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RESEARCH

A two-arm non-randomised trial of MedEx IMPACT: a community-based, physical activity behaviour change intervention for survivors of cancer

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Abstract

Purpose This two-arm non-randomised trial examined the short- and long-term effects of a usual care (UC) community-based exercise programme (MedEx Move On (MMO)), and UC combined with a physical activity (PA) behaviour change (BC) intervention (MedEx IMproved PA after Cancer Treatement (MedEx IMPACT)) on PA levels, cardiorespiratory fitness (CRF) and quality of life (QoL) among survivors of cancer.

Methods Cancer survivors referred to MMO were recruited ($n = 191$; mean age (± SD) 56 (± 10y), 73% female). Eighty-seven participants were assigned to UC, and 104 participants were assigned to the MedEx IMPACT intervention group (MI). UC and MI both received twice-weekly supervised exercise classes for 12-weeks. MI also received an independent PA programme, 4 PA information sessions and a 1:1 exercise consultation during the 12-week programme. Assessments of physical and psycho-social health, including 6-day accelerometry, the 6-min time trial and the Functional Assessment of Cancer Therapy-General QoL questionnaire, were conducted at baseline (T1), post-intervention (T2) and 3 months following programme completion (T3).

Results Linear mixed-model analyses of variance demonstrated significant main effects for time for both groups from T1 to T2 with increases in objectively measured daily steps ($p < 0.05$), CRF ($p < .001$) and QoL ($p < .01$), which were maintained for CRF ($p < .001$) at T3. MI participants also maintained increases achieved at T2, in steps and QoL, at T3 ($p < 0.01$).

Conclusion Twelve weeks of twice-weekly supervised exercise was effective in increasing PA, CRF and QoL among survivors of cancer. MI resulted in the maintenance of all improvements achieved 3 months following programme completion.

Keywords Physical activity · Cancer · Behaviour change

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Introduction

Treatment for cancer has been shown to negatively impact patients' physical and psycho-social well-being via decrements in a number of parameters including cardiorespiratory fitness (CRF) and quality of life (QoL) [1–6]. These reductions, in conjunction with poor nutritional status, are associated with prolonged hospitalisation, greater levels of treatment-related toxicity and poorer prognosis [2–4]. Cancer-related fatigue is the most frequently reported side-effect throughout the cancer journey, and is estimated to impact almost 1 in 2 survivors of cancer during treatment, and almost 1 in 3 in the context of survivorship [7, 8].

PA has been advocated as an adjunct to cancer treatment to assist in the management of treatment related side-effects and support the optimisation of patient outcomes [9, 10]. Indeed, exercise interventions have resulted in improvements in cancer-related fatigue, CRF, QoL, body composition and depression, and reductions in the risk of cancer recurrence and mortality [9–12]. The evidence demonstrating such benefits was conducted in controlled research settings [10, 12]. However, less is known about whether, or how, benefits obtained as part of exercise interventions conducted in such settings can be replicated and maintained when programmes are delivered in clinical- and community-based practice [13]. While knowledge in this area is growing [14–16], the available evidence provides only preliminary support for short term improvements across a relatively small number of outcomes, including PA, 6-min walk test distance and QoL [17–20]. The long-term impact of participating in community-based exercise programmes for survivors of cancer is currently not well understood [21]. Recent research has called for further studies to examine the effects of community-based exercise amongst more diverse cohorts of cancer survivors, while also examining a broad range of important clinical, physical, functional and psychological outcomes [15]. In addition, recommendations for future research have also advocated for the use of pragmatic study designs and the collection of follow-up data [14].

The purpose of this trial was twofold. Firstly, it aimed to determine the short- and long- term effects of MedEx Move On (MMO), a usual care (UC) community-based exercise programme, on the objective PA levels, CRF and QoL of a large, diverse sample of survivors of cancer. Secondly, it aimed to determine whether the inclusion of MedEx IMproved PA after Cancer Treatment (IMPACT), a low-tech PA intervention within MMO, which was tailored to cancer survivors' preferences and underpinned by behavioural theory, could achieve greater improvements, or maintenance of improvements, with regard to the outcomes assessed, 3 months following programme completion.

The development process and content of the MedEx IMPACT intervention has been described in detail elsewhere [22]. It was hypothesised that MedEx IMPACT in conjunction with MMO would result in significantly greater increases in PA levels (primary outcome), CRF and QoL (secondary outcomes) post-intervention (T2), and 3-months following intervention completion (T3 – primary end point).

Methods

Study design

The study protocol has been described in detail elsewhere [23]. In summary, this investigation utilised a two arm non-randomised comparison design consisting of a UC control group (UC), and the MedEx IMPACT intervention group (MI). Survivors of cancer who had been referred to MMO were recruited at induction to the programme. MMO ran in 12-week cycles. Recruitment to the study aligned with commencement dates for new cycles of the programme. Individuals referred to 2 cycles of the programme between November 2015 and April 2016 were assigned to UC. Individuals referred to 2 cycles of the programme between September 2017 and January 2018 were assigned to MI. Follow-up data collection was completed in August 2018. Trial completion was defined by completion of the 6-month re-assessment. All participants provided written informed consent before study procedures were initiated.

Setting and participants

The study was conducted in the leisure centre on the Dublin City University (DCU) campus. To be included in the study, participants had to: i) be $\geq$ 18 years of age, ii) have received a diagnosis of cancer and completed active treatment (e.g. chemotherapy, radiation therapy, surgery), iii) have received medical approval to participate in an exercise programme by a healthcare professional and iv) have been referred to MMO. Exclusion criteria included: i) an uncontrolled cardiovascular condition, ii) a significant musculoskeletal or neurological condition, or iii) significant mental illness or intellectual disability that restricted participation in an exercise training programme. Ethical approval for the study was granted by the DCU Research Ethics Committee (DCUREC2014227; DCUREC2017128).

Usual care control group (UC)

Participants in UC received 12 weeks of twice-weekly supervised exercise classes. As this study took place within the existing MMO service, the control group received the usual standard of care within this setting, and hence the term

'UC' has been applied to this group. Classes were led by exercise instructors accredited in Cardiac Prevention and Rehabilitation who had experience in delivering exercise oncology rehabilitation programmes. The programme also had medical oversight from its Chief Medical Officer (physician). The classes were 60 min in duration and focused on a combination of aerobic and resistance exercise. Participants were instructed to exercise at an intensity at which they were moderately breathless, had a red face and sweat. Staff adapted exercises and tailored sessions to meet the needs of those within the group in real time. Specific advice was shared with participants at induction regarding PA and side-effects participants may have been experiencing (e.g. participants with lymphedema were asked to always wear a compression garment when exercising).

Intervention group (MI)—MedEx improved physical activity after cancer treatment (IMPACT) intervention

The MedEx IMPACT intervention is a PA BC intervention designed to increase PA levels among cancer survivors [22]. In brief, the intervention development process was guided and informed by: i) the Medical Research Council's (MRC) framework for the development, evaluation and implementation of complex interventions [24], ii) the Behaviour Change Wheel (BCW) [25], iii) the Theoretical Domains Framework (TDF) [26], iv) findings from a review of the literature [22] and v) recommendations generated by survivors of cancer [27].

Further detail regarding the intervention content can be found elsewhere [22]. In summary, in addition to 12 weeks of twice-weekly supervised exercise classes, participants in MI also received an independent PA programme which consisted of a PA manual, PA logbook and a pedometer (SW-200 Yamax Digiwalker Pedometer, Yamax UK, Shropshire, United Kingdom), 4 PA information sessions and a 1:1 exercise consultation. The 30-min PA information sessions were held during weeks 0, 4, 6 and 10 of the programme and examined topics including benefits and barriers to PA after cancer, strategies for PA maintenance and relapse prevention and familiarisation with intervention resources (e.g. pedometer, PA manual, logbook). An individual with expertise in chronic illness rehabilitation and motivational interviewing delivered the sessions. Participants were encouraged to supplement their attendance at the supervised exercise classes with use of the independent PA programme from week 4 and to progressively increase their levels of PA participation over the remaining 8 weeks of the programme. Participants were invited to attend a 15-min 1:1 exercise consultation in week 10, 11 or 12 of the programme to develop an individualised action plan for PA. Consultations were delivered by a team of 5 trained researchers with expertise in exercise consultation/prescription and oncology rehabilitation. Participants set individualised goals for PA (including a daily step count goal) during goal setting and reviewing activities completed within the PA information sessions and 1:1 exercise consultation.

Adherence to the supervised exercise classes was defined as the mean percentage of classes attended (from a max. of 24 classes). Participants were classified as not having received the allocated intervention according to the following criteria:

- did not attend ≥ 50% of the supervised exercise classes, and/or
- did not attend ≥ 50% PA information sessions, and/or
- did not receive the independent PA programme, and/or
- did not attend the 1:1 exercise consultation.

Outcome measures

Assessments of physical and psycho-social health were conducted at baseline (T1), post-intervention (T2) and 3 months following completion of the 12-week programme (T3—primary end-point), during 2 visits, that were separated by 6 days. A detailed overview of the outcomes measures has been previously described [23]. A summary is presented below.

Primary outcome variable

The primary outcome measure was indices of PA, namely minutes of light-intensity PA (LIPA), minutes of moderate-to-vigorous PA (MVPA) and daily step count as measured by the ActivPAL[3] Micro accelerometer (PAL Technologies Ltd. Glasgow, Scotland). As described in the study protocol [23], participants wore the device 24h a day from receipt of the device until they returned for Day 2 of assessment ≥ 6 days later. Wear-time criteria was set as > 4 valid days (incl. 1 weekend day) where a valid day was defined as ≥ 600min of recording during the hours of 7am-11pm. Non-wear time was defined as ≥ 60 min of consecutive zero accelerometer counts.

Secondary outcome variables

The 6-min time trial (6MTT) was used to assess CRF [28, 29]. Participants were instructed to walk, run or a combination of both, between 2 cones on a flat indoor 20m course in order to cover the greatest distance possible in 6 min. QoL was measured using the Functional Assessment of Cancer Therapy-General (FACT-G) questionnaire which is a validated 27-item measure that includes sub-scales for the assessment of physical, social, functional and emotional well-being [30].

Sample size calculation and statistical analyses

G*Power software [31] was used to perform the sample size calculation. A retention goal of 64 participants (or 32 per group) was set to facilitate detection of a small to medium effect size = 0.40 ($p < 0.05$, power of 0.80). Data from the MMO service indicated a MMO drop-out rate between 20–50%. Consequently, a minimum of 60 participants were recruited to each group.

The statistical analysis of the data was conducted using SPSS statistics software (version 24) (IBM, New York, United States). Descriptive statistics were conducted to summarize participants' demographic information and baseline characteristics. To investigate treatment effects (i.e. UC vs. MI) on dependent variables across the 3 time points, adjusted linear mixed model analyses of variance incorporating a diagonal or first-order autoregressive (AR1) covariance structure, and random intercept of within subject, were conducted. The Akaike Information Criterion (AIC) and the Bayesian Information Criterion (BIC) were used as metrics to determine which covariance and model structure was most appropriate. The random intercept was removed if a non-significant value was reported by the estimates of covariance parameters ($p > 0.05$). Parameter estimates were used to identify where differences occurred following a significant fixed effects value. Main and interaction effects were assessed. Contrast estimates were conducted as a post-hoc analysis to identify where significant main and/or interaction effects occurred. A two-sided p value < 0.05 was used to determine statistical significance. Where applicable, analyses were adjusted for covariates identified using univariate analyses. To test the hypothesises model, data were analysed using restricted maximum likelihood (REML).

Results

Participants

One-hundred and ninety-one survivors of cancer were referred to MMO between November 2015-April 2016 (UC participants, $n = 87$) and September 2017-January 2018 (MI participants, $n = 104$). All participants consented to participate in the study. Figure 1 presents the participant flow diagram. 51% of participants ($n = 98$) completed the trial (UC, $n = 47$; MI, $n = 51$). Participant baseline characteristics are presented in Table 1. Participants' mean age was 56 ± 10.5 years (UC = 57 ± 10.5yrs; MI = 56 ± 10.6yrs) and mean BMI was 28.3 ± 5.7 kg/m^2 (UC = 28.2 ± 5.2 kg/m^2; MI = 28.4 ± 6.0 kg/m^2). 73% of participants were female (UC = 70%; MI = 75%). Sixty per cent, 16%, 13% and 11% of participants had had a breast, colorectal, prostate or other cancer diagnosis respectively (UC = 57, 16, 16, 11%; MI = 63, 15, 10, 12%). UC and MI were from similar socio-economic backgrounds. At baseline, UC had a statistically significant lower 6MTT score (mean difference = -33m), and higher QoL (i.e., FACT-G (mean difference = + 3.34) and emotional well-being (mean difference = + 1.15) when compared to MI.

Adherence

Adherence to the supervised exercise classes was 66% (± 25%) (UC = 67 ± 22%; MI = 66 ± 27%). Eighty-seven per cent of MI participants received the independent PA programme and 68% attended the 1:1 exercise consultation. On average, participants attended 3 out of 4 (75%) of the PA information sessions.

A little over one third (36%, $n = 37$) of MI participants were classified as not having received the allocated intervention.

Tables 2 and 3 present an overview of the results for PA variables, CRF and QoL outcomes at T1, T2 and T3, including estimated marginal means (± standard error).

Primary outcome variable: physical activity levels

There was no statistically significant difference for any of the objectively measured PA variables ($p > 0.05$) between UC and MI across the 3 time points.

Statistically significant main effects for time were found for UC and MI for both steps (Fig. 2) and LIPA (Fig. 3), with improvements occurring from T1 to T2 for both UC and MI (UC: steps, $p = 0.015$, LIPA, $p = 0.020$; MI: steps, $p = 0.007$, LIPA, $p = 0.008$), and for MI from T1 to T3 (steps, $p = 0.007$; LIPA, $p = 0.003$). There was no significant change in step count or LIPA between T2-T3 in MI. No significant main effects or interactions were found for MVPA in both UC and MI ($n = 171$).

Secondary outcome variables

Cardiorespiratory fitness

There was no statistically significant difference between UC and MI for 6MTT score at any time ($n = 182$). Performance in the 6MTT increased significantly from T1 to T2 ($p < 0.001$), and T1 to T3 ($p < 0.001$) for both UC and MI. There was no significant difference in 6MTT in UC and MI between T2 and T3.

Quality of life

There was no significant difference between UC and MI for total FACT-G or physical-(PWB), emotional-(EWB) or functional-(FWB) well-being subscales across the 3 time

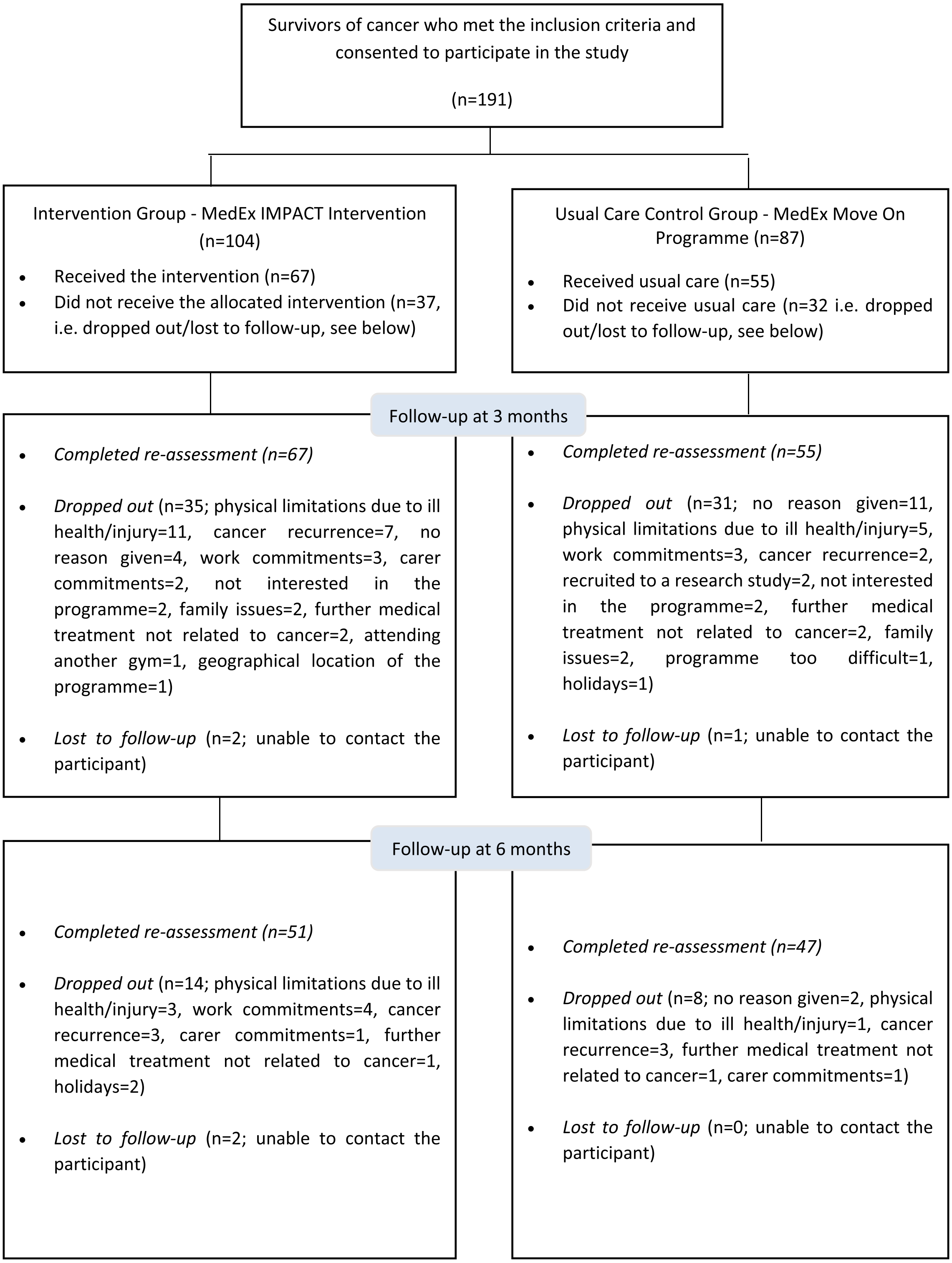

Fig. 1 Participant flow diagram

points. FACT-G score increased significantly from T1 to T2 for both groups ($n = 158$, $p < 0.001$) and from T1 to T3 for MI ($p < 0.001$).

Statistically significant main effects for time were identified from T1 to T2 ($p < 0.01$), and T1 to T3 ($p < 0.01$) for PWB and EWB for both UC and MI. A statistically

Table 1 Baseline participant characteristics for the full sample and by study group

Variable	Full sample (*n* = 191)	MedEx IMPACT intervention group (*n* = 104)	Usual care control group (*n* = 87)
Age (years)	56 ± 10.5 (29–82)	56 ± 10.6 (36–79)	57 ± 10.5 (29–82)
Gender			
Male	52 (27.2)	26 (25)	26 (30)
Female	139 (72.8)	78 (75)	61 (70)
Weight (kgs)	78.7 ± 17.6	78.3 ± 17.8	79.1 ± 17.4
BMI (kg/m^2)	28.3 ± 5.7	28.4 ± 6.0	28.2 ± 5.2
Waist to hip ratio	0.90 ± .09	0.9 ± .08	0.88 ± 0.1
Education			
No education	1 (0.6)	0 (0)	1 (1.1)
Some primary (not completed)	4 (2.2)	3 (3.0)	1 (1.1)
Junior certificate or equivalent	12 (6.5)	8 (8.0)	4 (4.8)
Leaving certificate or equivalent	38 (20.5)	16 (16.0)	22 (25.8)
Diploma/certificate	57 (30.8)	30 (30.0)	27 (31.8)
Primary degree	24 (13.0)	13 (13.0)	11 (13.0)
Postgraduate/higher degree	48 (25.9)	29 (29.0)	19 (22.4)
Don't know	1 (0.5)	1 (1.0)	0 (0)
Present Principle status			
Working for payment or profit	78 (42.6)	46 (46.0)	32 (38.6)
Looking for first regular job	1 (0.5)	1 (1.0)	0 (0)
Unemployed	9 (4.9)	5 (5.0)	4 (4.8)
Student or pupil	1 (0.5)	0 (0)	1 (1.2)
Looking after home or family	14 (7.7)	7 (7.0)	7 (8.4)
Retired from employment	47 (25.7)	23 (23.0)	24 (28.9)
Unable to work due to permanent sickness or disability	13 (7.1)	7 (7.0)	6 (7.2)
Other	20 (10.9)	11 (11.0)	9 (10.8)
Distance from the CBERP (kms)	13.7 ± 14.2	13.45 ± 14.87	14.03 ± 13.43
Marital status			
Married	124 (67.0)	68 (68.0)	56 (65.8)
Living with partner	9 (4.9)	4 (4.0)	5 (5.9)
Single (never married)	31 (16.8)	17 (17.0)	14 (16.5)
Separated	6 (3.2)	4 (4.0)	2 (2.4)
Divorced	8 (4.3)	5 (5.0)	3 (3.5)
Widowed	7 (3.8)	2 (2.0)	5 (5.9)
Cancer diagnoses			
Breast	114 (60.3)	65 (63.1)	49 (57.0)
Colorectal	30 (15.9)	16 (15.5)	14 (16.2)
Prostate	24 (12.7)	10 (9.7)	14 (16.2)
Other	21 (11.1)	12 (11.7)	9 (10.6)
Presence of other chronic conditions			
Heart disease	12 (6.4)	7 (6.7)	5 (5.7)
Chronic bronchitis, emphysema or chronic obstructive pulmonary disease	3 (1.6)	2 (2.0)	1 (1.1)
Other lung disease	3 (1.6)	1 (1.0)	2 (2.2)
Asthma	9 (4.8)	4 (3.9)	5 (5.7)
Type 2 diabetes	5 (2.7)	4 (3.9)	1 (1.1)
Type 1 diabetes	1 (0.5)	0 (0)	1 (1.1)
Depression	11 (5.9)	6 (5.9)	5 (5.7)
Anxiety or other emotional mental health condition	14 (7.5)	8 (7.8)	6 (6.9)
Arthritis or other rheumatic disease	21 (11.3)	14 (13.7)	7 (8.0)

Table 1 (continued)

Variable	Full sample ($n=191$)	MedEx IMPACT intervention group ($n=104$)	Usual care control group ($n=87$)
Other chronic condition	30 (16.0)	18 (17.6)	12 (13.8)
Smoking status			
Current smoker	7 (4.0)	4 (4.2)	3 (1.2)
Alcohol Consumption (yes)	127 (66.5)	70 (67.3)	57 (65.5)
Average no. of days	2 ± 2	2 ± 1	2 ± 2
Average number of units	3.2 ± 2.7	3.2 ± 2.8	3.2 ± 2.6
Diet quality			
Mean days of fast food consumption in a typical week	4 ± 1	4 ± 1	4 ± 1
Mean days preparing food from fresh ingredients in a typical week	2 ± 1	2 ± 1	2 ± 1

Continuous variables are displayed as mean ± standard deviation; age is displayed as mean ± standard deviation (range); Categorical variables are presented as n (%); CBERP = community-based exercise rehabilitation programme

Table 2 Summary of parameter estimates, standard error, df, and t and p values for physical and psycho-social outcomes across time

Variable	Time point	Estimate	Standard error	df	t value	*P* value
Steps	T1-T3	-1125.94	411.40	98.41	-2.74	.007*
	T2-T3	-345.09	404.57	91.71	-0.85	.396
LIPA	T1-T3	-0.17	0.06	103.90	-2.99	.003*
	T2-T3	-0.07	0.06	71.98	-1.37	.176
MVPA	T1-T3	-3.61	2.36	92.99	-1.53	.130
	T2-T3	-0.49	2.38	107.13	-0.21	.837
6-minute time trial score	T1-T3	-93.48	10.64	155.91	-8.79	.000*
	T2-T3	-15.75	9.22	64.06	-1.71	.092
FACT-G	T1-T3	-6.00	1.58	113.924	-3.79	.000*
	T2-T3	0.63	1.50	74.38	0.422	.674
Physical well-being	T1-T3	-2.94	0.50	153.91	-5.86	.000*
	T2-T3	-0.43	0.46	85.16	-0.94	.352
Emotional well-being	T1-T3	-1.69	0.43	144.26	-3.92	.000*
	T2-T3	0.11	0.34	94.76	0.32	.752
Functional well-being	T1-T3	-2.29	0.57	97.69	-4.01	.000*
	T2-T3	-0.03	0.67	88.52	-0.06	.954
Social well-being	T1-T3	0.02	0.48	113.36	0.05	.964
	T2-T3	0.14	0.47	97.63	0.30	.763

T1 baseline, *T2* 3 month follow-up, *T3* 6 month follow-up

*Denotes statistically significant results

significant main effect for time for FWB was observed from T1 to T2 for both groups ($p < 0.01$), and from T1 to T3 for MI ($p < 0.001$). FWB was not significantly different between T2-T3 for MI. Social well-being scores increased significantly in UC from T1 to T2 ($p < 0.05$).

Supplementary File 1 includes a completed Transparent Reporting of Evaluations with Nonrandomized Designs (TREND) Checklist [32] to support standardised reporting of this study.

Discussion

This study is novel as it examined both the short- and long-term effects of a community-based exercise programme, and a cancer-specific PA BC intervention, on objectively measured PA levels, CRF and QoL among a diverse cohort of survivors of cancer in a real-world setting. The results show that MMO was effective in increasing cancer

Table 3 Estimated marginal means (±standard error) for outcome variables for the usual care control group (UC) and MedEx IMPACT intervention group (MI) at baseline (T1) and 3 (T2) and 6 (T3) month follow-up

Variable	UC: T1	UC: T2	UC:T3	MI: T1	MI: T2	MI:T3
Steps	7788 ± 363	8587 ± 390	8053 ± 499	7929 ± 324	8710 ± 354	9055 ± 462
Light-intensity PA (mins/day)	72.2 ± 3	78.1 ± 3	78.4 ± 4.2	73.7 ± 3	79.6 ± 3	83.9 ± 3.6
Moderate-to-vigorous intensity PA (mins/day)	24 .8 ± 2.2	27.4 ± 2.4	23.8 ± 2.7	24.9 ± 1.9	28.0 ± 2.2	28.5 ± 2.5
6-minute time trial (metres)*	561 ± 14	664 ± 14	663 ± 16	594 ± 13	672 ± 13	688 ± 14
FACT-G Score*	82 ± 1.4	88 ± 1.5	85 ± 1.8	80 ± 1.2	87 ± 1.2	87 ± 1.5
Physical well-being	21 ± 0.5	23 ± 0.5	23 ± 0.5	21 ± 0.4	24 ± 0.5	24 ± 0.5
Functional well-being	19 ± 0.4	21 ± 0.6	20 ± 0.6	19 ± 0.3	21 ± 0.5	21 ± 0.5
Emotional well-being*	19 ± 0.5	21 ± 0.4	20 ± 0.5	17.8 ± 0.4	20 ± 0.4	20 ± 0.4
Social well-being	22 ± 0.6	24 ± 0.7	22 ± 0.7	22 ± 0.5	22 ± 0.6	22 ± 0.6

Abbreviations: *FACT-G* Functional assessment of cancer therapy – general questionnaire, *PA* physical activity

*Denotes variables that had a statistically significant difference between UC and MI at baseline

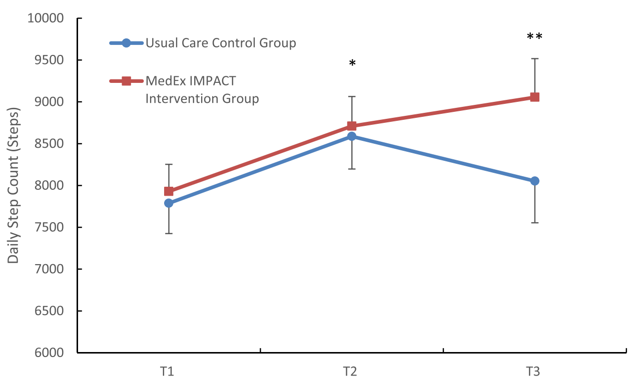

Fig. 2 Daily step count for the usual care control group and MedEx IMPACT intervention group at baseline (T1) and 3 (T2) and 6 (T3) month follow-up ($n=171$). Data presented as estimated marginal means ± standard error. *Denotes a statistically significant main effect for time for both groups from T1-T2. **Denotes a statistically significant main effect for time for the MI only from T1-T3

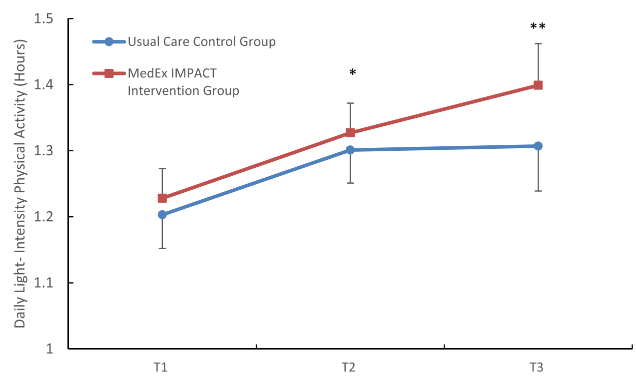

Fig. 3 Daily hours of light-intensity physical activity for the usual care control group and MedEx IMPACT intervention group at baseline (T1), and 3 (T2) and 6 (T3) month follow-up ($n=171$). Data presented as estimated marginal means ± standard error. *Denotes a statistically significant main effect for time for both groups from T1-T2. **Denotes a statistically significant main effect for time for the MI only from T1-T3

survivors' PA levels, CRF and QoL and in maintaining improvements in CRF 3 months post-programme completion. The findings also demonstrate that a low-tech intervention, which was tailored to cancer survivors' preferences, underpinned by behavioural theory and delivered within MMO, was effective in increasing PA levels, CRF and QoL and in maintaining improvements observed in all 3 variables 3 months post-programme completion.

On average, participants attended 66(±25)% of the supervised exercise classes during the 12 week programme, with similar rates of adherence being reported for the additional intervention components. Comparable rates of adherence to supervised exercise classes delivered within community-based settings have been reported [15, 33], with higher rates of adherence (≥80%) being observed within PA sessions delivered as part of PA interventions within controlled research environments [34]. Levels of PA participation can be influenced by cancer type, cancer treatment received, presence of treatment-related side-effects and stage of the cancer journey [35–37]. As such, heterogeneity among survivors of cancer who were referred to MMO, and subsequently recruited to this study, may have contributed to the observed differences in adherence rates between this investigation and interventions undertaken on more homogenous groups of cancer survivors in controlled research settings.

At 6-month follow-up, mean daily step counts for UC and MI participants were 8,053 and 9,055 steps respectively. Cancer survivors are at an increased risk for developing CVD [38]. Sugiura et al. [39] reported that attainment of 9,000 steps per day was associated with significant improvements in blood lipid parameters including reducing circulating levels of total cholesterol and increasing high-density lipoprotein cholesterol, in middle-aged women without cancer. MI participants may therefore have achieved a clinically meaningful improvement in their PA levels which could play an important role in reducing cancer survivors' risk for CVD.

The maintenance of improvements in objectively measured LIPA at 6 month follow-up for MI participants is a notable finding. LIPA is defined as activity performed > 1.5 but < 3 metabolic equivalents (METs) [40]. The replacement of sedentary behaviour with LIPA can assist in lowering the incidence of CVD and T2DM and the risk of cardiovascular and all-cause mortality among individuals who engage in little-to-no MVPA [41]. While the evidence regarding the benefits of LIPA for health and well-being have yet to be fully elucidated, recent research suggests that LIPA may provide an important therapeutic target within PA interventions, particularly for sedentary/insufficiently active populations [40, 42]. LIPA has been shown to attenuate functional decline in older (≥ 65 years) breast, prostate and colorectal cancer survivors who were ≥ 5 years post-cancer diagnosis [43]. Interventions like MI that increase and maintain improvements in LIPA may provide a promising solution to achieve benefits associated with regular PA among sedentary/insufficiently active populations.

Improvements in 6MTT score from baseline to 6-month follow-up were similar in CG (102m) and MI (94m). The majority of previous studies that used a field-based measure to estimate CRF in cancer survivors used a 6-min walk test, making it difficult to compare results with the 6MTT. Estimates for minimal clinically important differences in 6-min walk test distance of 17-86m have been reported among older adults and individuals with heart failure [44, 45]. Although a 6MTT was used in the present study, the results would suggest that community-based exercise rehabilitation is effective in eliciting a clinically meaningful change in CRF among survivors of cancer. Given the similar rates of improvement observed across both CG and MI, participation in the supervised exercise classes may have been the greatest contributor to the improvements observed.

The use of the 6MTT was purposeful as the 6-min walk test is not considered a valid test for predicting VO_{2peak} among survivors of cancer as it consistently underestimates VO_{2peak} [46]. Permitting participants to run, or engage in a combination of walking and running, within the 6MTT may have contributed to greater sensitivity in detecting changes in CRF over time. The 6MTT has been validated among young adults with Down Syndrome [29] and adolescents [28]. However, further research is needed to establish its validity and reliability among survivors of cancer.

The changes observed in QoL domains were clinically significant and consistent with previous literature [14]. For both groups, similar improvements in physical-, functional- and emotional-wellbeing were observed from T1-T2 with the magnitude of those effects being either small (PWB, FWB) or medium (EWB) when considered in the context of evidence-based interpretation guidelines [47]. Improvements in physical-wellbeing were maintained for both UC and MI at 3-month follow-up. MI participants also maintained improvements in functional- and emotional-wellbeing at T3.

The results from the current investigation are the first to report the benefits of community-based exercise rehabilitation on physical and psycho-social well-being among a diverse cohort of survivors of cancer within Ireland, and are supported by similar findings from previous studies conducted internationally [18, 33, 48]. The findings extend the existing evidence regarding the effectiveness of community-based exercise programmes by demonstrating the long-term positive effect of such programmes on PA levels and CRF. PA BC interventions like MI, that are based on participants' preferences and behavioural theory [22], may hold promise as a solution to support long-term maintenance of benefits associated with PA participation following completion of a community-based exercise rehabilitation programme.

Strengths and limitations

This investigation addresses a number of the recommendations for future research made in previous studies [14, 15], by including the use of an objective measure of PA, recruiting a diverse cohort of survivors of cancer, adopting a pragmatic research design and collecting follow-up data. The inclusion of follow-up assessment at 6 months provides important information, regarding the longer-term effectiveness of community-based exercise rehabilitation and the MedEx IMPACT intervention on PA levels, aerobic capacity and QoL among survivors of cancer, that has implications for clinical- and community-based practice.

Participants mean daily minutes of MVPA at baseline was 25 min, suggesting that participants would have been achieving in excess of the recommended 150 min of moderate intensity PA each week. As a result, a ceiling effect in terms of upper limits for improvement may have occurred. Therefore, implementing and evaluating MMO combined with MI among less active cohorts of survivors of cancer is warranted to assess its effectiveness for such populations.

As a result of poor data quality within referrals received, it was not possible to report information regarding participants' stage of the cancer journey (i.e. how far post-treatment completion participants were). This may have been a significant contributing factor to the heterogeneity of the cohort and may have influenced the study findings. Future research should collect more detailed participant information in order to facilitate sub-group analyses to determine if time since treatment completion and/or treatment modality itself (e.g. chemotherapy and surgery vs. surgery only groups) significantly influenced the outcomes measured at T2 and T3.

Conclusion

Participation in twice-weekly supervised exercise for 12-weeks significantly increased cancer survivors' objectively measured PA levels (daily step count and LIPA), CRF and QoL. The improvements in CRF were maintained at 6 months. The inclusion of a low-tech, PA BC intervention within usual care also resulted in the maintenance of improvements in objectively measured daily steps, LIPA and QoL at 6 months. PA BC interventions that are built upon cancer survivors' preferences, and underpinned behavioural theory, hold promise as an effective strategy to support the long-term optimisation of physical and psycho-social outcomes among survivors of cancer.

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Author contributions M.C. was involved in the development of the study concept and research design, and led data collection and analysis procedures. The first draft of the manuscript was written by M.C. and N.M., B.K. and A.McC. commented on subsequent versions of the manuscript. N.M., B.K., D.W., N.McC. and C.W. supervised this project, and were involved in the development of the study concept and research design. L.L. and F.S. supported data collection. K.D. and A.McC. provided guidance on the statistical analysis of the data. All authors read and approved the final manuscript.

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Declarations

Ethical approval 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. Ethical approval was granted by the Dublin City University Research Ethics Committee (DCUREC/2014/227; DCUREC/2017/128).

Consent to participate Informed consent was obtained from all individual participants included in the study.

Competing interests The authors declare no competing interests.

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