

# The Development of the MedEx IMPACT Intervention: A Patient-Centered, Evidenced-Based and Theoretically-Informed Physical Activity Behavior Change Intervention for Individuals Living With and Beyond Cancer

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## Abstract

Regular physical activity (PA) can address many of the negative side effects experienced by individuals following cancer treatment and support the optimization of physical and psychosocial well-being. However, many survivors of cancer are not sufficiently active to achieve these health benefits. The purpose of this study was to describe the development of a physical activity behavior change (PABC) intervention, MedEx IMPACT (IMprove Physical Activity after Cancer Treatment), which aims to increase cancer survivors' PA levels. A review of the literature and focus groups with survivors of cancer were conducted in order to generate recommendations to inform the intervention development process. This process was guided and informed by: (1) the Medical Research Council's (MRC) framework for the development, evaluation, and implementation of complex interventions, (2) the Behaviour Change Wheel (BCW), and (3) the Theoretical Domains Framework (TDF). Recommendations for strategies to support habitual PA and adherence to community-based exercise programs, generated by survivors of cancer who participated in 7 focus groups ( $n = 41$ ), were synthesized with 13 statements of findings that were generated from 10 studies included within the review of the literature. Detailed mapping exercises are presented which outline the link between these sources, the MRC framework, the BCW and TDF, and the intervention content. MedEx IMPACT is the first PABC intervention for survivors of cancer to be developed through the application of the MRC framework, BCW, and TDF. The next phase in this research is to test the acceptability and effectiveness of MedEx IMPACT.

## Keywords

physical activity, behavior change, intervention, cancer

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## Introduction

Advances in the screening, diagnosis, and treatment of cancer have contributed to significant increases in the number of individuals living with and beyond the condition.<sup>1</sup> Prevalence estimates from the World Health Organization indicate that globally, there are 32.6 million survivors of cancer who had a cancer diagnosis in the previous 5 years.<sup>2</sup> The term cancer survivor can be applied to an individual from the point of cancer diagnosis throughout the remainder of life.<sup>3,4</sup> The long-term and latent effects of cancer and its treatment can pose a number of challenges for these individuals including reductions in physical function and quality of life, the presence of cancer-related fatigue, increased risk of cancer morbidity and mortality, and increased risk for the development of other chronic conditions (eg, cardiovascular diseases, osteoporosis).<sup>5-9</sup>

To assist in addressing many of these negative consequences and to support the optimization of physical and psychosocial well-being, the inclusion of physical activity (PA) as an adjunct to cancer treatment has been advocated.<sup>10,11</sup> This is important in light of the fact that the majority of individuals living with and beyond cancer are not sufficiently active to achieve the health benefits associated with regular PA.<sup>12-15</sup>

Although the benefits of PA and exercise throughout the cancer journey have been well documented,<sup>16-19</sup> there is a dearth of evidence demonstrating the effectiveness of existing PA and exercise interventions to support sedentary individuals living with and beyond cancer to meet the recommended PA guidelines.<sup>12,15</sup> The need to identify the most effective methods to support survivors of cancer to increase and achieve long-term adherence to PA was highlighted in a recent publication which proposed the top 10 research questions for the field of PA and cancer survivorship.<sup>20</sup> Most of the available evidence regarding adherence to PA among individuals living with and beyond cancer is drawn from studies with short-term interventions (<12 weeks) and follow-up (3-6 months).<sup>12,15</sup> As a result, the long-term impact of such interventions remains unclear.<sup>12,15,21</sup> In addition, many studies have used self-report measures to assess PA levels, which can be subject to multifarious bias.<sup>12,15</sup>

Theoretically informed interventions enhance the effectiveness of behavior change (BC) components,<sup>22,23</sup> as the relation between constructs, that are predictive of BC, can be understood, translated into intervention content, and then examined for an explanation of how an intervention achieved, or not, its desired outcome.<sup>24</sup> The use of theory and the level of detail regarding its application within intervention design studies varies widely.<sup>23,25</sup> Consequently, assessing the intensity of theory application and its impact on BC can be difficult.<sup>23,25</sup> In a recent Cochrane review of interventions for promoting habitual exercise in people living with and beyond cancer, an analysis by BC theory and outcome was not possible given that only a minority of trials had stated a theoretical basis for their intervention.<sup>15</sup> The Medical Research Council's (MRC) framework for the development, implementation, and evaluation of complex interventions was designed to assist researchers in

adopting suitable methodologies.<sup>26</sup> According to the framework, within the development phase of complex interventions, researchers should identify the existing evidence for the topic under discussion (ie, review the existing literature) in order to gain an in-depth understanding of the problem and subsequently identify relevant theory to inform the intervention development process.<sup>26</sup>

To address the limitations of existing theoretical frameworks, including their broad scope and incoherent definitions of theoretical constructs,<sup>27,28</sup> The Behaviour Change Wheel (BCW) was developed.<sup>29,30</sup> The BCW provides a comprehensive and systematic approach to intervention design.<sup>29,30</sup> Its purpose is to synthesize BC theory and scientific evidence to promote a systematic and comprehensive analysis of all available options for an intervention.<sup>30,31</sup> Through this application of behavioral science, it aims to ensure that intervention components act synergistically.<sup>30,31</sup> This approach supports intervention designers to make the best use of the understanding of the target behavior and the resources available in order to arrive at a particular strategy.<sup>32</sup>

Details of the BCW and its method of application are described elsewhere.<sup>30</sup> In short, at the center of the BCW is the COM-B model, which focuses on how an individual's capability, opportunity, and motivation interact to influence behavior. The COM-B model is used to perform a behavioral diagnosis to assist in the identification of a target behavior for an intervention. Intervention designers then select which intervention functions to implement in order to support performance of the target behavior by the intended population. Each intervention function can in turn be linked with behavior change techniques (BCTs), which are specific strategies, embedded within an intervention, designed to change behavior.<sup>30</sup> As part of the BCW method, intervention designers are encouraged to apply the Theoretical Domains Framework (TDF).<sup>30,31</sup> This framework assists in further subdividing the factors identified in the COM-B behavioral diagnosis into 14 theoretical domains (eg, knowledge, skills, goals). The TDF provides comprehensive coverage of the possible influences on the target behavior and can address implementation problems by linking theories of BC with techniques of BC.<sup>31</sup> Further details of the TDF are described elsewhere.<sup>31,33</sup>

Another strategy that has received increasing attention for its potential to make research more relevant is the promotion of patient and public involvement (PPI).<sup>34,35</sup> PPI is defined by The National Institute for Health Research's Advisory Group (INVOLVE) as research that is being conducted with or by members of the public rather than to, about, or for them.<sup>35</sup> The inclusion of members of the public as active partners can ensure that all aspects of a project, from design to dissemination, are influenced by individuals' real-life experiences and therefore ensures that the research is relevant and meaningful to the intended population.<sup>36</sup> There is also evidence to suggest that PPI can improve research quality.<sup>37</sup>

MedEx is a community-based exercise rehabilitation program that offers supervised exercise classes to individuals living with chronic conditions. The MedEx IMPACT (IMprove Physical Activity after Cancer Treatment) intervention was

developed to be delivered to adults  $\geq 18$  years with an established diagnosis of cancer who had completed treatment, had been referred to MedEx, and given medical approval to participate in an exercise program by a health-care professional. Exclusion criteria for MedEx IMPACT were: (1) an uncontrolled cardiovascular condition, (2) a significant musculoskeletal or neurological condition, or (3) a significant mental illness or intellectual disability that restricted participation in an exercise training program. An investigation into the feasibility and effectiveness of the MedEx IMPACT intervention versus usual care (supervised exercise classes only) has been conducted. The purpose of this study is to systematically describe the development process of the MedEx IMPACT intervention, which adopted a patient-centered, evidenced-based and theoretically-informed approach. The primary aim of the MedEx IMPACT intervention is to increase the PA levels of individuals living with and beyond cancer who have been referred to a community-based exercise program.

## Methods

The intervention development process was guided by findings from a review of the literature, end-user recommendations, the MRC's framework for the development, implementation and evaluation of complex interventions,<sup>26</sup> the BCW<sup>30</sup> and the TDF.<sup>31</sup>

The development of the MedEx IMPACT intervention consisted of 5 phases:

- (1) a review of literature to: (a) establish the determinants of PA behavior, adherence, and maintenance for survivors of cancer and (b) review PA behavior change (PABC) interventions for this population;
- (2) engagement with individuals living with and beyond cancer through focus groups to: (a) explore individuals' experiences of PA throughout the cancer journey, (b) understand the factors that influence PA participation, and (c) obtain recommendations regarding strategies to support habitual PA and adherence to community-based exercise programs;
- (3) theoretical framework selection and application;
- (4) operationalizing findings into intervention components; and
- (5) engagement with a stakeholder expert panel (SEP) to determine intervention acceptability.

Table 1 presents an overview of how the intervention development phases were aligned with the stages of the MRC framework for the development, implementation and evaluation of complex interventions.<sup>26</sup>

## Procedure

### Medical Research Council Framework Stage 1—Identifying the Evidence Base

**Review of literature.** The following databases were searched during the review of the literature: The Cochrane Library, EMBASE, MEDLINE, CINAHL, PsycINFO, and SportDiscus

**Table 1.** Phases of the MedEx IMPACT Intervention Development Process Aligned With Stages of the MRC Framework for the Development, Implementation, and Evaluation of Complex Interventions.<sup>26</sup>

Key Elements From the MRC Framework for the Development of Complex Interventions	Phases of the MedEx IMPACT Intervention Development Process
Identifying the evidence base	(1) Review of the literature (2) Focus groups with individuals living with and beyond cancer
Identify/develop theory	(3) Theoretical framework selection and application
Modelling process and outcomes	(4) Engagement with a stakeholder expert panel

Abbreviations: IMPACT, IMprove Physical Activity after Cancer Treatment; MRC, Medical Research Council.

from inception to May 2016. Gray literature and conference proceedings were also searched. Details of the methodology for the review of the literature including key search terms and inclusion and exclusion criteria are presented in Supplementary Additional File 1. Four searches were conducted to identify the determinants of (1) PA behavior, adherence, and PA maintenance, for individuals living with and beyond cancer and (2) to identify components and/or strategies from previous BC interventions that have been effective in increasing the PA levels of individuals living with and beyond cancer. Recommendations were generated from the studies included within the review of the literature to inform intervention development.

**Focus groups.** Individuals attending a community-based exercise program for survivors of cancer (that offered 12 weeks of twice weekly supervised, structured exercise classes), and a cancer support center, were invited to participate in the focus groups. Individuals interested in taking part completed the PA screening questionnaire outlined in the National Exercise Referral Framework.<sup>38</sup> Participants were then allocated to a focus group depending on their current level of PA as categorized by the questionnaire and their level of engagement with the community-based exercise program (eg, current attender, nonattender, graduate of the program). Individuals recruited from the cancer support center participated in the same focus group. Ethical approval was granted by the Dublin City University Research Ethics Committee (DCUREC/2015/203).

Semi-structured interview scripts developed using the COM-B model<sup>30</sup> were used to guide the focus group discussions (Supplementary Additional File 2). Questions focused on exploring individuals' capability, opportunity and motivation to be regularly physically active. Prior to the focus group, participants completed an investigator developed questionnaire

regarding preferences for PA and opinions regarding strategies to support habitual PA. The focus groups included a discussion of the participants' responses to this questionnaire and potential strategies to support adherence to community-based exercise programs. Each focus group was audio recorded and conducted by a trained qualitative researcher. Each focus group lasted between 50 and 90 minutes. Audio recordings were transcribed verbatim and analyzed using a thematic analysis approach.<sup>39</sup> Further details regarding the methods for recruitment, data collection and analysis have been reported elsewhere.<sup>40</sup> Details of PPI within this study are outlined in the Guidance for Reporting Involvement of Patients and the Public short-form checklist.<sup>35</sup>

**Medical Research Council Framework Stage 2—Identify/Develop Theory**

*Theoretical framework selection and application.* Existing theoretical frameworks, including Social Cognitive Theory<sup>41</sup> and the Transtheoretical Model of Behavior Change,<sup>42</sup> were reviewed. The BCW and the TDF were selected to guide the intervention development process.<sup>30,31</sup> The BCW was chosen as it addresses limitations identified within existing theoretical frameworks and provides a systematic method for understanding BC.<sup>29,30</sup> In the first stage of the BCW process, the problem was defined in behavioral terms whereby the target population and behavior were selected. The target behavior, to increase cancer survivors' PA levels, was selected based on a number of criteria outlined by Michie and colleagues, including how easy it is likely to be to change the behavior (which may be influenced by a number of factors including financial and/or human resources, acceptability, and preference) and the ease of measurement.<sup>30</sup> The target behavior was specified according to the criteria presented in Table 2.<sup>30</sup> The application of the TDF is encouraged as part of the BCW method.<sup>30,31,33</sup> This framework assists in further subdividing the factors identified in the COM-B behavioral diagnosis into 14 theoretical domains that are specified within the TDF. The TDF provides comprehensive coverage of the possible influences on the target behavior and can address implementation problems by linking theories of BC with techniques of BC.<sup>31,33</sup> It has also been suggested that use of the TDF may further improve the planning and reporting of theory application within interventions and provide evidence for the use of specific BCTs and overall theoretical coherence.<sup>23,43</sup>

A behavioral diagnosis was undertaken which involved synthesizing findings from the focus groups and the review of the literature with COM-B model constructs to identify what strategies should be implemented to support performance of the target behavior.

In stage 2, the behavioral diagnosis was linked with intervention functions (eg, education, training, enablement) that were likely to increase cancer survivors' PA levels. The affordability, practicability, effectiveness, cost-effectiveness, acceptability, safety and equity (APEASE) criteria acknowledge that BC interventions are conducted within a social context and list important factors that should be considered during the

**Table 2.** Specification of the Target Behavior According to the Behaviour Change Wheel Criteria.<sup>30</sup>

The Target Behavior	Who Needs to Perform the Behavior?	What Does the Person Need to do Differently to Achieve the Desired Change?	When Will They Do It?	Where Will They Do It?	How Often Will They Do It?	With Whom Will They Do It?
To increase indices of physical activity among survivors of cancer (eg, daily minutes of light- and moderate-to-vigorous-intensity physical activity; daily step count)	Individuals who have completed adjunctive cancer treatment who have been referred to a community-based exercise rehabilitation program	Attend the community-based exercise program and engage in regular independent physical activity	Mondays and Wednesday (attendance at supervised exercise classes) and independent PA on other days of the week	At the center for the community-based exercise program and at home/independently	Progressively increase PA levels with the aim of being active on $\geq 5$ days a week	Fellow participants of the community-based exercise program; family and friends; alone

Abbreviation: PA, physical activity.

intervention design process including affordability, practicability, effectiveness, cost-effectiveness, acceptability, safety, and equity.<sup>30</sup> The APEASE criteria were applied in the selection of intervention functions. Policy categories were not applied within this intervention.

In stage 3, BCTs that could deliver the identified intervention functions were selected from the Behavior Change Technique Taxonomy.<sup>44</sup> The final stage in the intervention design process identified the optimal mode of delivery. The selected BCTs and mode of delivery were translated into intervention components.

A mapping exercise was undertaken to outline the links between intervention components, intervention functions, TDF constructs, and BCTs (see Tables 4 and 5).

*Operationalizing findings into intervention components.* Upon completion of phases 1 to 3, the key findings and recommendations from each phase were synthesized. In phase 4, the intervention content and format were developed based on this information. The BCW and TDF provided the theoretical framework for intervention design, while the recommendations, generated by focus group participants regarding strategies to support habitual PA and adherence to community-based exercise programs, formed the foundation for intervention content development. These recommendations were analyzed within the context of the results from the review of the literature, and the intervention content was further refined.

#### *Medical Research Council Development Stage 3—Modelling Process and Outcomes*

*Stakeholder expert panel.* To determine the acceptability of the intervention to the intended population and to obtain stakeholder feedback, the intervention was presented at a 2-hour workshop to an SEP (n = 11) which included: (1) individuals who were currently attending or had graduated from a community-based exercise program for survivors of cancer (n=4), (2) representatives from a national cancer charity (n = 3), (3) an oncology liaison nurse (n = 1), (4) exercise instructors involved in the delivery of a community-based exercise program for survivors of cancer (n = 2), and (5) a medical director for a community-based chronic illness exercise rehabilitation program (n = 1). Ethical approval was granted by the Dublin City University Research Ethics Committee (DCUREC/2017/076). During the workshop, an overview of the proposed intervention was presented, and stakeholders were asked to discuss questions that had been generated by the research team, regarding intervention acceptability and effectiveness. Following this exercise, the discussion was opened to the floor and stakeholders asked questions of the research team and shared their comments and recommendations to inform intervention design.

## **Results**

The results from each stage of the intervention development process are outlined below.

### *Medical Research Council Development Stage 1—Identifying the Evidence Base*

*Findings from the review of literature.* From the 4 searches that were conducted during the review of the literature, 10 studies were identified to inform the intervention development process. Table 3 provides an overview of statements of findings that were generated from the review of the literature to inform the intervention development process.

### *Medical Research Council Development Stage 1—Identifying the Evidence Base*

*Focus group findings.* Seven focus groups with 41 individuals living with and beyond cancer were conducted (56% female; mean [ $\pm$  standard deviation] age 57.7 [ $\pm$  9.1 years]). Participants had a cancer diagnosis of breast (41%), prostate (27%), colorectal (20%), or “other” (12%—including lung, cervical, and melanoma) cancer. The focus group discussions provided valuable information regarding individuals’ experiences of PA throughout the cancer journey and the factors that influence PA participation. These findings and the 8 recommendations for strategies to support habitual PA and adherence to community-based exercise programs that were generated from the discussions are described in detail elsewhere.<sup>40</sup> In summary, the 8 recommendations advocated for the inclusion of: (1) individualized exercise prescription, (2) group-based supervised exercise classes with peers (ie, individuals who have also undergone treatment following a cancer diagnosis), (3) goal setting and action planning, (4) quantification and measurement of PA, (5) provision of information regarding additional health behaviors (ie, healthy eating, smoking cessation, alcohol consumption, and stress management), (6) both supervised and home-based PA sessions, (7) assessments of fitness, and (8) face-to-face counselling from exercise specialists regarding PA within a community-based exercise program to support long-term PA adherence.<sup>40</sup>

### *Medical Research Council Development Stage 2*

*Application of theoretical framework to inform intervention development.* The target behavior selected for the MedEx IMPACT intervention, upon completion of stage 1 of the BCW process, was to increase cancer survivors’ levels of PA. Factors that influence cancer survivors’ capability, opportunity, and motivation to be physically active were identified through the BCW, TDF, and findings from the focus groups (see Supplementary Additional File 3). The salient COM-B and TDF constructs that were identified were mapped to 5 intervention functions and 35 BCTs which were included within the MedEx IMPACT intervention. Table 4 provides an overview of the

**Table 3.** Statements of Findings Generated From the Review of the Literature to Inform the Intervention Development Process.

Statements of Findings (Generated From Literature That Investigated the Determinants of Physical Activity Behavior, Adherence, or Maintenance Among Survivors of Cancer)	Source, First Author, Year
1. BMI, emergency room visits in the past year, and number of comorbidities were associated with lower levels of PA among overweight or obese breast cancer survivors.	<sup>a</sup> Liu et al, 2016 <sup>14</sup>
2. Baseline fatigue and chronic musculoskeletal symptoms were significant determinants of PA maintenance accounting for 20% of the variance among survivors of breast cancer following participation in a community-based PA program.	<sup>a</sup> Lee et al, 2016 <sup>45</sup>
3. Colorectal cancer survivors at risk for physical inactivity were those with low perceived behavioral control for PA, low social norm for PA, who had neuropathy and were older.	<sup>a</sup> Packel et al, 2015 <sup>46</sup>
4. Older age, higher body mass index, lower self-efficacy, and less social support were significantly correlated with lower PA among breast cancer survivors.	<sup>b</sup> Kampshoff et al, 2016 <sup>47</sup>
5. Task self-efficacy played a more important role in exercise adoption among post-treatment breast cancer survivors, whereas barrier self-efficacy played a more important role in exercise maintenance.	<sup>a</sup> Short et al, 2014 <sup>48</sup>
6. Higher task self-efficacy for resistance training and greater goal-setting behavior were identified as significant predictors of meeting the resistance training guidelines among post-treatment breast cancer survivors.	<sup>a</sup> Short et al, 2014 <sup>48</sup>
7. Breast cancer survivors with poorer quality of life and higher fatigue, as well as those reporting lower confidence to change behaviors and overcome barriers, less social support, and use of goal setting may be most in need of physical activity intervention and/or additional support during intervention.	<sup>a</sup> Short et al, 2014 <sup>48</sup>
8. General self-efficacy and enjoyment were fundamental and important determinants in explaining PA among breast cancer survivors. In contrast, the relationship between social support, lack of time, and lack of company, and PA was more dynamic and dependent on the working status of the women. Only in working breast cancer survivors did lack of time and lack of company prevent PA, whereas social support from partner and friends contributed to more PA.	<sup>a</sup> Charlier et al, 2013 <sup>49</sup>
Statements of Findings (Generated From Literature That Investigated Physical Activity Behavior Change Interventions for Survivors of Cancer)	Source, First Author, Year
9. Community-based interventions that met in groups and used behavior change strategies (eg, cognitive behavioral therapy) produced the largest improvement in physical functioning among survivors of cancer.	<sup>b</sup> Swartz et al, 2017 <sup>50</sup>
10. Interventions that were associated with increased PA behavior among cancer survivors shared common characteristics, including <ul style="list-style-type: none"> <li>• self-monitoring or coaching techniques in various combinations, with varying media, eg, several studies supplied research-grade pedometers or accelerometers to participants, in addition to self-report tools, a strategy known to support measurement validity and help participants monitor their progress.</li> <li>• workshops (including PA-specific and nonspecific workshops) and/or peer support groups of some kind during the intervention.</li> <li>• individual counselling to motivate participants and address barriers to PA.</li> <li>• home exercise and walking as the primary type of exercise were emphasized in all the interventions in some form, which has also been a successful component in lifestyle studies with similar populations.</li> </ul>	<sup>b</sup> Bluethmann et al, 2015 <sup>51</sup>
11. An intervention based on social cognitive theory that included supervised and home-based exercise sessions, face-to-face counselling sessions with an exercise specialist, and group discussion sessions regarding self-efficacy, exercise barriers, behavioral capability, goal setting with self-monitoring, behavioral modification strategies, time management, stress management, safety, cognitive reframing, relapse prevention, and role models was effective in increasing PA, aerobic fitness, and quality of life among survivors of breast cancer.	<sup>a</sup> Rogers et al, 2015 <sup>52</sup>
12. Interventions that combine supervision of exercise training in tandem with a requirement for independent exercise are likely to promote better adherence to PA among cancer survivors.	<sup>b</sup> Bourke, 2013 <sup>12</sup>
13. Programming set goals, prompting self-monitoring and practicing and generalizing behavior are common features of interventions that have reported better adherence to PA among cancer survivors.	<sup>b</sup> Bourke et al, 2013 <sup>12</sup>

Abbreviations: BMI, body mass index; PA, physical activity.

<sup>a</sup>A primary research paper

<sup>b</sup>A systematic review, meta-analysis, and/or review paper.

mapping process and links intervention components with the selected BCTs. For example, within the supervised exercise classes, exercise instructors demonstrate how exercises (eg, squats, lunges) should be performed and subsequently provide participants with feedback regarding their technique. As such,

the supervised exercise classes were mapped to the BCTs of “4.1 Instruction on how to perform the behavior” and “2.2 Feedback on behavior.” Table 5 provides an overview of the mapping process between the intervention components and the COM-B model, TDF, and the selected intervention functions.

**Table 4.** Mapping of the MedEx IMPACT Intervention Components to the Selected Behavior Change Techniques.

Behavior Change Techniques	Intervention Components						
	Supervised Exercise Classes	Physical Activity Manual	Physical Activity Logbook	Pedometer	Physical Activity Information Sessions	1:1 Exercise Consultation	Assessments of Physical and Psychological Health
1.1 Goal setting behavior					✓	✓	✓
1.2 Problem solving					✓	✓	✓
1.3 Goal setting (outcome)					✓	✓	
1.4 Action planning					✓	✓	✓
1.5 Review behavior goal(s)					✓	✓	✓
1.6 Discrepancy between current behavior and goal					✓	✓	
1.7 Review outcome goal(s)					✓	✓	
1.8 Behavioral contract					✓	✓	
1.9 Commitment					✓		
2.2 Feedback on behavior	✓	✓	✓	✓		✓	✓
2.3 Self-monitoring of behavior	✓	✓	✓	✓	✓	✓	
2.4 Self-monitoring of outcome of behavior	✓	✓	✓	✓	✓	✓	
2.6 Biofeedback							✓
2.7 Monitor and provide feedback on the outcome of performance of the behavior	✓					✓	✓
3.1 Social support (unspecified)	✓				✓	✓	✓
4.1 Instruction on how to perform the behavior	✓	✓			✓		
5.1 Information about health consequences					✓		
5.2 Salience of consequences					✓		
5.3 Information about social and environmental consequences					✓		
5.4 Monitoring of emotional consequences					✓	✓	
5.6 Information about emotional consequences					✓		
6.1 Demonstration of the behavior	✓	✓					
7.1 Prompts/cues					✓		
8.1 Behavioral practice/rehearsal	✓	✓	✓	✓	✓	✓	
8.2 Behavior substitution						✓	
8.3 Habit formation		✓	✓	✓	✓	✓	
8.4 Habit reversal						✓	
8.6 Generalization of a target behavior	✓	✓	✓		✓	✓	
8.7 Graded tasks	✓	✓	✓	✓	✓	✓	
9.1 Credible source					✓		
9.2 Pros and cons					✓		
12.1 Restructuring the physical environment					✓	✓	
12.2 Restructuring the social environment					✓	✓	
15.1 Verbal persuasion about capability					✓	✓	
15.3 Focus on past success					✓	✓	✓

Abbreviation: IMPACT, IMprove Physical Activity after Cancer Treatment.

**Table 5.** Mapping of the MedEx IMPACT Intervention Components to the COM-B Model, TDF, and the Selected Intervention Functions.

Intervention Component	COM-B Constructs	TDF Constructs	BCW Intervention Functions
Supervised exercise classes	Capability—physical and psychological	Knowledge Skills Memory, attention, and decision processes	Education Training Environmental restructuring
	Opportunity—physical and social	Behavioral regulation Environmental context and resources Goals	Enablement
Physical activity manual	Capability—physical and psychological	Knowledge Skills Memory, attention, and decision processes	Education Training Environmental restructuring
	Opportunity—physical	Behavioral regulation Environmental context and resources Goals	Enablement
Physical activity logbook	Capability—psychological	Knowledge Skills Memory, attention, and decision processes	Education Training Environmental restructuring
	Motivation—Reflective	Behavioral regulation Environmental context and resources Goals	Enablement
Pedometer	Capability—psychological	Knowledge Skills Memory, attention, and decision processes	Education Training Environmental restructuring
	Motivation—reflective and automatic	Behavioral regulation Environmental context and resources Goals	Enablement
Physical activity information sessions	Capability—psychological	Knowledge Memory, attention, and decision processes	Education Persuasion
	Opportunity—physical and social	Behavioral regulation Beliefs about capabilities Beliefs about consequences	Training Environmental restructuring
	Motivation—reflective and automatic	Goals Environmental context and resources	Enablement
1:1 Exercise consultation	Capability—psychological	Knowledge Skills Memory, attention, and decision processes	Education Persuasion
	Opportunity—physical and social	Behavioral regulation Beliefs about capabilities Intentions	Training Environmental restructuring
	Motivation—reflective and automatic	Goals Reinforcement	Enablement
Assessments of physical and psychological health	Motivation—reflective and automatic	Knowledge Environmental context and resources Behavioral regulation Beliefs about capabilities Beliefs about consequences Goals Reinforcement	Education Persuasion Environmental restructuring Enablement

Abbreviations: BCW, Behaviour Change Wheel; COM-B, Capability, Opportunity, and Motivation Model of Behavior; IMPACT, IMprove Physical Activity after Cancer Treatment; TDF, Theoretical Domains Framework.

*Operationalizing findings into intervention components.* Table 6 details the mapping of focus group recommendations and statements of findings generated from the review of the literature to intervention components. In the first column in Table 6, relevant papers which supported focus groups findings are listed. This is to aid the incremental advances within this area through synthesis of existing evidence-building within intervention development.

### Medical Research Council Development Stage 3

*Stakeholder expert panel findings.* An overview of the feedback from the SEP is reported in Supplementary Additional File 4 under the following headings: (1) description of expert feedback; (2) illustrative quote of the issue, and (3) recommendation/how it is addressed within the MedEx IMPACT intervention.



**Table 6.** Mapping of Focus Group Recommendations and Statements of Findings Generated From the Review of the Literature to the MedEx IMPACT Intervention Components.

Associated Statements of Findings: Statement Number		Focus Group Recommendation	Intervention Component
1 <sup>14</sup> 3 <sup>46</sup> 4 <sup>47</sup> 5-7 <sup>48</sup> 8 <sup>49</sup>	9 <sup>50</sup> 10 <sup>51</sup> 11 <sup>52</sup> 12-13 <sup>12</sup>	Individualized exercise prescription  Exercising as part of a group of individuals who have completed treatment for cancer  Supervised exercise classes and a home-based exercise program	Supervised exercise classes
1 <sup>14</sup> 3 <sup>46</sup> 4 <sup>47</sup> 5-7 <sup>48</sup> 8 <sup>49</sup>	9 <sup>50</sup> 10 <sup>51</sup> 11 <sup>52</sup> 12-13 <sup>12</sup>	Supervised exercise classes and a home-based exercise program	Physical activity manual
1 <sup>14</sup> 3 <sup>46</sup> 4 <sup>47</sup> 5-7 <sup>48</sup> 8 <sup>49</sup>	9 <sup>50</sup> 10 <sup>51</sup> 11 <sup>52</sup> 12-13 <sup>12</sup>	Goal setting and action planning  Quantifying and measuring physical activity	Physical activity logbook
1 <sup>14</sup> 3 <sup>46</sup> 4 <sup>47</sup> 5-7 <sup>48</sup> 8 <sup>49</sup>	8 <sup>49</sup> 9 <sup>50</sup> 10 <sup>51</sup> 12-13 <sup>12</sup>	Quantifying and measuring physical activity	Pedometer
1 <sup>14</sup> 3 <sup>46</sup> 4 <sup>47</sup> 5-7 <sup>48</sup> 8 <sup>49</sup>	9 <sup>50</sup> 10 <sup>51</sup> 11 <sup>52</sup> 12-13 <sup>12</sup>	Face-to-face counselling from exercise specialists regarding physical activity  Individualized exercise prescription  Goal setting and action planning	Physical activity information sessions
1 <sup>14</sup> 3 <sup>46</sup> 4 <sup>47</sup> 5-7 <sup>48</sup> 8 <sup>49</sup>	9 <sup>50</sup> 10 <sup>51</sup> 11 <sup>52</sup> 12-13 <sup>12</sup>	Individualized exercise prescription  Goal setting and action planning	1:1 exercise consultation
1 <sup>14</sup> 2 <sup>45</sup> 4 <sup>47</sup> 5-7 <sup>48</sup> 8 <sup>49</sup>	9 <sup>50</sup> 11 <sup>52</sup> 12-13 <sup>12</sup>	Goal setting and action planning  Fitness assessments	Assessments of physical and psychological health

Abbreviation: IMPACT, IMprove Physical Activity after Cancer Treatment.

The range of experts deemed that the intervention was acceptable and would educate, motivate, and encourage participants attending the 12-week program to continue to be physically active upon completion of the supervised exercise classes. A number of recommendations to optimize intervention implementation and impact were proposed and are presented in Supplementary Additional File 4. An example of feedback received from the SEP was that within the 1:1 exercise consultations, there was the potential for participants to disclose or discuss issues of a personal/sensitive nature that may not directly relate to PA participation. To address this, the lead investigator (MC) MC responsible for intervention

implementation received training from a cancer patient support services coordinator regarding how the boundaries of consultations could be clearly defined to ensure participants were aware of the aims of the session. Members of the research team involved in intervention delivery received training from MC following this session. Protocols were also developed to clearly describe how issues raised by participants, which were beyond the scope of the intervention, should be addressed. This included identifying external support services that participants could be sign-posted and/or referred to.

An overview of the proposed components and timeline for the MedEx IMPACT intervention are presented in Tables 7 and

**Table 7.** The Components of the MedEx IMPACT Intervention.

Intervention Component	Description
Supervised exercise classes	Participants attend a community-based exercise program <sup>a</sup> that consists of two 60-minute supervised exercise classes each week for 12 weeks.
Independent physical activity program	This consists of a PA manual, a pedometer, and a PA logbook. Participants receive these materials in week 4 of the 12-week program.
Physical activity manual	Participants receive a PA manual and are encouraged to supplement attendance at the supervised exercise classes with use of this manual at home.
Pedometer	Participants receive a research-grade pedometer and are encouraged to wear the pedometer daily.
Physical activity logbook	Participants receive a PA logbook and are encouraged to record their daily step counts and minutes of PA.
Physical activity information sessions	Participants attend four 30-minute PA information sessions in weeks 0, 4, 6, and 10 of the intervention. Session 1 discusses the benefits of PA for health and an overview of the MedEx IMPACT. Intervention is presented. Issues and concerns for being physically active after cancer treatment are also discussed. Session 2 focuses on introducing participants to the PA manual, pedometer, and PA log book. Session 3 focuses on setting individualized PA goals. The group discusses challenges to PA participation and solutions to overcome these difficulties. Session 4 focuses on reviewing PA goals. Long-term strategies to support habitual PA and manage lapses in PA behavior are discussed.
1:1 Exercise consultation	Participants attend a 15-minute 1:1 exercise consultation in week 10, 11, or 12 of the intervention which focuses on developing an individualized action plan for PA to guide PA upon completion of the supervised exercise classes.
Assessments of physical and psychological health	Participants complete assessments of physical function, PA levels, and quality of life at baseline and months 3, 6, and 12. Participants attend a group exercise consultation at each assessment and receive feedback reports at months 3, 6, and 12.

Abbreviations: IMPACT, IMprove Physical Activity after Cancer Treatment; PA, physical activity.

<sup>a</sup>A community-based exercise rehabilitation program is defined, in this instance, as a supervised, structured, group exercise program that takes place in a community-based setting, such as a local gym or sports hall.

8. Supplementary Additional File 5 includes the Template for Intervention Description and Replication (TIDieR) checklist to ensure the completeness of reporting and replicability of interventions.<sup>53</sup>

## Discussion

The aim of this article was to systematically describe the development of the MedEx IMPACT intervention, a multi-component PABC intervention that aims to increase cancer survivors' PA levels. This intervention extends behavioral science methodology as it is, to the authors' knowledge, the first PABC intervention for survivors of cancer that has been developed using the MRC framework for the development, implementation, and evaluation of complex interventions, the BCW and TDF.

Theoretically informed interventions have the potential to increase the efficacy of PABC interventions for survivors of cancer by providing a valuable insight into the relation between targeted constructs and their impact on the desired behavior.<sup>23</sup> However, the application of theory within PABC studies for individuals living with and beyond cancer is generally poor, with many studies failing to outline explicit links between the theoretical framework cited and the design, implementation, and evaluation of the intervention.<sup>23</sup> Systematic reporting and greater transparency regarding how theory has informed and is embedded within PABC interventions are required in order to further advance our understanding of its role in optimizing

intervention effectiveness and to facilitate intervention replicability.<sup>22,23</sup> The use of the TIDieR checklist is advocated to overcome insufficiently detailed reporting within interventions and assist the implementation of interventions in clinical practice.<sup>53</sup>

The development of the MedEx IMPACT intervention contributes to the advancement of implementation science and intervention design research by providing a detailed account of the intervention development process and clearly outlining how BC theory has informed, and been embedded within, a PABC intervention for individuals living with and beyond cancer. The systematic approach to the design process led to the development of a novel intervention that is patient-centered, evidenced-based and theoretically-informed. It is becoming increasingly recognized that implementation strategies are essential to achieving the full benefits of evidence-based health care.<sup>54</sup> The delivery of this intervention within a real-world setting will provide important insights regarding intervention implementation and effectiveness to that end. Given that the ultimate goal of intervention development is to optimize patient care, the need for an understanding of the factors that contribute to intervention success and/or failure is urgently needed in order to facilitate greater likelihood of intervention success and more appropriate resource allocation.<sup>40</sup>

As the burden of cancer continues to grow,<sup>2</sup> so too does the need to develop effective interventions that can support

**Table 8.** The Timeline for the MedEx Impact Intervention.

Week	Twice-Weekly Supervised Exercise Classes	Physical Activity Manual (Used to Supplement Attendance at Supervised Exercise Classes) <sup>a,b</sup>	Pedometer (Worn Daily) <sup>b</sup>	Physical Activity Logbook (Records Kept Daily) <sup>b</sup>	Physical Activity Information Sessions	1:1 Exercise Consultation <sup>c</sup>	Assessments of Physical and Psychological Health
0					✓		✓
1	✓						
2	✓						
3	✓						
4	✓	✓	✓	✓	✓		
5	✓	✓	✓	✓			
6	✓	✓	✓	✓	✓		
7	✓	✓	✓	✓			
8	✓	✓	✓	✓			
9	✓	✓	✓	✓			
10	✓	✓	✓	✓	✓	✓	
11	✓	✓	✓	✓		✓	
12	✓	✓	✓	✓		✓	✓
24							✓
52							✓

Abbreviation: IMPACT, IMprove Physical Activity after Cancer Treatment.

<sup>a</sup>Participants are encouraged to supplement attendance at the supervised exercise classes with (1)  $\geq 1$  independent exercise session(s) from week 4-8, (2)  $\geq 2$  independent exercise sessions from week 9-12.

<sup>b</sup>Participants are encouraged to continue use of this component of the intervention following completion of the 12-week supervised exercise classes.

<sup>c</sup>The exercise consultation took place in either week 10, 11, or 12.

individuals living with and beyond cancer to become habitually physically active, optimize their physical and psychosocial well-being, and reduce their risk of cancer morbidity and mortality.<sup>12,20</sup> The potential impact of previous PABC interventions may have been limited due to a poor understanding of the needs and challenges facing survivors of cancer in adopting PA and the poor application/lack of theory within the intervention development process. Selected intervention strategies may be chosen to overcome expected barriers based on previous experience, as opposed to systematically identifying salient barriers for the chosen population prior to intervention implementation.<sup>54</sup> In addition, health care professionals may not be providing sufficient guidance to survivors of cancer to achieve PA adoption and adherence due to a lack of knowledge of PA prescription for survivors of cancer and a lack of resources regarding PA for this population.<sup>55</sup>

As individuals' PA behavior can be affected by cancer type, treatment modality, and stage of the cancer journey, it is essential that intervention designers identify the motivators and barriers to PA participation that are salient to the cancer cohort that an intervention is intended to benefit. This information can inform a more appropriate selection of BCTs to support the desired BC and could therefore contribute to an increased likelihood of intervention success.

### Strengths and Limitations

Although many previous PABC interventions for survivors having cancer have reported using theory, the majority fail to provide a transparent overview of how theory has informed and is embedded within interventions. This research aims to address this gap within the scientific literature and enable greater transparency to assist with future intervention replication. Another strength of this work is how data derived from a number of sources were synthesized to inform and guide the intervention development process and thus enabled the development of an intervention that is patient-centered, evidenced-based, and theoretically-informed.

The scientific literature that was used to inform the development of MedEx IMPACT largely focused on survivors of breast, prostate, and colorectal cancer. Focus group recommendations were obtained from the intended intervention end users. As such, the BCTs embedded within the intervention may not be salient to other cancer cohorts who were not represented and therefore not generalizable to the broader community of individuals living with and beyond cancer. Future research which investigates the implementation and evaluation of MedEx IMPACT within cohorts of survivors of cancer who have had less common cancer diagnoses and in different socioeconomic settings is therefore warranted.

## Conclusion

The integration of patient developed recommendations with evidence from the scientific literature and theoretical frameworks of BC could assist in the development of effective PABC interventions for survivors of cancer. The absence of this combined approach may have contributed to the dearth of effective interventions for this population to date. The synthesis of findings from this formative research guided by the MRC framework, BCW, and TDF has resulted in the development of a novel intervention to support increased PA participation by individuals living with and beyond cancer. The next phase in this research is to test the acceptability and effectiveness of the MedEx IMPACT intervention.

## Authors' Note

Ethical approval for the focus groups and stakeholder expert panel workshop was granted by the Dublin City University Research Ethics Committee (DCUREC/2015/203; DCUREC/2017/076). All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This article does not contain any studies with animals performed by any of the authors. Informed consent was obtained from all individual participants included in the study.

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## Supplemental Material

Supplemental material for this article is available online.

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