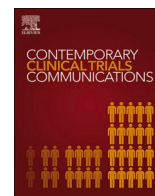


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Study protocol for the investigation of the clinical effectiveness of a physical activity behaviour change intervention for individuals living with and beyond cancer

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ABSTRACT

Most individuals living with and beyond cancer are not sufficiently active to achieve the health benefits associated with regular physical activity (PA). The purpose of this study was to describe the study protocol for a two-arm non-randomised comparison trial conducted within a community-based setting, which aimed to investigate the clinical effectiveness of a cancer-specific PA behaviour change (BC) intervention, namely MedEx IMPACT (IMprove Physical Activity after Cancer Treatment), compared to a general exercise rehabilitation programme, among survivors of cancer. Individuals who had completed active-cancer treatment who were referred to a community-based exercise rehabilitation programme were invited to participate in the trial. Participants in the control group (CG) attended twice-weekly supervised exercise classes for 12 weeks. Classes were delivered as part of a chronic illness exercise rehabilitation programme. Participants in the MedEx IMPACT intervention group (IG) also attended the twice-weekly supervised exercise classes for 12 weeks and received cancer-specific materials, namely an independent PA programme, 4 PA information sessions and a 1:1 exercise consultation. The primary outcome was PA levels measured by 6-day accelerometry and self-report PA. Secondary outcomes included cardiorespiratory fitness (CRF), quality of life (QoL) and sedentary behaviour. Outcomes were measured at baseline and months 3, 6 and 12. Few effective PA BC interventions for individuals living with and beyond cancer have been identified. The results of this study will have implications for the planning and provision of community-based exercise oncology rehabilitation programmes for individuals living with and beyond cancer.

1. Introduction

Regular physical activity (PA) is associated with reductions in the risk of cancer development and recurrence, and can assist in mitigating many of the negative side-effects associated with cancer treatment including fatigue and psychosocial distress [1,2]. Many individuals experience a decline in PA levels following a cancer diagnosis, which can persist during treatment and survivorship [3–6]. Indeed, the majority of individuals living with and beyond cancer do not achieve the minimum

recommended levels of daily PA [7–11]. Barriers to physical activity (PA) participation that have been reported by this population include environmental- (e.g. financial cost, weather), patient- (e.g. decreased confidence, lack of motivation, time constraints), and treatment-related (e.g. fatigue, reduced physical function, ill health, pain) barriers [12–14]. Effective PA behaviour change (BC) interventions are required to increase PA levels among individuals living with and beyond cancer [15].

The efficacy of PA interventions to increase physical and psycho-

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social well-being among survivors of cancer is well-established when investigated within controlled research settings [15]. However, due to the dearth of effectiveness trials, little is known about how to translate these findings into real-world programmes and services [15–17]. The need for research that prioritises the measurement and evaluation of implementation outcomes under real-world conditions within cancer survivorship has been highlighted, in order to identify strategies to support the successful implementation of exercise interventions in the oncology setting [18]. Knowledge translation studies that evaluate interventions within community-based settings are warranted in order to contribute real-world experiences that can inform decisions regarding programme development and dissemination [19].

Community-based exercise rehabilitation programmes (CBERPs) have been associated with a number of benefits for survivors of cancer including improvements in physical and psycho-social well-being, fatigue and quality of life (QoL) [19–21]. MedEx was a CBERP located at Dublin City University in Ireland that offered a general exercise rehabilitation programme to individuals living with different chronic conditions (e.g. cardiovascular disease, pulmonary disease). MedEx Move On (MMO), was the programme that provided such classes to individuals who had completed cancer treatment.

A cancer-specific, PA BC intervention, namely MedEx IMPACT (IMprove Physical Activity after Cancer Treatment), was specifically designed to be implemented and evaluated within the community-based setting of MMO. MedEx IMPACT aimed to increase cancer survivors' PA levels. A two arm non-randomised comparison trial was conducted to investigate the clinical effectiveness of MedEx IMPACT, as a cancer-specific PA BC intervention, versus MMO, a general exercise rehabilitation programme, in order to determine whether a cancer-specific PA BC intervention for this population would yield greater improvements. This paper describes the protocol for this trial.

Details of the development of MedEx IMPACT have been described in detail elsewhere [13,22]. In summary, recommendations, generated by individuals living with and beyond cancer ($n = 41$), for strategies to support long-term PA adherence [13] were combined with statements of findings generated from a review of literature that assessed the determinants of PA behaviour, adherence or maintenance among survivors of cancer, and strategies that were associated with intervention success in PA BC interventions for this population. Behavioural theory, in the form of The Behaviour Change Wheel [23] and Theoretical Domains Framework [24], was embedded within all intervention components. The application of behavioural theory within interventions may contribute to improved programme effectiveness [25,26]. A detailed account of how theoretical constructs and BCTs were embedded within the intervention has been described elsewhere [22]. The Medical Research Council's framework for the development and evaluation of complex interventions guided the intervention development process [27]. MedEx IMPACT is patient-centred, evidenced-based and theoretically-informed and could provide a novel and effective solution to support habitual PA among individuals living beyond cancer.

The primary aim of this trial was to compare the effects of MedEx IMPACT to MMO on short- and long-term PA levels among survivors of cancer. PA levels were assessed by both accelerometry and self-report at baseline and 3, 6 and 12 months. A secondary aim of the study was to compare the effects of MedEx IMPACT, to MMO, on cardiorespiratory fitness (CRF), QoL and sedentary behaviour. Tertiary aims included comparing the effects of the intervention versus MMO on body composition, strength, flexibility and fatigue. It was hypothesised that compared to MMO, participation in MedEx IMPACT would result in higher PA levels and greater improvements in secondary and tertiary outcomes at 3, 6 and 12 months. An exploratory analysis was conducted on psychosocial determinants of PA to examine the extent to which changes mediated PA BC.

2. Methods

2.1. Study design

The study utilised a two arm non-randomised comparison design consisting of an intervention group (IG) and a control group (CG). Both groups attended twice weekly supervised exercise classes for 12 weeks which were delivered as part of a general chronic illness rehabilitation programme. In addition, the IG received materials developed specifically for survivors of cancer, namely: i) an independent PA programme (which consisted of a PA manual, PA logbook and a pedometer), ii) 4 PA information sessions and iii) a 1:1 exercise consultation. Participants were recruited at induction to the MMO programme following referral by healthcare professionals. Participants completed assessments of physical and psychological health at baseline (T1 – pre-intervention), and 3 months (T2 – following completion of the 12-week programme), 6 months (T3 – 3 months post-intervention) and 12 months (T4 – 9 months post-intervention). Ethical approval was obtained from the Dublin City University Research Ethics Committee (DCUREC2014227; DCUREC2017128). The study algorithm is presented in [Appendix A](#).

2.2. Participants - Selection criteria (eligibility)

Adults ≥ 18 years of age with an established diagnosis of cancer who had completed treatment, had been referred to MMO, and given medical approval to participate in an exercise programme by a healthcare professional were recruited to participate in the study. Exclusion criteria were: i) an uncontrolled cardiovascular condition, ii) a significant musculoskeletal or neurological condition, or iii) a significant mental illness or intellectual disability that restricted participation in an exercise training programme. Decisions regarding what constituted a significant musculoskeletal or neurological condition, mental illness or intellectual disability were made by the Medical Director who oversaw the MedEx programme, and included conditions that would limit an individual's ability to effectively participate in the group-based exercise intervention.

MMO ran in cycles, with a new group of approximately 40–50 participants starting the programme every 12 weeks. Recruitment to the study occurred in cycles aligned with programme commencement dates. Individuals referred to 2 cycles of MMO between November 2015 and April 2016 were invited to participate in the control arm of the trial. Individuals referred to 2 cycles of the programme between September 2017 and January 2018 were invited to participate in the intervention arm of the trial. The programme was a user-pay model of community-based exercise rehabilitation.

2.3. Recruitment

Individuals referred to MMO were contacted with an appointment for induction. During this appointment, participants were provided with a comprehensive oral explanation of the study and a written plain language statement. Participants provided written consent prior to participating in the study. Participants assigned to the IG were advised that declining to participate in the intervention arm of the trial did not preclude them from participating in the supervised exercise classes only (i.e. MMO). Participants were recruited between November 2015–April 2016 and September 2017–January 2018.

2.4. Statistical power and sample size

G*Power software [28] was used to perform the sample size calculation. A retention goal was set at 64 participants (or 32 per group) which allowed detection of a small to medium effect size ($\rho = 0.40$ ($p < 0.05$, power of 0.80)). Unpublished data indicated a MMO drop-out rate between 20 and 50%. Consequently, a minimum of 60 participants were recruited to each group.

2.5. Procedure

Assessments of physical and psychological health were undertaken at baseline, and 3, 6 and 12 months. An overview of the assessment procedures is presented in [Appendix B](#).

Following referral, participants were invited to attend programme induction which occurred over 2 days. The control and intervention groups underwent the same induction process. On Day 1, participants were welcomed to the programme by the Medical Director and provided with information regarding programme logistics (i.e. car parking facilities, class times, access to the gym). Participants underwent a series of tests to measure height, weight, waist and hip circumference, lower and upper body strength and flexibility and completed a questionnaire that assessed self-reported PA, barriers specific self-efficacy for exercise, intentions for PA, social support for PA, fatigue and QoL. Participants were given an accelerometer and asked to return it when they attended for Day 2 of assessment, which was ≥ 6 days later. During this visit, participants completed an assessment of CRF and a second questionnaire which assessed psychological well-being, depression and self-regulatory self-efficacy for exercise.

Testing procedures were conducted by a team of experienced researchers. On occasions where participants were unable to attend the group-based assessments, individual appointments were scheduled and identical procedures and timeframes were adhered to.

2.6. Control group

Following induction and assessment, participants in the CG were advised to attend two 60-min supervised exercise classes each week for the 12-week period. The classes were delivered by accredited exercise instructors who had experience in delivering exercise oncology rehabilitation programmes. At least 2 exercise instructors were present at each class. Participants were supervised at a ratio of 1:15. The delivery of the programme was overseen by the MedEx Medical Director. Classes focused on a combination of aerobic and resistance exercise as detailed in the exercise prescription presented in [Table 1](#).

Assessments were repeated at 3, 6 and 12 months using identical procedures to those used at baseline. In addition, participants attended a group-based exercise consultation on the second assessment day, where they received an individualized feedback report detailing changes in their fitness (i.e. body composition, CRF, strength, flexibility). The group-based exercise consultations were delivered by researchers with expertise in health BC. The sessions were 15 minutes in duration and focused on discussing: i) the results of the feedback report, including tables of normative values for each variable, ii) successes and challenges experienced in adhering to PA and iii) strategies to overcome challenges identified and optimise long-term PA adherence. This group-based exercise consultation was part of usual care and was therefore offered to

Table 1

Exercise prescription for the supervised exercise classes.

Frequency	2 supervised exercise classes each week for 12-weeks
Intensity	Moderate to vigorous intensity. Participants were instructed to exercise at an intensity at which they were moderately breathless, had a red face and sweat.
Time	60 min including a 15-min warm up, 35-min main phase and 10-min cool-down.
Type	<ul style="list-style-type: none"> • Warm up and cool down: Combination of aerobic exercise, range of motion exercises and stretches. <p>The main phase for each class consisted of a combination of the below:</p> <ul style="list-style-type: none"> • Aerobic exercise: use of cardiorespiratory exercise equipment including treadmills, stationary bicycles, rowers and cross-trainers. • Resistance exercise: Inclusion of 10–15 exercises focusing on lower and upper body strength including body weight exercises, weight machines and free weights. • Instructor led exercise sessions: including step aerobics, circuits, total body resistance exercise (TRX) and spinning.

participants in both arms of the trial.

2.7. Intervention development

A novel approach to intervention development was adopted in the design of the MedEx IMPACT intervention and as discussed previously, has been described in detail elsewhere [[13,22](#)]. An overview of the resultant intervention is described below.

2.8. MedEx IMPACT intervention

In addition to 12 weeks of twice-weekly supervised exercise classes and assessments of physical and psychological health at baseline and months 3, 6 and 12, participants received an independent PA programme, 4 information sessions regarding PA and a 1:1 exercise consultation, which were specifically developed for survivors of cancer.

2.9. Independent physical activity programme

To encourage and support engagement in independent PA, in addition to participation in the supervised exercise classes, participants were given a PA manual, an SW-200 Yamax Digiwalker Pedometer (Yamax UK, Shropshire, United Kingdom), and a PA logbook (henceforth referred to as the independent PA programme). Participants were given this programme in week 4 of the 12-week supervised exercise programme.

2.10. Physical activity manual

The 43-page PA manual included information regarding the benefits of PA for individuals living with and beyond cancer, the PA guidelines for survivors of cancer, solutions for overcoming barriers to PA participation and strategies that could be implemented (e.g. goal setting, action planning, enlisting social support) to support long-term PA adherence and exercise sessions that could be completed at home without equipment. To foster use of the PA manual and support initiation/continuation of independent PA, participants were encouraged to supplement their attendance at the supervised exercise classes with the exercise sessions in the manual or other independent PA. At the end of the 12-week programme, participants were encouraged to use the independent PA programme to transition from the supervised classes to autonomous PA.

2.11. SW-200 Yamax Digiwalker Pedometer

Each participant received an SW-200 Yamax Digiwalker pedometer (Yamax UK, Shropshire, United Kingdom) which they were encouraged to wear daily and to continue wearing following completion of the 12-week supervised exercise programme.

2.12. Physical activity logbook

The PA logbook contained weekly templates for recording PA participation. The templates included prompts for the recording of the frequency, intensity, duration and type of PA performed as well as daily step count (as recorded by the pedometer). The template prompted participants to calculate their total weekly minutes of PA, record successes and challenges to PA participation experienced each week and develop a plan to address these challenges. The logbook also contained templates for setting and reviewing short-, medium- and long-term PA goals (at weeks 6, 10 and 20 of the intervention).

2.13. Physical activity information sessions

Participants were invited to attend four 30-min PA information sessions, after a supervised exercise class, in week 0 (on Day 2 of

assessment), 4, 6 and 10 of the 12-week programme. Sessions were delivered by an individual with expertise in chronic illness rehabilitation and motivational interviewing. Session 1 discussed the benefits of PA for health, and issues and concerns for being physically active after cancer treatment. An overview of the MedEx IMPACT intervention was also presented and participants were given a welcome pack which included print materials from a National Cancer Charity regarding other health behaviours associated with reducing cancer risk, namely smoking cessation, reduced alcohol consumption, healthy eating and sun safety. During session 2 the participants were introduced to the PA manual, pedometer and PA logbook. Session 3 focused on setting individualized PA goals, discussing challenges to PA participation and identifying solutions to overcome barriers that were identified. Finally, session 4 involved a review of the PA goals set during session 3 and discussed strategies to support habitual PA and lapses in PA participation.

2.14. Exercise consultation

Participants were invited to attend a 15 min 1:1 exercise consultation during week 10, 11 or 12 of the 12-week programme. The consultation focused on developing an individualized action plan for PA to guide PA participation upon completion of the supervised exercise classes. Consultations adopted a motivational interviewing style and were delivered by a team of 5 trained researchers with expertise in exercise consultation/prescription and oncology rehabilitation. The consultations included discussions regarding challenges to PA participation and strategies to overcome barriers to PA participation, and the development of a weekly plan for PA. Following the consultations, individualized action plans were typed, laminated and distributed during the last supervised exercise class. A timeline of the components of the MedEx IMPACT intervention is presented in Table 2.

3. Outcomes

Table 3 provides a tabulated summary of the study flow including the study schedule, assessments and primary, secondary and tertiary outcomes.

3.1. Primary study outcome

3.1.1. Physical activity levels

PA was objectively measured using six-day accelerometry

Table 2
The MedEx IMPACT intervention components and timeline.

Week	Twice-weekly supervised exercise classes	Physical activity manual (Used to supplement attendance at supervised exercise classes) ^{a,c}	Pedometer (Worn daily) ^c	Physical activity logbook (Records kept daily) ^c	Physical activity information sessions	1:1 Exercise consultation ^b	Assessments of physical and psychological health
0					✓		✓
1	✓						
2	✓						
3	✓						
4	✓	✓	✓	✓	✓		
5	✓	✓	✓	✓			
6	✓	✓	✓	✓	✓		
7	✓	✓	✓	✓			
8	✓	✓	✓	✓			
9	✓	✓	✓	✓			
10	✓	✓	✓	✓	✓	✓	
11	✓	✓	✓	✓		✓	
12	✓	✓	✓	✓		✓	✓
24							✓
52							✓

^a Participants were encouraged to supplement attendance at the supervised exercise classes with i) ≥ 1 independent exercise session(s) from week 4–8 (where appropriate), ii) ≥ 2 independent exercise sessions from week 9–12 (where appropriate).

^b The exercise consultation took place in either week 10, 11 or 12.

^c Participants were encouraged to continue use of this component of the intervention following completion of the 12-week supervised exercise programme.

(ActivPAL³ Micro (PAL Technologies Ltd. Glasgow, Scotland)). The ActivPAL³ Micro is a triaxial accelerometer that samples at 10 Hz for 15 s epochs. The device was covered with a water-resistant nitrile sleeve and attached to the midpoint of the anterior aspect of the right thigh using a 3M Tegaderm™ (Kooperationspartner Wundversorgung, Germany) film adhesive dressing. Participants wore the ActivPAL³ Micro 24 h a day from the time they received the device until they attended for Day 2 (≥6 days later). Participants were instructed to perform their usual activity and to remove the device only during full water immersion activities (i.e. swimming, bathing). Participants were given written and oral instructions regarding how to apply the monitor and contact information for the research team. On Day 2 of induction, the accelerometer data was downloaded and reviewed to ensure the wear-time criteria had been met (i.e. ≥ 4 valid days (incl. 1 weekend day)) [29]. A valid day was defined as ≥ 600mins of recording during daytime hours (7am-11pm) [30]. Non-wear time was defined as ≥ 60 min of consecutive zero accelerometer counts [31].

The ActivPAL™ proprietary software (ActivPAL™ Professionals VX) was used for the analysis, where algorithms classify activities into sitting/lying time, standing time, stepping time, step count and activity counts. Data was exported to Microsoft Excel (Microsoft Excel 2010, Microsoft Corporation, WA, USA) where data from each category (i.e. standing, stepping, etc.) was presented in 15s epochs. The total time spent sitting/lying, standing and stepping was calculated by summing the values for each 24-h period that the device was worn. Average values for each behaviour category were calculated. Moderate to vigorous PA was defined as ≥ 25 steps per 15s epoch [32]. Light-intensity PA was defined as activity performed <25 steps per 15s epoch excluding sitting, lying and standing.

Where possible, participants were asked to wear the device on a second occasion if wear-time criteria were not met. The primary outcome measure was indices of PA including weekly minutes of moderate-to-vigorous-, and light-intensity PA, and daily step count.

To facilitate comparison with the objective accelerometer data, participants were asked to complete the 7-day short International Physical Activity Questionnaire (IPAQ) [33]. The results from the IPAQ are reported in categories of PA (i.e. low, moderate and high levels of PA) and as a continuous variable (MET-minutes-per-week).

Table 3
Study flow.

Timeline	Study Period				
	Enrolment	Baseline	3 mth	6 mth	12 mth
Timepoint	T0	T1	T2	T3	T4
Enrolment:					
Eligibility screen	x				
Informed consent	x				
Demographic data	x				
Intervention:					
MedEx IMPACT Intervention Group		◆	◆		
MedEx Move On Control Group		◆	◆		
Assessments:					
<i>Primary outcome:</i>					
Physical activity					
Accelerometry		x	x	x	x
IPAQ		x	x	x	x
<i>Secondary outcomes:</i>					
Cardiorespiratory Fitness					
6-minute time trial		x	x	x	x
Health-related quality of life					
FACT		x	x	x	x
PHQ-8		x	x	x	x
SWLS		x	x	x	x
SWEMWBS		x	x	x	x
Sedentary behaviour		x	x	x	x
<i>Tertiary outcomes:</i>					
Other components of physical fitness					
Body composition		x	x	x	x
Strength		x	x	x	x
Flexibility		x	x	x	x
Fatigue		x	x	x	x
<i>Exploratory outcomes</i>					
Psychosocial determinants of physical activity					
Barriers specific self-efficacy		x	x	x	x
Self-regulatory self-efficacy for exercise		x	x	x	x
Social support for physical activity		x	x	x	x
Intentions for physical activity		x	x	x	x
<i>Process evaluation</i>					
Attendance data		x	x	x	x
Intervention debrief questionnaire				x	
Intervention debrief focus groups				x	

Abbreviations: MedEx (Medical Exercise); IMPACT (Improve Physical Activity after Cancer Treatment); IPAQ (International Physical Activity Questionnaire) FACT (Functional Assessment of Cancer Therapy questionnaire); PHQ-8 (Patient Health Questionnaire); SWLS (Satisfaction with Life Scale); SWEMWBS (Short Warwick-Edinburgh Mental Well-being Scale)

3.2. Secondary outcomes

3.2.1. Cardiorespiratory fitness (secondary study outcome #1)

CRF was assessed using the 6-minute time trial (6MTT) [34,35]. Participants were instructed to cover the greatest distance possible in 6 minutes while walking, running or a combination, between 2 cones on a flat indoor 20m course. No warm-up was permitted. Instructions for test participation were given to participants that were adapted from the American Thoracic Society guidelines for the 6-minute walk test [36]. The point on the course where the participant stopped was marked with a cone and the distance covered in the final partial lap was measured to the nearest metre. The total distance covered was calculated and recorded.

3.2.2. Quality of life (secondary study outcome #2)

QoL was measured using the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire [37]. The 27-item instrument includes sub-scales of physical well-being (PWB), social well-being (SWB), emotional well-being (EWB) and functional well-being (FWB). Sub-scale scores are calculated by multiplying the sum of responses given to each item on a 5-point Likert scale, by the total number of items in the subscale. This score is divided by the number of items answered to yield the final score. Overall QoL is measured by calculating the sum of scores to the sub-scales. Individuals with a breast, prostate or colorectal cancer diagnosis also completed the additional scales from the relevant FACT questionnaires (i.e. FACT-B (breast), FACT-P (prostate), FACT-C (colorectal)) [38–40]. Higher scores indicate greater quality of life.

In addition to the cancer-specific measure of QoL, global satisfaction with life was assessed using the Satisfaction with Life scale (SWLS) [41] and mental well-being, focusing entirely on positive aspects of mental health, was assessed using the short Warwick-Edinburgh Mental Well-being scale (SWEMWBS) [42]. The SWLS score is the product of the summed responses given by participants to 5 items on a 7-point Likert scale (1 = strongly disagree, 7 = strongly agree). The SWEMWBS is scored by first summing the score for each of the seven items and then transforming the total raw scores to metric scores using a conversion table. The Patient Health Questionnaire depression scale (PHQ-8) was used to assess levels of depression [43]. The score is the sum of the 8 items, where a score >10 indicates major depression and a score ≥20 indicates severe major depression.

3.2.3. Sedentary behaviour (secondary study outcome #3)

Sedentary behaviour characteristics were examined using a customized MATLAB® (version 7.0.1, The Mathworks Inc, Natick, MA, USA) software programme [31]. The programme has been described elsewhere [31]. In short, the programme analyses the ActivPAL data output file epoch by epoch and categorises bouts as sedentary or non-sedentary. Sedentary epochs are classified as a full epoch spent sitting/lying. Non-sedentary epochs are classified as <15s of sitting/lying. The number and duration of total sedentary bouts per day was calculated.

3.3. Tertiary outcomes

3.3.1. Body composition

Height and weight were measured using a stadiometer and electronic scale (model 707 balance scales: Seca GmbH, Hamburg, Germany). BMI was calculated using the equation body mass in kilograms divided by squared height in metres. Waist and hip circumference measurements were taken by the same trained researcher at all time points. The waist circumference measurement was taken at approximately the midpoint between the last palpable rib and the top of the iliac crest. The hip measurement was taken around the widest portion of the buttocks. Waist-to-hip ratio was calculated.

3.3.2. Muscular strength

The 10-repetition sit-to-stand test was used to assess lower body strength [44]. Participants completed the test twice and the fastest time taken to complete 10 sit-to-stands was recorded. A hand-held dynamometer was used to assess hand-grip strength in the dominant arm (Takei 5401 digital hand grip dynamometer, Takei Scientific Instruments Co. Ltd., Japan). The average of 3 attempts was recorded.

3.3.3. Flexibility

Flexibility was measured using a modified sit and reach test [45]. Participants were asked to sit on a bench with their legs fully extended and feet flat against the sit and reach box (Eveque Leisure Equipment Ltd, Cheshire, UK). Participants were asked to flex forward to reach their fingertips as far as possible along the measurement scale. The best of 3 attempts was recorded.

3.3.4. Fatigue

Fatigue was measured using the 13-item Functional Assessment of Chronic Illness Therapy – Fatigue scale (FACIT-F) [46]. Fatigue scores are calculated by summing the responses given to each item on a 5-point Likert scale. This number is multiplied by the total number of items in the scale and divided by the number of items answered to yield the final score. Higher scores indicate higher QoL.

3.4. Exploratory outcomes

3.4.1. Self-efficacy

Barrier specific self-efficacy for exercise was assessed using a validated 13-item scale [47]. Participants rated their confidence regarding their capability to be physically active in the presence of common barriers (e.g. bad weather, exercising alone) on a Likert scale from 0 (not confident at all) to 100 (very confident). The mean score was calculated.

Self-regulatory self-efficacy for exercise was assessed using a modified 11-item scale [48,49]. Questions focus on task, scheduling and recovery self-efficacy. Participants rated their confidence to be physically active on a Likert scale from 0 (not confident at all) to 100 (very confident). The mean score was calculated.

3.4.2. Social support

Social support from family and friends for PA was assessed using a 10-item validated tool [50]. On a 1–5 Likert scale, participants rated the degree of social support for PA that they receive from family and friends. The mean score was reported with higher values indicating greater social support for PA.

3.4.3. Intentions

To assess intentions for PA and intentions to attend the community-based exercise programme, a modified 6-item measure was used [51]. Participants recorded their responses on a Likert scale ranging from 1 (completely disagree) to 4 (totally agree). A higher score indicated greater intentions for PA/attendance at the community-based exercise programme.

3.4.4. Process evaluation

Objective attendance was recorded for all intervention components. Data regarding adherence to the supervised exercise classes (defined as the mean percentage of classes attended from a maximum of twice-weekly classes for 12 weeks), and percentage of the allocated intervention received will be reported.

All participants were asked to complete an intervention debrief questionnaire at 6-month follow-up (T3). The debrief questionnaire was used to develop an understanding of the participants' experiences and opinions regarding the intervention, and their independent PA participation, upon completion of the 12-week programme. The 25-item investigator-developed questionnaire aimed to explore participants' attitudes towards, and experiences of, each intervention component.

To further explore the feedback received from participants regarding their experiences of the intervention, 4 intervention debrief focus groups (n = 18) were conducted by a trained qualitative researcher. The purpose of the focus groups was to gain an in-depth understanding of participants' experiences of each intervention component and how the programme could be optimised for future implementation. Purposive sampling was undertaken to recruit male and female survivors of cancer of all ages.

Process evaluation data will be used to determine the acceptability of the intervention by survivors of cancer.

3.5. Statistical methods

3.5.1. Quantitative analysis

Data was entered into SPSS statistics software (version 24) (IBM, New York, United States). Demographic and baseline characteristics of all participants will be summarized. Continuous variables will be reported as estimated marginal means \pm standard error. Categorical variables will be reported as n and percentages. To investigate treatment effects (i.e. CG vs. IG) on dependent variables across the 3 time points, adjusted linear mixed model analyses of variance will be conducted. The Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC) will be used as metrics to determine which covariance and model structure are most appropriate. Contrast estimates will be conducted as a post-hoc analysis. A two-sided p value < 0.05 will be used to determine statistical significance.

In an analysis of the exploratory outcomes, adjusted linear mixed model analyses of variance will be conducted that include social support- (from family and friends), intentions- and self-efficacy (barrier and self-regulatory) for PA as covariates to investigate their effect on indices of PA, CRF and QoL.

3.5.2. Qualitative analysis

Audio material from the focus groups will be transcribed verbatim. Thematic analysis (TA) as outlined by Braun and Clarke [52] will be conducted using NVivo qualitative data analysis software (version 10 for Windows) (QSR International UK Ltd., Cheshire, United Kingdom). The TA will include a 6-step approach to analysis which will encompass exploration of initial codes and themes, systematically coding interesting data across transcripts, collating potential themes, developing thematic maps and refining and defining themes. An inductive approach to the identification of themes will be adopted.

4. Discussion

In an agenda for translating PA, nutrition and weight management interventions for survivors of cancer into clinical and community practice, Basen-Engquist and colleagues [53] highlighted the need to expand dissemination and implementation research to test models for service delivery of evidence-based interventions. Previous research had focused primarily on internal validity, with little attention to translation to real-world settings [53]. Indeed, a review of the National Cancer Institute's research portfolio of lifestyle interventions for individuals living with and beyond cancer highlighted the dearth of dissemination and implementation research available in this area [54]. This study aims to address this gap by evaluating the effectiveness of delivering a PA BC intervention for survivors of cancer within a community-based setting. Findings from this research have the ability to have an immediate impact on programme delivery and therefore minimise the delay in optimising patient outcomes. The inclusion of both quantitative and qualitative research methods within the evaluation will ensure that data regarding the impact of the intervention on indices of physical and psycho-social health, as well as participants' experiences and recommendations for intervention improvement, will be captured. Such information is vital to inform intervention refinement, future replication and sustainability.

A limitation of previous research has been the use of subjective measures of PA, which are subject to multifarious bias, and short-term follow-up procedures, which inhibit assessment of intervention effectiveness on long-term PA adherence [7,11]. The significance of this research is further strengthened by the use of an objective measure of PA and the inclusion of long-term follow-up procedures.

To the authors knowledge, MedEx IMPACT is the first PA BC intervention for individuals living with and beyond cancer to be developed using the BCW and TDF, coupled with recommendations generated by survivors of cancer and statements of findings distilled from a review of the literature. This unique approach to intervention development aims to ensure that the intervention is relevant and meaningful to the intended population, while also building upon findings from previous scientific literature to further advance our understanding of long-term adherence to PA for individuals living with and beyond cancer.

Social support can act as a coping strategy for individuals who have been affected by cancer and is positively associated with PA participation [55,56]. Group-based PA programmes are common in the oncology setting [57]. Research has reported the benefits of social support associated with these types of programmes, including their ability to create an accepting and supportive exercise environment where changes in physical appearance and/or functional capacity, caused by cancer and its treatment, are non-judgementally accepted and understood [13,58]. The COVID-19 pandemic has necessitated further exploration and application of alternate delivery models for services, programmes and research efforts that aim to support increased PA participation by individuals with and beyond cancer (e.g. e- and m-Health programmes). While existing evidence indicates that e- and m-Health interventions may contribute to improvements in cancer survivors' quality of life, PA levels and body mass index [59,60], how in-person social support for PA can be effectively re-created in a remote setting is not yet well understood. Faro and colleagues explored strategies to support cancer survivors' PA and social health during and after COVID-19 [61]. Results showed that while individuals expressed an interest in online PA programmes, during (28%) and after (51%) the pandemic, a significant proportion (up to 43% of respondents) had a preference for PA that incorporated in-person interaction [61]. Social support for PA was deemed important by respondents, and in-person strategies for social support for PA were the most popular, as reported by almost 70% of respondents, in comparison with remote methods (e.g. video calls, social media groups, texting) [61]. While the COVID-19 pandemic may have accelerated research efforts in, and increased receptiveness and interest among individuals living with and beyond cancer to, online PA programmes, it has not eliminated the need for in-person programmes for many within this population. Indeed, as the world transitions to a post-pandemic era, future research that investigates determinants for PA among survivors of cancer who are given the option to self-select the delivery mode for a PA programme from a menu-based approach, that offers remote, in-person and a hybrid delivery (i.e. combined remote and in-person) could provide valuable evidence to better inform the allocation of scarce resources to fund PA programmes and services for this population.

The inclusion of BC theory within exercise interventions is often viewed as essential [11] and has been proposed as a mechanism for optimising the effectiveness of BC interventions [25,26]. BC theory can link relevant causal factors of the target behaviour to mechanisms of change, and can provide valuable insight into how theory integration within intervention design, implementation and evaluation may contribute to desired changes in the target behaviour [25,62]. Despite this, the application of BC theory is often poor, ambiguous and seldom analysed in the context of intervention effectiveness [11]. A detailed analysis of how theoretical constructs and BCTs have been embedded within MedEx IMPACT has been published [22]. An examination of the theoretical constructs will provide an insight into how changes in PA behaviour are mediated, and may provide valuable information for intervention designers by highlighting key constructs that should, or

should not, be targeted within PA BC interventions for individuals living with and beyond cancer.

MedEx IMPACT aimed to empower individuals living with and beyond cancer to become habitually physically active through the delivery of individual- and group-based components that taper to self-directed PA. Intervention sustainability and cost-effectiveness were important considerations in the intervention development process and further work to conduct formal assessments of both is planned. Maximising intervention quality and effectiveness with a low-tech and moderately-resource intensive community-based programme has been an important goal in designing this intervention.

The authors acknowledge that a limitation of this study is the absence of a non-exercise control group and randomisation procedures. As the study was conducted within an existing exercise rehabilitation programme, withholding access to the service to facilitate a more rigorous study design would have raised ethical concerns.

5. Conclusion

As the number of individuals living with and beyond cancer continues to grow, the need to identify effective PA BC interventions for this population and translate them into community settings has never been greater. Conducting intervention studies in this setting can provide actionable information that can be implemented with immediate effect and minimise the delay in optimising patient outcomes. The results of this study will provide such information and can inform the planning and provision of community-based exercise rehabilitation programmes for survivors of cancer.

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Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.conctc.2021.100882>.

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