

The effect of participating in MedEx Wellness, a community-based chronic disease exercise rehabilitation programme, on physical, clinical and psychological health: A study protocol for a cohort trial

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ABSTRACT

Background: Community-based exercise rehabilitation programmes for chronic disease are an effective alternative to traditional hospital-based programmes. MedEx Wellness is a novel community-based exercise rehabilitation programme that integrates a range of chronic diseases. The aim of this trial was to investigate the effect of participating in MedEx Wellness on physical, clinical and psychological health.

Methods/design: A prospective cohort study was conducted. Participants were recruited at induction to the MedEx Wellness programme following referral from healthcare professionals. Participants underwent a baseline assessment before commencing the exercise programme and repeat assessments at 3, 6 and 12 months. The primary outcome was cardiorespiratory fitness (6 minute time trial) at 12 months. Secondary outcomes included health-related quality of life (EuroQoL-5D, Satisfaction with Life Scale, Warwick Edinburgh Mental Wellbeing Scale, Patient Health Questionnaire 8, Functional Assessment of Cancer Therapy (FACT) Questionnaire), free living activity behavior (accelerometer) and healthcare utilization (recall questionnaire). Tertiary outcomes included blood pressure (24 h), biomarkers (lipids, glucose and C-reactive protein), other components of physical fitness, including strength (handgrip test, sit-to-stand test); flexibility (sit-and-reach test); body composition (body mass index and waist-to-hip ratio), and falls risk (timed up and go test); cognitive function, including attention (Attention Network Task), memory (Luck & Vogel Visual Working Memory Task) and cognitive reserve. Exploratory outcomes included psychosocial determinants of physical activity (self-efficacy, social support, intentions).

Discussion: This trial will evaluate whether participation in the MedEx Wellness programme has positive effects on physical, clinical and psychological health in men and women with a range of chronic diseases

Trial Registration: ISRCTN Registry ISRCTN10351412.

KEYWORDS: Chronic disease, exercise rehabilitation, community-based, cardiorespiratory fitness,

ABBREVIATIONS

6 MTT – 6 Minute Time Trial

BMI – Body Mass Index

BP – Blood Pressure

CBP – Community-Based Programme

CVD – Cardiovascular Disease

DCU – Dublin City University

EQ-5D – EuroQoL-5D-3L questionnaire

HSE – Health Service Executive

NCD – Non-Communicable Disease

PHQ-8 – The Patient Health Questionnaire

SAE – Serious Adverse Event

SWLS – The Satisfaction with Life Scale

TUG – Timed Get Up & Go Test

WEMWS - Warwick Edinburgh Mental Wellbeing Scale

HDL-C – High-Density Lipoprotein Cholesterol

LDL-C – Low-Density Lipoprotein Cholesterol

CRP – C-Reactive Protein (CRP)

INTRODUCTION

Noncommunicable diseases, also known as chronic diseases, account for greater than half of the overall global disease burden [1]. The burden of chronic disease is predicted to continue to rise [2] and threatens to overwhelm current healthcare systems. Identifying effective approaches to implementing evidence-based treatment strategies is crucial. Substantial evidence has been established for the beneficial effect of exercise in the secondary prevention of multiple chronic diseases [4,5]. Indeed, there are exceptionally few chronic diseases in which the burden of the disease, the comorbidities related to the disease, and the disease-related quality of life are not improved with exercise [4,5].

Exercise rehabilitation has traditionally been delivered in a hospital-based setting primarily through cardiac or pulmonary rehabilitation programmes. Community-based programmes (CBP) offer an effective alternative setting for the delivery of exercise-based rehabilitation [6,7]. CBP offer greater accessibility to patients and may help to address the poor participation rates in hospital-based exercise rehabilitation programmes [8].

Previous research involving CBP have focused primarily on single chronic disease populations [9–11] including cardiac [12], pulmonary [7,13], cancer [10,14], stroke [15], osteoarthritis [16], and peripheral arterial disease [17] cohorts. A systematic review of CBPs across chronic disease populations identified that the design and components of programmes were similar, irrespective of disease [18]. Considering the overlap in these programmes and the high prevalence of multi-morbidity [19], defined as the co-existence of two or more chronic conditions within an individual [20], an integrated approach to community-based exercise for chronic disease management represents a more resource efficient strategy.

MedEx Wellness (now rebranded as ExWell Medical) is a novel community-based exercise rehabilitation programme for individuals with chronic disease in Ireland. It offers group exercise classes with medical oversight for people with a range of chronic diseases including cardiovascular disease (CVD), pulmonary disease, diabetes and cancer. The MedEx Wellness model provides a shared programme across chronic diseases and avoids duplication of programme infrastructure and content. The programme is a significant resource for healthcare professionals and individuals living with chronic disease and hosts approximately 700 participant visits per week. The MedEx model is also unique in that it does not have a fixed duration. Participants can attend the programme on a continuous basis or intermittent basis. They are however, encouraged to establish a lifelong relationship with MedEx Wellness.

In this manuscript, we describe an observational trial that investigated the effect of participating in the MedEx Wellness programme for 12 months on physical, clinical and psychological health in individuals living with chronic disease.

AIMS

The aims of this trial were to evaluate the following hypotheses:

Primary Hypothesis

Twelve months of participation in the MedEx Wellness programme will result in a significant improvement in physical health (cardiorespiratory fitness) assessed using the 6-minute time trial in individuals with a range of established chronic diseases.

Secondary Hypotheses

Twelve months of participation in the MedEx Wellness programme will result in a significant improvement in:

- a) Psychological health: assessed by EuroQoL-5D, Satisfaction with Life Scale, Warwick Edinburgh Mental Wellbeing Scale, the Patient Health Questionnaire and the Functional Assessment of Cancer Therapy (FACT) Questionnaire.
- b) Free Living Activity Behavior: Physical activity and sedentary behaviors assessed by body-worn activity monitoring.
- c) Clinical health: healthcare utilisation assessed by a recall questionnaire.

Tertiary Hypotheses:

Twelve months of participation in the MedEx Wellness programme will significantly improve:

- a) Clinical health: blood pressure assessed using a 24 hr monitor and biomarkers including lipids, glucose and C-reactive protein.
- b) Physical health: strength assessed by handgrip test and sit-to-stand test; flexibility assessed by sit-and-reach test; body composition assessed by body mass index and waist-to-hip ratio; and falls risk assessed by timed up and go test.
- c) Psychological health: cognitive function, including attention assessed by Attention Network Task and working memory assessed by Luck & Vogel Visual Working Memory Task.

Exploratory Hypotheses:

Twelve months of participation in the MedEx Wellness programme will significantly improve:

- Psychological health: psychosocial determinants of physical activity assessed by self-efficacy, social support, intentions.

METHODS/DESIGN

Study Design

A prospective cohort study was conducted. Participants were recruited from patients referred to the MedEx Wellness programme by healthcare professionals and were observed over the course of 12 months of participation in the programme. Outcomes were assessed at baseline and 3, 6 and 12 months (Figure 1). The trial was funded by the Health Service Executive (HSE) and approved by Dublin City University Ethics Committee (DCUREC: 2014/227). ISRCTN Registry ISRCTN10351412. This manuscript is reported using the PRISMA reporting guidelines.

Study Setting

The trial was conducted at Dublin City University (DCU), Ireland. The MedEx Wellness programme operates as a partnership between members of academic staff from the School of Health and Human Performance DCU and the Sports Services department in the institution on DCU campus.

Participants

Eligibility criteria for inclusion were individuals aged >18 years with established non-communicable disease (NCD) referred to the MedEx Wellness programme by consultant physicians, phase III (outpatient) cardiac rehabilitation teams from three major tertiary hospitals and general practitioners in the local area. Exclusion criteria

included uncontrolled cardiovascular disease (CVD), significant musculoskeletal or neurological conditions, cognitive decline and significant mental illness or intellectual disability that restricted participation in a physical training programme.

Recruitment

Participants were recruited at induction to the MedEx Wellness programme. Programme inductions took place weekly and involved 10-20 individuals per week. Potential participants were provided with a full oral explanation and a plain language statement detailing the trial. Participants provided written informed consent at this visit.

MedEx Wellness Community-based Exercise Programme

The exercise intervention was delivered as part of the MedEx Wellness programme, which is outlined in Figure 2. Participants underwent an induction to the programme, which involved 3 visits that provided i) information on the programme purpose, structure and logistics; ii) a group exercise consultation and iii) a beginner exercise class. The exercise consultation was delivered by researchers trained in exercise consultation delivery and adhering to a motivational interviewing style. The aim of the consultation was to use behavior change techniques to improve exercise adherence. The consultations focused on the benefits and barriers to exercise, problem solving, goal setting, and action planning. The exercise consultations were repeated at 1, 3, 6 and 12 months and involved a review of behavior goals and feedback on progress. The beginner class followed the same format as regular MedEx Wellness classes but involved a smaller group size (approx. 10–15 participants). The beginner classes introduced the participants to the exercise equipment and demonstrated proper techniques with the aim to improve self-efficacy and foster social support to improve programme initiation and adherence.

Following induction, participants were advised to attend 2 MedEx Wellness supervised group exercise classes per week. The number of participants at the exercise classes ranged from 30 to 75 (dependent on day of the week) and classes were supervised at a ratio of one instructor to 15 participants. MedEx Wellness staff are certified in Cardiac Prevention and Rehabilitation and the programme has medical oversight from the MedEx Wellness Chief Medical Officer (physician). The cost of participation was €7/8 (with/without a medical card) per session or €45/50 (with/without a medical card) per month (parking was included in this payment). The MedEx Wellness exercise intervention is described subsequently using the FITT (frequency, intensity, time, type) principle.

Frequency

Participants were advised to attend ≥ 2 supervised group exercise classes per week and encouraged to attend the same classes every week in order to foster social-support and habit formation.

Intensity

For the aerobic component of the exercise classes, participants were instructed to work at an intensity at which they “feel moderately breathless, have a red face and sweat”. For the resistance component of the exercise classes, participants aimed to achieve 15-20 repetitions at resistance that felt “tough” at each station.

Time

The class included a 15 min warm-up followed by a 40 min exercise training phase and a 5 min cool-down. For the exercise training phase, depending on the class size, participants were split into two or three groups: if ≤ 30 participants were present, the class was divided into two groups that alternated between 20 min of aerobic exercise and 20 min resistance exercise; and if >30 participants were present, the class was

divided into three groups that rotated between 10 min of aerobic exercise, 10 min of resistance exercise and 10 min of a combined aerobic and resistance circuit. For the resistance component, participants performed exercises at each resistance station for 60 sec aiming to achieve 15-20 repetitions.

Type

The aerobic component of the exercise classes involved the use of different equipment based on participant preference and ability, including treadmills, cycle ergometers, rowers and elliptical ergometers. Resistance training involved a circuit of 10-15 stations that included upper and lower body exercises using body weight resistance, weight machines and hand-weights. The combined aerobic and resistance circuit was led by an instructor and involved a combination of free aerobic exercises and calisthenics, for example, jumping jacks, toe taps, squats and wall press.

Following completion of the class, participants engaged in a social tea or coffee. Adherence to the programme was monitored as the number of sessions attended, which was electronically recorded by swipe access to the facility.

Outcome Measures

Participants underwent a series of outcome assessments at baseline and 3, 6 and 12 months. The assessments were conducted over 2 visits and 3 visits for individuals with intermittent claudication. Figure 3 provides an overview of the flow of data collection. Visit 1 and 2 were separated by 6 days and visit 2 and 3 by 24 hours. Outcome measurements are presented in Table 1. Visit 1 involved a fasting blood sample, questionnaire completion to obtain demographic information and assess the psychosocial determinants of physical activity, and assessment of body composition, strength and flexibility. Participants were provided with a take home questionnaire to

assess health-related quality of life and an activPAL³ micro activity monitor (PAL Technologies Ltd. Glasgow, Scotland) to wear for 6 days. Visit 2 involved assessments of cognitive function, cardiorespiratory fitness and falls risk. Participants were provided with an ambulatory BP monitor to wear for 24 hours and a take home questionnaire to assess cognitive reserve. Participants were encouraged to complete questionnaires independently but where required, a member of the research team or a family member or friend provided assistance. Participants with intermittent claudication performed a treadmill test at visit 3, which was organized prior to a scheduled exercise class.

Primary Outcome

Physical health: cardiorespiratory fitness assessed using the 6-minute time trial (6MTT) [21,22]. Participants were instructed to cover as much distance as possible in 6 minutes while walking, running or a combination, back and forth on a flat indoor 20-metre course. Participants received a standard set of instructions adapted from the ATS guidelines for the 6-minute walk test [23]. No warm-up was permitted. The position on the 20 m course at which the participant stopped at the end of the 6 minutes was marked with a cone and the distance covered in the final partial lap was measured to the nearest metre using a measuring tape. The total distance covered was recorded.

Secondary Outcomes

Psychological health assessed by the following questionnaires:

- The EuroQoL-5D-3L (EQ-5D) [24,25] which consists of two components: health state description and health evaluation. The description component is comprised of five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension has 3 levels: no

problems, some problems and extreme problems. The evaluation component records the patient's self-rated health on a vertical visual analogue scale where the endpoints are labelled 'best imaginable health state' and 'worst imaginable health state'.

- The Satisfaction with Life Scale (SWLS), a 5-item scale designed to measure global cognitive judgment of subjective wellbeing [26]
- The Warwick Edinburgh Mental Wellbeing Scale (WEMWS), a 14-item positively worded scale covering both feeling and functional aspects of mental wellbeing [27]
- The Patient Health Questionnaire (PHQ-8) an 8-item validated and widely used diagnostic and severity measure for depression [28].
- The Functional Assessment of Cancer Therapy (FACT) questionnaire was completed by participants with cancer. This is a 40-item questionnaire that includes five domains: physical, social/family, emotional, function and cancer-specific, to evaluate quality of life and fatigue in patients with cancer. [29]. It is composed of a general component (FACT-G) and cancer specific subscales (ECS).

Free living activity behavior assessed using:

The activPAL³ micro accelerometer, a device that measures bodily accelerations using a triaxial accelerometer, sampling at 20 Hz. The device was worn on the midpoint of the anterior aspect of the thigh. It was covered with a water-resistant nitrile sleeve and attached to the skin using a Tegaderm film adhesive dressing. Participants were instructed to wear the device continuously for 6 consecutive days, except during water immersion activities (i.e. swimming and bathing).

Raw acceleration data were processed and stored in a range of file formats, including csv files or 15 second epoch summary files. Proprietary algorithms classify activities into sitting/lying time, standing time, stepping time, step count and activity counts. Only datasets that provides ≥ 4 valid days of activity data, including 1 weekend day, will be processed for analysis. A valid day will be defined as ≥ 600 min of recording during daytime hours (i.e. 7 am to 11 pm) [18]. Non-wear time will be defined as ≥ 60 min of consecutive zero accelerometer counts [19]. Sedentary behavior characteristics will be examined using a customized MATLAB® (version 7.0.1, The Mathworks Inc, Natick, MA, USA) software programme [19]. The programme has been previously described [19]. Briefly, the number and duration of sedentary bouts per day will be calculated. Sedentary bouts will be categorized by specific durations, namely < 5 min, 5-10 min, 11-20 min, 21-30 min, 31-40 min, 41-60 min, > 60 min, > 90 min. The number of sedentary bouts and the total duration in sedentary bouts in each category will be calculated.

Clinical health assessed by:

An 8-item *healthcare utilization questionnaire* developed based on The Irish Longitudinal Study on Ageing (TILDA) [30,31]. The questionnaire captured self-reported 12-month recall of health service use. Participants were asked about: i) medical card cover; ii) GP visits; iii) hospital emergency service visits; iv) outpatient hospital visits; v) whether an outpatient hospital visit was a public/private visit; vi) nights spent in hospital; vii) whether nights spent in hospital were a public/private visit; viii) days taken off work due to illness.

Tertiary Outcomes

Clinical health assessed by:

- An ambulatory BP monitor (Oscar 2, SunTech Medical, Inc, NC USA), issued to participants to wear for 24 hours. Data was retrieved from the device using the AccWin Pro 3 PC (SunTech Medical, Inc, NC USA). Average systolic and diastolic daytime, night-time and 24-hour blood pressures were derived.
- Venous blood samples were taken following an overnight fast. Serum vacutainers were left to stand for 30 min before centrifugation at 3000 rpm (1600 g) for 15 min at 4°C. Serum triglycerides, total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), fasting glucose and c-reactive protein (CRP) were determined using spectrophotometric assays, performed on an automated bench-top clinical chemistry system (ACE®, Alfa Wassermann B.V., Netherlands) using the appropriate reagents, calibrators and controls (Randox Laboratories, UK).

Physical health assessed by:

- Body composition: Height and body mass was measured using a stadiometer and electronic scale (model 707 balance scales: Seca GmbH, Hamburg, Germany), respectively. Body mass index (BMI) was calculated as body mass in kilograms divided by squared height in metres. Waist and hip circumferences were measured by a trained researcher using a tape measure and waist to hip ratio was derived.
- Muscle strength: Lower body strength was assessed using the 10 repetition sit to stand test [32], which records the time taken to stand and sit 10 times as fast as possible. The better of two attempts was recorded. Handgrip strength was measured in the dominant arm using a hand-held dynamometer (Takei 5401 Handgrip Digital Dynamometer). The average of three attempts was recorded.

- Flexibility: assessed using a modified sit and reach test [33], whereby a sit and reach box (Eveque Leisure Equipment Ltd, Cheshire, UK) was placed on a bench. While sitting on the bench with their legs fully extended and feet flat against the box, participants flexed forward to reach their fingertips as far as possible along the measurement scale. The best of three attempts was recorded.
- Falls risk: A 3-item questionnaire was used to identify participants who reported falling one or more times in the previous year or reported a fear of falling or problems with balance or walking. A Timed Get Up and Go (TUG) Test [34] assessed the time taken to rise from a chair of standardized height, walk a fixed distance of 3 metres, turn, return to the chair, and sit down again. The better of two attempts was recorded.
- Claudication time: An incremental treadmill walking test using the Gardner protocol [35] of 3.2 km.h⁻¹ and 0% grade, with a subsequent 2% increase in grade every 2 min was used to determine time to the onset of and absolute claudication pain in participants with symptoms of intermittent claudication resulting from peripheral arterial disease.

Psychological health assessed by:

- Attention control: assessed using the Attention Network Task [36]. The computerised task measured three functionally and independent aspects of attention control crucial to everyday cognitive functioning by recording performance accuracy and average reaction time to a correctly detected target amongst flankers (i.e. a set of response inhibition tests used to assess the ability to suppress responses that are inappropriate in a particular context): (1) alertness, (2) attentional orienting, and (3) executive function.

- Visual working memory: measured using the Luck & Vogel Visual Working Memory Task [37]. The computerised task measures performance accuracy and average reaction times to correct detection of a change in a visual array of objects. The set size of the object array varies from small to large.

Both computerized tasks are used with open permissions from the Psychology Experiment Building Language (PEBL) site:

<http://peblblog.blogspot.ie/2014/07/overview-of-some-of-new-tests-in-pebl.html>.

Benchmark tests have been reported within various populations to establish timing precision [38].

- Cognitive reserve: was assessed at baseline only using the Cognitive Reserve Questionnaire, <http://www.cognitivereserveindex.org/> [39]. The questionnaire measures demographics, education, and working activity including physical, social and intellectually challenging activity.

Exploratory Outcomes

Selected psychosocial determinants of physical activity were assessed. Barrier self-efficacy and self-regulatory self-efficacy for physical activity were assessed using an established 13-item scale [40] and a modified 11-item scale [41,42], respectively. Social support from family and friends for physical activity was assessed using a validated 10-item tool [43]. A modified 6-item measure was used to assess intentions for exercise [44].

Safety

Any adverse event was recorded and reported to the MedEx Wellness Chief Medical Officer and the principal investigator. Serious adverse events (SAE) were defined as

all-cause mortality or hospitalization for cardiovascular complications. Other adverse events included training-related adverse events such as musculoskeletal problems that prevented exercise participation or other adverse events that interrupted the exercise intervention. Follow-up telephone calls to schedule repeat assessments provided an opportunity for participants to report adverse events. There was also opportunity during the exercise classes for participants to report adverse events to the exercise instructors or the programme's Chief Medical Officer, which were then communicated to the research team.

Data analysis

Sample size

The critical determination of the sample size was the standard deviation of the change in 6MTT distance from baseline to 12 months. The standard deviation estimate used was 90 m [45]. The minimum difference to be detected was 25 m [46]. For a power of 80% and two-sided significance of 5%, a sample size of 104 participants was required. To account for drop out, 400 was the target sample size.

Procedures for data checking and entering

Primary and secondary outcome data for physical health and psychological health (except cognitive assessments) outcomes will be handled using double data entry and cleaning. Due to lack of resources, all other outcome measures will be handled using single data entry.

Statistical analyses

Analyses will be performed using IBM SPSS Statistics 24. Continuous variables will be reported as mean (range), mean (standard deviation) or median (inter-quartile range), depending on distribution, and categorical variables as frequency (%). Baseline demographics and number of chronic diseases (including type) will be reported

descriptively. Prior to statistical analysis, the Shapiro-Wilks test will be applied to check for normality. To investigate longitudinal changes in repeated measures variables, linear mixed model analysis (MMA) will be used. A MMA is an appropriate approach to modelling time series data that contains repeated measures for numerous subjects [47]. It does not require complete data sets and it will not exclude participants missing a repeat assessment timepoint [48]. Bonferroni post-hoc stratified analysis comparing estimated marginal means at each timepoint will be performed for variables that indicate a significant main effect for time.

DISCUSSION

Exercise is an evidence-based secondary prevention strategy for chronic disease. It is associated with reductions in recurrent events, future complications, hospital readmissions and mortality in several chronic diseases [4,49]. Exercise can also restore health, including improving physical function, functional independence and health-related quality of life [3,5]. Despite the established benefits, referral, uptake and adherence rates to exercise rehabilitation programmes in the hospital setting are suboptimal, with less than 35% of eligible patients participating in cardiac rehabilitation [12,50]. Commonly cited barriers to participation in exercise rehabilitation programmes include environmental factors, such as distance to the facility, lack of transport and health system resources [51,52]. A quantitative review of 32 cardiac rehabilitation studies found that patients were more likely to participate when the programmes were easily accessible [34]. Embedding exercise rehabilitation services within the community may improve uptake and compliance, as well as shift the resource burden from the healthcare system.

CBPs are effective models of exercise rehabilitation, with some research reporting similar benefits compared to hospital-based programmes [6,7]. They have been associated with improvements in physical function and health-related quality of life in a variety of clinical populations, including cardiac [12], pulmonary [7,13], cancer [10,14], stroke [15], osteoarthritis [16], and peripheral arterial disease [17]. These previous studies have focused on the effect of CBPs on a single chronic disease. However, multi-morbidity, commonly defined as the co-existence of two or more chronic conditions within an individual [20], is a growing challenge for health care systems and is associated with the ageing population [19]. The increasing levels of multi-morbidity threaten the sustainability of current healthcare approaches and

necessitate fundamental change to the current model [53]. In relation to exercise rehabilitation, a common chronic disease model is warranted.

A systematic review of the structure and delivery of CBPs across chronic disease populations identified that the design and components of programmes were similar, irrespective of chronic disease [18]. Specifically, the primary components of >85% of the programmes included a combination of aerobic and resistance exercise. The frequency of exercise sessions was typically 2-3 days per week and sessions were generally 40-60 min in duration. These findings highlight that it is unnecessary to have separate programmes for single chronic conditions and that such programmes can be easily applied across a range of conditions with minimal disease-specific adjustments. An integrated model is likely to represent a more resource efficient approach.

The novelty of the MedEx Wellness model is that it integrates a range of chronic diseases with a shared common infrastructure and content, including facilities, staffing, operating procedures and standards, patient information handling, exercise prescription and programme content, and the programme is financially self-sufficient; its business model has been described in the National Exercise Referral Framework [54]. It is also unique in terms of programme duration; it is not a fixed duration, participants can attend the programme on a continuous basis. Other CBP range from 8 weeks to 18 months in duration [15]. The MedEx Wellness approach supports the long-term maintenance of physical activity and exercise. All of these features combine to make the MedEx Wellness model scalable and sustainable and it represents a potential public health model for chronic disease rehabilitation.

Study Limitations

The primary limitation of this study is the lack of a usual care comparison group. As the study setting was within an established programme in the community, withholding

service to allow for a controlled trial was not considered ethically appropriate. Maturation may threaten the study validity given the population included, as changes in health status may have occurred over the 12-month period. Selection bias is present as participants were recruited from those who attended induction to the community-based exercise rehabilitation programme and no data was collected on those that were not referred or declined to attend. Additionally, study uptake rates (screening logs) were not recorded, although very few patients attending programme induction declined to participate. Study limitations also included a high risk of performance and detection bias: both participants and personnel delivering the intervention were not blinded, and additionally the assessor was not blinded to outcome measures. Attrition is common in exercise studies but follow-up telephone calls at 1, 3, 6 and 12 months to schedule exercise consultations and outcome assessments attempted to minimise attrition.

Conclusion

This trial investigated the clinical effectiveness of the MedEx Wellness programme. The extent of the trial outcome measures will provide a holistic view of the physical, clinical and psychological effect of the programme.

DECLARATIONS

Ethical approval and consent to participate: The trial protocol has been approved by the Dublin City University Research Ethics Committee (DCUREC: 2014/227).

Consent for publication:

Availability of data and material

Competing Interests: None to declare.

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Author's contributions: NMcC, NM, and CW conceived the study. BK, LB, LD, NM, CW and NMc contributed to the study design. BK, LL, FS, MC and NMcC conducted data collection. BK, LL and FS prepared the manuscript, which underwent revision by all authors.

Trial Status: Data collection is complete.

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