioral physical activity interventions using activity monitors in adults who were overweight or obese. They found that behavioral physical activity interventions with an activity monitor increased physical activity in adults who were overweight or obese. Furthermore, Cleland et al. (2017) systematically reviewed and assessed the effectiveness of interventions to increase physical activity and/or decrease sedentary behavior among rural adults.<sup>154</sup> They found that overall, there was no effect on physical activity (standardized mean difference (SMD) = 0.11, 95% confidence interval (CI), -0.04, 0.25) or sedentary behavior (SMD = 0.07, 95% CI -0.11, 0.10).<sup>154</sup> However, in the physical activity subgroup analyses, studies employing objective measures demonstrated effects in favor of the intervention (SMD = 0.65, 95% CI 0.30,1.00), while those using self-report measures did not (SMD = 0.00, 95% CI -0.11, 0.10).<sup>154</sup> Patnode et al. (2017) and the USPSTF systematically reviewed RCTs of behavioral interventions targeting improved diet, increased physical activity, decreased sedentary time, or both interventions in adults with no known cardiovascular risk factors (hypertension, dyslipidemia, or diabetes) in clinical settings and found that the diet and physical activity behavioral interventions resulted in consistent, modest benefits across a variety of health outcomes for 6 – 12 months. It is important to note that only 11 of the 88 (12.5%) studies included used some form of activity monitors (accelerometers or pedometers) to capture objective measures of physical activity, something that the current systematic review will address.<sup>24</sup>

Two gaps in the previously reviewed research are the lack of clarity of reporting on who delivered the interventions in clinical settings and the length of each intervention provided. To the best of the investigative team's knowledge, these issues have not been systematically analyzed. Provider initiated interventions may require different doses (i.e., length) based on who the delivery agent is in the clinical setting. For example, Orrow et al. (2012) observed a wide variety of health professionals who

administered the various interventions; primary care doctors, nurses, physiotherapists, trained facilitators.<sup>55</sup> Conversely, the systematic review of reviews conducted by Sanchez et al. (2015) did not identify the program delivery agents in their included studies.<sup>155</sup> These shortcomings are important because the impact of differential delivery agents and the length of the interventions may impact outcomes.

The limitations of self-reported physical activity measures have been widely discussed in the literature, and thus, make it difficult for providers to determine whether patients are actually compliant with therapeutic recommendations concerning health behavior in clinical settings.<sup>158,159</sup> Despite advances in methods to objectively monitor physical activity and sedentary time, much of the recently funded health and behavioral research examining physical activity as an exposure or outcome relies on self-report as the principal method of data collection.<sup>160</sup> Increased use of pedometers, accelerometers, or other wearable devices for objective assessment (e.g., FitBit<sup>®</sup>) in clinical practice may help ameliorate some of these challenges.<sup>18</sup> However, there is currently limited information available to guide providers in the integration of activity monitors into their clinical workflow.

The lack of consistent approaches and reporting in the assessment and promotion of physical activity in clinical settings, as well as the outcomes measured raises questions about the varying method(s) for physical activity promotion in clinical settings. While numerous reviews have summarized the effectiveness of physical activity interventions in clinical settings<sup>24,55,60,61,154,155,157,161</sup>, the authors are currently not aware of any that have focused solely on objective physical activity measures using activity monitors or compared differential outcomes based on who delivered the intervention in US-based studies. Therefore, the primary purpose of this systematic review was to evaluate the impact of physical activity assessment and promotion in clinical settings from published reports of RCTs that used physical activity monitors as primary outcome measures. A secondary purpose was to evaluate the potential differential impacts of physical activity assessment and promotion, based

on study length and who delivered the intervention (e.g., nurses, medical doctors etc.). The present study extends previous systematic reviews in this area of inquiry by focusing on RCTs in the US and coding key methodological information not addressed in previous systematic reviews (e.g., who delivered the intervention, length of intervention, and whether the physical activity intervention increased patient activity levels). This information could be used by policymakers, educators, and professional societies or clinical teams to develop and apply interventions in clinical settings, and ultimately, lead to improved, consistent physical activity assessment and promotion and subsequent improvements in the health of patients.

### **3.3 Methods**

#### *Overview*

We followed the recently updated Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) guidelines and include the PRISMA checklist regarding such (Appendix C).<sup>15</sup> The protocol for this study was registered in the systematic review trial registry PROSPERO (CRD42021270852) but not published in a peer reviewed journal (Appendix D).<sup>63,162</sup>

#### *Eligibility Criteria*

Studies were eligible for inclusion if they met the following criteria: (1) RCTs; (2) practicing health professionals (licensed, allied, and non-medical health professionals), (3) adult humans 18 years of age or older; (4) use of activity monitors (e.g., pedometers, accelerometers, FitBit®, etc.) as part of the intervention, (5) comparative control group (wait-list control, attention-control, usual care, etc.); (6) changes in physical activity described for both intervention and control groups; (7) full-text articles published in peer-reviewed English-language journals; (8) trials conducted in the US; and (9) published and indexed between January 1, 2008 and July 15, 2021, with a bridge search conducted on July 14, 2023. The rationale for the search dates are based on the release of EIM® by the ACSM in late 2007,<sup>28</sup> the initial release of the National Physical Activity Guidelines (NPAG) in 2008,<sup>66</sup> and the release of the

2<sup>nd</sup> Edition of the NPAG in late 2018.<sup>67</sup> The focus was on US studies because of the different systems of healthcare delivery in other countries. Any study not meeting all the aforementioned criteria were excluded. Reasons for exclusion included, but were not limited to, the following: (1) conference abstract, research letter, editorial note, or commentary; (2) intervention did not contain assessment or promotion of physical activity with the use of activity monitors; or 3) not a RCT.

### *Information Sources and Search Strategy*

Nine electronic databases were searched for potentially eligible studies: (1) Academic Search Complete, (2) APA PsychINFO, (3) Cumulative Index to Nursing and Allied Health Literature (CINAHL), (4) Health Source, (5) MEDLINE, (6) Sport Medicine and Education Index (formerly Physical Education Index), (7) PubMed, (8) SCOPUS, and (9) SPORTDiscus using the EBSCOhost research platform.<sup>163</sup> Keywords included physical activity, exercise, promotion, counseling, prescription, referral, clinical setting, and primary care. Relevant Medical Subject Headings (MeSH) terms identified by the U.S. National Library of Medicine's thesaurus were also considered when identifying the final search strings.<sup>64</sup> Based on PRISMA guidelines,<sup>164</sup> an example of the search strategy can be found in Appendix E. In addition, the reference lists from these publications and systematic reviews were reviewed to identify studies that had not been previously identified. To avoid multiple publication bias, all included studies were examined to ensure that each study was independent of all others. Multiple publication bias was addressed by including the most recent/relevant study from multiple studies using data from the same cohort.

### *Study Selection and Eligibility*

The initial searches were conducted by KG and PG on July 15, 2021, separately, and downloaded as a separate file using Endnote X8.<sup>65</sup> A bridge search was conducted on July 6, 2023 by KG and PG, following the same protocol.

Independent, dual selection of studies was performed by KG and PG. This process included two phases; (1) an initial screening phase to review titles, abstracts, and keywords, followed by (2) full-text eligibility screening for inclusion in the subsequent analysis. Reasons for exclusion were coded based on one or more of the components of the PICOS (Population, Intervention, Comparison, Outcomes, and Study Design/Setting) framework and can be found in Supplementary File 3.<sup>73</sup> Differences in appraisal were resolved by reaching consensus.

#### *Data Abstraction*

Independent, dual data abstraction was performed by KG and PG using a standard extraction codebook (Supplemental File 4). Extracted data from the articles included: (1) first author, publication year, and study location, (2) participant attributes, (3) methodological features; (4) intervention characteristics; (5) outcome measures; and (6) study results. Types of information coded included continuous and categorical variables as well as free text information. The final codebook was confirmed once an entire article was coded without any additions needed to the codebook categories. Differences in appraisal were resolved by reaching consensus.

#### *Study Risk of Bias Assessment and Reporting*

Risk of bias for each study was assessed using the Cochrane Risk of Bias instrument for RCTs (ROB 2).<sup>165</sup> This instrument assesses risk of bias in five distinct domains: 1) bias arising from the randomization process, 2) bias due to deviations from intended interventions, 3) bias due to missing outcome data, 4) bias in measurement of the outcome, and 5) bias in selection of the reported result. Based on signaling questions, each domain was assessed as either “low risk,” “high risk,” or “some concerns.” Based on responses to each domain, the overall risk of bias for each study was then assessed as either “low risk,” “high risk,” or “some concerns.” Independent, dual assessment of risk of bias was conducted by KG and PG (Supplemental File 5). Discrepancies between the raters were resolved in a consensus meeting.



## *Data Synthesis*

Descriptive data including author, study year, study design, type of healthcare professional, participant population, gender, and mean age were extracted from each of the selected studies. The studies used a range of different instruments and measures to assess change in activity levels. These included continuous measures such as composite scores on activity questionnaires and duration of exercise, as well as dichotomous measures such as being active at a specified level. Because of the expected heterogeneity with respect to such things as study design, participant characteristics, intervention and outcome variables being measured, an a priori decision was made to assess all results qualitatively.

### **3.4 Results**

#### *Study Selection*

Figure 2 contains a flow diagram that depicts the results of the literature search, additional articles located, and data screening. Of the 686 studies originally screened, eight met the criteria for final inclusion, with three additional studies identified through a bridge search.<sup>166-176</sup> A comprehensive reference list of the 1,280 studies (including bridge search results), with reasons for exclusion, is available upon request from the corresponding author. All percentages were calculated from the eight articles included in the review.

**[INSERT FIGURE 3.2]**

#### *Study Characteristics*

Selected study-level characteristics are shown in Table 1 with additional information described below. Studies were published between 2008 and 2023 in eleven different journals in which impact data were available ranging from 0.33 to 44.424. All 11 studies reported funding sources with two<sup>169,176</sup> reporting more than one source of funding. Funding was derived from government (n=10, 90.9%),<sup>166-171,173-176</sup> university (n=2, 25%),<sup>174,176</sup> or other public and private sources (n=3, 27.3%).<sup>171,172,175</sup>

### [INSERT TABLE 3.1]

Five (45.5%) studies included identified as pilot RCTs<sup>166,169,170,172,175</sup>, while one study was identified as a prospective RCT.<sup>167</sup> Four studies (36.4%) reported a guiding theory to support their intervention, three used social cognitive theory<sup>167,169,170,177</sup> and one study used behavioral economic theory<sup>173,178</sup> in the development and delivery of their intervention. Three studies (27.3%) included an attention-control group,<sup>167,168,170</sup> seven (63.6%) reported usual-care controls<sup>166,169,171,173-176</sup> and one (9.1%) reported the use of an active comparator.<sup>172</sup> Studies were implemented across various clinic types including primary care,<sup>167,168,170-172,175</sup> specialty care,<sup>166,169,176</sup> and community clinics,<sup>174</sup> as well as veterans affairs facilities.<sup>167,168,174</sup> One study (Pearl et al) did not specify the type of clinic used in the study.<sup>173</sup> To deliver the study intervention, two studies (18.2%) utilized nursing staff,<sup>167,174</sup> four (36.4%) used research personnel,<sup>170,172,173,175</sup> one (9.1%) used an exercise/health coach,<sup>169</sup> and one (9.1%) delivered the intervention through electronic materials.<sup>168</sup> Ladapo et al. used a combination of trained individuals to implement the intervention including a clinical psychologist, registered dietitian, and postdoctoral psychology fellow.<sup>171</sup> Two studies (18.2%) did not specify a program delivery agent.<sup>166,176</sup>

The average sample size was 175, ranging from 40<sup>172</sup> to 668.<sup>173</sup> A total of 1,929 participants were included in this review. Five (45.5%) studies were conducted in the state of California,<sup>166,169,171,172,175</sup> while the remaining studies were conducted across Colorado,<sup>170</sup> Florida,<sup>173</sup> Mississippi,<sup>167</sup> Michigan,<sup>174</sup> New York,<sup>171</sup> Pennsylvania,<sup>168,173</sup> and Washington.<sup>176</sup> For those studies reporting study length (n=8, 72.7%), the average length of intervention was 7.63 months with three (27.3%) lasting only 3 months<sup>170,172,176</sup> and three (27.3%) lasting up to one year.<sup>168,171,174</sup> Five studies (45.5%) reported providing a monetary incentive to participants.<sup>166-168,171,173</sup>

#### *Study Measures*

For use of wearable technology across studies, the majority of studies (n=7, 63.6%) used accelerometers<sup>167-171,173,176</sup> while four (36.4%) studies used pedometers<sup>166,172,174,175</sup> as an objective

measure of physical activity. In addition, studies also utilized self-report measures of physical activity including questionnaires like the 7-Day Physical Activity Recall,<sup>167,172</sup> Community Health Activities Model Program for Seniors (CHAMPS),<sup>167,168</sup> selected Behavioral Risk Factor Surveillance Survey (BRFSS) questions surrounding aerobic exercise, flexibility, and muscle strength,<sup>166</sup> daily activity diaries,<sup>175,176</sup> and other specialty surveys.<sup>166,170</sup> For the studies utilizing accelerometers, calculated measures of physical activity and interpretation of recorded data varied across included studies. Dubbert et al used a cut point for moderate physical activity in older men of 984 counts/min or greater, while Gao et al used a 290-6166 count/min cut point for the same classification.<sup>167,168</sup> Hartman et al and Pearl et al identified using cut points identified by Freedson et al<sup>179</sup> to classify sedentary, light, moderate and vigorous physical activity.<sup>169,173</sup> Ladapo et al. and Huebschmann et al. did not specify the cut points used to confirm the specified measurement of physical activity data collected from accelerometer data.<sup>170,171</sup> Additionally, Steele et al. measured body movement in vector magnitude units (VMU) from accelerometer data rather than intensity.<sup>176</sup>

Physical function and fitness was also assessed objectively in five (45.5%) of the included studies with three (27.3%) studies using the six minute walk test,<sup>166,167,176</sup> three (27.3%) using the eight foot-up-and-go assessment,<sup>166,167,172</sup> two (18.2%) using the 30-second chair-rise-and-stand for balance, mobility and coordination,<sup>166,167</sup> two (18.2%) using an arm curl for strength and muscular endurance,<sup>166,167</sup> one (9.1%) using the chair-sit-and-reach for flexibility,<sup>166</sup> one (9.1%) using a ten meter walk test for gait speed,<sup>167</sup> and one (9.1%) using the Balke Treadmill exam.<sup>170</sup> Various questionnaires were also used to measure physical function through participant self-report with four (36.4%) studies using the 36-Item Short-Form Health Survey (SF-36),<sup>167,172,175,176</sup> and one (9.1%) using the Patient-Reported Outcomes Measurement Information System (PROMIS) Short Form for Physical Function.<sup>172</sup> Sheshadri et al also measured physical performance using the Short Physical Performance Battery.<sup>175</sup>

### *Study Outcomes*

Increased physical activity was the primary outcome measure for six (54.5%) of the included studies,<sup>166-168,172,174,175</sup> with one (9.1%) study focusing on weight loss,<sup>169</sup> and one (9.1%) study focusing on maintaining daily activity and adherence (Table 1).<sup>176</sup> Additional study outcomes of interest included decreased cardiovascular risk,<sup>172,173</sup> depressive symptoms, and diabetes risk factors.<sup>170,171,173,174</sup> For these reasons and the small number of studies meeting eligibility criteria, a meta-analysis of this data was not feasible.

### *Risk of Bias in Studies*

Overall risk of bias based on the Cochrane Risk of Bias assessment instrument (v 2.0)<sup>165</sup> is shown in Figure 3, while study level results are shown in Supplementary File 5. As can be seen, the overall risk of bias for most studies was unclear (n=5, 62.5%)<sup>167-169,172,174</sup> with three (37.5%) reported as having a high risk of bias.<sup>166,175,176</sup>

**[INSERT FIGURE 3.3]**

### **3.5 Discussion**

This systematic review aimed to evaluate the impact of physical activity assessment and promotion in clinical settings, specifically focusing on studies that used physical activity monitors as the primary outcome measure. Our findings demonstrated that objectively measured physical activity interventions in clinical settings had a positive impact on participants' physical activity levels on more than half of studies included.<sup>166,168,169,171,172,174,175</sup> Several studies reported statistically significant increases in physical activity among intervention groups compared to control groups.<sup>166,168,171,174,175</sup> Notably, studies using accelerometers showed promising results, with one study reporting significantly increased odds of meeting moderate-to-vigorous physical activity (MVPA) recommendations in the intervention group at the 6-month follow-up.<sup>168</sup> Another study found favorable effect sizes in physical activity and general health for the intervention group.<sup>172</sup> However, it is important to acknowledge that

not all studies reported significant improvements in physical activity and there were noted biases in all the studies.

Further analysis of intervention success highlighted the importance of study length and intervention delivery agents. Studies with longer intervention durations tended to show more substantial and sustained increases in physical activity levels.<sup>166,168,174</sup> Although our review only evaluated eight studies, this reinforces that prolonged exposure to physical activity promotion and counseling may be necessary to achieve meaningful behavior change.<sup>180</sup> Furthermore, the choice of intervention delivery agents may also influence outcomes. Studies that utilized trained research personnel or exercise/health coaches as delivery agents saw positive effects on physical activity levels.<sup>169,172,175</sup> This finding identifies that specialized personnel can be effective in promoting physical activity reducing the burden on healthcare providers.<sup>21,61</sup> However, more research is needed in this area to identify the most suitable delivery agents for physical activity interventions in clinical settings.

Our study adds valuable insights to the existing literature by focusing on studies that used objective measures of physical activity. However, if researchers and clinicians continue to utilize self-report measures, it is important to use previously validated tools. For example, Coleman et al (2017) distributed a self-report questionnaire to all study participants containing validated measures of sedentary activity and aerobic exercise, flexibility, and muscle strength questions from the Behavioral Risk Factor Surveillance Survey (BRFSS).<sup>166</sup> Although the study specific questionnaire was not a validated measure as a whole, it contained previously validated questions from the larger BRFSS. This allows for researchers to make comparisons across studies that also utilize this same, publicly available tool.

These findings, along with others, provide qualified support for the continuation of physical activity assessment and promotion in clinical settings. Our risk of bias assessment indicated all studies were at an unclear or high risk of bias. Although this analysis identified key concerns, studies were

judged to be strong in their aims and objectives, methods used for recruitment, and data collection. However, several lacked or failed to explicitly describe relevant theoretical frameworks,<sup>166,168,172,174,176,181</sup> a priori study protocol,<sup>166,167</sup> or data analysis plans.<sup>169</sup> Our risk of bias analysis highlights concerns for the included studies in Domain 1 (randomization process), Domain 4 (measurement of the outcome) and Domain 5 (selection of the reported results).

One key concern with the randomization of our included studies was if proper blinding was successful. While blinding is essential in maintaining the integrity of RCTs, it can be challenging to achieve, particularly in physical activity interventions. Participants are likely to be aware of whether they are receiving the intervention (or not), as they experience and engage in different activities during the study. This lack of blinding can lead to performance bias, where participants may change their behavior based on their knowledge of the group assignment. Additionally, in some physical activity interventions, it may be challenging to blind the intervention providers (such as exercise/health coaches) to group assignments. Providers may know which participants are receiving the intervention and adjust their interactions or support, accordingly, potentially influencing the outcomes. Blinding outcome assessors can also be challenging when outcomes involve clinical measurements or observations of participants activity levels, as many of our included studies assess.

Conversely, some physical activity interventions may involve complex or multifaceted components, making it impractical or unfeasible to blind participants, providers, or assessors. For example, if the intervention includes group exercise sessions or personalized coaching, it may be difficult to maintain blinding. Fully blinding participants may not be feasible or ethical in certain cases, such as when participants need to provide informed consent to engage in specific activities. Participants beliefs or expectations about an intervention's effectiveness can also influence their behavior and responses, leading to biased outcomes. Despite these challenges, there are instances where blinding is possible in physical activity interventions. For example, in trials comparing two exercise programs that

are similar in format but differ in intensity, blinding may be feasible by ensuring both groups engage in comparable activities without revealing the intensity differences. When blinding is not achievable, researchers can take steps to minimize bias, such as using objective outcome measures, like activity monitors to record physical activity levels, implementing standardized protocols, and employing intention-to-treat analysis. A recent systematic review and meta-analysis by van der Wardt et al (2021), assessed the effectiveness of physical activity interventions in primary care and found that most studies reported insufficient details regarding randomization, group allocation, blinding, and fidelity.<sup>157</sup> The results of this assessment support claims made by van der Wardt and strengthen the argument to improve intervention implementation in this field. Additionally, transparent reporting of the blinding process and potential limitation is crucial to enhance the study's validity and interpretation of results.

In addition to changes in physical activity levels, our review also highlights positive outcomes on physical function and various clinical measures such as cardiovascular risk factors and depressive symptoms.<sup>174</sup> These findings suggest that such devices and interventions can have broader health benefits beyond increasing activity levels. This further supports the importance of integrating objective measures of physical activity into routine clinical care. Additionally, the focus of this review on physical activity assessment and promotion in clinical settings, mostly in primary care and veterans' affairs clinics, is particularly relevant. As primary care providers play a crucial role in preventive healthcare and disease management, the findings of this review have direct implications for clinical practice. By highlighting the potential benefits of integrating objectively measured physical activity into non-acute primary care visits, this review supports the continuation of these practices.

### **3.6 Strengths and Limitations**

#### *Strengths*

One of the notable strengths of our systematic review is that it adhered to the PRISMA guidelines.<sup>15</sup> By following these guidelines, we ensured a comprehensive and transparent approach to

conducting the review, from the initial search to data extraction and risk of bias assessment. As part of this process, we conducted a comprehensive literature search. Our extensive search using MeSH terms and reaching across nine electronic databases and additional manual searches of references lists demonstrates a rigorous approach to identify relevant studies. This comprehensive search strategy helps ensure our review included a wide range of studies, minimizing the risk of selection bias. In addition to following preferred guidelines, the use of the Cochrane Risk of Bias instrument for RCTs to assess the risk of bias in each study addresses the quality of evidence and its potential impact on the overall findings.

Another strength of our study is the focus on objective measures of physical activity. Utilizing physical activity monitors as the primary outcome measure allowed for a more accurate and precise assessment of changes in participants' physical activity levels. Objective measures are less prone to recall bias and provide more reliable data compared to self-reported measures, thereby enhancing the validity of results.

### *Limitations*

Some limitations should be acknowledged. First, the overall risk of bias in the included studies was unclear or high in some cases. This might have affected the internal validity of the findings and introduced potential sources of bias in the interpretation of results. Additionally, the number of studies available for inclusion was relatively small (eight), limiting the power of subgroup analyses and generalizability of our findings to broader populations. Although we focused on US-based studies to account for difference in healthcare delivery systems, this may also limit the generalizability of our findings to other countries. In line with our a priori decision to forgo meta-analysis, the heterogeneity in study designs, intervention types, and outcome measures across the included studies would have influenced the ability to conduct a meta-analysis. Therefore, a qualitative synthesis of the data was employed to provide a comprehensive overview of the literature. Despite these limitations, our



systematic review adds valuable insights to the literature on physical activity interventions in clinical settings. By employing PRISMA guidelines, we ensured a rigorous and transparent approach, contributing to the credibility and trustworthiness of our findings.

### **3.7 Conclusions**

#### *Implications for Theory, Policy, and Practice*

The evidence from this review provides a methodological blueprint for future research on improving the implementation of physical activity promotion practice in clinical settings. First, the use of physical activity monitors in clinical settings can enhance the accuracy of physical activity assessment, enabling more targeted and personalized interventions. Healthcare providers should consider incorporating activity monitors into routine assessments to better understand patients' physical activity levels and tailor interventions accordingly. Second, interventions aimed at promoting physical activity in clinical settings should be of sufficient duration to achieve sustainable behavior change. Prolonged exposure to physical activity counseling and support may be necessary to foster long-term adherence to recommended guidelines. Third, healthcare providers may need to consider specialized personnel, such as exercise/health coaches, to deliver physical activity interventions effectively. The presence of trained professionals with expertise in physical activity promotion may enhance patients' engagement and success in adopting healthier behaviors.

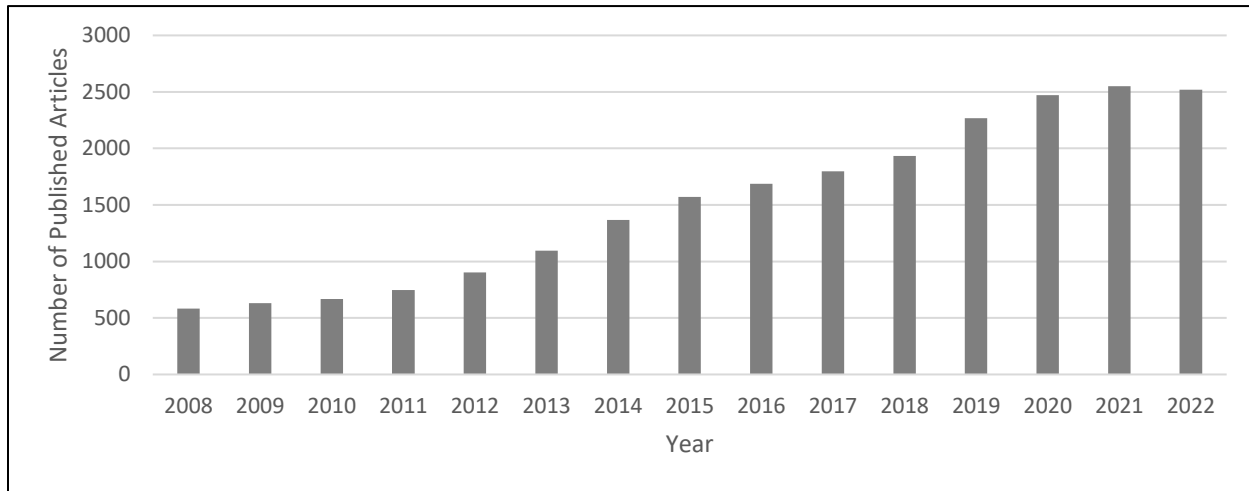
From the lens of clinical research, this assessment indicated that most of the included studies lacked theoretical frameworks. This is important because it is generally believed that theory-based interventions are more effective in health behavior change because they account for multiple determinants and processes for behavior change.<sup>182</sup> Future studies should be structured to relevant theoretical framework to enhance the overall quality and scholarly impact of a study. Finally, researchers and clinicians are encouraged to be detailed and transparent when designing, implementing, and reporting clinical trials to ensure a broader understanding of results and implications for future studies.

## *Conclusions*

The results of the current systematic review of RCTs suggest that exercise interventions, particularly with pedometer/accelerometer support, as well as combined counseling, are associated with increased physical activity levels and improvements in physical activity levels, physical function and multiple cardiometabolic risk factors among US adults. However, the generally low strength of evidence suggests a need for future well-designed and conducted RCTs on the effects of physical activity interventions in clinical settings utilizing wearable technology. Healthcare providers and policymakers should consider adopting these objective measures to enhance physical activity promotion in clinical settings. Moreover, studies should explore the impact of intervention length and delivery agents to optimize the success of physical activity interventions in primary care. By addressing physical inactivity through effective interventions in clinical settings, we can take a significant step toward improving population health and reducing the burden of chronic diseases associated with sedentary lifestyles.

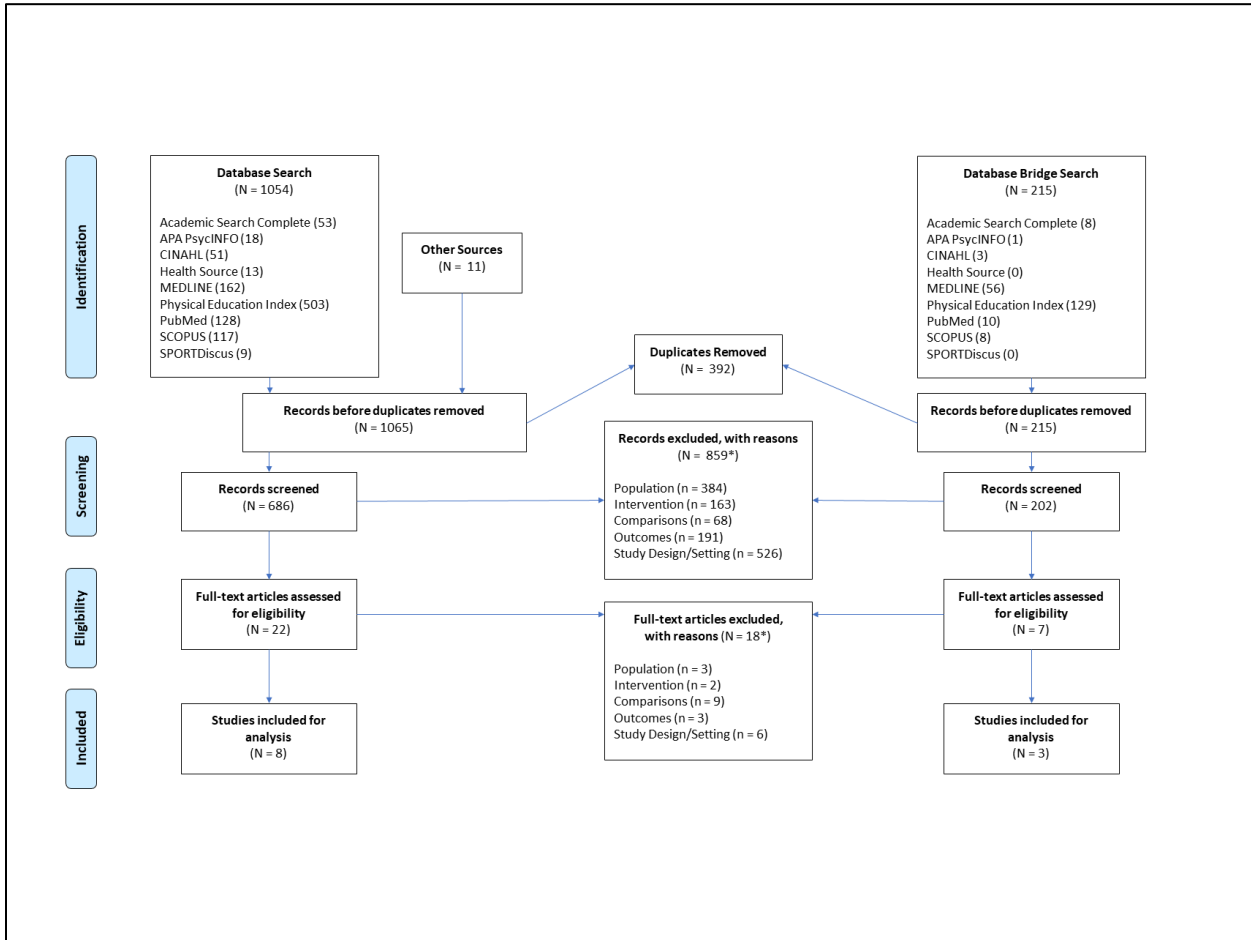
### 3.7 Tables & Figures

**Figure 3.1**



**Figure 3.3:** *Number of PubMed-referenced articles published between 2008 and 2022 concerning 'physical activity' and 'primary care.'*

**Figure 3.2**






**Figure 3.4: PRISMA Flow Diagram**

**Table 3.1:** Characteristics and results reported by study (N=11).

| <b>Author (Year)</b>                          | <b>Study Setting</b>                | <b>Program Delivery Agent</b>   | <b>Sample Size</b> | <b>Activity Monitor Type Used</b> | <b>Reported Physical Activity Results</b>   |
|---|-------------------------------------|---|--------------------|-----------------------------------|---|
| <b>Coleman et al (2017)<sup>166</sup></b>     | Specialty Clinic                    | N/A   | 51                 | Pedometer                         | Intervention group saw improvements in yards walked in 6 min, seconds for 8-foot up-and-go, number of arm curls, and distance in inches for chair sit-and-reach.* |
| <b>Dubbert et al (2008)<sup>167</sup></b>     | Veterans Affairs & Primary Care     | Nurse   | 224                | Accelerometer                     | Over half the intervention group averaged $\leq 30$ min of MVPA at 10-month follow-up.* No significant difference between groups for MVPA overall.                |
| <b>Gao et al (2016)<sup>168</sup></b>         | Veterans Affairs & Primary Care     | Electronic Materials  | 232                | Accelerometer                     | Intervention group showed increased odds of meeting MVPA at 6 months and borderline significantly increased odds at 12 months.*                                   |
| <b>Hartman et al (2016)<sup>169</sup></b>     | Specialty Clinic                    | Exercise/Health Coach/Counselor   | 54                 | Accelerometer                     | Intervention group showed a higher increase total MVPA compared to control group.   |
| <b>Huebschmann et al (2022)<sup>170</sup></b> | Primary Care & Specialty Clinic     | Research Personnel  | 50                 | Accelerometer                     | Physical activity increased in both groups, but group differences in wear time and changes in MVPA levels were not significantly different.                       |
| <b>Ladapo et al (2022)<sup>171</sup></b>      | Primary Care                        | Clinical Psychologist, Registered Dietitian, Postdoctoral Psychology Fellow | 105                | Accelerometer                     | Intervention group showed significant increases in physical activity at 6 months but not 12 months.*  |
| <b>Lewis et al (2020)<sup>172</sup></b>       | Primary Care                        | Research Personnel  | 40                 | Pedometer                         | Effect sizes were favorable to intervention group for physical activity and general health, but not all measures.   |
| <b>Pearl et al (2023)<sup>173</sup></b>       | Unspecified (primary care referral) | Research Personnel  | 668                | Accelerometer                     | Both groups increased physical activity but showed no significant difference.   |

|   |                                     |                    |     |               |  |
|---|-------------------------------------|--------------------|-----|---------------|--|
| <b>Piette et al (2011)<sup>174</sup></b>    | Community Clinic & Veterans Affairs | Nurse              | 339 | Pedometer     | Intervention group showed increased step-counts and greater reductions in depressive symptoms at 12 months.* |
| <b>Sheshadri et al (2020)<sup>175</sup></b> | Primary Care                        | Research Personnel | 60  | Pedometer     | Intervention group showed increased average daily step count compared to control group at 3 months.*         |
| <b>Steele et al (2008)<sup>176</sup></b>    | Specialty Clinic                    | N/A                | 106 | Accelerometer | No differences in daily activity at 20 weeks or with any variable at 12 months between groups.               |

**Figure 3.3**

| <u>Study ID</u>          | <u>Experimental</u>                   | <u>Comparator</u>  | <u>Outcome</u>            | <u>Weight</u> | <u>D1</u> | <u>D2</u> | <u>D3</u> | <u>D4</u> | <u>D5</u> | <u>Overall</u> |  |
|--------------------------|---------------------------------------|--------------------|---------------------------|---------------|-----------|-----------|-----------|-----------|-----------|----------------|--|
| Coleman et al (2017)     | Exercise Intervention (pedometer)     | Usual Care Control | Physical Activity (MVPA)  | 1             | +         | +         | +         | +         | !         | !              |  Low risk<br> Some concerns<br> High risk<br><br>D1 Randomisation process<br>D2 Deviations from the intended interventions<br>D3 Missing outcome data<br>D4 Measurement of the outcome<br>D5 Selection of the reported result |
| Dubbert et al (2008)     | Exercise Intervention (accelerometer) | Attention Control  | Physical Activity (MVPA)  | 1             | +         | !         | +         | !         | !         | !              |  |
| Gao et al (2015)         | Exercise Intervention (accelerometer) | Attention Control  | Physical Activity (MVPA)  | 1             | !         | !         | +         | +         | !         | !              |  |
| Hartman et al (2016)     | Exercise Intervention (accelerometer) | Usual Care Control | Physical Activity (MVPA)  | 1             | !         | +         | +         | +         | !         | !              |  |
| Huebschmann et al (2022) | Exercise Intervention (accelerometer) | Attention Control  | Physical Activity (Steps) | 1             | +         | !         | +         | +         | +         | !              |  |
| Ladapo et al (2022)      | Exercise Intervention (accelerometer) | Usual Care Control | Physical Activity (MVPA)  | 1             | !         | !         | +         | !         | +         | !              |  |
| Lewis et al (2020)       | Exercise Intervention (pedometer)     | Active Comparator  | Physical Activity (MVPA)  | 1             | -         | +         | +         | !         | +         | -              |  |
| Pearl et al (2023)       | Exercise Intervention (accelerometer) | Usual Care Control | Physical Activity (MVPA)  | 1             | +         | !         | +         | !         | +         | !              |  |
| Piette et al (2011)      | Exercise Intervention (pedometer)     | Usual Care Control | Physical Activity (Steps) | 1             | +         | !         | +         | !         | !         | !              |  |
| Sheshadri et al (2020)   | Exercise Intervention (pedometer)     | Usual Care Control | Physical Activity (Steps) | 1             | +         | +         | +         | +         | +         | +              |  |
| Steele et al (2008)      | Exercise Intervention (accelerometer) | Usual Care Control | Physical Activity (MVPA)  | 1             | -         | +         | +         | +         | +         | -              |  |

**Figure 3.5:** *Cochrane Risk of Bias (v 2.0) assessment results.*

## CHAPTER 4

### 4 Patient Acceptability and Usability of an Electronic Health Application for Patient Engagement and Activation in Weight Management

#### 4.1 Abstract

*Background:* Finding ways to engage patients in weight management in clinical settings has potential to address chronic disease. One promising method for enhancing patient engagement and activation in promoting healthy weight management behaviors is incorporating mHealth technology in the clinical setting.

*Objective:* The primary purpose of this pilot study was to test the acceptability and usability of an application-based patient activation tool for weight management during primary care wait times.

*Patient Involvement:* After using the developed app throughout their clinic visit, patients assessed whether the application was easy to understand and use. They were also encouraged to provide feedback through open-ended comments and questions.

*Methods:* This was a pilot feasibility study in an evening outpatient family medicine clinic. The outcome assessed was the acceptability, usability, and overall friendliness of the mWRAPPED tablet application for patients visiting the acute care clinic.

*Results:* 88% of patients approached took the tablet, and 75% completed the survey. The mWRAPPED application demonstrated initial acceptability and usability (above average, >68) for primary care patients in an academic outpatient family medicine clinical setting. All participants reported the app as easy to use.

*Discussion:* Results of the current study help to support the use of this application in future studies as a novel approach to delivering guidance-based weight management information to patients.

*Practical Value:* This study demonstrates the acceptability and usability of the developed patient-activation tool. Furthermore, the mWRAPPED app does not impact clinical workflow, and patients reported no negative feedback.



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*Keywords:* Weight Management, Patient Activation, Acceptability, Usability, Clinical Waiting Area

## **4.2 Introduction**

### *Background*

More than 34% of men and 27% of women in the United States (US) are obese, putting over two-thirds of US adults at increased risk for hypertension, dyslipidemia, type 2 diabetes, cardiovascular disease, osteoarthritis, sleep apnea, cancer, depression, and reduced life expectancy.<sup>183-190</sup> A joint statement by the American Heart Association (AHA), American College of Cardiology (ACC), and The Obesity Society recommends that physicians screen for overweight and obesity in their practices and offer or refer patients with risk factors for cardiovascular disease to intensive behavioral counseling.<sup>191</sup> Furthermore, the U.S. Preventive Services Task Force (USPSTF) also recommends that providers “offer or refer adults with a body mass index (BMI) of 30 or higher to intensive, multicomponent behavioral interventions.”<sup>184,185,192</sup> In 2011, the Centers for Medicare & Medicaid Services (CMS) passed a decision to reimburse primary care providers (PCP) for delivering intensive behavioral therapy to treat patients with obesity.<sup>131</sup> Despite these initiatives, there is mounting evidence that many PCPs do not adequately address overweight/obesity.<sup>193,194</sup>

Strategies for improving the quality of care in the US include focusing on the patient’s role in managing one’s health.<sup>195</sup> Because patients play such a prominent role in determining both the need for and outcomes of care, there is a growing awareness that patients should be more active and effective managers of their health and health care.<sup>196</sup> The volume of patients requiring weight management in a PCP practice suggests that the ability to refer these patients to an obesity expert is an unrealistic

expectation. Instead, providers may want to consider using available shared decision making (SDM) and self-management tools to activate their patients with weight problems. These tools and clinic workflow modifications enhancing patient identification, engagement, and support using the health care team can allow PCPs to address weight management with the same intensity they address diabetes.<sup>130,194</sup>

Greater than 80% of Americans embrace internet use for health information.<sup>130,197</sup> Technology, like mobile health (mHealth) applications (apps), offers exciting new opportunities to allow remote access for patients.<sup>198,199</sup> With the potential to be (relatively) cheap, easily distributable, and delivered at multiple locations, healthcare providers can incorporate technology to assist their patients better. This can be done at times convenient for patients, offer as many interventions as they need or want, and provide continuing support in an attractive, tailored format to suit patients' needs.<sup>200</sup> Technology-focused interventions (both computer-based and mHealth) have the potential to provide ongoing self-management support, re-enforce the benefits over time, and optimize the management of chronic diseases by empowering patients through better health self-monitoring and education.<sup>201 202</sup>

The primary purpose of this study was to test the acceptability of the mWRAPPED (mobile Weight management in Rural Appalachia through Patient and Physician Empowerment of Discussions) application in a PCP setting in West Virginia (WV). WV is the only state entirely within the Appalachia region and faces numerous health disparities. The state ranks at or near the bottom for multiple chronic diseases, including heart disease, cancer, and adult obesity, and leads the nation in drug deaths.<sup>203</sup> The use of mWRAPPED in West Virginia is particularly innovative because there is evidence that its population uses digital sources of health information to a lesser degree than the rest of the United States population.<sup>204</sup>

### *Objective*

This study examines the patient acceptability and usability of the tablet-based application while patients wait for regularly scheduled appointments. The app follows the AHA/ACC weight management

guidelines to support weight management through patient-initiated discussions with their healthcare provider.<sup>191</sup> The current study describes acceptability testing in the clinical setting with patients through observation, use of the application, and acceptability and usability ratings.

#### *Patient Involvement*

After using the app throughout their clinic visit, patients assessed whether the application was easy to understand and use. They were also encouraged to provide feedback through open-ended comments and questions.

### **4.3 Methods**

#### *The Application*

mWRAPPED is a tablet-based app developed with a patient-engaged approach to be used in clinical settings before their clinic visit. Patients input their height and weight in the first screen of the application then receive information about their body mass index (BMI) and a patient-friendly explanation of this number. Patients are then provided information about risk factors associated with their BMI. Next, they are provided nutrition services, exercise options, and surgical options (in severe cases) that are locally available. Patients are allowed to select items for which they wish to receive further information from that list. The patient is then given guidance and encouragement initiating a discussion about weight management with their PCP. This includes a review of their current BMI and guided questions for additional support to gain, maintain, or lose weight. The patient is then e-mailed a summary of the services selected and their weight management plan. Examples of the application and generated reports can be found in Supplemental File 5.

#### *Sample and Design*

We examined patient acceptability using a convenience sample of patients seen during their regularly scheduled clinic visits to the selected family medicine clinic during the evening clinic times. Participants were approached after checking in for their clinic visit by study staff. They were then

informed about the study and asked to consent to participate. For those who provided written consent, they were provided the tablet device (a Samsung tablet) containing the mWRAPPED app to use during wait time prior to their appointment. Participants were promoted to enter their age, height, and weight. After calculating patient's BMI, information regarding cardiovascular risk, as well as patient centered information on managing/controlling their risk was provided. The tablet and information were available to the participants while they waited in the waiting room and throughout their time in the clinic prior to checking out. Ethical approval for this study was granted by the West Virginia University Institutional Review Board (Supplemental File 6).

### *Data Collection*

Upon checking out from their appointment, research staff directed participants to a follow-up survey available on the same tablet. Study data were collected and managed using REDCap (Research Electronic Data Capture) electronic data capture tools.<sup>205</sup>

### *Measures*

#### *Application Accessibility*

We used two different measures of application acceptability as an outcome. First, *Overall Friendliness* was assessed with the question “*Overall, I would rate the user friendliness of this product as*” using a 1 (worst imaginable) to 7 (best imaginable) scale. Second, *Application Acceptability* was assessed by yes/no questions about participants experience with the tablet application: “*Did you feel you had enough time to review the weight management tablet application*”; “*Did the weight management tablet application fit into your clinic visit*”; and “*Did you feel that the weight management application was easy to use*”.

#### *Application Usability*

To assess the usability of this application, we utilized the System Usability Scale (SUS).<sup>206</sup> This established questionnaire includes 10 questions asking about how user friendly the application was.

Participants respond to each question using a 1 (strongly disagree) to 5 (strongly agree) scale. To calculate an overall usability score, all odd numbered questions have -1 taken from the selected score while all even numbered questions subtract the selected score from 5.<sup>207</sup> Then, these scores are summed and multiplied by 2.5 to obtain an overall usability score with higher scores representing greater usability ratings of the application (scores can range from 0-100).

### *Clinical Impact*

Participants responded yes/no to two questions after they completed their visit with their physician to assess whether they brought up weight management during their clinic visit. The first question was “*Did you discuss a weight management plan or weight loss with your personal doctor?*”. The second question was “*Did you discuss desire for a weight management plan with the nursing staff?*”.

### *Demographics*

Participants reported their height, weight, age, gender, race, ethnicity, and highest grade or level of schooling completed. Only height and weight were collected as true values. The remaining demographics were collected categorically with pre-determined options via the survey platform. Participants also rated their overall health categorically as *Excellent, Very Good, Good, Fair, or Poor*.

### *Open Ended Text Fields*

Participants were provided several opportunities to expand on questions asked. First, they were offered the opportunity to elaborate on their use of applications with “*Which health apps are you using regularly?*”. They were also provided a space to express any concerns they have using technology with “*What other concerns do you have for using smartphone/tablet PC apps?*”. Participants were also given the opportunity to provide additional feedback regarding the application through, “*Is there anything you feel could be improved in the mobile application?*”.

### *Statistical Analysis*

Descriptive statistics (including frequencies and valid percentages for categorical data and means and standard deviations for continuous data) were calculated for demographic variables to characterize the sample. Due to small sample size, participants with missing variable data were not dropped from analysis, but identified when reported.<sup>208</sup>

#### **4.4 Results**

Of 50 patients approached, 44 (88%) agreed to participate, completed the informed consent, and enrolled in the study. Of the enrolled participants, 33 (75%) completed the acceptability survey while 23 completed the usability measure. Table 1 describes the demographic characteristics of the study participants but some of the demographic questions were not completed showing missingness in different categories. Most participants were white (93.9%) and non-Hispanic (84.9%). There were an equal number of individuals identifying as male or female (n=16, 48.5% each), with one missing entry. The largest group of participants were between the ages of 25 and 34 (27.3%). Just over one-third (33.3%) of participants have more than a 4-year college degree. Nearly half (n=16, 48.5%) of participants ranked their overall health as “Very Good,” with two (6.1%) claiming “Excellent” health. The average BMI of the participants was 32.2 [SD = 9.48, range 19.1 – 62.0] (obese).

#### **[INSERT TABLE 4.1]**

Of the 33 participants, all (100%) identified owning/using a smartphone with over half (n=17, 51.5%) downloading “Health and Lifestyle” apps. Twenty-five (75.8%) reported using their smartphone or tablet PC to obtain/manage health related information, while 27 (81.8%) said they were aware of the availability of health apps. Additionally, 25 (75.8%) and 26 (78.8%) said they would download a health app related to “Fitness” and/or “Diet and Nutrition,” respectively.

To better understand their relationship with their provider, participants were asked a series of questions on their relationship in the clinic. Twenty-six (78.8%) participants said their personal doctor was the one they normally see if they needed a check-up, wanted advice, or when they get sick or hurt.

Notably, 66.7% of participants have been coming to their provider for over one year, with eight (24.2%) having been with the same provider for five or more years.

### *Acceptability*

All 33 (100%) participants indicated that the mWRAPPED app was easy to use. The majority (75.8%) of participants rated the “friendliness” of the application as “Good” or “Excellent,” with two (12.1%) identifying it as “Best Imaginable.” All but two (12.1%) participants said they had enough time to review the tablet app during their clinic visit. Comparatively, only nine (27.2%) participants said the app didn’t “fit” into their clinic visit.

### *Usability*

Twenty-three (69.7%) participants completed the System Usability Scale survey. The overall average SUS score was 77.9 [SD = 13.8, range 50 - 100]. Of the survey completers, 18 (78.3%) participants that found the application usable provided an average SUS score of 83.2 [SD = 10.0, range 70 - 100]. Five (21.7%) participants found the application to be unusable with an SUS score of less than 68 with an average SUS score of 59 [SD = 7.2, range 50 – 67.5]. Due to a data collection issue with our survey software, ten (30.3%) responses were dropped from analysis of the SUS.

### *Clinical Impact*

Although nearly half (45.5%) of participants had previously discussed a weight management plan or weight loss with their physician, only six (18.2%) participants spoke with their personal doctor and three (9.1%) spoke with nursing staff after using the mWRAPPED app during their clinic visit.

### *Open Ended Test Fields*

Twenty participants (60.6%) used the open text field to share what health apps they are using. Ten participants identified using “MyChart,” and six participants (18.75%) reported using “My Fitness Pal,” as the two most commonly used apps. No participants noted any concerns they identified with the

mWRAPPED app presented. Lastly, when asked about improvements to the applications four (12.5%) participants provided limited feedback, as shown below.

*“Some people already have had bariatric surgery so telling them about it doesn’t help.”*

*“Suggestions for and risks of people that are under weight. Seems mostly geared to people overweight.”*

*“Hyperlinks shown, we’re not clickable.”*

*“When it is available for use. I’m interested.”*

#### **4.5 Discussion**

This study used a patient-centered approach to test the acceptability and usability of an electronic health application, mWRAPPED, to promote patient activation for weight management prior to their primary care visit. Results indicated that the majority of the current sample of adult primary care patients did find mWRAPPED to be acceptable, while over half (54.5%) of participants found the app generally usable. Overall, many participants ranked the app as user friendly and felt the application could provide benefit in the clinical setting. However, very few spoke to their doctor about weight management after using mWRAPPED.

Sustaining patient engagement in weight loss efforts remains difficult for both patients and providers, with each exhibiting fatigue with regard to the challenges of obesity management.<sup>130</sup> Many studies have examined the effects of technology on patient satisfaction, improvement of knowledge, and changes in clinical decision-making.<sup>209-213</sup> Previous work has found that patients are satisfied with the use of technology in the clinical setting for education<sup>209,210</sup> and some studies have shown that there is an improvement in patient knowledge.<sup>209,212,213</sup>

Policy makers and practitioners should continue to pursue innovations designed to engage individuals in their health and health care.<sup>151</sup> Patient engagement and activation are central pillars of health policy, based on evidence that links better health outcomes with more engaged and activated



patients.<sup>208</sup> Initiatives used in patient engagement and activation include shared decision-making, wellness activities, and self-management techniques.<sup>214</sup> However, initiatives used in sustaining patient engagement in weight loss efforts remains difficult for both patients and providers, with each exhibiting fatigue with regard to the challenges of obesity management.<sup>130,194</sup> Despite the fact that physician recommendations to lose weight are effective in motivating and supporting patients with obesity, PCPs are reluctant to advise their patients about weight loss.<sup>151,194,215,216</sup>

#### **4.6 Strengths and Limitations**

We acknowledge limitations to this study. First, this study is observational in nature, and is open to the limitations of such designs including self-reporting and reporting bias. Second, there were no intrinsic safeguards to prevent the same participant from taking the survey twice because of the anonymous nature of the survey. However, research personnel present in the clinic kept documentation of patients presenting for return visits within data collection window mitigating this limitation as much as possible. Additionally, conclusions drawn from this study only apply to this sample due to the nature of the convenience sample. Finally, there are several points of missing data from the study sample. This was taken into consideration when reporting participant characteristics, usability and acceptability, and other questions. Due to a data collection error, participant responses were unusable and dropped from analysis of the SUS. Other missing data was limited to participant characteristics (race, ethnicity, age, etc.), which did not impact the acceptability or usability analysis and were therefore retained. Results of the current study, limited in generalizability, have helped to improve the overall acceptability and usability of the application. This is an important first step before more large-scale testing.

#### **4.7 Conclusions**

This application was found to be acceptable by primary care patients in this academic outpatient family medicine clinic. This understanding will help strengthen the need for development of new resources utilizing mobile health technology for patient activation in rural areas like West Virginia. Next

steps include improving the design per patient comments and completing acceptability testing with the healthcare providers to further understand the applications use and impact in clinic workflow before conducting a larger trial focusing on patient activation measures.<sup>214</sup>

## 4.7 Tables & Figures

**Table 4.1:** Characteristics of Participants, N=32\*

| <b>Variable</b>   | <b>Category</b>               | <b>n</b> | <b>Percentage (%)</b> |
|-------------------|-------------------------------|----------|-----------------------|
| Gender            | Female                        | 16       | 50.00%                |
|                   | Male                          | 16       | 50.00%                |
| Age               | 18-24                         | 4        | 12.50%                |
|                   | 25-34                         | 9        | 28.13%                |
|                   | 35-44                         | 6        | 18.75%                |
|                   | 45-54                         | 8        | 25.00%                |
|                   | 55-64                         | 3        | 9.37%                 |
|                   | 65-74                         | 2        | 6.25%                 |
| Race              | White                         | 31       | 96.87%                |
|                   | Multiracial                   | 1        | 3.13%                 |
| Ethnicity         | Non-Hispanic                  | 28       | 87.5%                 |
|                   | Hispanic                      | 2        | 6.25%                 |
|                   | Missing                       | 2        | 6.25%                 |
| Education         | Some High School              | 1        | 3.13%                 |
|                   | High School Diploma/GED       | 4        | 12.50%                |
|                   | Some College/2-yr Degree      | 12       | 37.50%                |
|                   | 4-yr College Degree           | 4        | 12.50%                |
|                   | More than 4-yr College Degree | 11       | 34.37%                |
| Self-rated Health | Excellent                     | 2        | 6.25%                 |
|                   | Very Good                     | 16       | 50.00%                |
|                   | Good                          | 10       | 31.25%                |
|                   | Fair                          | 4        | 12.50%                |
| Body Mass Index   | Normal (18.5 – 24.9)          | 5        | 15.625%               |
|                   | Overweight (25 – 29.9)        | 14       | 43.75%                |
|                   | Obese (30+)                   | 13       | 40.625%               |

\*One participant discontinued the survey early; therefore, demographic information is missing. Other missing data reported at category level.

## CHAPTER 5

### 5 Summary and Conclusion

#### 5.1 Summary of Key Findings

This dissertation has explored the critical subject of physical activity assessment, promotion, and counseling within clinical settings. It comprises three main studies, each contributing unique insights to this field. The first study presented a scoping review, identifying the diverse landscape of physical activity interventions across clinical disciplines. It highlighted the importance of healthcare providers in promoting physical activity and suggested a need for standardized assessment methods, electronic activity monitors, and consistent reporting. The second study systematically reviewed the impact of physical activity interventions in clinical settings, emphasizing the use of physical activity monitors and prolonged interventions for sustainable behavior change. It also suggested involving specialized personnel in intervention delivery and adopting theoretical frameworks in future studies. The third study introduced a mobile health application, mWRAPPED, and assessed its acceptability among primary care patients, pointing to the potential of technology to enhance patient activation in clinical settings.

#### 5.2 Significance

The significance of this work lies in its multifaceted exploration of physical activity promotion within clinical settings. The findings underscore the importance of integrating physical activity assessment and promotion as a standard of care across various clinical disciplines. This integration can positively impact patient health, reduce comorbidities, and contribute to the prevention and management of chronic diseases. Furthermore, the research demonstrates that the collaborative efforts of diverse healthcare team members can assist physicians in overcoming common barriers to physical activity promotion, broadening the reach and effectiveness of interventions.

This work also highlights the need for accurate and consistent measures of physical activity. The adoption of electronic activity monitors provides a promising avenue for enhancing assessment

precision. Furthermore, the recommendations to extend intervention durations and involve specialized personnel can lead to more successful behavior change in patients. The inclusion of theoretical frameworks in future studies can further advance the scholarly impact of research in this area, improving the quality and effectiveness of interventions.

The findings from the third study indicate that technology, such as mobile health applications, can be a valuable tool for promoting patient activation, especially in underserved or rural areas. This has broad implications for improving healthcare accessibility and engagement, particularly in regions with limited resources.

### **5.3 Strengths and Limitations**

#### *Strengths*

Each of the three studies presented in this dissertation possesses its own set of strengths and limitations. The scoping review mapped the literature on physical activity assessment and promotion in clinical settings, offering a comprehensive overview. The systematic review followed PRISMA guidelines, ensuring a transparent and rigorous approach to evidence synthesis. The evaluation of the mWRAPPED application assessed its acceptability in a real-world clinical setting, providing insights into the feasibility of technology-based interventions.

#### *Limitations*

The scoping review was qualitative, and the diverse outcomes and methodological heterogeneity made quantitative analysis challenging. The systematic review had a relatively small number of included studies, affecting the power of subgroup analyses and generalizability. The mWRAPPED study focused on a convenience sample, limiting its generalizability to a broader population.

### **5.4 Future Research**

Future research in this field should address several areas based on the findings and limitations of the current studies including further investigations into the development and adoption of standardized

methods for physical activity assessment. Comparative studies between different assessment tools can help identify the most accurate and reliable measures. As technology continues to advance, research should explore innovative ways to integrate electronic activity monitors and mobile health applications into clinical practice. This includes evaluating the impact of technology on patient activation and engagement.

Comparative studies between different interventions, delivery agents, and lengths of interventions can help identify the most effective strategies for promoting physical activity in clinical settings. Future studies can expand on the concept of prolonged intervention duration. Investigating the optimal length for different populations and exploring strategies to maintain long-term adherence to physical activity recommendations can provide valuable insights. Additionally, incorporating theoretical frameworks in intervention design should be a priority. Research can focus on comparing theory-based interventions with atheoretical approaches to assess their impact on behavior change and patient outcomes.

Collaboration between healthcare team members from diverse disciplines should be studied further to understand the most effective ways to leverage their collective expertise in promoting physical activity. The role of specialized personnel, such as exercise/health coaches, in delivering physical activity interventions warrants further exploration. Studies can assess the effectiveness of these professionals in enhancing patient engagement and the sustainability of behavior change.

Lastly, expanding the focus beyond the US to different countries with varying healthcare systems can provide insights into the cultural and systemic factors influencing physical activity assessment and promotion in clinical settings.

## **5.5 Conclusions**

This dissertation contributes to the evolving field of physical activity assessment, promotion, and counseling in clinical settings. The findings emphasize the importance of integrating physical activity as

a standard of care, leveraging technology to enhance assessment and promotion, and the potential of specialized personnel in delivering interventions. The use of theoretical frameworks and interdisciplinary collaboration can further enhance the effectiveness of these interventions. This work sets the stage for future research that can advance healthcare practices, improve patient outcomes, and address the growing burden of chronic diseases associated with physical inactivity.

## CHAPTER 6

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## CHAPTER 7

### 7 Appendices

#### Appendix A: Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist\*

| SECTION   | ITEM | PRISMA-ScR CHECKLIST ITEM  | REPORTED ON PAGE # |
|---|------|--|--------------------|
| <b>TITLE</b>  |      |  |                    |
| Title   | 1    | Identify the report as a scoping review.   | 6                  |
| <b>ABSTRACT</b>                                       |      |  |                    |
| Structured summary                                    | 2    | Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.  | 6                  |
| <b>INTRODUCTION</b>                                   |      |  |                    |
| Rationale   | 3    | Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.   | 7-10               |
| Objectives  | 4    | Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.                                  | 10                 |
| <b>METHODS</b>  |      |  |                    |
| Protocol and registration                             | 5    | Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.   | 10                 |
| Eligibility criteria                                  | 6    | Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.   | 10-12              |
| Information sources*                                  | 7    | Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.  | 10                 |
| Search  | 8    | Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.  | 11                 |
| Selection of sources of evidence†                     | 9    | State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.  | 12-13              |
| Data charting process‡                                | 10   | Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators. | 12-13              |
| Data items  | 11   | List and define all variables for which data were sought and any assumptions and simplifications made.   | 13                 |
| Critical appraisal of individual sources of evidence§ | 12   | If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).  | N/A                |
| Synthesis of results                                  | 13   | Describe the methods of handling and summarizing the data that were charted.   | 12-13              |
| <b>RESULTS</b>  |      |  |                    |
| Selection of sources of evidence                      | 14   | Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.   | 13                 |
| Characteristics of sources of evidence                | 15   | For each source of evidence, present characteristics for which data were charted and provide the citations.  | 13-14              |

| SECTION                                       | ITEM | PRISMA-ScR CHECKLIST ITEM   | REPORTED ON PAGE # |
|---|------|---|--------------------|
| Critical appraisal within sources of evidence | 16   | If done, present data on critical appraisal of included sources of evidence (see item 12).  | N/A                |
| Results of individual sources of evidence     | 17   | For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.   | 13                 |
| Synthesis of results                          | 18   | Summarize and/or present the charting results as they relate to the review questions and objectives.  | 13-16              |
| <b>DISCUSSION</b>                             |      |   |                    |
| Summary of evidence                           | 19   | Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups. | 16-21              |
| Limitations                                   | 20   | Discuss the limitations of the scoping review process.  | 21-22              |
| Conclusions                                   | 21   | Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.                                       | 22-23              |
| <b>FUNDING</b>                                |      |   |                    |
| Funding                                       | 22   | Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.                 | N/A                |

## **Appendix B: Scoping Review Search Strategy**

(physical activity OR exercise OR fitness OR physical exercise) AND (counseling OR counselling OR health promotion OR health education OR patient education) AND (primary care OR primary health care OR primary healthcare OR family practice OR community care OR general practitioner OR generalists OR clinical setting OR clinical practice)

## Appendix C: Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) Checklist

| Section and Topic       | Item # | Checklist item   | Location where item is reported |
|-------------------------|--------|--|---------------------------------|
| <b>TITLE</b>            |        |  |                                 |
| Title                   | 1      | Identify the report as a systematic review.  | 38                              |
| <b>ABSTRACT</b>         |        |  |                                 |
| Abstract                | 2      | See the PRISMA 2020 for Abstracts checklist.   | 38                              |
| <b>INTRODUCTION</b>     |        |  |                                 |
| Rationale               | 3      | Describe the rationale for the review in the context of existing knowledge.  | 39-44                           |
| Objectives              | 4      | Provide an explicit statement of the objective(s) or question(s) the review addresses.   | 43-44                           |
| <b>METHODS</b>          |        |  |                                 |
| Eligibility criteria    | 5      | Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.  | 44-45                           |
| Information sources     | 6      | Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.  | 45                              |
| Search strategy         | 7      | Present the full search strategies for all databases, registers and websites, including any filters and limits used.   | 45<br>(Appendix E)              |
| Selection process       | 8      | Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.                     | 46-47                           |
| Data collection process | 9      | Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process. | 45-47                           |
| Data items              | 10a    | List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.                        | 46                              |
|                         | 10b    | List and define all other variables for which data were sought (e.g. participant and intervention  | 46                              |



| Section and Topic             | Item # | Checklist item  | Location where item is reported |
|-------------------------------|--------|---|---------------------------------|
|                               |        | characteristics, funding sources). Describe any assumptions made about any missing or unclear information.  |                                 |
| Study risk of bias assessment | 11     | Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process. | 46                              |
| Effect measures               | 12     | Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.   | 47                              |
| Synthesis methods             | 13a    | Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).  | 47                              |
|                               | 13b    | Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.   | 47                              |
|                               | 13c    | Describe any methods used to tabulate or visually display results of individual studies and syntheses.  | 47                              |
|                               | 13d    | Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.       | 47                              |
|                               | 13e    | Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).  | 47                              |
|                               | 13f    | Describe any sensitivity analyses conducted to assess robustness of the synthesized results.  | N/A                             |
| Reporting bias assessment     | 14     | Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).   | N/A                             |
| Certainty assessment          | 15     | Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.   | N/A                             |
| <b>RESULTS</b>                |        |   |                                 |
| Study selection               | 16a    | Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.  | 47                              |
|                               | 16b    | Cite studies that might appear to meet the inclusion criteria, but which were excluded, and   | 47                              |

| Section and Topic             | Item # | Checklist item   | Location where item is reported |
|-------------------------------|--------|--|---------------------------------|
|                               |        | explain why they were excluded.  | (Supplemental File 1)           |
| Study characteristics         | 17     | Cite each included study and present its characteristics.  | 59-60<br>(Table 3.1)            |
| Risk of bias in studies       | 18     | Present assessments of risk of bias for each included study.   | 50<br>(Figure 3.3)              |
| Results of individual studies | 19     | For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.   | 47-50                           |
| Results of syntheses          | 20a    | For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.   | 50<br>(Figure 3.3)              |
|                               | 20b    | Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect. | 47-50                           |
|                               | 20c    | Present results of all investigations of possible causes of heterogeneity among study results.   | 50                              |
|                               | 20d    | Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.   | N/A                             |
| Reporting biases              | 21     | Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.  | N/A                             |
| Certainty of evidence         | 22     | Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.  | N/A                             |
| <b>DISCUSSION</b>             |        |  |                                 |
| Discussion                    | 23a    | Provide a general interpretation of the results in the context of other evidence.  | 50-56                           |
|                               | 23b    | Discuss any limitations of the evidence included in the review.  | 54-55                           |
|                               | 23c    | Discuss any limitations of the review processes used.  | 54-55                           |
|                               | 23d    | Discuss implications of the results for practice, policy, and future research.   | 55                              |
| <b>OTHER INFORMATION</b>      |        |  |                                 |

| Section and Topic                              | Item # | Checklist item   | Location where item is reported |
|--|--------|--|---------------------------------|
| Registration and protocol                      | 24a    | Provide registration information for the review, including register name and registration number, or state that the review was not registered.   | 44<br>(Appendix D)              |
|  | 24b    | Indicate where the review protocol can be accessed, or state that a protocol was not prepared.   | 44                              |
|  | 24c    | Describe and explain any amendments to information provided at registration or in the protocol.  | N/A                             |
| Support  | 25     | Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.  | N/A                             |
| Competing interests                            | 26     | Declare any competing interests of review authors.   | N/A                             |
| Availability of data, code and other materials | 27     | Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review. | N/A                             |

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. *BMJ* 2021;372:n71. doi: 10.1136/bmj.n71

## **Appendix D: PROSPERO International Prospective Register of Systematic Reviews**

**[CRD42021270852]**

### **Physical Activity Assessment and Promotion Using Activity Monitors in Clinical Settings: A Systematic Review of Randomized Controlled Trials in the United States**

*Kristin Grogg, Peter Giacobbi, Treah Haggerty, George Kelley, Christa Lilly, Carena Winters, Emma Blair*

To enable PROSPERO to focus on COVID-19 submissions, this registration record has undergone basic automated checks for eligibility and is published exactly as submitted. PROSPERO has never provided peer review, and usual checking by the PROSPERO team does not endorse content. Therefore, automatically published records should be treated as any other PROSPERO registration. Further detail is provided [here](#).

#### **Citation**

Kristin Grogg, Peter Giacobbi, Treah Haggerty, George Kelley, Christa Lilly, Carena Winters, Emma Blair. Physical Activity Assessment and Promotion Using Activity Monitors in Clinical Settings: A Systematic Review of Randomized Controlled Trials in the United States. PROSPERO 2021 CRD42021270852 Available from: [https://www.crd.york.ac.uk/prospero/display\\_record.php?ID=CRD42021270852](https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42021270852)

#### **Review question**

Primary: to evaluate the impact of physical activity assessment and promotion in clinical settings from published reports of randomized controlled trials that used physical activity monitors as primary outcome measures.

Secondary: to evaluate the potential differential impacts of physical activity assessment and promotion based on the length and who delivered the intervention.

#### **Searches**

KG and PG will be responsible for conducting the preliminary (to identify the potentially relevant papers) and final searches. The following electronic databases will be searched: (1) PubMed (MEDLINE), (2) Academic Search Complete, (3) PsycINFO, (4) Cumulative Index to Nursing and Allied Health Literature (CINAHL), (5) SPORTDiscus, and (6) Health Source. The search strategy will

be limited to human participants and English language journal articles only, published in peer-reviewed journals. The reference lists of included studies will also be searched. Keywords will include physical activity, exercise, promotion, counseling, prescription, referral, clinical setting, and primary care.

Relevant Medical Subject Heading (MeSH) terms identified by the U.S. National Library of Medicine's thesaurus will also be considered when identifying the final search strings.

### **Types of study to be included**

Randomized Controlled Trials

### **Condition or domain being studied**

Physical inactivity is a major risk factor for chronic disease (World Health Organization, 2018). Many US adults are insufficiently active (Center for Disease Control and Prevention, 2018). Physical activity assessment and promotion is effective in clinical settings for modifying negative health behaviors and improving health outcomes (Ahmed et al., 2017). Systematic reviews with and without meta-analysis have demonstrated the effectiveness of exercise referrals and interventions in clinical settings (Cleland et al., 2017; Sanchez et al., 2015; Lamming et al., 2017; Patnode et al., 2017; de Vries et al., 2016). Several shortcomings of the previously reviewed research include little focus on (1) who delivered the interventions, (2) the varying lengths of interventions conducted or included in previous reviews, and (3) the use of activity monitors to measure physical activity in participants. These observations raise questions about the varying method(s) for physical activity counseling in clinical settings. This study extends previous systematic reviews in this area by focusing on randomized controlled trials and coding key methodological information not addressed in previous reviews (e.g., who delivered the intervention, length of intervention, and whether the physical activity intervention increased patient activity levels).

### **Participants/population**

Inclusion: Participants aged 18 years or older

Exclusion: Participants aged younger than 18 years of age.

### **Intervention(s), exposure(s)**

Inclusion: Randomized controlled trials involving practicing health professionals (licensed, allied, and non-medical health professionals) with a physical activity or exercise intervention that included the use of activity monitors (e.g., pedometers, accelerometers, FitBit, etc.).

Exclusion: Physical activity or exercise interventions conducted in clinical settings that did not utilize activity monitors as well as interventions that did not include provider assessment, counseling, or promotion, and were only recruited through clinical practices.

### **Comparator(s)/control**

Inclusion: (1) RCTs; (2) practicing health professionals (licensed, allied, and non-medical health professionals), (3) adult humans 18 years of age or older; (4) use of activity monitors (e.g., pedometers, accelerometers, FitBit®, etc.) as part of the intervention, (5) comparative control group (usual care, wait-list control, attention-control, physical activity promotion and exercise referral, non-physical activity/exercise interventions, etc.); (6) changes in physical activity described for both intervention and control groups; (7) full-text articles published in peer-reviewed English-language journals; (8) trials conducted in the US; and (9) published and indexed between January 1, 2008 and July 15, 2021. The rationale for the search dates are based on the release of EIM® by the ACSM in late 2007, 34 the initial release of the National Physical Activity Guidelines (NPAG) in 2008, 35 and the release of the 2nd Edition of the NPAG in late 2018.<sup>11</sup> Studies will be limited to those conducted in the US because of the different systems of healthcare delivery in other countries.

Exclusion: (1) conference abstracts, research letters, editorial notes, or commentaries; (2) intervention without the use of activity monitors in both arms; or 3) not a RCT.

### **Context**

Intervention studies in clinical settings

### **Main outcome(s)**

Physical activity collected and measured using activity monitors

### ***Measures of effect***

Physical activity: increases/decreases in participant physical activity

### **Additional outcome(s)**

Physical fitness if/when applicable

### **Data extraction (selection and coding)**

KG and PG will extract data independently using a previously developed codebook. Any discrepancies will be identified and resolved through discussion and if necessary, with input from GK. In addition to study authors and date of publication, the following data will be extracted in line with the PICO convention: Participant characteristics (sample size, age, gender, etc.), Intervention parameters (exercise mode, program and session duration, intensity, when available), Control comparison information and Outcome measures.

### **Risk of bias (quality) assessment**

Risk of bias for each study will be assessed using the Cochrane Risk of Bias instrument for RCTs (ROB 2, Stern et al., 2019). This instrument assesses risk of bias in five distinct domains: 1) bias arising from the randomization process, 2) bias due to deviations from intended interventions, 3) bias due to missing outcome data, 4) bias in measurement of the outcome, and 5) bias in selection of the reported result. Based on signaling questions, each domain is assessed as either “low risk”, “high risk”, or “some concerns” (Sterne et al., 2019). Based on responses to each domain, the overall risk of bias for each study is then assessed as either “low risk”, “high risk”, or “some concerns” (Sterne et al., 2019). We will use this instrument over the other various study quality instruments, including those focused on exercise intervention studies (e.g., Maher et al., 2003; Smart et al., 2015) given the difficulty of the latter in differentiating between the quality of reporting and the quality in the conduct of a study (Sterne et al., 2019). Risk of bias will be independently assessed by two authors (KG and PG). If agreement cannot be reached, GK will make a recommendation.

### **Strategy for data synthesis**

Descriptive data including author, study year, study design, type of healthcare professional, participant population, gender, and mean age will be extracted from each of the selected studies. It is expected that these studies will have used a range of different instruments and measures to assess change in activity levels, including continuous measures such as composite scores on activity questionnaires and duration of exercise, as well as dichotomous measures such as being active at a specified level. Because of the

expected heterogeneity with respect to such things as study design, participant characteristics, intervention and outcome variables being measured, an a priori decision has been made to assess all results qualitatively. Any missing data collected or that we are unable to collect will be recorded.

### **Analysis of subgroups or subsets**

Qualitative subgroup analysis of effects according to outcome measure.

### **Contact details for further information**

Kristin Grogg

kristin.grogg@mail.wvu.edu

### **Organisational affiliation of the review**

West Virginia University

### **Review team members and their organisational affiliations**

Miss Kristin Grogg. West Virginia University

Dr Peter Giacobbi. West Virginia University

Dr Trea Haggerty. West Virginia University

Dr George Kelley. West Virginia University

Dr Christa Lilly. West Virginia University

Dr Carena Winters. Jacksonville University

Miss Emma Blair. West Virginia University

### **Type and method of review**

Systematic review

### **Anticipated or actual start date**

29 July 2021

### **Anticipated completion date**

31 August 2021

### **Funding sources/sponsors**



None

**Conflicts of interest**

**Language**

English

**Country**

United States of America

**Stage of review**

Review Ongoing

**Subject index terms status**

Subject indexing assigned by CRD

**Subject index terms**

Exercise; Health Promotion; Humans; Randomized Controlled Trials as Topic; United States

**Date of registration in PROSPERO**

29 August 2021

**Date of first submission**

29 July 2021

**Stage of review at time of this submission**

| <b>Stage</b>  | <b>Started</b> | <b>Completed</b> |
|---|----------------|------------------|
| Preliminary searches  | Yes            | No               |
| Piloting of the study selection process                         | Yes            | No               |
| Formal screening of search results against eligibility criteria | No             | No               |
| Data extraction   | No             | No               |

| <b>Stage</b>                      | <b>Started</b> | <b>Completed</b> |
|-----------------------------------|----------------|------------------|
| Risk of bias (quality) assessment | No             | No               |
| Data analysis                     | No             | No               |

*The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.*

*The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.*

## Appendix E: Systematic Review Search Strategy

### PUBMED

((("counsel\*[tiab] OR "therapy"[tiab] OR "psychotherapy"[tiab] OR "treatment"[tiab] OR "health promotion"[tiab] OR "health education"[tiab] OR "patient education"[tiab] OR "patient education as topic"[mesh])) AND (("physical activity"[tiab] OR exercise[tiab] OR fitness[tiab] OR "physical exercise"[tiab] OR "physical inactivity"[tiab] OR "exercise"[mesh])) AND (("fitness tracker"[tiab] OR "activity tracker"[tiab] OR "sport tracker"[tiab] OR "wearable device"[tiab] OR "wearable technology"[tiab] OR "smart watch"[tiab] OR pedomet\*[tiab] OR "activity monitor"[tiab] OR "steps"[tiab] OR "acceleromet\*" [tiab] OR "actigraph\*" [tiab] OR "fitness trackers"[mesh])) AND (("primary care"[tiab] OR "primary health\*" [tiab] OR "general pract\*" [tiab] OR "internal med\*" [tiab] OR "family practice"[tiab] OR "community care"[tiab] OR "general prac\*" [tiab] OR "generalists"[tiab] OR "clinical setting"[tiab] OR "clinical practice"[tiab] OR "primary health care"[mesh] OR "family practice"[mesh])) AND (("randomized control\*" or "rct" or "randomised control\*" or "randomized clinical\*"))))

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### SCOPUS

TITLE-ABS ("counsel\*" OR "therapy" OR "psychotherapy" OR "treatment" OR "health promotion" OR "health education" OR "patient education" OR "patient education as topic") AND TITLE-ABS ("physical activity" OR "exercise" OR "fitness" OR "physical exercise" OR "physical inactivity") AND TITLE-ABS ("fitness tracker\*" OR "activity tracker" OR "sport tracker" OR "wearable device" OR "wearable technology" OR "smart watch" OR pedomet\* OR "activity monitor" OR "steps" OR "acceleromet\*" OR "actigraph\*") AND TITLE-ABS ("primary care" OR "primary health\*" OR "general pract\*" OR "internal med\*" OR "family pract\*" OR "community care" OR "general pract\*" OR "generalists" OR "clinical setting" OR "clinical pract\*" OR "primary health care") AND TITLE-ABS ("randomized control\*" OR "rct" OR "randomised control\*" or "randomized clinical\*")

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### EBSCO Host (Academic Search Complete, APA PsycINFO, CINAHL, Health Source, SPORTDiscus)

*Adding each of these strings to separate lines using the advanced search feature*

TI "counsel\*" OR AB "counsel\*" OR TI "therapy" OR AB "therapy" OR TI "psychotherapy" OR AB "psychotherapy" OR TI "treatment" OR AB "treatment" OR TI "health promotion" OR AB "health promotion" OR TI "health education" OR AB "health education" OR TI "patient education" OR AB "patient education" OR TI "patient education as topic" OR AB "patient education as topic"

TI "physical activity" OR AB "physical activity" OR TI "exercise" OR AB "exercise" OR TI "fitness" OR AB "fitness" OR TI "physical exercise" OR AB "physical exercise" OR TI "physical inactivity" OR AB "physical inactivity"

TI "fitness tracker\*" OR AB "fitness tracker\*" OR TI "activity tracker" OR AB "activity tracker" OR TI "sport tracker" OR AB "sport tracker" OR TI "wearable device" OR AB "wearable device" OR TI "wearable technology" OR AB "wearable technology" OR TI "smart watch" OR AB "smart watch" OR TI "pedomet\*" OR AB "pedomet\*" OR TI "activity monitor" OR AB "activity monitor" OR TI "steps" OR AB "steps" OR TI "acceleromet\*" OR AB "acceleromet\*" OR TI "actigraph\*" OR AB "actigraph\*"

TI "primary care" OR AB "primary care" OR TI "primary health\*" OR AB "primary health\*" OR TI "general pract\*" OR AB "general pract\*" OR TI "internal med\*" OR AB "internal med\*" OR TI "family pract\*" OR AB "family pract\*" OR TI "community care" OR AB "community care" OR TI "general pract\*" OR AB "general pract\*" OR TI "generalist\*" OR AB "generalist\*" OR TI "clinical setting" OR AB "clinical setting" OR TI "clinical pract\*" OR AB "clinical pract\*" OR TI "primary health care" OR AB "primary health care"

TI "randomized control\*" OR AB "randomized control\*" OR TI "rct" OR AB "rct" OR TI "randomised control\*" OR AB "randomised control\*" OR TI "randomized clinical\*" OR AB "randomized clinical\*"

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### **EBSCO Host (MEDLINE)**

"counsel\*" OR "therapy" OR "psychotherapy" OR "treatment" OR "health promotion" OR "health education" OR "patient education" OR "patient education as topic"

"physical activity" OR "exercise" OR "fitness" OR "physical exercise" OR "physical inactivity"

"fitness tracker\*" OR "activity tracker" OR "sport tracker" OR "wearable device" OR "wearable technology" OR "smart watch" OR pedomet\* OR "activity monitor" OR "steps" OR "acceleromet\*" OR "actigraph\*"

"primary care" OR "primary health\*" OR "general pract\*" OR "internal med\*" OR "family pract\*" OR "community care" OR "general pract\*" OR "generalists" OR "clinical setting" OR "clinical pract\*" OR "primary health care"

"randomized control\*" OR "rct" OR "randomised control\*" OR "randomized clinical\*"

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### **ProQuest (Physical Education Index)**

TI "counsel\*" OR AB "counsel\*" OR TI "therapy" OR AB "therapy" OR TI "psychotherapy" OR AB "psychotherapy" OR TI "treatment" OR AB "treatment" OR TI "health promotion" OR AB "health promotion" OR TI "health education" OR AB "health education" OR TI "patient education" OR AB "patient education" OR TI "patient education as topic" OR AB "patient education as topic"

TI "physical activity" OR AB "physical activity" OR TI "exercise" OR AB "exercise" OR TI "fitness" OR AB "fitness" OR TI "physical exercise" OR AB "physical exercise" OR TI "physical inactivity" OR AB "physical inactivity"

TI "fitness tracker\*" OR AB "fitness tracker\*" OR TI "activity tracker" OR AB "activity tracker" OR TI "sport tracker" OR AB "sport tracker" OR TI "wearable device" OR AB "wearable device" OR TI "wearable technology" OR AB "wearable technology" OR TI "smart watch" OR AB "smart watch" OR TI "pedomet\*" OR AB "pedomet\*" OR TI "activity monitor" OR AB "activity monitor" OR TI "steps" OR AB "steps" OR TI "acceleromet\*" OR AB "acceleromet\*" OR TI "actigraph\*" OR AB "actigraph\*"

TI "primary care" OR AB "primary care" OR TI "primary health\*" OR AB "primary health\*" OR TI "general pract\*" OR AB "general pract\*" OR TI "internal med\*" OR AB "internal med\*" OR TI "family pract\*" OR AB "family pract\*" OR TI "community care" OR AB "community care" OR TI "general pract\*" OR AB "general pract\*" OR TI "generalist\*" OR AB "generalist\*" OR TI "clinical setting" OR AB "clinical setting" OR TI "clinical pract\*" OR AB "clinical pract\*" OR TI "primary health care" OR AB "primary health care"

TI "randomized control\*" OR AB "randomized control\*" OR TI "rct" OR AB "rct" OR TI "randomised control\*" OR AB "randomised control\*" OR TI "randomized clinical\*" OR AB "randomized clinical\*"

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## Appendix F: mWRAPPED Usability Study Protocol Document (Protocol #: 180290671)

|                                |  |
|--------------------------------|--|
| <b>Protocol Title:</b>         | mWRAPPED Application Usability Study   |
| <b>Principal Investigator:</b> | Treah Haggerty   |
| <b>Co-Investigators:</b>       | Kristin Grogg, Peter Giacobbi, Courtney Pilkerton  |
| <b>Study Coordinator:</b>      | N/A  |
| <b>Population:</b>             | Up to 200 WVU Medicine Family Medicine Patients (regularly scheduled, voluntary participation) |
| <b>Number of Sites:</b>        | Ruby Memorial Hospital or Other WVU Healthcare Site & WVU Campus                               |
| <b>Study Duration:</b>         | March 2018   |
| <b>Subject Duration:</b>       | Approximately 10 minutes (immediately following regularly scheduled appointment times)         |

### General Information

mWRAPPED (mobile Weight management in Rural Appalachia through Patient and Physician Empowerment of Discussions) is a tablet based application that was developed to deliver American Heart Association (AHA) 2013 Weight Management Guidelines to Primary Care patients in the clinical setting prior to their clinic visit. The application was developed using a patient engaged approach. The presented study has been developed to test the usability and acceptability of the mWRAPPED application in the practice setting.

### Background Information

Appalachian states such as Mississippi, Arkansas, Louisiana, Alabama, and West Virginia experience the highest mortality rates from cardiovascular disease (CVD) nationwide.<sup>1</sup> Similar results exist for cardiovascular risk factors with these same states reporting the highest rates of tobacco use, saturated fat consumption, physical *inactivity*, and obesity.<sup>2</sup> In particular, West Virginia is also one of twelve states with over 40% of the population having four or more risk factors for heart disease.<sup>3 4</sup> West Virginia has the second lowest prevalence of ideal cardiovascular health<sup>5</sup> and between 2003 and 2009 had decreases in the prevalence of ideal blood pressure, body mass index, physical activity, and diet.<sup>6</sup>

Recent reports from the Centers for Disease Control and Prevention (CDC) revealed that 11.1% of total healthcare expenditures are associated with inadequate levels of physical activity.<sup>7</sup> By 2030, it is

expected the prevalence of CVD will increase by 10% and direct medical costs will triple.<sup>8</sup> In today's era of concern for healthcare costs, quality of care, and managed healthcare, it is increasingly important to utilize resources that will improve upon sustained health outcomes through evidence based programs. To counter this cost prediction, population based efforts in advancing cardiovascular health include national initiatives such as Healthy People 2020 and the AHA Strategic Impact Goals.<sup>9</sup> <sup>10</sup> The Affordable Care Act has drawn attention to the cost-effective value of primordial and primary prevention policies,<sup>11</sup> while the AHA has recently released a reimbursement plan for delivery of physical activity counseling with an exercise prescription by healthcare providers.<sup>12</sup>

Primary care providers are increasingly called upon to initiate physical activity counseling with their patients to manage conditions like obesity, diabetes, and cardiovascular diseases. Exercise promotion has repeatedly shown to be effective for modifying negative health behaviors and conversely, improve health outcomes. Still, recent reports indicate that only 10% of primary care visits include some type of physical activity counseling.<sup>13</sup> Barriers continue to include competing health demands, time for counseling, as well as a perceived lack of knowledge regarding physical activity programming and counseling.<sup>14</sup>

New technology – like objective mobile health (mHealth) software applications (apps) – offers some exciting new opportunities to allow remote access for patients to clinically significant applications and information. With the potential to be relatively cheap, easily distributable, and delivered at multiple locations (clinical, community-based, at home, or on the move), healthcare providers can lean on this technology to better assist their patient population. This can be done at times convenient for patients, offer as many interventions as they need or want, and offer continuing support in an attractive, tailored format to suit patients' needs.<sup>15</sup> Desktop, laptop or handheld computers (tablets), and mobile phones (smart phones) have the processing power to handle information and algorithms that may be able to target most of the components of cardiovascular health. Computer-based interventions have the potential to provide ongoing self-management support to re-enforce the benefits over time.<sup>16</sup> Mobile health technology has shown the potential to optimize the management of CVD and other chronic diseases by empowering patients through better health self-monitoring and education.<sup>17</sup> mWRAPPED and other weight management initiatives, have been successfully developed to assist healthcare providers in providing information and education to patient populations.

The overall objective of this study is to investigate weight management and counseling practice within the population of West Virginia. We propose to collect data related to the mWRAPPED tablet-based application. Specifically, this study will examine the usability, feasibility, and acceptability of the

mWRAPPED tablet based application by patients and providers in the clinic setting. The results will inform a larger examination of weight management and counseling in the clinic setting with which it is associated throughout the state with the aim of developing new prevention approaches to cardiovascular health and overall wellbeing.

## **Objectives**

**Aim 1:** To determine the usability of providing a tablet-based application to annual and routine follow-up clinic visits.

Objective 1.1: Establish baseline knowledge/understanding of technology usage in the patient population.

Objective 1.2: Determine the usability of the mWRAPPED app in the clinic patient population.

Objective 1.3: Determine feasibility to providers and staff of incorporating the mWRAPPED app to the clinic flow.

**Aim 2:** To determine whether providing patients with information on weight management via tablet-based application leads to further engagement with their provider for information and lifestyle changes.

Objective 2.1: Establish baseline knowledge/understanding of patient/provider relationship and engagement.

Objective 2.2: Determine effectiveness of the mWRAPPED app in clinical engagement between provider and patient.

Objective 2.3: Determine overall acceptability of the mWRAPPED app of patients and providers.

## **Study Design**

We will conduct a cross-sectional, convenience sample study with up to 200 patients seen during their regularly scheduled clinic visits to the WVU Medicine University Town Center Family Medicine Clinic. The study will take place during the Wednesday evening clinic hours throughout the month of March, 2018. This will provide four (4) clinic days for data collection, which should allow for the necessary enrollment. If enrollment is less than expected, more Wednesday evening clinic days will be added through the month of April, 2018 until an appropriate sample size is obtained. The tablet device (a Samsung tablet) will contain the mWRAPPED application. This application will ask the participant their



age, height, and weight. From the provided information the application will calculate the participants BMI. The application will then use the calculated BMI to offer information regarding cardiovascular risk, as well as information on managing/controlling their risk. Information asked by the mWRAPPED application is not saved or stored, therefore complying with all HIPAA regulations. The device will also contain the REDCap application. This will be utilized after the participant completes their regularly scheduled appointment and agrees to participate in the anonymous survey. The follow-up survey does not contain Protected Health Information (PHI), will be totally anonymous, and will NOT be added to the patients' electronic health record.

This study qualifies for Exempt Research Category Two (2) because the procedures include anonymous survey procedures on the patient participant population, as well as interviews with participating healthcare providers. The survey questions can be found in the notes at attachments section of the WVU KC system.

### **Study Population**

We will conduct a convenience sample, cohort usability/feasibility/acceptability study enrolling patients during annual or routine follow up clinic visits with participating providers at WVU Medicine University Town Center Family Medicine clinic over a one month period.

The key inclusion criteria for this study are: Individuals aged 18 to 89 years who are at an annual or routine follow up clinic visit of a participating provider and who are presenting to the clinic for non-acute care.

The key exclusion criteria for this study are: Persons who are pregnant, incarcerated, or who are presenting to clinic for acute specific conditions or symptoms such as, dementia, mental illness, acute disease or injury (defined as any illness/injury with an abrupt onset and short duration) or terminal illness (defined as any illness expected to result in death within a short period of time). These conditions and symptoms are identified as exclusion criteria as they represent vulnerable populations and/or affect the ability to obtain informed consent (dementia, mental illness), or knowingly affect both physiologic and psychologic status (terminal illness).

### **Study Procedures**

- A. All patients meeting the inclusion criteria and entering the clinic for their regularly scheduled annual or routine follow-up appointment will be approached by research personnel.

The researcher will offer the patient a tablet containing the application, and explain that they may voluntarily use the application while they wait for/during their time at the clinic.

a. Participant Approach Script:

*Good Afternoon.*

*My name is \_\_\_\_\_. I am a \_\_\_\_\_ at West Virginia University, conducting research with Dr. Treah Haggerty. My team and I are conducting research in the clinic, and I am inviting you to participate because you have a regularly scheduled appointment today.*

*We are asking interested individuals if they would like to use our newly developed App on the tablets we have in the clinic today. If you are interested, I can leave the tablet with you while you are in the clinic, and will collect it after you check out. We would also like to ask you about your experience with the App in a survey before you leave. It will take approximately 10 minutes to complete, and is completely voluntary.*

*If you have any questions or would like to participate in the research, please do not hesitate to approach me. I can also provide you with my*

If patient says, “Yes”: Explain the basics to use the tablet and open the app, and leave the tablet with them.

If patient says, “NO”: Respond with, ‘Thank you for your time. Have a good day!’”

- B. The patient attends their regularly scheduled appointment with their provider. When the patient is called back to the exam room for their appointment, they will be allowed to take the tablet to use during down time.
- C. When the appointment time has ended and the patient has been check-out, the researcher will collect the tablet and ask the participant if they would complete a survey. The survey will be tablet-based, using the REDCap system, and take approximately 10 minutes to complete. Participation in the survey will be completely voluntary, and can be stopped at any time.

b. Survey Approach Script:

*Thank you for returning your tablet! Would you be interested in filling out an anonymous survey about the App that was available? It will take approximately 10 minutes to complete, and is completely voluntary.*

*If you have any questions or would like to participate in the research, please do not hesitate to approach me. I can also be reached at \_\_\_\_\_ or \_\_\_\_\_ if you have any further questions.*

- D. At the end of the recruitment period, approximately one month, the providers who participated will be interviewed. The unstructured interview will be modeled to understand the application's impact on the clinical appoint (if the patient asked about weight management), and the feasibility of having such a medium in the clinic.
- E. All data collected will be reported in the aggregate, and will be used to gain a better understanding of the mWRAPPED application as it related to clinical use. All results from the surveys will be reported in the aggregate for the study sample as a whole, not for each individual.

### **Data and Safety Monitoring**

Only the subjects meeting the eligibility criteria (18 years old) will be enrolled. The informed consent process will be performed, as described previously in this protocol, prior to conducting any study procedures. All data collection/procedures will be collected from participants by research personnel. Upon entry to the study, all participants will be assigned a unique, non-identifiable study number to be used as the unique patient identifier for throughout the study.

The REDCap system has been selected for this study, which has been provided to researchers by the WVCTSI for the purposes of data collection is backed up offsite nightly and hosted in a secure environment maintained by the iBi. WVCTSI also employs a strict security measure to protect data. Only research team members as necessary will have access to the REDCap database via individual passwords. Data collected in REDCap will be downloaded (and removed) from the REDCap system and stored in a secure, password-protected, and encrypted database on a WVU-HSC-based server (with limited access to the server location/directory). No "hard-copy" data will be obtained or stored, therefore eliminating further breach of data safety/confidentiality.

The PI (Trea Haggerty), senior research personnel, and only research team members as necessary will be able to access this database. Data will be used only as specified in this

protocol. When it is time to destroy the data, all paper forms and files (if produced) will be disposed of using the shredding and disposable document services at HSC known as PACE Shredding.

### **Statistics**

The proposed sample size (200) is an estimate of the available population, therefore without knowledge of the total population size, it is unfair to attempt to estimate a necessary sample size. This is a “best guess estimate” at this time. We currently consider that a convenience sampling plan will be adequate for us to achieve the desired number of participants.

SAS 9.3 will be used for data management. Descriptive summaries and prevalence estimates will be assessed using frequencies, proportions, means, and standard deviation. Data will be summarized descriptively and compared using parametric and nonparametric analyses including Student’s t-tests, Chi-squared tests, and Fisher’s exact test. Tests for differences with categorical variables will be examined using Rao-Scott chi-square test of independence. Ordinal data will be subject to Mann-Whitney U-Test and Wilcoxon Signed-Ranks. Qualitative feedback will be discussed with research team.

### **Ethics**

The research presented is designed to address the key issues of informed consent and confidentiality. Informed consent is addressed by providing information as the first step in participant enrollment (for both provider and patient) which included information on the research team and the purpose of the research in the form of a cover letter. Confidentiality is addressed by ensuring that all data is held and/or stored securely and is anonymous. This study is submitted for approval to the Institutional Review Board of West Virginia University (Protocol #1802980671).

### **Conflict of Interest**

None.

### **ATTACHMENTS** *(found in WVU KC)*

1. Participant Cover Letter
2. Participating Provider/Nursing Staff Cover Letter
3. Participant Survey via REDCap

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