ISRCTN10351412 https://doi.org/10.1186/ISRCTN10351412

Evaluation of the effectiveness of MedEx Wellness

Submission date	Recruitment status	[_] Prospectively registered
01/12/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
26/01/2016	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
21/07/2020	Circulatory System	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
It is well known that exercise has a beneficial effect on health. Many studies have shown that taking part in regular physical activity can help to improve the health of people suffering from long-term (chronic) illnesses, by strengthening the heart, lowering blood pressure and maintaining a healthy weight. MedEx Wellness is a new community-based chronic illness rehabilitation programme, which offers medically supervised physical activity classes to patients with a range of chronic illness. Currently, classes are provided to patients with cardiovascular disease (heart and blood vessel disease), pulmonary disease (lung disease), diabetes and cancer. MedEx is unique in that it combines rehabilitation for all of these different chronic conditions into one programme, making the roll-out of the MedEx model throughout the country a real opportunity. The MedEx model could potentially become the standard model used for chronic illness rehabilitation throughout Ireland. The aim of this study is to test the effectiveness of the MexEd programme at improving the physical and mental wellbeing of patients with a range of different chronic illnesses.

Who can participate?
Adults suffering from established cardiovascular disease, pulmonary disease, diabetes or cancer

What does the study involve?
Before beginning the MedEx programme, they are asked to attend Dublin City University for three days of testing. On the first visit, participants have a blood sample taken, height, weight, waist and hip circumference measured; complete a questionnaire and some simple tests of strength and flexibility. They are also given a device to wear on their leg for 7 days to monitor their physical activity. On the second visit, participants perform attention and memory tests, a 6 minute walk test (to test how well their body copes with exercise), and set goals for their exercise programme. Participants are also provided with blood pressure monitor to wear for 24 hours. On the third visit, participants take part in a beginner exercise class as well as having specific tests about how their bodies cope with exercise related to their specific conditions (e.g. patients with lung problems will have lung function tests). After the testing visits, participants being the MedEx programme, which involves attending 2 exercise sessions a week for 12 months. At 3, 6 and 12 months, participants repeat the initial tests in order to see whether the exercise programme is having any effect on their weight and general health.

What are the possible benefits and risks of participating?
As well as the general health benefits of taking part in physical activity, participants may benefit from improved knowledge about the best amount of exercise for people living with chronic conditions, and how best to achieve this. Participants will also benefit from meeting other people in similar situations to themselves and will be provided with a supportive and safe environment in which they can exercise. There is a risk of muscle soreness and tiredness from taking part in the exercise sessions, as well as the possibility of pain or bruising from the blood tests.

Where is the study run from?
MedEx Wellness, Dublin City University Sports Complex (Ireland)

When is the study starting and how long is it expected to run for?
September 2015 to March 2018

Who is funding the study?
Health Service Executive (Ireland)

Who is the main contact?
Dr Noel McCaffrey

Study website
https://www.dcu.ie/dcusport/medex-wellness-programmes.shtml

Contact information

Type(s)
Scientific

Contact name
Dr Noel McCaffrey

Contact details
School of Health and Human Performance
Dublin City University
Glanevin
Dublin 9
Ireland
D09 W6Y4

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Evaluation of the MedEx Wellness programme as a public health model for community-based chronic illness rehabilitation

Study objectives
MedEx Wellness will significantly improve physical and psychological wellbeing in patients with a diverse range of chronic illnesses.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dublin City University Research Ethics Committee, 06/01/15, ref: DCUREC2014/227

Study design
Single-centre single-arm intervention pre-post comparison study

Primary study design
Interventional

Secondary study design
Single arm intervention pre-post comparisons

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic illness, primarily:
1. Cardiovascular disease
2. Peripheral arterial disease
3. Pulmonary disease (including chronic obstructive pulmonary disease, pulmonary fibrosis)
4. Diabetes
5. Cancer

Interventions
All participants will attend DCU for 3 days of testing. On Day 1 participants will have a blood sample taken, height, weight, waist and hip circumference measured, complete a questionnaire and some simple tests of strength and flexibility. Participants will be provided with a device to wear on your leg for 7 days to measure physical activity. On Day 2 participants will perform attention and memory tests, a 6min walk test, and set goals for your exercise programme. Participants will be provided with blood pressure monitor to wear for 24 hours. On Day 3

participants will take part in a beginner exercise class and some participants will perform tests – participants with claudication will perform a treadmill test, participants with lung conditions will perform lung function tests, and participants at risk of falling will perform a balance test. After testing, all participants will begin the MedEx programme, which involves two medically supervised exercise classes per week for 12 months. Classes are 60 min and consist of a combination of aerobic and resistance exercise.

Specifically, the class format comprises of:
1. Warm-up: 10 minutes of aerobic exercise and range of motion exercises
2. Aerobic exercise: Using cycle ergometers, treadmills, elliptical machines to accumulate 20 minutes of exercise through a mixture of short (~5 minute) and long (~10 minute) intervals. Participants are instructed to exercise at a moderate intensity at which they feel modestly breathless and perspire.
3. Resistance exercise: A circuit of 8-10 stations alternating upper and lower body exercises using both cable machines and light hand weights. Participants are instructed to select an intensity to allow them to perform continuous repetitions for 60 seconds at each station. The circuit is completed twice.
4. Cool down: 10 minutes of aerobic exercise and range of motion exercises

Intervention Type
Behavioural

Primary outcome measure
Cardiorespiratory fitness measured using the 6 minute walk test at baseline, 3, 6 and 12 months.

Secondary outcome measures
1. Quality of life measured using Medical Outcomes Study Short Form-12 and disease specific measures (COPD Assessment Tool, Functional Assessment of Cancer Therapy, Walking Impairment Questionnaire) at baseline, 3, 6 and 12 months
2. Daily physical activity measured using accelerometry and the International Physical Activity Questionnaire at baseline, 3, 6 and 12 months
3. Health care utilisation measured using at baseline from patient records and throughout the trial using a healthcare utilisation diary at baseline, 3, 6 and 12 months
4. Blood pressure using a 24 h ambulatory blood pressure monitor at baseline, 3, 6 and 12 months
5. Lipids measured by a blood sample at baseline, 3, 6 and 12 months
6. Body composition measured using body mass index and waist-to-hip ratio at baseline, 3, 6 and 12 months
7. Strength measured using the sit-to-stand test and handgrip test at baseline, 3, 6 and 12 months
8. Flexibility measured using the sit-and-reach test at baseline, 3, 6 and 12 months
9. Cognitive function measured using the cognitive reserve questionnaire, the Attention Network Task and the Luck and Vogel Visual Working Memory Task at baseline, 3, 6 and 12 months
10. Claudication time measured by the Gardner claudication treadmill test at baseline, 3, 6 and 12 months
11. Respiratory function measured by spirometry at baseline, 3, 6 and 12 months
12. Falls risk measured using the Timed Up and Go Test at baseline, 3, 6 and 12 months

Overall study start date
25/09/2015

Completion date
01/02/2019

Eligibility

Key inclusion criteria
1. Aged 18 years or over
2. Established non-communicable disease

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
The critical determination of the sample size is the standard deviation of the change in 6MWT distance, time 1 (baseline) to time 2 (12 months). The standard deviation estimate used is 90 m. This is based on values given in or derived from Polkey et al., (2013) and Redelmeier et al., (1997). The minimum difference to be detected is 25 m as described in the literature. For a power of 80% and two-sided significance of 5%, a sample size of 104 is required.

Key exclusion criteria
1. Uncontrolled cardiovascular conditions
2. Significant musculoskeletal or neurological conditions, cognitive decline, mental illness or intellectual disability that restricts participation in a physical training programme

Date of first enrolment
25/09/2015

Date of final enrolment
25/09/2016

Locations

Countries of recruitment
Ireland

Study participating centre
MedEx Wellness
DCU Sports Complex
Dublin City University

Collins Avenue Extension
Dublin
Ireland
D09 W6Y4

Sponsor information

Organisation
Health Service Executive

Sponsor details
Health Intelligence
Health Services Executive
Red Brick House
Stewarts Hospital Campus
Palmerstown
Dublin
Ireland
D20 N292

Sponsor type
Government

Website
http://hse.ie/eng/about/Who/healthwellbeing/knowledge/Health_Intelligence/

ROR
https://ror.org/04zke5364

Funder(s)

Funder type
Government

Funder Name
Health Service Executive

Results and Publications

Publication and dissemination plan
1. The findings will be disseminated to the following end-users:
1.1. Project Sponsor: Health Service Executive

1.2. Individuals with established NCDs
1.3. Individuals at risk of developing NCDs
1.4. Healthcare professionals
1.5. Academics and researchers
2. Dissemination may be assisted by the following dissemination partners:
2.1. Health Service Executive
2.2. National Clinical Care Programmes
2.3. NCD charities, e.g. Irish Heart Foundation, Irish Cancer Society
2.4. NCD patient support groups
2.5. Healthcare professional representative bodies, e.g. Irish College of General Practitioner, Irish Society of Chartered Physiotherapists
2.6. NCD healthcare professional societies, e.g. Irish Thoracic Society
3. Dissemination may occur through the following channels:
3.1. Scientific journals: publications in high impact peer-reviewed journals in domains relevant to the proposed research, including clinical exercise (Medicine & Science in Sport & Exercise), general medicine (British Medical Journal) and rehabilitation (Archives of Physical Medicine & Rehabilitation)
3.2. Conferences: international and national scientific conferences, e.g. American College of Sports Medicine, European Respiratory Society International Congress, Irish Association of Cancer Research Annual Meeting. The concept of a MedEx Conference is in development, which will focus on chronic illness exercise rehabilitation.
3.3. Technical reports: to the HSE and healthcare professionals
3.4. Media releases: to lay media (e.g. newspapers), professional media (e.g. ICGP newsletter), and special interest newsletters
3.5. Lay summaries: to participants, NCD patients, and interest groups
3.6. Presentations: to end-users and dissemination partners
3.7. Web: MedEx website and social media
3.8. Stakeholders, participants and dissemination partners will be asked to contribute on the best methods to disseminate research findings
4. The following is the workplan for dissemination:
4.1. Financial resources: dissemination has been accounted for in the project budget
4.2. Human resources: the Researcher and Project Manager will draft dissemination materials for editing and final review by the Project Director and Project Sponsor
4.3. Timeline: Given the relatively short timeframe of this study, the majority of dissemination will commence following final data analysis at month 34. Three months have been assigned for the sole purpose of dissemination. Interim reports will be disseminated to the Project Sponsor.

Intention to publish date
01/02/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	18/06/2020	21/07/2020	Yes	No