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A multi-centred randomised trial to assess if adding web-based support to exercise referral schemes for individuals with metabolic, musculo-skeletal and mental health conditions can increase physical activity after 12 months

Submission date	**Recruitment status**	[X] Prospectively registered
23/12/2014	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/02/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
31/10/2024	Other	

Plain English summary of protocol

Background and study aims

The NHS routinely offers a service in which a doctor or healthcare professional refers a patient with a medical condition that can benefit from exercise, to an exercise referral scheme (ERS). Schemes involve a supervised programme of both aerobic and resistance exercise tailored to the patient's needs at an exercise facility or physical activity counselling support. However, uptake and adherence can be low, and there is a lack of evidence to show long-term change in physical activity. Extensive input from patients and ERS professionals suggests that longer-term motivational support is needed beyond the traditional 10-12 week programme. There is rapidly growing interest in new technologies to support health behaviour change, including websites, text messaging, and apps on smartphones. The Lifeguide website has provided support that has been appreciated by patients to self-manage various medical conditions but has not been used to support patients who are also attending an ERS. An existing form of interactive web-based support (Lifeguide) is being refined into something called e-coachER, which can help patients with common long-term medical conditions, namely obesity, high blood pressure, type 2 diabetes, osteoarthritis and depression, to be more likely to attend an ERS and help with long-term motivation to do physical activity and improve their quality of life. The e-coachER intervention provides consistent and coherent support that seeks to empower individuals through increased confidence to be physically active, and to be more proactive in self-managing their condition with types of physical activity that are the most sustainable. The aim of this study is to compare standard ERS with ERS plus the e-coachER intervention, introduced to patients at the point of referral and remaining accessible during and beyond the usual ERS.

Who can participate?

Patients aged 16-74 years with one or more of the following: obesity, high blood pressure, type 2 diabetes, pre-diabetes, lower limb osteoarthritis, depression

What does the study involve?
At the point of referral a nurse randomly allocates patients who meet certain criteria to receive either the usual exercise referral scheme (ERS) or ERS plus e-coachER. Only those in the latter group are given login details to access e-coachER and given facilitator and technician support to use it. The ERS provides usual support (i.e., structured exercise or physical activity counselling) to all participants, but e-coachER gives additional support that is expected to help patients to remain physically active after 12 months. Research is conducted in ERS in Glasgow, Devon /Cornwall and West Midlands. The two groups are assessed to see if differ in terms of total weekly minutes of moderate to vigorous physical activity over 1 week after 12 months. Physical activity, health-related quality of life and resource use are also assessed after 4 and 12 months to compare the groups. The long-term benefits for the NHS are also considered. The use of the web-based support and its effects are assessed among the six medical conditions, although some patients may have more than one condition.

What are the possible benefits and risks of participating?
All participants will benefit from the support provided by an exercise practitioner within the ERS. Becoming more physically active can have significant physical and mental health benefits. Your doctor will not refer participants to an ERS unless it meets accepted national health and safety standards. Any exercise, especially at a vigorous intensity or if it is something unfamiliar, increases the temporary risk of an acute health problem such as muscle soreness, heart palpitations and dizziness. Within an ERS a fully qualified instructor will help participants to identify the most suitable physical activities for them, based on guidance from their doctor and their own experiences and preferences. The e-coacher support focuses on encouraging participants to increase moderate intensity physical activity in what should be a safe, progressive and enjoyable way.

Where is the study run from?
Peninsula Clinical Trials Unit (PenCTU) (UK)

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

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Wendy Ingram
wendy.ingram@plymouth.ac.uk

Study website
http://clahrc-peninsula.nihr.ac.uk/research/e-coacher-investigation-of-a-web-based-behavioural-support-exercise-referral-scheme

Contact information

Type(s)
Scientific

Contact name
Dr Wendy Ingram

ORCID ID
http://orcid.org/0000-0003-0182-9462

Contact details
Clinical Trials and Population Studies Group
Plymouth University Peninsula Schools of Medicine & Dentistry
Room N6
ITTC1
Plymouth Science Park
Derriford
Plymouth
United Kingdom
PL6 8BX

Type(s)
Scientific

Contact name
Prof Adrian Taylor

ORCID ID
http://orcid.org/0000-0003-2701-9468

Contact details
Clinical Trials and Population Studies Group
Plymouth University Peninsula Schools of Medicine & Dentistry
Room N6
ITTC1
Plymouth Science Park
Derriford
Plymouth
United Kingdom
PL6 8BX

Additional identifiers

EudraCT/CTIS number

IRAS number
170179

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/25/20

Study information

Scientific Title

A multi-centred randomised controlled trial of an augmented exercise referral scheme using web-based behavioural support in individuals with metabolic, musculo-skeletal and mental health conditions

Acronym
e-coachER

Study objectives
Current hypothesis as of 16/09/2016:
1. To determine whether the e-coachER intervention, compared to control, increases the total weekly minutes of moderate to vigorous physical activity (MVPA) achieved by participants at 12 months.
2. To determine whether the e-coachER intervention, compared to control, increases the proportion of participants who take up the opportunity to attend an initial consultation with an exercise practitioner (uptake), maintain objectively assessed and self-reported physical activity (PA), and improve health related quality of life at 4 and 12 months.
3. To quantify the additional costs of delivering the intervention and determine the differences in health utilisation and costs between intervention and control at 12 months.
4. To assess the intervention cost-effectiveness compared with control at 12 months (incremental cost per quality adjusted life years [QALY]) and over the lifetime perspective (incremental cost per QALY) using a previously developed decision model to estimate future costs and benefits.
5. To quantitatively and qualitatively explore if the impact of the intervention is moderated by medical condition, age, gender and socioeconomic status, or ERS characteristics.
6. To quantitatively and qualitatively explore the mechanisms through which the e-coachER intervention may impact on the outcomes.

Previous hypothesis:
The aims of the internal pilot and full trial are as follows:
1. To determine whether the e-coach intervention, compared to control, increases the proportion of participants who achieve the public health target of 150 min of moderate /vigorous physical activity (MVPA) at 12 months.
2. To determine whether the e-coach intervention, compared to control, increases the proportion of participants who take up the opportunity to attend an initial consultation with an exercise practitioner (uptake), maintain objectively assessed and self-reported physical activity (PA), and improve health related quality of life at 4 and 12 months.
3. To quantify the additional costs of delivering the intervention and determine the differences in health utilisation and costs between intervention and control at 12 months.
4. To assess the intervention cost-effectiveness compared with control at 12 months (incremental cost per quality adjusted life years [QALY]) and over the lifetime perspective (incremental cost per QALY) using a previously developed decision model to estimate future costs and benefits.
5. To quantitatively and qualitatively explore if the impact of the intervention is moderated by medical condition, age, gender and socioeconomic status, or ERS characteristics.
6. To quantitatively and qualitatively explore the mechanisms through which the e-coach intervention may impact on the outcomes.

More details can be found at http://www.nets.nihr.ac.uk/projects/hta/132520
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0009/136998/PRO-13-25-20.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North West - Preston, 11/05/2015, ref: 15/NW/0347

Study design
Parallel two-arm individually randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
GP practice

Study type(s)
Prevention

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

Health condition(s) or problem(s) studied
Primary care patients with a medical condition (i.e., obesity, hypertension, pre-diabetes, type 2 diabetes, osteoarthritis or history of depression) who are suitable for an intervention to increase moderate intensity physical activity

Interventions
There is currently no single model for exercise referral schemes in the UK but the predominant mode of delivery, according to a national survey (BHF, 2010) and descriptions provided in peer reviewed articles on ERS evaluations (including RCTs and prospective studies) involves referral to a programme (e.g., 10-12 weeks) of structured, supervised exercise at an exercise facility (e.g., gym or leisure centre). The operational components, from patient selection to programme content and evaluation, were defined in the National Quality Assurance Framework for ERS (DH, 2001). Exercise practitioners are expected to have an appropriate level of training and competence that is matched to the patients' physical and psychological needs (see www. exerciseregister.org). The NQAF provides a distinction between the terms advice, recommendation and referral. The GP Physical Activity Care pathway notes that GPs should provide advice to all patients to achieve public health guidelines for PA unless otherwise contraindicated. GPs may also recommend that patients attend a specific exercise programme or service to achieve specific health-related outcomes. A referral normally involves an agreement with an exercise service or provider to support patients with specific medical needs. Increasingly, patients are offered support sessions to achieve their PA goals, rather than direct referral to a gym, as is the case in Glasgow. A PA counsellor may provide behaviour change support and help a patient to identify appropriate opportunities to do structured exercise or increase daily PA. Both ERS modes of delivery have the potential to benefit from augmented web-based personalised support. In brief, ERS operate diversely to accommodate patient choice and local availability of facilities but there is a common goal to reduce the risk of long-term metabolic,

musculo-skeletal and mental health conditions due to physical inactivity. We expect that e-coachER will augment the range of usual ERS offered.

The planned e-coachER intervention involves several components, namely:
1. Access to e-coachER which offers a range of interactive opportunities to enhance motivation to increase uptake and maintain a more physically active lifestyle
2. An e-coachER facilitator (mirroring, in part, the role of an NHS Health Care Assistant) who will provide motivational support to participants to use e-coachER
3. A part-time Lifeguide technical support person to resolve user issues (e.g., re-issuing passwords) and update links to other relevant websites and sources of informational and social support (as identified by recruitment site researchers)
4. Each patient in the intervention arm will be given a Welcome Pack to include a pedometer, fridge magnet with paper slips to record step counts and physical activity, and a booklet to introduce the e-coacher intervention at baseline. E-coachER will encourage participants to use a range of behavioural change techniques such as self-monitoring and goal setting.

Patients will receive either usual ERS (control), or usual ERS plus access to web-based e-coachER support, and motivational and technical support (intervention).

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 11/10/2018:
Total weekly minutes of MVPA in >10 minute bouts, recorded objectively by GeneActiv accelerometer, over one week at 12 months. To be included participants need to provide activity recorded on at least 4 days, including a weekend day, for at least 16 hours per day.
[This clarification was signed off in the Statistical Analysis Plan for this trial on 21 May 2018.]

Previous primary outcome measure as of 16/09/2016:
Total weekly minutes of MVPA in >10 minute bouts, recorded objectively by GeneActiv accelerometer, over one week at 12 months

Previous primary outcome measures:
Objectively assessed PA and the achievement of at least 150 min of MVPA (recorded by GeneActiv accelerometer - http://www.geneactiv.co.uk/) over a week, at 12 months

Secondary outcome measures
Current secondary outcome measures as of 11/10/2018:
1. Achievement of at least 150 minutes of MVPA, measured objectively by accelerometer, over 1 week at 4 months post-randomisation
2. Self-reported achievement of at least 150 minutes of MVPA over one week using the Seven Day Physical Activity Recall Questionnaire at 4 and 12 months post randomisation
3. Self-reported health-related quality of life, assessed by the EQ-5D-5L and SF12v2 at 4 and 12 months post randomisation
4. Self-reported symptoms of anxiety and depression, assessed by the Hospital Anxiety and Depression Scale (HADS) at 4 and 12 months post randomisation
5. Average daily hours/minutes of sleep and sedentary behaviour (objectively measured by accelerometer) over 1 week at 4 and 12 months post randomisation
6. Uptake of the ERS according to the attendance records held by the ERS service provider, with imputed patient-reported attendance at 4 weeks and/or 4 months where the ERS service data

are missing. [A convention for analysing participants' uptake of the ERS was agreed and signed off in the Statistical Analysis Plan for this trial on 27 Sept 2018.]
7. Adherence to the ERS, using a composite measure to describe the proportion in each arm of the trial that achieved the primary outcome at 4 months and were still doing so at 12 months
8. Process measures, to be described and included in mediation analysis including 1-4 self-reported survey items for each of the following: self-efficacy/confidence to be physically active; importance of being physically active; relatedness (perceived frequency and availability of support); perceived autonomy/control over physically active choices; involvement in self-monitoring and planning PA
9. In the intervention group, measures of engagement with e-coachER, and its content, and use of self-monitoring and goal-setting functions, captured by the software platform (LifeGuide)
10. Qualitative interviews with participants in the intervention arm, focusing on their experiences with ERS and the intervention. Also, interviews with eligible participants who decline to enter the study to assess acceptability of trial methods

Previous secondary outcome measures as of 16/09/2016:
1. Achievement of at least 150 minutes of MVPA, measured objectively by accelerometer, over 1 week at 4 months post-randomisation
2. Self-reported achievement of at least 150 minutes of MVPA over one week using the Seven Day Physical Activity Recall Questionnaire at 4 and 12 months post randomisation
3. Self-reported health-related quality of life, assessed by the EQ-5D-5L and SF12v2 at 4 and 12 months post randomisation
4. Self-reported symptoms of anxiety and depression, assessed by the Hospital Anxiety and Depression Scale (HADS) at 4 and 12 months post randomisation
5. Average daily hours/minutes of sleep and sedentary behaviour (objectively measured by accelerometer) over 1 week at 4 and 12 months post randomisation
6. Uptake of the ERS by participant self-report at approximately 4 weeks and 4 months post randomisation.
7. Adherence to the ERS, using a composite measure to describe the proportion in each arm of the trial that achieved the primary outcome at 4 months and were still doing so at 12 months
8. Process measures, to be described and included in mediation analysis including 1-4 self-reported survey items for each of the following: self-efficacy/confidence to be physically active; importance of being physically active; relatedness (perceived frequency and availability of support); perceived autonomy/control over physically active choices; involvement in self-monitoring and planning PA
9. In the intervention group, measures of engagement with e-coachER, and its content, and use of self-monitoring and goal-setting functions, captured by the software platform (LifeGuide)
10. Qualitative interviews with participants in the intervention arm, focusing on their experiences with ERS and the intervention. Also, interviews with eligible participants who decline to enter the study to assess acceptability of trial methods

Previous secondary outcome measures:
1. Achievement of at least 150 min of MVPA (recorded by GeneActiv accelerometer) at 4 months
2. Self-reported PA (achievement of at least 150 min of MVPA over a week using the 7-day physical activity recall questionnaire, Blair et al, 1985) at 4 and 12 months
3. Health-related quality of life assessed by the EQ-5D-5L and SF36v2 at 4 and 12 months
4. Sleep and sedentary behaviour (recorded by GeneActiv accelerometer) at 4 and 12 months
5. Uptake: participants in both arms of the trial will receive an e-mail within 4 weeks of a referral to an exercise practitioner to determine if an initial patient assessment (of PA support requirements) has taken place and whether any plans had been established for increasing PA

6. Adherence: a composite measure of adherence will be developed to reflect maintenance of PA change by calculating the proportion in each arm of the trial who achieved the primary outcome at 4 months and were still doing so at 12 months

Overall study start date
01/01/2015

Completion date
30/09/2018

Eligibility

Key inclusion criteria
Current inclusion criteria as of 16/09/2016:
1. Aged 16-74 years
2. With one or more of the following:
2.1. Obesity (BMI 30-40)
2.2. Hypertension (Stage 1: SBP 140-159 or DBP 90-99; or Stage 2: SBP 160-179 or DBP 100-109)
2.3. Pre-diabetes
2.4 Type 2 diabetes
2.5. Lower limb osteoarthritis
2.6. Recent history of treatment for depression (i.e., last 2 years) but may not be currently receiving treatment
3. Participants who are in the follow two lowest (of four) groups identified using the GP Physical Activity Questionnaire recommended for use in the physical activity care pathway:
3.1. Inactive sedentary job and no physical exercise or cycling
3.2. Moderately inactive sedentary job and some but < 1 hour physical exercise and/or cycling per week OR standing job and no physical exercise
4. Have an e-mail address and at least some experience of using the internet

Previous inclusion criteria:
1. Aged 16-74 years
2. With one or more of the following:
2.1. Obesity (BMI 30-35)
2.2. Hypertension (Stage 1: SBP 140-159 or DBP 90-99; or Stage 2: SBP 160-179 or DBP 100-109)
2.3. Type 2 diabetes
2.4. Lower limb osteoarthritis
2.5. Recent history of treatment for depression (i.e., last 2 years) but may not be currently receiving treatment
3. Participants who are in the follow two lowest (of four) groups identified using the GP Physical Activity Questionnaire recommended for use in the PA Care Pathway:
3.1. Inactive sedentary job and no physical exercise or cycling
3.2. Moderately inactive sedentary job and some but < 1 hour physical exercise and/or cycling per week OR standing job and no physical exercise
4. Have an e-mail address and at least some experience of using the internet

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Upper age limit
74 Years

Sex
Both

Target number of participants
413

Total final enrolment
450

Key exclusion criteria
1. Unstable severe and enduring mental health problem that may limit involvement in the trial
2. Being treated for an alcohol problem or drug addiction
3. Inability to use written materials in English
4. Contra-indicated for moderate intensity PA
5. Have at least one medical condition that would exclude them from referral based on standard operating procedures for the ERS

Date of first enrolment
01/09/2015

Date of final enrolment
31/03/2017

Locations

Countries of recruitment
England

Scotland

United Kingdom

Study participating centre
Life Centre
Everyone Active exercise referral scheme
Mayflower Drive
Plymouth
United Kingdom
PL2 3DG

Study participating centre
Be Active Plus
Manor House
40 Moat Lane
Birmingham
United Kingdom
B5 5BD

Study participating centre
Live Active Exercise Referral Scheme
Public Health Directorate
NHS Greater Glasgow & Clyde
West House Gartnavel Royal Hospital
1055 Great Western Road
Glasgow
United Kingdom
G12 0XH

Sponsor information

Organisation
Plymouth University

Sponsor details
Peninsula School of Medicine & Dentistry
John Bull Building
Derriford
Plymouth
England
United Kingdom
PL6 8BU

Sponsor type
University/education

ROR
https://ror.org/008n7pv89

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The plan is to publish the trial protocol by the end of recruitment in March 2017, followed soon after by a paper describing the intervention justification and development in more detail. At the end of the trial a final HTA report will be published as well as a main paper describing the main outcomes in late 2018. Other papers describing the process evaluation and economic analysis will also be published at the end of the study. Other dissemination activity will take place throughout the study, and particularly at the end to inform policy and practice.

Intention to publish date
01/06/2020

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2020	30/11/2020	Yes	No
Protocol article	protocol	21/09/2018	17/12/2020	Yes	No
Results article	results	01/04/2021	17/12/2020	Yes	No
Results article	process evaluation	29/09/2022	30/09/2022	Yes	No
HRA research summary			28/06/2023	No	No
Other publications	Qualitative study	29/10/2024	31/10/2024	Yes	No