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Adding web-based behavioural support to exercise referral schemes for inactive adults with chronic health conditions: the e-coachER Randomised Controlled Trial

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Data Sharing

All data requests should be submitted to the corresponding author for consideration. Access to available anonymised data may be granted following review and appropriate agreements being in place.

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Abstract

Background: There is modest evidence that exercise referral schemes (ERS) increase physical activity (PA) of inactive individuals with chronic health conditions. There is a need to identify additional ways to improve the effects of ERS on long-term PA.

Objectives: To determine if adding the e-coachER intervention to ERS is more effective and cost-effective in increasing PA after one year, compared to usual ERS.

Design: Pragmatic, multicentre 2 arm randomised trial, with mixed methods process evaluation and health economic analysis. Participants were allocated 1:1 to either ERS plus e-coachER (intervention) or ERS alone (control).

Setting: Patients referred to ERS in Plymouth, Birmingham and Glasgow.

Participants: N = 450, aged 16-74 years, with BMI 30-40, hypertension, pre-diabetes, type 2 diabetes, lower limb osteoarthritis, or a current/recent history of treatment for depression; inactive; contactable via email; and an internet user.

Intervention: e-coachER was designed to augment ERS. Participants received a pedometer and fridge magnet with PA recording sheets, and a User Guide to access the web-based support in the form of 7 Steps to Health. e-coachER aimed to build the use of behavioural skills (e.g. self-monitoring) while strengthening favourable beliefs in importance for doing PA, competence, autonomy in PA choices and relatedness. All participants were referred to a standard ERS programme.

Primary outcome measure: Minutes of moderate and vigorous PA (MVPA) in ≥10 min bouts measured by accelerometer over one week at 12 months, worn ≥16 hours per day for ≥4 days including ≥1 weekend day.

Secondary outcomes: Other accelerometer-derived PA measures, self-reported PA, ERS attendance, EQ-5D-5L and HADS were collected at 4 and 12 months.

Results: Participants had a BMI mean (SD) of 32.6 (4.4), were primarily referred for weight loss, and were mostly confident self-rated IT users. Primary outcome analysis involving those with usable data showed a weak indicative effect in favour of the intervention group (N=108) compared with the control group (N=124); 11.9 weekly minutes MVPA, 95% CI -2.1 to 26.0; p = 0.10. 64% of intervention participants logged on at least once with generally positive feedback on the web-based support. The intervention had no effect on other PA outcomes, ERS attendance (78% v 75% in control and

intervention, respectively), EQ-5D-5L or HADS scores, but did enhance a number of process outcomes (i.e. confidence, importance and competence) compared with the control group at 4 months but not at 12 months. At 12 months, compared to control, the intervention group incurred an additional mean cost of £439 (95% CI £-182, £1060) but generated more mean quality adjusted life years (QALYs); (0.026, 95% CI 0.013, 0.040) with an incremental cost effectiveness ratio of additional £16,885 per QALY.

Limitations: A significant proportion (46%) of participants were not included in the primary analysis, due to study withdrawal, and insufficient device wear time and the results must be interpreted with caution. The regression model fit for the primary outcome was poor, because of the considerable proportion of participants (142/243 (58%)) who recorded zero minutes of ≥10 minute bouted MVPA at 12 months.

Future work:

The design and rigorous evaluation of cost-effective and scalable ways to increase ERS uptake and maintenance of MVPA are needed among patients with chronic conditions.

Conclusion: Adding e-coachER to usual ERS had only a weak indicative effect on long-term rigorously defined, objectively assessed MVPA. The provision of the e-coachER support package led to an additional cost and has a 63% probability of being cost-effective based on the UK threshold of £30,000/QALY. The intervention did improve some process outcomes as specified in our Logic Model.

Study registration: ISRCTN15644451

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Abbreviations

7-D PAR   7-day Physical Activity Recall questionnaire

Accel.   Accelerometer

BMI   Body mass index

CACE   Complier Average Causal Effect

CRF   Case Report Form

CONSORT   Consolidated Standards of Reporting Trials

CRN   Clinical Research Network

CTU   Clinical Trials Unit

DMC   Data Monitoring Committee

ERS   Exercise referral scheme(s)

EQ-5D-5L   EuroQol -5 dimension – 5 level

GPPAQ   GP Physical Activity Questionnaire

HADS   Hospital Anxiety and Depression Scale

ISRCTN   International Standard Randomised Controlled Trials Number

ITT   Intention to treat

MedDRA   MedDRA Terminology SOC List Internationally Agreed Order Version 19.0, March

                2016

                (https://www.meddra.org/sites/default/files/guidance/file/intguide_19_0_english.p

                df)

MVPA   Moderate and vigorous physical activity

OR   Odds ratio

PA   Physical activity

PPI   Patient and Public Involvement

QALY   Quality Adjusted Life Year

RCT   Randomised Controlled Trial

REC   Research Ethics Committee

SAE   Serious Adverse Event

SF12v2   12-Item Short Form Health Survey version 2

TSC   Trial Steering Committee

Plain English Summary

When healthcare professionals refer patients with chronic conditions to an exercise referral scheme (ERS) the effects on long-term increases in physical activity are limited. We therefore developed the e-coachER support package, to add to usual ERS, to prompt the use of skills such as self-monitoring and goal setting, and empower patients to increase physical activity long-term. The 7-Step programme was delivered online (via an interactive website). As part of the package, we mailed a guide for accessing the online programme, a pedometer and a fridge magnet with a notepad to record physical activity. We aimed to determine if adding the e-coachER support to usual ERS resulted in lasting changes in moderate and vigorous physical activity and whether it offers good value for money, compared with ERS alone.

A total of 450 inactive individuals were recruited across Plymouth, Birmingham and Glasgow, and were referred to an ERS for the following participant-reported main reasons: weight loss (50%); low mood (19%); osteoarthritis (12%); type 2 diabetes (10%); and high blood pressure (8%).

Half the individuals were given access to the e-coachER support and half weren't. All individuals were mailed a wrist-worn movement sensor (accelerometer) to wear for one week, and a survey to assess other outcomes at the start of the study, and at 4 and 12 months.

At the start of the study, the participants were inactive, most had multiple health conditions, had an average body mass index of 33, and an average age of 50 years. Most (83%) were white.

Participants with access to e-coachER support were only slightly more active at 12 months compared to those who didn't but we can't be confident in the findings because we had data from fewer participants than planned. The lack of a clear effect may have been due to about one third not accessing the website, though there was otherwise reasonable engagement. The provision of the e-coachER support package led to an additional cost of £439 per participant over a 12 months period.

Scientific Summary

Background: From meta-analyses of randomised trials there is evidence that primary care exercise referral schemes (ERS) result in a modest increase in the proportion of participants achieving 90-150 minutes of self-reported moderate and vigorous physical activity (MVPA) at least 6 months after randomisation, compared with usual care. Rigorous research is needed to assess the effectiveness of new approaches to increase ERS uptake, adherence and change in long-term objectively assessed MVPA, among inactive patients with chronic conditions.

E-health interventions for promoting PA have become popular because they offer an opportunity to target a wide range of people at low cost, but no studies have explored their use alongside ERS which offer face to face support. We developed a bespoke support system, using the LifeGuide© platform, to empower ERS patients with physical and mental health conditions to become more physically active and remain motivated to do so. Building on Self-Determination Theory as a framework, we incorporated evidence-based components into a 7 Steps to Health web-based programme called e-coachER, with support available for up to 12 months. At the same time as an exercise referral, participants were mailed a free pedometer, fridge magnet with attached tear-off strips to record daily steps or minutes of MVPA, and a User Guide with instructions on how to access the web-based support. The e-coachER Steps to Health programme aimed to increase favourable beliefs in the importance for being physically active, confidence in being regularly physically active, being autonomous in choosing what, where and when to be active, and finding and using support to be physically active, whether that be face-to-face at the ERS, with friends and family or online. We defined getting to Step 5 (setting a goal and reviewing a goal online) as a sufficient 'dose' of the intervention to impact on minutes of MVPA, though recognised that merely mailing a pedometer could be an effective intervention alone.

Objectives: The overall aim of the study was to determine if adding the e-coachER intervention to usual ERS was more effective and cost-effective in increasing PA after one year, compared to usual ERS alone.

Research questions:

The specific research questions were:

* Does the e-coachER intervention when added to usual ERS, compared to usual ERS alone, increase the total weekly minutes of accelerometer assessed MVPA (in bouts of at least 10 minutes) at 12 months post-randomisation?

* Does the e-coachER intervention when added to usual ERS, compared to usual ERS alone, increase:

- ERS attendance?

- Other accelerometer and self-reported measures of MVPA?

- Quality of life and mental health?

- Process outcomes (e.g. confidence to and importance of doing PA, a sense of autonomy in deciding what PA to do and when, a sense of relatedness to others in doing PA, and use of self-monitoring and goal setting)?

- Is the e-coachER intervention when added to usual ERS, compared to usual ERS alone, cost-effective?

- Is the effect of the intervention moderated by participant and ERS characteristics?

- What are the mechanisms through which the intervention impacts on the outcomes?

Methods: The study involved an individually randomised, pragmatic, multicentre 2 arm randomised trial with follow-up at 4 and 12 months, with embedded mixed methods process evaluation and health economic analysis. Patients were referred to a local ERS in the UK cities of Plymouth, Birmingham and Glasgow and invited to join the study by primary care or exercise practitioners. To maximise the generalisability of the findings, recruitment sites were chosen to reflect a range of cultural and contextual factors, including the way in which ERS operated.

Participants were aged 16-74 years with a body mass index (BMI) of 30-40; had one or more of the following conditions: hypertension, pre-diabetes, type 2 diabetes, lower limb osteoarthritis, a current or recent history of treatment for depression. Participants were eligible if they were inactive or moderately inactive (using the GP Physical Activity Questionnaire, GPPAQ), and were an internet user and contactable via email.

The primary outcome was minutes of moderate and vigorous PA (MVPA) in ≥10 minute bouts measured by accelerometer over one week at 12 months, worn ≥16 hours per day for ≥ 4 days including ≥1 weekend day. Other accelerometer-derived PA measures (e.g. not in ≥10 minute bouts), self-reported PA (7-day Recall of PA), ERS attendance (at initial session with ERS practitioner), non-validated process measure survey items, EuroQol (EQ-5D-5L) and Hospital Anxiety and Depression Scale (HADS; anxiety and depression) were collected at baseline, and then 4 and 12 months post-randomisation.

Results: The sample (N=450) had a BMI mean (SD) of 32.6 (4.4), and the primary participant-reported reasons for referral to the ERS were weight loss (50%); low mood (19%); osteoarthritis (12%); type 2 diabetes (10%); and high blood pressure (8%). Participants identified additional reasons for referral, which were weight loss (81%); low mood (54%); osteoarthritis (24%); type 2

diabetes (26%); and high blood pressure (33%), which indicated the high degree of co-morbidity in the sample. At baseline, only 4% of the sample achieved ≥150 minutes of MVPA (accumulated in bouts of ≥10 minutes) for one week at 12 months.

Primary analysis: Loss to follow-up and incomplete data reduced the sample size to N=232 for the primary analysis (intervention n=108, control n=124). ITT complete case adjusted comparison of groups at 12 months showed a weak indicative effect in favour of the intervention group (N=232; 11.8 weekly minutes, 95% CI -2.1 to 26.0; p=0.10). Because of the large proportion of participants who had zero values for the primary outcome, five different statistical models were run in the primary analysis, and only one showed a significant (p<0.01) effect in favour of the intervention. A secondary analysis showed that with only those with complete data at baseline, 4 and 12 months, there was also no significant effect. In further sensitivity analyses of the primary outcome, with less rigorous criteria applied to including participants with four different wear-time completion thresholds (i.e. ≥4 days regardless of whether weekday or weekend days for ≥16 hours per day; ≥4 days regardless of weekend or weekday for ≥10 hours per day; ≥4 days including 1 weekend day for ≥10 hours per day; ≥4 days including 1 weekend day for ≥10 hours per day and weighted by number of days of valid days), there remained no significant between group differences. A Complier Average Causal Effect (CACE) analysis, with consideration of whether or not participants had completed an a priori definition of adequate intervention dose (i.e. Step 5: completed ≥1 goal review in e-coachER), also revealed no intervention effect.

The results of the primary analysis were not influenced by age, gender, trial site, participant's reported main chronic condition for referral or IT literacy level.

In exploratory analysis of ≥10 min bouted accelerometer data, with only participants who were included in the ITT complete case adjusted analysis, the control group showed a significant mean (SD) increase of 8.2 (32.1) minutes of MVPA from baseline to 4 months, but a non-significant decline from baseline to 12 months. The intervention group did not change from baseline to either 4 or 12 month assessment.

Secondary analysis: Applying the same approach as in the primary analysis, there were no between group differences at 12 months in any of the other accelerometer derived or self-reported MVPA outcomes, with one exception. In ITT imputed comparison at 12 months the intervention group were more likely to self-report that they had achieved 150 minutes of weekly MVPA (OR 1.55; (0.99, 2.42), p=0.05), compared with the control group. The intervention had no effect on ERS attendance: in the control group, (78%) of the 223 participants for whom we had ERS attendance data attended the ERS at least once; compared with 167 (75%) of 223 in the intervention group. The intervention also had no effect on EQ-5D-5L or HADS scores at 12 months, compared with the control group. In

ITT imputed comparison at 12 months the intervention group had lower HADS depression and anxiety scores than the control group.

Intervention engagement: Among the intervention participants, 64% logged on to the online support at least once with generally positive feedback on its value. The mean (SD) number of goal reviews was 2.5 (4.5) with a range of 0-24. The 144 participants who registered, logged into the online support for a mean (SD) and median number of times of 14.1 (16.7) and 6, respectively, with a range of 1-101.

Of the 81 (36%) participants who did a goal review, the mean (SD) and median number of reviews was 14.4 (13.8) and 4.5, respectively, with a range from 1-52. Overall, participants who did register online spent mean (SD) and median of 6.47 (7.45) and 4.08 minutes each time they logged into the e-coachER website. The engagement data, from the LifeGuide© platform indicate reasonable levels of engagement were achieved and analysis of qualitative data from 38 interviews with 26 participants suggests a generally positive assessment of the content and functionality of e-coachER as a valuable resource, though some people identified limitations and made recommendations for improvements.

Process outcomes: Our Logic Model predicted that e-coachER engagement would strengthen various beliefs that would in turn translate into increases in MVPA, compared with usual ERS support. Among only the participants included in the primary analysis, the intervention did increase the following up to 4 months, but not 12 months, compared with the control group: perceived importance of doing at least 30 minutes of moderate intensity PA (e.g. brisk walk) on at least 5 days a week; confidence in achieving at least 30 minutes of moderate intensity PA on at least 5 days a week; and perceived competence in being regularly physically active. Changes (from baseline to 4 months) in these process outcomes did not mediate changes in the primary outcome at 12 months.

The e-coachER intervention incurred an additional cost of £439 (95% CI £-182, £1060) (from additional service use and intervention delivery) and compared to ERS alone generated over 12 months a small increase in adjusted life years (0.026, 95% CI 0.013, 0.040), with an incremental cost effectiveness ratio of £16,885 per QALY.

Conclusion: We believe this to be the most rigorous study to date on the effectiveness and cost-effectiveness of adding web-based behavioural support to usual ERS. Adding the e-coachER intervention to usual ERS led to only a weak indicative effect on objectively assessed MVPA at one year. Given this result and the small numbers analysed, the findings must be interpreted with caution. The e-coachER intervention had little or no benefit on other PA measures of MVPA, health-related quality of life or mental health. We explored a number of ways of analysing the data and the

findings were consistent. However, the cost of the e-coachER intervention and the gains (albeit small) in QALY indicate that e-coachER has a probability of 63% to be a cost-effective intervention at NICE's willingness to pay threshold of £30,000 QALY. The intervention did improve some process outcomes as specified in our Logic Model, but changes in perceived importance, confidence and competence associated with being physically active from baseline to 4 months did not mediate intervention effects on the primary outcome.

Implications for healthcare: Our findings suggest that clinically meaningful increases in PA may not be derived from the e-coachER intervention, but given its additional cost and associated small gains in QALYs (main outcome for the economic evaluation) that such an intervention could still be a cost-effective addition to usual ERS (offered in different ways) for increasing PA for up to 12 months. In other words, sending patients a pedometer and fridge magnet with tear-off PA self-monitoring strips, and access to a website which requires virtually no human support, could be a cost-effective way to improve quality of life in inactive patients with certain chronic conditions. The process evaluation interviews identified a number of ways in which e-coachER could be improved, such as giving patients more information about their specific health conditions. Alternatively, improvements could be made by providing more structured guidance in the User Guide on the overall aim and content of web-based e-coachER support, including where to find links to more information about exercise and medical conditions.

Recommendations for research:

The modest engagement in the on-line e-coachER support suggests work is needed to understand what factors influenced intervention engagement and how best to further develop low-cost and scalable support to increase ERS uptake and maintenance of PA. Once this has been done, further research could examine the effects of a modified e-coachER type intervention for participants with chronic conditions involved in the present study and others (e.g. with cancer, back pain and in cardiac rehabilitation).

The e-coachER study has provided a rich data set which offers the chance to explore additional questions including the following:

What were the characteristics of participants that predicted changes in 4 and 12 month PA?

How did different measures of MVPA (self-report and accelerometer-derived) influence the findings, beyond what we present here?

What other aspects of intervention engagement (derived from the LifeGuide© platform) were used, and did any influence changes in process and behavioural outcomes?

Among subsets of the sample (e.g. those with low mood), what changes in quality of life, depression and anxiety occurred as a result of the intervention versus usual ERS?

Trial registration

This trial is registered as ISRCTN15644451.

Funding

Chapter 1: Introduction

Scientific background

As described elsewhere,[1] evidence-based guidelines recommend both aerobic and strength training for improving health markers and quality of life among those with common chronic metabolic conditions[1-5] and musculo-skeletal conditions,[6] and mostly aerobic exercise for preventing and reducing depression.[7] Public health guidelines of 150 minutes of moderate activity (accumulated in bouts of 10 minutes or more) or 75 minutes of vigorous activity per week are only met by 66 per cent of men and 58 per cent of women aged 19 or older in England, similar to results from the Scottish Health Survey 2014 (68% men; 59% women), based on self-report data from a national representative survey.[8, 9] The guidelines also highlight the importance of reducing sedentary behaviour and regularly doing bouts of resistance exercise. Physical inactivity, from data from 2013-14, collected by Clinical Commissioning Groups in the UK, cost the NHS £455m.[10]

Even small increases in PA and reduced sedentary time, especially among the least active,[10] are likely to provide health benefits.[11, 12] Patients with obesity, hypertension, type 2 diabetes, osteoarthritis and depression do less PA than the general population,[2] and report greater barriers to increase PA.

Exercise Referral Schemes in the UK

A variety of approaches have been explored to promote PA within primary care, such as referring patients to 'exercise on prescription', i.e. an ERS. As described previously[1] In the UK, ERS have been popular with an estimated 600 schemes involving up to 100,000 patients per year in 2008.[13] There is currently no one model for ERS in the UK, but they mainly involve referral to a programme (e.g. 10-

12 weeks) of structured, supervised exercise at an exercise facility (e.g. gym or leisure centre) or a counselling (and sign-posting) approach to support patients to engage in a variety of types of PA.[13] ERS operate diversely to accommodate patient choice and local availability of facilities, the common goal being to reduce the risk of long-term metabolic, musculo-skeletal and mental health conditions due to physical inactivity.

Evidence from a meta-analysis of eight randomised trials involving 5190 participants eligible for ERS[14] indicated only a small increase in the proportion of participants who achieved 90-150 minutes of PA of at least moderate intensity per week, compared to no exercise control at 6 to 12 month follow-up among at risk individuals. But uncertainty remains regarding the effects for patients with specific medical conditions, no study assessed long-term PA objectively, and many of the eight studies reviewed had relatively small sample sizes.

A review[15] reported the average ERS uptake (attendance at the first ERS session) ranged from 66% in observational studies to 81% in RCTs, and average levels of 'adherence' from 49% in observational studies to 43% in RCTs. Predictors of uptake and adherence have been explored; women were more likely to begin an ERS, but less likely to adhere to it than men; and older people were more likely to begin and adhere to an ERS.[15] As an example of a large observational retrospective study[16], 6894 participants who had attended an ERS scheme over 6 years, 37.8% (n=2608) dropped out within 6 weeks and 50.03% (n=3449) by the final 12th week, and males (p <0.001) and older people (p <0.001) were more likely to adhere than females and younger people, respectively. ERS may help patients become familiar with[17] medical condition, and target key processes of behaviour change. However, the following features of an ERS may reduce uptake and adherence: inconvenience, cost, limited sustainable PA support (e.g. for 10 weeks), and low appeal for structured exercise and/or the medical model, i.e. 'exercise on prescription', which may in some schemes do little to provide autonomous support nor empower patients to develop self-determined behaviour to manage chronic medical conditions.[13 18 19]

It therefore appears that additional support may be needed which is accessible, low cost, can be tailored to support a wide range of individual needs, and empowers patients to develop and use self-regulatory skills (e.g. self-monitoring, goal setting) to self-manage their chronic conditions. In one study training for ERS staff to foster self-determined behaviour increased PA more than when the ERS was delivered by untrained staff at 3 and 6 months[20]. Similarly, training of ERS staff in behaviour change techniques and motivational interviewing led to small additional changes in self-reported PA after 12 months[17] compared with no ERS. Challenges in training staff across a wide geographic area across Wales and monitoring intervention fidelity were noted.

Intervention technologies to promote physical activity

To address the challenges noted above with face-to-face promotion of PA and encompass the growing use and availability of new technologies, a wide variety of online and mobile support has been developed and used to promote PA.

As described previously[1] there is growing evidence on the effectiveness of technology-based interventions for promotion of PA.[21, 22] Studies include a wide range of interventions (from quite simple self-monitoring to interventions with complex multiple behaviour change components), targeted at different clinical groups with different baseline levels of PA, with various PA outcomes reported (very few using objective measures), and with mostly short-term follow-ups. Also, some comparisons are between intervention versus no intervention and others versus human contact, though none report on the effects of adding web-based support to complement face-to-face support provided by ERS. The impact for web-based and technology interventions on increasing PA is small to moderate (an effect size ≤0.4). However, there is evidence from more rigorous studies, that interventions with more behaviour change components, and ones targeting less active populations are more effective.[21, 22] A systematic review[23] highlighted the importance of maximising sustained engagement in web-based interventions for enhancing change in the target behaviour. A recent study[24] highlighted that self-monitoring of PA and tailored feedback were important to increase engagement, and periodic communications helped to maintain participant engagement.

The LifeGuide© platform (www.LifeGuideonline.org/) has been extensively used to develop and evaluate the acceptability and impact of online behaviour change and self-management interventions with a variety of clinical groups, including in primary care.[25-27] As an example, when adding online LifeGuide© support to face-to-face support there was a greater lasting reduction in obesity than face to face dietetic advice alone.[28] The LifeGuide© platform provides a researcher-led tool to develop theory driven interventions and evidence of the effectiveness of techniques.[29, 30] It also provides the opportunity to capture intervention engagement and assess the utility of different behaviour change components.

The potential for e-coachER

Following iterative development work and user group testing and involvement, drawing on some online modules used in other LifeGuide© interventions, for example in secondary prevention of coronary heart disease,[25] we developed a bespoke intervention, called 'e-coachER' to support patients with chronic physical and mental health conditions who have been referred from primary care to an ERS to receive face-to-face support[1]. The overarching aim of the e-coachER intervention was to facilitate long-term PA by promotion of evidence-based self-regulatory skills and encourage interaction with others (including the ERS professional, family and friends), and founded on Self-

Determination Theory[31] to build a sense of competence in managing PA, autonomy or control over PA, and connection or relatedness with others. We wanted to encourage uptake and adherence to the ERS but if that was not acceptable or feasible for participants then we offered support to find alternative ways to be physically active in a way that may support their needs as someone who was inactive. It was also important that the intervention could be scaled up to promote PA for patients with obesity, hypertension, type 2 diabetes, osteoarthritis and risk of depression at probably low cost[32, 33] and also potentially make it available for patients with other chronic medical conditions (e.g. low back pain, heart disease, cancer).

Developing the e-coachER intervention

The intervention development, included the piloting of the Welcome Pack and development of an initial version of e-coachER, built on wide ranging experiences from the development of other self-management interventions using the LifeGuide© platform,[34] and beta-testing over 7 months. Co-applicants and researchers then provided feedback on a time-truncated version, and ERS users provided feedback on a real-time version, for 5 months before the website was locked for the RCT.

The development of all components of the e-coachER intervention followed a logic model as shown in Figure 1[1].

Figure 1: Logic Model for e-coachER intervention

INTERVENTION COMPONENTS

Initial package includes free pedometer, fridge magnet and access to e-coachER; a website to promote PA via specific behaviour change techniques (BCTs):

Step 1: Information about physical and mental health consequences

Understand benefits of exercise and PA goal setting. How to manage setbacks.

Step 2: Social support

Encouraged to seek support from friends and family/exercise coach to implement & maintain PA.

Step 3: Self-monitoring of behaviour

Monitor steps/PA.

Step 4: Goal setting

Set weekly step & PA goals.

Step 5: Action planning

Making plans to achieve goals.

(NB – These are the priority BCTs. For full list of BCTs, see

CONTEXT

Participants' engagement with e-coachER may be moderated by participant socio-demographic and health characteristics, type and location of ERS scheme and relationship with ERS coach.

Participant motivation and PA might also be moderated by the same contextual factors.

INTERVENTION DELIVERY

Participants progress through e-coachER.

CHANGES TO MOTIVATION & BEHAVIOUR

Participant motivation for PA is mediated by autonomy, competence and relatedness.

Participant autonomy, competence and relatedness is enhanced by using the website and implementing behaviour change techniques.

LONG-TERM OUTCOMES

Health and economic benefits. Quantitative outcome data in both trial arms, including weight, quality of life.

FEEDBACK LOOP

Increased use of website and BCTs, motivation, achievement of PA goals reinforce each other (e.g. motivation is enhanced as levels of PA increase).

SHORT-TERM OUTCOMES

MVPA increases, sedentary time decreases. Quantitative outcome data in both trial arms.

The key components of e-coachER include the following:

- Upon allocation to the intervention all participants received a 'Welcome Pack' (Figure 2) that contained a User Guide and the participant's unique user log-in and registration details to access the e-coachER website; a simple pedometer (step-counter) with instruction sheet; and a fridge magnet with tear-off sheets to record daily PA (complete with trial branding and e-coachER helpline). Participants were encouraged to use the pedometer and the PA record sheets for self-monitoring and goal setting in conjunction with the website.

Figure 2: e-coachER Welcome Pack

Welcome pack comprised of a User Guide, pedometer, and magnet notepad for recording PA.

- The e-coachER support system, hosted on the LifeGuide© platform, provided support through seven 'Steps to Health' lasting approximately 5-10 minutes each, as shown in Table 1.

- Table 1The Steps were designed to do the following: encourage participants to think about the benefits of PA (motivation); seek support from an ERS practitioner, friends/family, and the internet (support /relatedness); set progressive goals; self-monitor PA with a pedometer and upload step counts or minutes of MVPA (self-regulation, building confidence /autonomy); and find ways to increase PA more sustainably in the context of day-to-day life, and deal with setbacks (building confidence). The sequential content, objectives, and how

this was implemented were mapped against a taxonomy for behaviour change techniques also shown in Table 1.[35] The website content is illustrated in Appendix 1.

- Participants were encouraged to use e-coachER support as an interactive tool by using pre-set or personally set reminders to upload step counts or minutes of MVPA, and messages of encouragement. A lack of engagement (e.g., not reviewing a goal by entering step counts a week later, or not signing into the website for 1, 2, and 4 weeks) triggered reminder e-mails. Participants were reminded by prompts to review goals the next day.

- An avatar was used throughout the content to avoid having to represent a range of individual characteristics such as age, gender and ethnicity. The avatar delivered brief narratives to normalise and support behaviour change and encourage the use of e-coachER. Automatic and user-defined e-mails generated by the LifeGuide© system promoted on-going use of functions such as recording weekly PA and goal setting. Participants were provided with links to reputable generic websites for further information about the chronic conditions of interest and lifestyle, links to other websites and apps for self-monitoring health behaviour and health, as well as modifiable listings of local opportunities to engage in PA.

- The only webpages that were not 'locked' after the initial participant began the intervention were pages for the respective recruitment sites which displayed links to the following websites: (1) local community opportunities for engaging in PA; (2) disease specific (e.g. Diabetes UK; Royal College of Psychiatrists) informational sites about the role of PA in preventing and managing the condition; (3) sites about other ways to optimise ways to be physically active (e.g. more sophisticated technologies to self-monitor).

- Our aim was to maximise accessibility and usage. Therefore, a local researcher provided technical support if requested, but did not support behaviour change directly. If participants did not register on the e-coachER website within the first few weeks, they were followed up with a phone call to offer support to use e-coachER. If technical support to resolve any user operational issues with the website (e.g. re-issuing passwords) was needed, participants were referred to a centralised technician within the LifeGuide© team for further support.

Table 1 Sequential components within the e-coachER intervention and objectives mapped against behaviour change techniques, and explanation of the implementation strategy

Sequential components	Objectives	Behaviour Change Techniques [35]	Implementation Strategy
Welcome pack and pedometer & Introduction to web-based support for self-directed PA	To introduce the user to the philosophy of the website to become personal coach	10. Self-monitoring	Explain philosophy of using website to become own personal coach.
			Links provided to local services and other self-help resources to highlight patient autonomy and choice.
	Build on personal support provided by ERS using web-based platform		Offers e-coachER facilitator to help with using technology. Provide link to IT support in Southampton.
	Support those who don't want to /can't engage with ERS personnel		
	Support achievement of personal goals for PA to enhance health		
Step 1 - Thinking about	Elevate importance of PA	82. Information about health consequences, 83.	Quiz to engage participants using positive framing

the benefits of PA		Information about emotional consequences	Provide evidence of multiple benefits of PA especially for relevant health condition(s)
			Elicit and address concerns about PA, describing support given as part of ERS and by website.
Step 2: Support to get active	To encourage user to access and create social support networks	1.Social support (practical), 2.Social support (emotional), 3.Social support (unspecified)	Explain how to make the most out of the ERS support to learn how to become own personal trainer in future.
			Explain how user can create a personal 'PA challenge' and share it with family, friends, peers, and exercise and health professionals. The patient may be encouraged to tell others about how e-coachER has been used to support behaviour change.
	To encourage user to take advantage of exercise referral scheme and face to face support offered.		Suggest ways of involving family or friends in longer-term support for continued PA.
			Link to online sources of local support (e.g., local walking or jogging group, or British Trust for Conservation Volunteers).
			How to use website to send personalised email/text reminders, motivational messages to self.

| | | | Draw on positive normative beliefs; identify benefits of social interaction (companionship). Sharing personal PA challenge with others, involve friends and family, online local support links.

Identify benefits of informational support (from ERS scheme) in addition to emotional support from family and friends). |
|---|---|---|---|
| Step 3: Counting your steps | To encourage and support the user to monitor step counts using a pedometer over a week.

Emphasise personal experimentation. | 10. Self-monitoring of behaviour | Provide guidance on how to count steps/use pedometer.

Provide guidance on how steps can be implemented into lifestyle.

Encourage self-monitoring using diary. |
| Step 4: Making your step plans | To set explicit step count goals for the following week. | 66. Goal setting (behaviour) | Give rationale and evidence for goal-setting for graded increase in PA.

User sets specific, achievable goals for next week (e.g. sessions completed, step count using the supplied pedometers).

Links provided to local services and other resources. |

Step 5: Making your activity plans	To encourage and support the user to identify behavioural goals (types of activities).	68. Action planning	User selects walking or 'other physical activities' (which includes options for facility-based activity with practitioner support within ERS). Present options for facility and lifestyle-based activity. Sets specific, achievable goals for next week with a particular focus on avoiding days with less activity by planning walking or other activities. Keeping a PA diary.
Weekly goal and PA review	To promote adherence and graded increase in PA by providing tailored feedback and advice based on self-reported goal progress.	66. Goal setting behaviour, 68. Action planning, 69. Review behaviour goals.	User records extent to which goals achieved in previous week, gets progress graph and personalised feedback: Praise for any goal achievement, encouragement to set a more challenging goal if not yet meeting target PA criteria. Encouragement where goals not attained, with links to webpages to assist with increasing motivation or confidence, selecting different activities or goals, making better plans, accessing support, overcoming setbacks (with links to relevant sessions below).

			Each session completed ends with new links to reputable information and resources (e.g. NHS Choices, condition-specific PA advice websites).
			Help user plan gradual increases in PA.
Step 6 – Finding ways to achieve your plans	To help the user harness their environment to provide support for PA. Identifying personal motivations, building confidence.	30. Restructuring the physical environment 31. Restructuring the social environment, 32. Avoidance /reducing exposure to cues for behaviour	Make plan to use environment to automatically support PA (with examples e.g. fitness equipment in living room, route to work/shops that involves more PA, committing self to specific routine). Advise user on how to use website to send personalised email/text reminders, motivational messages. Overcoming barriers in work, leisure, home and travel. Building self-efficacy. Using smart phone apps for mobile support (e.g. PowerTracker, MyFitnessPal). Invite user to identify personal motivations for becoming more active.
Motivational Messages (text or/and emails)	To provide reminders of users personal reasons (not necessarily health	15. prompts/cues	Invite user to write motivational message to be sent weekly or monthly detailing their own motivations for becoming more active

	reasons) for becoming more active.		
Step 7 – Dealing with setbacks	To provide strategies for overcoming relapse in levels of PA.	5. Reduce negative emotions	Identify possible causes of relapse (e.g., illness, holidays, change in work hours, new caring responsibilities) and plan ways to overcome barriers.
			Challenging catastrophic negative thoughts about lapses from intended PA.
			How to learn from a lapse and plan to avoid or overcome in future.
			Provide salient role models of people overcoming barriers to successfully engage with PA.

Trial aim and objectives

The overarching aim was to determine if e-coachER online support combined with usual ERS provided an effective and cost-effective approach to supporting increases in PA in people referred to ERS with a range of chronic conditions.

The specific objectives are as follows:

- To determine whether in the intervention arm compared to the control arm, there is an increase in the total weekly minutes of MVPA at twelve months post-randomisation.
- To determine whether in the intervention arm compared to the control arm, there is an increase in the proportion of participants who:
  - Take up the opportunity to attend an initial consultation with an exercise practitioner
  - Maintain objectively assessed PA at four and twelve months post-randomisation
  - Maintain self-reported PA at four and twelve months post-randomisation
  - Have improved health-related quality of life at four and twelve months post-randomisation

- To quantify the additional costs of delivering the intervention, and determine the differences in health utilisation and costs between the intervention and control arms at twelve months post-randomisation.
- To assess the cost-effectiveness of the intervention compared with control at twelve months post-randomisation (incremental cost per QALY) using a previously developed decision model to estimate future costs and benefits.
- To quantitatively and qualitatively explore whether the impact of the intervention is moderated by medical condition, age, gender and socioeconomic status, IT literacy or ERS characteristics.
- To quantitatively and qualitatively explore the mechanisms through which the intervention may impact on the outcomes, through rigorous mixed methods process evaluation and mediation analyses (if appropriate).

Chapter 2: Methods

Study design

This was a multi-centre parallel two group randomised controlled trial with participant allocation to usual ERS alone (control) or usual ERS plus web-based behavioural support (intervention) with parallel economic and mixed methods process evaluations.[1] The trial design is summarised in Figure 3, from Ingram et al.[1]

Recruitment to the trial took place over a 21 month period (July 2015 to March 2017) in three areas in the UK, i.e. Greater Glasgow, West Midlands, and South West England (including Plymouth, Cornwall and Mid Devon). The majority of participants lived in urban locations. Further information about the characteristics of the cities involved and the respective ERS to which participants were referred is given in Ingram et al. [1]

Figure 3 Participant pathway
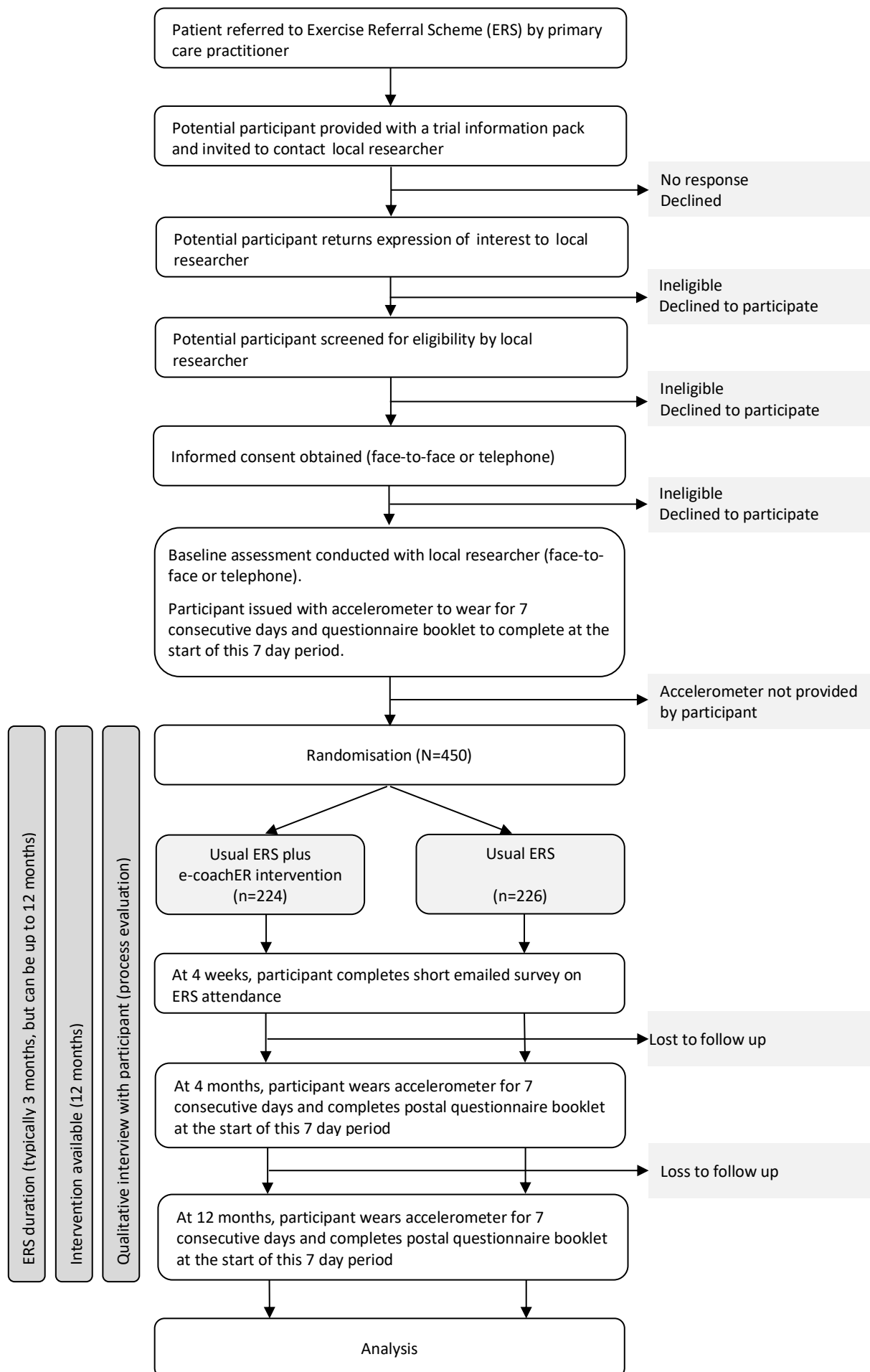
Ethics approval and research governance

Ethical approval for the study was granted by North West Preston NHS Research Ethics Committee (REC) in May 2015 (reference number 15/NW/0347). Approval for activity at non-NHS sites was obtained from the same REC for the following ERS: Everyone Active (Plymouth), Teignbridge District Council (Cornwall), Tempus Leisure (Cornwall), Be Active Plus (West Midlands) and Live Active (Glasgow) in December 2015, and Docspot (West Midlands) in November 2016.

NHS Research and Development approval was granted by the Royal Devon and Exeter NHS Foundation Trust Shared Management Service for the Plymouth site (July 2015); NIHR Clinical Research Network (CRN) West Midlands for the Birmingham site (July 2015); and the NHS Greater Glasgow & Clyde Health Board for the Glasgow site (January 2016).

Prior to commencing recruitment, the trial was registered with the International Standard Randomised Controlled Trial Register (ISRCTN) under reference number 16900744 and NIHR CRN Portfolio 19047. A summary of the changes made to the original protocol is given Chapter 2.

Patient and Public Involvement

Aim:

The aim was to involve public representatives throughout the study to ensure the intervention and trial methods were appropriate for the target population.

Methods:

The target trial population was comprised of patients with one or more physical and mental health condition; there was no single patient support group or user group that could be invited to contribute as PPI representatives. Hence PPI representatives, with diverse clinical conditions, were sought from an ERS provider in Plymouth. Others involved in the delivery of ERS as managers or practitioners were also consulted to ensure the methods and intervention was aligned with usual ERS, especially in the recruitment locations.

There was comprehensive PPI in intervention development. PPI representatives provided critical feedback, in informal focus groups, on the e-coachER website and registration processes, on the use of the pedometer and the fridge magnet (with recording strips) as a motivational tool in the e-coachER support package.

PPI representatives with experience of ERS also contributed to the study via their membership of the e-coachER Project Management Group and Trial Steering Committee (TSC).

Results:

Notable benefits included having access to PPI representatives' perspective on (i) participant-facing documents such as the e-coachER invitation materials and participant newsletter, (ii) usability of the e-coachER intervention package, and (iii) suggestions to overcome barriers to recruitment.

Discussion:

One PPI representative was influential with regard to including a 'personal message' from an ERS user in the periodic participant newsletter; the aim being to convey the importance and value of taking part in the study from the perspective of someone who has been referred to an ERS. There were no negative aspects to the PPI activities undertaken in the study.

Reflections:

Being a resident of Plymouth, one PPI representative was able to attend all meetings held at the CI's institution in person. Face-to-face contact with the PPI representative meant that a rapport was more readily generated than would have been if teleconferencing had been used.

The PPI representative on the TSC provided a welcome contribution to the various discussions on the problems faced with recruitment in the pilot phase of the trial. He took a keen interest in the wider issues faced by the trial team, such as ERS provision in the UK, national guidelines for physical activity and the choice of cut-points for accelerometer-derived data that informed the primary outcome. The PPI representative provided a 'real-life' perspective on such matters, as he saw them.

Participants

The study population was comprised of patients who had been referred to an ERS administrator, or were about to be referred, mostly by a General Practitioner (GP), and occasionally by a nurse to a local ERS for a programme of support to increase PA. Patients were eligible for the study if they were aged between 16 and 74 years inclusive; had one of more of the following conditions: obesity (Body Mass Index (BMI), 30-40), a diagnosis of hypertension, pre-diabetes, type 2 diabetes, lower limb osteoarthritis, or a current or recent history of treatment for depression; were categorised as 'inactive' (i. e., 0 hours per week of physical exercise and in a sedentary occupation) or 'moderately inactive' (i. e. some but <1 hour per week and sedentary occupation OR 0 hours per week of physical exercise and in a standing occupation) according to the GP Physical Activity Questionnaire [36]; were contactable via email, and had some experience of using the internet. Patients were excluded for the following reasons: they did not meet the eligibility criteria for their local ERS; they had an unstable, severe and enduring mental health problem or were being treated for an alcohol or drug

addiction that may have limited their involvement with the study; or were unable to use written

materials in English, unless there was a designated family member or friend to act as translator.

Intervention

All participants had been offered usual ERS. Participants allocated to the intervention arm were

additionally offered access the e-coachER web-based support package. Development and delivery of

the intervention is fully described in Chapter 1: Developing the e-coachER intervention.

Usual care

There is currently no single model for ERS in the UK, but the predominant mode of delivery involves

referral to a programme (e.g. 10-12 weeks) of structured, supervised exercise at an exercise facility

(e.g. gym or leisure centre) or a counselling approach to support patients to engage in a variety of

types of PA.[13] ERS operate diversely to accommodate patient choice and local availability of

facilities, the common goal being to reduce the risk of long-term metabolic, musculoskeletal and

mental health conditions due to physical inactivity. The three participating sites were selected from

different regions of the UK (different ERS providers) to provide diversity of approach; the schemes

are described in Ingram et al.[1]

Recruitment procedures

Patients were identified as potentially eligible for the trial (i) by healthcare professionals in primary

care at the point of being actively referred to an ERS or having been opportunistically found to be

eligible for an ERS at a consultation with the primary care practitioner, (ii) via a search of patient

databases at the participating GP practices (conducted by the local NIHR Primary Care Research

Network team), (iii) via patient self-referral to the GP arising from community-based publicity for the

trial, (iv) by the ERS programme administrator on receipt of an ERS referral form from a GP practice,

or (v) by exercise advisors at the ERS service at enrolment on the ERS. With the patient's consent,

the exercise advisor provided the local researcher with the patient's contact details for the purposes

of the trial.

Potentially eligible patients were approached by the primary care practitioner or the local

researcher, depending on how the patient had been identified. Some patients self-referred to the

local researcher in response to publicity campaigns. These various means of identification and

approach were designed to accommodate the variation in usual care referral pathways to ERS across the participating sites and individual GP practices.

Amenable patients were offered a study-specific Participant Information Sheet (supplied as a supplementary file), either by post, via email or by hand (the route used largely depended on the preference of the participating GP practice or ERS service). Interested patients were asked to communicate their expression of interest to the local researcher via a prepaid reply slip, by telephone or by email. On receipt of an expression of interest, the local researcher contacted the potential participant by telephone to discuss the trial, confirm eligibility and seek informed consent.

Informed consent

Informed, written consent (supplied as a supplementary file) was obtained prior to undertaking the baseline assessment, either over the telephone or at a face-to-face visit, depending largely on the patient's preference but also on the availability of suitable venues such as the GP practice. The original completed Informed Consent Forms were held securely at the site, with a copy provided to the participant.

In the case of telephone consent, the researcher was required to sign and date the Informed Consent Form, but the participant was not required to sign or date their copy.

Patients deemed to be ineligible for inclusion in the study were informed of this outcome.

Randomisation, concealment & blinding

On receipt of the baseline accelerometer at the Peninsula Clinical Trials Unit (CTU) (after one week's wear), participants were randomised to usual ERS or usual ERS plus access to e-coachER in a 1:1 ratio, stratified by site with minimisation by participant's perception of main medical referral reason (i.e. weight loss, diabetes control, reduce blood pressure, manage lower limb osteoarthritis symptoms, manage low mood/depression) and by self-reported IT literacy level on a visual analogue scale (i.e. lower or higher confidence).

To maintain concealment, the minimisation algorithm retained a stochastic element.

Randomisation was conducted by means of a secure, password protected web-based system created and managed by the CTU.

Blinding of participants was not possible, given the nature of the intervention. Given that the primary outcome was an objective measure of PA recorded by accelerometer, and the secondary outcomes were assessed by participant self-completion questionnaire, the risk of assessor bias was considered to be negligible in this study. However, to minimise any potential bias, the statistical analysis was kept blinded and the code for group allocation not broken until the primary and secondary analyses had been completed. The ERS practitioners would not have been aware of trial participants' treatment allocations.

Process evaluation: qualitative interviews

Participants who had engaged with the e-coachER website (i.e. logged on to the website, as a minimum) were invited to participate in one or more qualitative interview to inform the process evaluation. See Chapter 4: Qualitative process evaluation.

Data collection and management

Data were collected and stored in accordance with the Data Protection Act 1998 / General Data Protection Regulation 2018.

Subject numbering

Following receipt of expression of interest, each patient was allocated a unique number and was then identified in all study-related documentation by their identification number and initials. A record of names, addresses, telephone numbers and email addresses linked to participants' identification numbers were stored securely on the study database at the CTU for administrative purposes only.

Data collection

Data were recorded on study-specific paper-based case report forms (CRFs) by the local researcher, and participants completed a paper-based questionnaire booklet comprising validated and non-validated self-report outcome measures.

Accelerometers (GENEActiv™ Original accelerometer, Active Insights Kimbolton, UK; http://www.geneactiv.org/) were configured for use prior to issue to participants by the local researcher at baseline and the CTU thereafter, using GENEActiv software. A recording window of 10 days, starting at midnight of the day of issue and recording at 75Hz, was pre-set, thus accounting for transits in the post whilst optimising the battery life of the device.

Accelerometers received by the CTU following one weeks' wear by the participant were physically cleaned with liquid detergent according to manufacturer's instructions before data were downloaded and linked to the participant identification number (see Accelerometer data processing). Accelerometers were then issued to other participants in the trial as required.

Data on participants' uptake of the ERS were collected via participant self-report at 4 weeks post-baseline and 4 months post-randomisation, and via the ERS service provider.

The recording and reporting of non-serious AEs in this study was not required. Serious Adverse Events (SAE) were reported to the CTU via the self-report questionnaire booklet administered at 4 and 12 months, but were also reported to the CTU or local researcher by the participant (or relative) outside of these time-points, until the end of follow-up. SAEs were categorised using the MedDRA Terminology Systems Organ Classification List Internationally Agreed Order Version 19.0, March 2016

All persons authorised to collect and record study data at each site were listed on the study site delegation logs, signed by the Principal Investigator.

Data processing

Accelerometer data processing
Accelerometer data were downloaded using the GENEActiv PC software (Version 3.0_09.02.2015) and analysed in software R using package GGIR version 1.2-8 (https://cran.r-project.org/web/packages/GGIR/index.html).[37] GGIR performs auto calibration with the reference of local gravity.[38] Raw acceleration data are used to compute Euclidean Norm Minus One (ENMO; milli-g (mg)[39]). Data were analysed from the first to the final midnight using 5 second epochs. Participants were included in the main analysis if they achieved a minimum of 16 hours of wear time for a minimum of 4 days (including at least 1 weekend day). Non–wear was detected if the standard deviation of two axis was <13mg with a range of <50 mg in windows of 60 minutes. Time spent in activity intensities were established using published thresholds.[40]

Computed variables included average daily MVPA accumulated in any 5 second epochs. Ten minute bouts of MVPA were detected when at least 80% of a 10 minute period was above the MVPA

intensity threshold.[41] Total time accumulated in MVPA and bouted MVPA were calculated by multiplying the average daily values by seven to represent a full week.

Diurnal activity and nocturnal periods of inactivity were also estimated, to determine if the intervention had an effect on reducing daytime inactivity and increasing sleep. Sleep duration was established using sustained nocturnal inactivity bouts. An inactivity bout occurred when no change in arm angle larger than 5° was observed for at least 5 minutes.[42] Diurnal inactivity represents the sustained inactivity bouts (>5 minutes) that occur in the day,[41] this includes naps, but omits other inactivity that result in measureable movement.[43] However it is likely that some misclassification of this inactivity may occur.[41]

In order to explore if different ways of processing accelerometer data influenced the findings, four additional wear time criteria were calculated: 1) ≥16 hours over any four days (irrespective of week / weekend), 2) ≥10 hours for 4 days (including at least one weekend day), 3) ≥10 hours over any four days (irrespective of week / weekend), 4) A minimum wear criteria of 1 day for 10 hours but with individuals weighted by the number of valid days with a minimum of 10 hours wear.

CRFs and questionnaire booklets

Original CRFs and questionnaire booklets were posted to the CTU, with copies of the CRF retained at the site. All data were double-entered by CTU staff on to a password-protected SQL Server database and encrypted using Secure Sockets Layer. Double-entered data were compared for discrepancies using a stored procedure and discrepant data was verified using the original CRF. Incomplete, incoherent, unreadable or other problem data in the CRF pages were queried by the CTU with site staff during data entry to ensure a complete and valid dataset. Self-reported data in the questionnaire booklet was not queried with participants.

The CTU completed further validation of data items, and performed logical data checks after data collection had been completed. After all data cleaning duties had been performed by the CTU, the final export of anonymous data was transferred to the statistician and health economist for analysis.

Baseline assessment

Consented participants attended a baseline assessment with the local researcher. This assessment was conducted over the telephone, or in person at a suitable venue in the community.

Demographic data were collected, i.e. age, gender, BMI, blood pressure, ethnic group, relationship status, domestic residents status, smoking status, employment status, education status, GP Physical

Activity Questionnaire score, internet use capability ~~IT literacy level was determined using a visual analogue scale for self-reported 'confidence using the internet': scores of 1-5 indicated a low literacy level and scores of 6-10 a high literacy level, for the purposes of this study~~, requirement for translator for trial purposes and clinical condition. ~~participant's perception of the reason for referral to the ERS - where more than one medical condition was stated, the participant ranked these in order of importance – the most important reason was used as a stratification variable~~.

IT literacy level was determined using a visual analogue scale for self-reported 'confidence using the internet'~~: scores of 1-5 indicated a low literacy level and scores of 6-10 a high literacy level, for the purposes of this study~~ where 1=not at all confident and 10=totally confident. Arbitrarily, scores of 1-5 were set to indicate a low literacy level and scores of 6-10 a high literacy level, for the purposes of stratification.

'Clinical condition' was the participant's perception of the reason for referral to the ERS - where more than one medical condition was stated, the participant ranked these in order of importance – the most important reason was used as a stratification variable.

The participant was issued with the wrist-worn waterproof accelerometer to wear constantly for one whole week (day and night), and a self-report questionnaire booklet to complete at the beginning of the week-long period. At face to face baseline assessments, the accelerometer was fitted by the local researcher; at telephone visits, the accelerometer (and self-report questionnaire booklet) were posted to participants. All participants were provided with a bespoke guidance sheet for wearing the accelerometer (supplied as a supplementary file), including instructions to wear the accelerometer on the wrist of the non-dominant hand (i.e. the hand not favoured for writing). After one week's wear, participants were required to post the accelerometer and completed questionnaire to the CTU in a pre-addressed padded envelope provided. A pre-paid postal service was used so as not incur costs to the participant.

The measures collected at baseline are summarised in Table 2.

Table 2 Schedule of baseline & follow-up measures

Measure	Baseline	4 weeks post-baseline	4 months post-randomisation	12 months post-randomisation	On completion of participants' ERS programme at site
Demographics	X				

Engagement with the ERS: self-reported		X	X		
Engagement with the ERS: ERS service provider's record					X
Accelerometer recorded MVPA	X		X	X	
Self-reported MVPA	X		X	X	
Self-reported health and social care resource use	X		X	X	
Self-reported quality of life measure (EQ-5D-5L)	X		X	X	
Self-reported Hospital Anxiety and Depression Scale (HADS)	X		X	X	
Self-reported process evaluation outcomes (confidence to be physically active; importance of	X		X	X	

being physically active, perceived frequency and availability of support; perceived autonomy over choices; involvement in self-monitoring and action planning PA).				
Qualitative interviews as part of the process evaluation focusing on participants' experiences with the ERS and the intervention (optional for participants)		X		
Engagement with e-coachER (captured from the LifeGuide© platform)		X		

Follow-up assessments

The measures collected at follow-up are summarised in Table 2.

At 4 weeks post-baseline, a short survey on initial uptake of the ERS was administered via email.

At 4 and 12 months post-randomisation, participants were sent an accelerometer (along with the guidance sheet on how to wear the accelerometer), a questionnaire booklet, and a pre-addressed pre-paid envelope to return the items to the CTU.

To maximise data completeness at follow-up assessments, participants were sent standard letters from the CTU: (i) 7 days before delivery of the accelerometer, (ii) 3 days into the 10 day recording window as a prompt to begin wearing the accelerometer (if not already doing so), and (iii) at 3 and 5 weeks after issue as a reminder to post the accelerometer to the CTU (for those participants that had not already done so). If a participant had not sent the accelerometer to the CTU after 6 weeks, the local researcher telephoned the participant to remind them to return the device. Participants who returned the accelerometer to the CTU were provided with a £20 voucher for an online store as a token 'thank you', to maximise response rates.

Once a participant's involvement in the ERS had concluded, the ERS service providers completed a simple proforma to confirm whether the participant attended an appointment with the exercise specialist, and how many appointments were available to the participant.

Measures

Primary outcome measure:

The primary outcome was the number of weekly minutes of MVPA, in ≥10 minute bouts, measured objectively by GENEActiv Original accelerometer[44] , over one week at twelve months post-randomisation compared with the control group. To be included participants had to have provided activity recorded over 4 days, including a weekend day, for at least 16 hours per day.

Secondary outcome measures:
- Total weekly minutes of MVPA in ≥10 minute bouts, measured objectively by accelerometer, over one week at four months.

- Achievement of at least 150 minutes of MVPA, measured objectively by accelerometer, over one week at four and twelve months.

- Self-reported achievement of at least 150 minutes of MVPA over one week using the 7 day recall of PA[45] (7-day PAR) at four and twelve months.

- Self-reported weekly minutes of MVPA at four and twelve months.

- Average daily hours of sedentary behaviour measured objectively by accelerometer over one week at four and twelve months.

- Self-reported average daily hours of sleep over one week at four and twelve months.

- Self-reported health-related quality of life, assessed by the EQ-5D-5L[46] at four and twelve months.

- Self-reported symptoms of anxiety and depression, assessed by the Hospital Anxiety and Depression Scale[47] at four and twelve months.

- Uptake of the ERS according to the attendance records held by the ERS service provider, with imputed participant-reported attendance at 4 weeks and/or 4 months where the ERS service data are missing.

- Adherence to PA, using a composite measure to describe the proportion in each arm of the trial that achieved at least 150 minutes of MVPA in bouts of at least 10 minutes at four months and were still doing so at twelve months.

Self-reported survey process measures:

- The following survey items were adapted from existing measures or originally developed, using processes to be reported elsewhere in more detail, were used as process measures: importance and confidence to be physically active (single items); perceived competence in being regularly physically active (4 items); autonomous in decisions about PA (4 items); availability of support (3 items); frequency of support (3 items); action planning (5 items); and self-monitoring (2 items). The respective measures were not validated but exploratory analysis, to be reported in more detail elsewhere, indicated Cronbach alpha coefficients of all scales were in excess of 0.77, using data from participants included in the primary analysis.

- In the intervention group, measures of engagement with e-coachER including whether or not the participant visited the website at least once, and whether they reached a stage of the online support to indicate they have set and reviewed at least one PA goal (i.e. Step 5 - users make their SMART activity plan, and then review their step goal and SMART activity goal).

Sample size

In the absence of a published minimally important difference for MVPA, assuming a 'small' to 'moderate' standardised effect size of 0.35, we estimated that 413 participants were required at 88% power and a 2-sided alpha of 5% assuming 20% attrition, or 90% power at a 2-sided alpha of 5% allowing for 16% attrition (using 'sampsi' in STATA v.14). Given that the intervention was delivered at the level of the individual participant, clustering was not factored into the sample size calculation. Based on the baseline standard deviation for MVPA total weekly minutes in ≥10 minute bouts of 104 to 113,[48] an effect size of 0.35 corresponds to a between group difference of 36 to 39 minutes of MVPA per week.

Statistical analysis

Analyses were in accord with ICH-9 statistical guidelines for clinical trials and updated CONSORT reporting guidelines for non-drug trials. All primary and secondary analyses were undertaken and reported in accord a pre-specified detailed statistical analysis plan that was agreed with the Project Management Group, TSC and Data Monitoring Committee (DMC).

Following data lock by the CTU data manager, the statistician undertook primary analyses blinded to group i.e. randomised groups were coded 'A' or 'B'. Following the blinded presentation of the primary results to the Project Management Group, and agreed interpretation of the results, the groups were un-blinded.

Descriptive analyses

A summary of baseline characteristics and baseline outcome values in intervention and control groups was undertaken and between group equivalence assessed descriptively. Since differences between randomised groups at baseline could have occurred by chance, no formal significance testing will be conducted.

Interim analysis

No interim inferential analysis was planned, and none were conducted.

Inferential analyses

Definition of comparison groups

Intention to treat (ITT) complete case: groups according to original randomised allocation in participants with complete data (i.e. meeting required accelerometer wear time) at 12 months follow up.

ITT imputed: groups according to original randomised allocation in all participants.

Per protocol (CACE): ITT complete case participants who have completed Step 5 - Making your activity plans.

Primary analysis

The primary analysis using linear model (continuous outcomes – using STATA 'regress') or logistic model (binary outcomes – using STATA 'logistic' command) compared primary and secondary outcomes between groups according to the principle of intention to treat (i.e. according to original randomised allocation) in participants with complete outcomes at twelve months adjusting for baseline outcome values and stratification (site) and minimisation variables (participant's perception of main medical reason for referral to the ERS; and IT literacy level). Given age and gender are known to be predictive of PA, these baseline characteristic were also added to the adjusted model.

Given the over-dispersion and high frequency of the primary outcome, the primary mixed effects model was found to be poorly fit. Alternative post-hoc regression models were therefore explored for the analysis of the primary outcome. These included: log transformed mixed effects (with a constant added), mixed effect model with outliers removed, negative binomial, and zero-inflated binomial models.

Secondary analyses

Secondary analyses were undertaken to compare groups at follow up across all follow up points using a mixed model repeated measures approach (using STATA 'xtmixed' command). Secondary per protocol analysis using a CACE approach (using STATA 'ivregress' command) was undertaken to examine the impact of adherence to the intervention on primary and secondary outcomes at 12 months.

Subgroup analyses

The primary analysis model was extended to fit interaction terms to explore possible subgroup differences in intervention effect in stratification and minimisation variables for the primary outcome at 12 months. Given the relatively low power for testing interactions, these results were to be considered as exploratory only.

Sensitivity analysis to test the effects of different ways for processing accelerometer data

Sensitivity analysis was undertaken using four additional wear time criteria 1) ≥16 hours over any four days (irrespective of week / weekend), 2) ≥10 hours for 4 days (including at least one weekend day), 3) ≥10 hours over any four days (irrespective of week / weekend), 4) A minimum wear criteria of 1 day for 10 hours but with individuals weighted by the number of valid days with a minimum of 10 hours wear.

Handling of missing data

Missingness was defined as those participants with the absence of data at follow-up for one or more outcomes. Given the proportion of patients with missing accelerometry data out the total number of participants who fulfil the criteria of includable PA data (N = 243) was small (i.e. 0-10 participants or <5%) no imputation was undertaken for the primary outcome or any of the derived secondary outcomes. For EQ-5D and HADS, missing data was replaced using multiple imputation using the covariates of age, gender, reason for referral, confidence in IT, assuming unobserved measurements were missing at random (using STATA 'mi' command).Using the same primary analysis model as described above, between group outcomes were compared in ITT complete case and imputed data sets for primary and secondary outcomes at 12 months.

Adverse events

Safety data and adverse events were listed descriptively by group and include details of the event, and the likely relatedness to either treatment.

Data presentation

Results were reported as between group mean differences with 95% confidence intervals; global P-values were provided with regard to categorical explanatory variables. The threshold for

determining significant effects was P<0.05. No adjustment of P-values was made to account for multiple testing, although the implications of multiple testing were considered when evaluating the results of the analyses.

Model checking and validation

All analyses were undertaken using Stata v14.2.

Stata coding for the primary analysis was prepared independently and the analyses were cross checked.

Checks were undertaken to assess the robustness of models, including assessment of model residual normality and heteroscedasticity.

Changes to the project protocol

Primary outcome measure and sample size.

The original protocol featured an internal pilot. During the internal pilot phase, 180 participants were to be recruited over 3 months to provide sufficient information to justify progression to a main trial. Progression from the internal pilot to the main trial was dependent on recruitment rate and engagement with the intervention according to the scenarios in Table 3. In the main trial, an additional 1220 participants were to be recruited, giving a total of 1400 participants (recruited over 16 months).

Table 3 Internal pilot to main trial progression rules

Criteria	Scenario 3	Scenario 2	Scenario 1
% of internal pilot sample size target (180 participants) recruited.	< 65%	65- 79%	≥ 80%
Intervention engagement (% participants who access e-coachER at least once)	< 65%	65-79%	≥ 80%
Proposed action	No progression	Discuss with Trial Steering Committee (TSC) and funder about progression and resources needed to achieve target.	Proceed to full trial.

The recruitment rate during the internal pilot phase was lower than expected, due to: limitations on the time primary care practitioners had available to approach potential participants; delayed start at one of the research sites; poor uptake when patients were approached via a postal mailshot; and high ineligibility rate amongst patients who were identified via a primary care database.

In response to poor recruitment, the following strategies to increase recruitment were introduced, in November 2015:

- The inclusion criterion for BMI was aligned with the ERS entry (upper BMI limit for the trial was originally 35 and was raised to 40), and prediabetes was included as an inclusion criterion.

- Provision was made for the Birmingham and Plymouth sites to recruit participants via the ERS service (a strategy already in place at the Glasgow site), in addition to recruitment via primary care.
- Incentive payments to participants (for returning an accelerometer) were increased from a maximum of £40 per participant (£10 at baseline, £10 at 4 months and £20 at 12 months) to a maximum of £60 per participant (£20 at each of the aforementioned time-points).

Having implemented these measures, the conditions for progression in terms of recruitment rate and engagement with the intervention were not met by the end of the internal pilot phase, despite a 4 month extension period. A 'recovery plan' was developed in collaboration with the funders, based on amending the choice of primary outcome.

The original primary outcome was achievement of at least 150 minutes of MVPA measured objectively by accelerometer over one week at twelve months. This outcome was based on the findings of a systematic review of ERS[14, 49] demonstrating that trials had primarily reported their outcomes according to percentage of participants reaching the NICE guidelines for PA level, i.e. 150 minutes of MVPA per week. We estimated that recruiting 700 participants per group would allow us to detect a difference at 12 months follow up of at least 10% (intervention group: 53% vs. control group: 43%), assuming an attrition rate of 20% and small effect of clustering (ICC: 0.006) at 90% power and 5% alpha. Thus the original sample size was 1400 participants, to be recruited over 16 months.

From the outset, the TSC and DMC had recommended that this dichotomous primary outcome measure be replaced with a continuous variable, i.e. total weekly minutes of MVPA. This was because:

(a) a continuous primary outcome measure would be more relevant in this study population, in terms of detecting a small but clinically significant increase in minutes of MVPA.

b) based on sample size calculations, this would offer greater statistical power than to the categorical assessment of whether participants reach a threshold of 150 minutes of MVPA. This would therefore afford a reduction in sample size.

The TSC and funders agreed these changes (in August 2016) and the original sample size was reduced in accordance with this new primary outcome measure and revised sample size calculation, from 1400 to 413 participants (to be recruited over 21 months). A similar reduction in sample size was incorporated into the qualitative component of the process evaluation work.

The primary outcome was subsequently specifically defined as: total weekly minutes of MVPA in ≥10 minute bouts recorded objectively by accelerometer over one week at twelve months, in participants with activity recorded for at least 16 hours per day on at least 4 days, including a weekend day.

Capture of ERS attendance data

Initially, uptake of the ERS was solely self-reported, captured via an emailed survey at approximately four weeks and a postal questionnaire at four months. Owing to poor compliance (especially at 4 weeks), data were sought from the ERS service providers, in addition to the self-reported data. Participants consented to the ERS service sharing their attendance data for the purposes of the trial.

Omission of SF12 data analysis

Owing to an error in the compilation of the participant self-report questionnaire booklet, the SF12 data collected could not be analysed in this study. It was intended to administer the SF12 version 2 at each of the study time points, but it transpired that a number of the response options for SF12 version 1, instead of SF12 version 2, had been printed in the questionnaire booklet in error.

Chapter 3 Trial results: quantitative results

Participant recruitment

450 participants were recruited (randomised) to the trial over a 20 month period (03.09.2016 to 10.04.2017).

Table 4 shows the number (%) of participants who entered the trial by referral source (i.e. by mailout from the GP or opportunistically in primary care; at the point of initial contact with the ERS providers; or by word of mouth or community advert), across the different sites.

Table 4: Route of participants in to the study.

	Plymouth		Birmingham		Glasgow		Total	
Referral source	Number of participants	%	Number of participants	%	Number of participants	%	Number of participants	%
ERS	38	25%	109	71%	141	100%	288	64%
Primary care	102	66%	45	29%	0	0%	147	33%
Self-referral	15	10%	0	0%	0	0%	15	3%
Total	155	100%	154	100%	141	100%	450	100%

Flow of participants in the trial

Figure 4 shows the flow of participants through the trial. Of those expressing an interest in participating, 477 (63%) individuals were eligible. The main reasons for ineligibility were: BMI too high (n=104, 14%), too active according to the GPPAQ (n=47, 6%) and clinical condition of interest not present (n=26, 3%). An additional 27 (4%) individuals could not be contacted following their expression of interest. A detailed CONSORT diagram is given in Appendix 2.

Figure 4 Participant flow

| Accelerometer wear-time criteria met n=207; not met n=17 | Accelerometer wear-time criteria met n=201; not met n=25 |

Received intervention (logged in to the e-coachER website one or more times) (n=144)

| Lost to follow-up (n=20) Participant not contactable (n=12) Declined (n=8) | Lost to follow-up (n=13) Participant not contactable (n=9) Declined (n=4) |

4 month follow-up

| Accel. received at CTU (n=183) Wear-time criteria met n=109; not met n=74 Accelerometer not received (n=17) | Accel. received at CTU (n=190); Wear-time criteria met n=128; not met n=62 Accelerometer not received (n=22) |

| Lost to follow-up (n=32) Declined (n=18) Participant not contactable (n=14) | Lost to follow-up (n=29) Declined (n=17) Participant not contactable (n=12) |

12 month follow-up

| Accel received at CTU n=160; Wear-time criteria met n=110; not met n=50 | Accel received at CTU n=169; Wear-time criteria met n=133; not met n=36 |

Accelerometer not received (n=12)	Accelerometer not received (n=15)
Analysed (n=110)	Analysed (n=133)

Baseline comparability

The baseline characteristics of the whole sample (N=450) and those who were included in the primary analysis (N=232) are shown in Table 5 and Table 6, respectively. The groups were well-balanced.

Table 5 Baseline demographic and health-related characteristics of the sample

		Control group	Intervention	Both groups
N		226	224	450
Gender - n male (%)		84 (37)	76 (34)	160 (36)
Age - mean (SD) [range]		51 (14) [18 to 75]	50 (13) [20 to 73]	50 (12) [18 to 75]
BMI – mean (SD) [range]		32.5 (4.4) [18.8 to 40.5]	32.7 (4.5) [18.8 to 40.4]	32.6 (4.4) [18.8 to 40.5]
GP PAQ score – n (%)	2 (inactive)	144 (63.7%)	149 (66.5%)	293 (65.1%)
	3 (moderately inactive)	82 (36.3%)	75 (33.5%)	157 (34.9%)
Participant's perception of any medical reason(s) for referral to ERS – prevalence– n (%)	Prediabetes	8 (4.0 %)	15 (7.7 %)	23 (5.8 %)
	Type 2 diabetes	47 (20.8%)	42 (18.8%)	89 (19.8%)
	Osteoarthritis	64 (28.3%)	45 (20.1%)	109 (24.2%)
	Weight loss	182 (80.5%)	182 (81.3%)	364 (80.9%)
	Low mood	122 (54.0%)	121 (54.0%)	243 (54.0%)
	High blood pressure	79 (35.0%)	68 (30.4%)	147 (32.7%)
Ethnicity – n (%)	White	195 (86.3%)	179 (79.9%)	374 (83.1%)

		Control group	Intervention	Both groups
	Black Caribbean	3 (1.3 %)	8 (3.6 %)	11 (2.4 %)
	Black African	3 (1.3 %)	6 (2.7 %)	9 (2.0 %)
	Black Other	1 (0.4 %)	4 (1.8 %)	5 (1.1 %)
	Indian	4 (1.8 %)	12 (5.4 %)	16 (3.6 %)
	Pakistani	7 (3.1 %)	4 (1.8 %)	11 (2.4 %)
	Bangladeshi	1 (0.4 %)	0 (0 %)	1 (0.2 %)
	Chinese	0 (0 %)	0 (0 %)	0 (0 %)
	Other	13 (5.8 %)	10 (4.5 %)	23 (5.1 %)
Relationship status - n (%)	Single	78 (34.5%)	78 (34.8%)	156 (34.7%)
	Married	97 (42.9%)	110 (49.1%)	207 (46.0%)
	Civil partnership	5 (2.2 %)	2 (0.9 %)	7 (1.6 %)
	Divorced or dissolved civil partnership	35 (15.5%)	25 (11.2%)	60 (13.3%)
	Widowed or surviving civil partnership	11 (4.9 %)	9 (4.0 %)	20 (4.4 %)
Domestic residence status (live with ...) – n (%)	Live alone	59 (26.1%)	48 (21.4%)	107 (23.8%)
	Partner	120 (53.1%)	130 (58.0%)	250 (55.6%)
	Parent	11 (4.9 %)	13 (5.8 %)	24 (5.3 %)
	Child <18y	66 (29.2%)	67 (29.9%)	133 (29.6%)
	Child ≥18y	39 (17.3%)	53 (23.7%)	92 (20.4%)
	Other family	10 (4.4 %)	8 (3.6 %)	18 (4.0 %)

		Control group	Intervention	Both groups
	Non-family	9 (4.0 %)	12 (5.4 %)	21 (4.7 %)
Education status – n (%)	No qualifications	52 (23.0%)	29 (12.9%)	81 (18.0%)
	GCEs	146 (64.6%)	162 (72.3%)	308 (68.4%)
	A-level	71 (31.4%)	96 (42.9%)	167 (37.1%)
	First degree	36 (15.9%)	54 (24.1%)	90 (20.0%)
	Higher degree	22 (9.7 %)	20 (8.9 %)	42 (9.3 %)
	Other	108 (47.8%)	104 (46.4%)	212 (47.1%)
Smoking status - n (%)	Smoker	34 (15.0%)	32 (14.3%)	66 (14.7%)
	Ex-smoker	90 (39.8%)	89 (39.7%)	179 (39.8%)
	Never smoked	102 (45.1%)	103 (46.0%)	205 (45.6%)
Requirement for translator for trial purposes – n (%)		3 (1.3 %)	3 (1.3 %)	6 (1.3 %)
IT literacy level - n (%)	Low	36 (16%)	35 (16%)	72 (16%)
	High	190 (84%)	189 (84%)	379 (84%)
Site - n (%)	Birmingham	78 (34%)	76 (34%)	154 (34%)
	Glasgow	69 (31%)	72 (32%)	141 (31%)
	Plymouth	79 (35%)	76 (34%)	155 (35%)
Participant reported main reason for referral- n (%)	High blood pressure	19 (8%)	18 (8%)	37 (8%)
	Low Mood	42 (18%)	42 (19%)	84 (19%)
	Osteoarthritis	27 (12%)	26 (12%)	53 (12%)

		Control group	Intervention	Both groups
	Type 2 diabetes and prediabetes	24 (11%)	25 (12%)	49 (11%)
	Weight loss	114 (50%)	113 (50%)	227 (50%)

Table 6 Baseline demographic and health-related characteristics for those included in the primary analysis

		Control group	Intervention	Both groups
N		124	108	232
Gender - n male (%)		44.0 (35.5)	36.0 (33.3)	80 (34.4)
Age - mean (SD) [range]		52.1 (13.4) [18.0 to 74.7]	49.9 (12.9) [20.6 to 72.9]	51.1 (13.2) [18.0 to 74.7]
BMI – mean (SD) [range]		32.3 (4.3) [18.8 to 40.5]	32.6 (4.9) [18.8 to 40.4]	32.4 (4.6) [18.8 to 40.5]
GP PAQ score – n (%)	2 (inactive)	82 (66.1)	70 (64.8)	152 (65.5)
	3 (moderately inactive)	42 (33.9)	38 (35.2)	80 (34.5)
Participant's perception of any medical reason(s) for referral to ERS – prevalence– n (%)	Prediabetes	4 (3.7 %)	4 (4.3 %)	8 (4.0 %)
	Type 2 diabetes	26 (21.0%)	15 (13.9%)	41 (17.7%)
	Osteoarthritis	40 (32.3%)	22 (20.4%)	62 (26.7%)
	Weight loss	100 (80.6%)	84 (77.8%)	184 (79.3%)
	Low mood	65 (52.4%)	57 (52.8%)	122 (52.6%)
	High blood pressure	47 (37.9%)	38 (35.2%)	85 (36.6%)

		Control group	Intervention	Both groups
Ethnicity – n (%)	White	109 (87.9%)	95 (88.0%)	204 (87.9%)
	Black Caribbean	2 (1.6 %)	3 (2.8 %)	5 (2.2 %)
	Black African	2 (1.6 %)	3 (2.8 %)	5 (2.2 %)
	Black Other	0 (0 %)	0 (0 %)	0 (0 %)
	Indian	1 (0.8 %)	3 (2.8 %)	4 (1.7 %)
	Pakistani	4 (3.2 %)	0 (0 %)	4 (1.7 %)
	Bangladeshi	0 (0 %)	0 (0 %)	0 (0 %)
	Chinese	0 (0 %)	0 (0 %)	0 (0 %)
	Other	6 (4.8 %)	4 (3.7 %)	10 (4.3 %)
Relationship status - n (%)	Single	40 (32.3%)	37 (34.3%)	77 (33.2%)
	Married	57 (46.0%)	50 (46.3%)	107 (46.1%)
	Civil partnership	3 (2.4 %)	2 (1.9 %)	5 (2.2 %)
	Divorced or dissolved civil partnership	19 (15.3%)	13 (12.0%)	32 (13.8%)
	Widowed or surviving civil partnership	5 (4.0 %)	6 (5.6 %)	11 (4.7 %)
Domestic residence status (live with ...) – n (%)	Live alone	30 (24.2%)	29 (26.9%)	59 (25.4%)
	Partner	69 (55.6%)	58 (53.7%)	127 (54.7%)
	Parent	6 (4.8 %)	6 (5.6 %)	12 (5.2 %)
	Child < 18y	39 (31.5%)	26 (24.1%)	65 (28.0%)

		Control group	Intervention	Both groups
	Child ≥18y	19 (15.3%)	25 (23.1%)	44 (19.0%)
	Other family	4 (3.2 %)	3 (2.8 %)	7 (3.0 %)
	Non-family	3 (2.4 %)	6 (5.6 %)	9 (3.9 %)
Education status – n (%)	No qualifications	29 (23.4%)	11 (10.2%)	40 (17.2%)
	GCEs	84 (67.7%)	83 (76.9%)	167 (72.0%)
	A-level	39 (31.5%)	50 (46.3%)	89 (38.4%)
	First degree	18 (14.5%)	28 (25.9%)	46 (19.8%)
	Higher degree	16 (12.9%)	9 (8.3 %)	25 (10.8%)
	Other	59 (47.6%)	49 (45.4%)	108 (46.6%)
Smoking status - n (%)	Smoker	13 (10.5%)	12 (11.1%)	25 (10.8%)
	Ex-smoker	52 (41.9%)	51 (47.2%)	103 (44.4%)
	Never smoked	59 (47.6%)	45 (41.7%)	104 (44.8%)
Requirement for translator for trial purposes – n (%)		0 (0.0 %)	3 (2.8 %)	3 (1.3 %)
IT literacy level - n (%)	Low	17 (13.7)	14 (13.0)	31 (13.4)
	High	107 (86.3)	94 (87.0)	201 (86.6)
Site - n (%)	Birmingham	43 (34.7)	34 (31.5)	77 (33.2)
	Glasgow	29 (23.4)	34 (31.5)	63 (27.2)
	Plymouth	52 (41.9)	40 (37.0)	92 (39.7)

		Control group	Intervention	Both groups
Participant reported main reason for referral- n (%)	High blood pressure	10 (8.1)	10 (9.3)	20 (8.6)
	Low Mood	15 (12.1)	22 (20.4)	37 (15.9)
	Osteoarthritis	18 (14.5)	13 (12.0)	31 (13.4)
	Type 2 diabetes and prediabetes	14 (11.3)	10 (9.3)	24 (10.3)
	Weight loss	67 (54.0)	53 (49.1)	120 (51.7)

Study attrition

Loss to follow-up

Four hundred and fifty participants were randomised. A total of 94 participants (21% of those randomised) were lost to follow-up: 47 (10%) participants declined to participate further and 47 (10%) participants were non-contactable. See Appendix 2 (CONSORT diagram).

There were no differences in age, BMI, gender, IT literacy, and educational attainment between participants who were included in the primary analysis and those who weren't.

Accelerometer and questionnaire booklet return rates

Accelerometer and questionnaire booklet return rates are given in Table 7. Receipt of the baseline accelerometer at the CTU is a prerequisite for randomisation hence there is a 100% return rate for this accelerometer.

At 12 months, 329 participants returned the accelerometer (return rate of 92%). The wear-time criteria was met by 243 participants, this being 54% of those randomised (Table 8). At this time-point, 325 participants returned the questionnaire booklet (return rate of 91%), i.e. 72% of those randomised.

In Table 8 the number of participants meeting the wear-time criteria is shown as shaded [orange] area. A day was 'valid' when the accelerometer was worn for ≥16 hours on that day. Participants who did not achieve any valid days (n=181) included 94 participants lost to follow-up prior to the 12 month time-point, 27 participants who were still in follow-up but did not return the accelerometer, and 60 participants who returned an accelerometer but failed the wear-time criteria.

Loses to follow-up, and non-compliance in returning the accelerometer, were balanced across the two trial arms. Failure to meet the wear-time threshold was less consistent across the two trial arms.

Table 7 Accelerometer and questionnaire booklet return rates

Time-point	Sent to participant (n)			Returned to CTU (n, % of sent)		
	Intervention	Control	Total	Intervention	Control	Total
Accelerometer: Baseline	224	226	450	224 100%	226 100%	450 100%
Accelerometer: 4 month	203	213	417	183 90%	190 89%	373 89%
Accelerometer: 12 month	172	184	356	160 93%	169 92%	329 92%
Questionnaire: Baseline	224	226	450	220 98%	220 97%	440 98%
Questionnaire: 4 month	204	213	417	166 81%	183 86%	349 84%
Questionnaire: 12 month	172	184	356	155 90%	170 92%	325 91%

Table 8 Accelerometer wear-time compliance at 12 months

Number of valid week days	Number of valid weekend days					
	0	1	2	3	4	Total
0	181					181
1	3	2	2			7
2	1		4			5
3	7	6	5			18
4	6	10	31			47
5	5	30	77	16	2	130
6		2	49	7		58
7			4			4
Total	203	50	172	23	2	450

Intervention engagement

Table 9 shows the level of engagement in the various Steps offered online.

The sample was evenly split, with 36% not registering and logging in to e-coachER, and 36% progressing through the support to record at least one goal review (i.e. having set a PA goal review, participant logged back in about 1 week later to record PA against the goal, and obtain feedback on the PA achieved against the goal set). Participants were routinely 'locked out' of accessing the web-based support to ensure they did not complete it in one or two visits to the website, and then reminded by e-mail after one week to log in and continue with the Steps, and later record their PA minutes, set goals and review them. Reaching Step 5 involved over 4 weeks of intervention engagement.

Table 9 Intervention engagement

Stage started	Summary of content	Number (% of 224 in intervention arm)
Did NOT register		81 (36%)
Step 1	Quiz on benefits of PA	144 (64%)
Step 2	Support to get active	133 (59%)
Step 3	Encourage self-monitoring of steps	107 (48%)
Step 4	Setting SMART step-count goals for next week	99 (44%)
Step 5	Setting SMART goals for any PA for next week	96 (43%)
Goal review	Review goal and personalised feedback	81 (36%)
Step 6	Ways to achieve goals/overcoming barriers (optional)	N/A
Step 7	Overcoming setbacks (optional)	N/A

Among all participants allocated to the intervention arm, the mean (SD) number of goal reviews was 2.5 (SD 4.5) with a range of 0-52. The 144 participants who registered, logged into e-coachER for a mean (SD) and median number of times of 14.1 (16.7) and 6, respectively, with a range from 1-101.

Of the 81 (36%) participants who did a goal review, the mean (SD) and median number of reviews was 14.4 (13.8) and 4.5, respectively, with a range from 1-52.

Table 10 shows the mean, SD and median time spent during the respective stage (session) for the 144 participants who registered or 81 participants who did at least one goal review. This data comes with the limitation that participants may have left their browser open after some sessions rather than logging off, which leads to an overestimation of time spent. 'N' refers to the number of visits used to estimate the descriptive data for the time in sessions 1-5, the number of visits when a goal was first set, and the number of sessions when a goal was reviewed.

Table 10 Descriptive data for time (in minutes) spent engaging in the intervention

Status	Mean (minutes)	SD	Median (minutes)	N
Visited Steps 1-5 (from 144 participants who registered)	9.53	9.68	6.45	539
Goal set initial session (from 91 participants who set a goal)	7.81	7.54	5.92	91
Goal review session (from 81 participants doing ≥ goal review)	4.75	5.25	3.18	1034
Total	6.47	7.45	4.08	1664

On the basis that participants spent approximately 6 minutes logged in for Steps (sessions) 1-5, and for 3 minutes for each goal review, for those 144 participants who registered, the total mean (SD) and the median time that participants spent on Steps 1-5 was 24.1 (5.9) minutes and 30 minutes respectively.

For those 81 participants who did at least one goal review the overall mean (SD) and median time that participants spent doing goal reviews was 43.3 (37.3) minutes and 21 minutes respectively. The 144 participants who registered spent a total mean (SD) and median time of 48.4 (41.9) minutes and 36 minutes respectively. The range was 6-186 minutes.

Descriptive data for the primary and secondary outcomes by group and time

The descriptive statistics for the primary and secondary outcomes at baseline and 4 and 12 months follow up are shown in Table 11, for all participants who provided data.

The groups were well balanced at baseline. Only 4% achieved at least 150 minutes of accelerometer recorded MVPA (in ≥10 minute bouts) over a week at baseline, and the average weekly minutes of MVPA (un-bouted) was 49 minutes, which reflects our success at recruiting inactive or moderately inactive participantswith chronic conditions. In contrast, 80% achieved 150 minutes of accelerometer recorded MVPA without regard for ≥10 minute bouts at baseline. Others have also shown lower levels of accelerometer recorded MVPA minutes when data are processed using ≥10 minute bouts compared with bouts of at least 1 minute.[50] That proportion drops to 36% for self-reported MVPA, reflecting the way that the 7-D PAR measure focuses on only discrete bouts of memorable MVPA.

There were also no baseline differences between groups for the EQ-5D-5L and the two HADS scales.

Descriptive data for PA and participant reported outcomes are also shown in Table 11 for those providing data at baseline, 4 and 12 months, by trial arm, without controlling for baseline or other co-variates. Qualitatively, the intervention group, compared with the control group, were more active than the control group at 4 and 12 months for all primary and secondary outcomes. The intervention group also qualitatively had higher well-being (EQ-5D-5L) and lower depression and anxiety scores, compared with the control group, at 4 and 12 months.

Table 11 Summary descriptive data for primary and secondary outcomes at baseline and 4 and 12 months follow up

	Baseline		4 months follow up		12 months follow-up	
	Control group **N Mean (SD)** **or n/N (%)**	**Intervention group** **N Mean (SD)** **or n/N (%)**	**Control group** **N Mean (SD)** **or n/N (%)**	**Intervention group** **N Mean (SD)** **or n/N (%)**	**Control group** **N Mean (SD)** **or n/N (%)**	**Intervention group** **N Mean (SD)** **or n/N (%)**
Primary outcome						
Total weekly minutes of MVPA in ≥10-minute bouts[a]	201 30.2 (105.8)	207 31.8 (53.7)	128 30.9 (64.5)	109 38.4 (74.5)	133 18.7 (37.6)	110 35.4 (78.3)
Secondary outcomes						
Average dailyminutes of MVPA[a]	201 45.6 (35.6)	207 53.1 (35.9)	128 46.3 (37.8)	109 58.3 (35.9)	133 42.6 (30.1)	110 51.9 (36.6)
Weekly achievement of at least 150 minutes of MVPA in ≥10-minute bouts[a]	8/201 (4%)	9/207 (4%)	2/128 (2%)	7/109 (6%)	3/133 (2%)	6/110 (5%)
Weekly achievement of at least 150 minutes of MVPA[a]	149/201 (74%)	178/207 (86%)	98/128 (76%)	99/109 (91%)	99/133 (74%)	93/110 (85%)
Weekly achievement of at least 150 minutes of MVPA self-reported	83/220 (37%)	77/220 (48%)	94/183 (51%)	88/166 (53%)	76/170 (45%)	76/154 (49%)

Average daily diurnal inactivity (hours)[a]	199 1.7 (1.1)	205 1.5 (1.1)	125 1.4 (1.1)	109 1.4 (0.9)	99 1.4 (1.0)	78 1.5 (1.0)
Average daily sleep (hours)[a]	199 6.8 (1.5)	205 6.9 (1.2)	125 6.7 (1.3)	109 6.7 (1.4)	128 6.8 (1.5)	110 7.0 (1.5)
EQ-5D-5L (Devlin values)	216 0.74 (0.24)	215 0.76 (0.23)	162 0.72 (0.26)	148 0.76 (0.25)	158 0.72 (0.26)	138 0.73 (0.27)
HADS-D	217 7.6 (4.5)	214 7.4 (4.7)	164 7.4 (4.8)	147 6.0 (4.7)	156 7.1 (4.8)	139 6.3 (5.1)
HADS-A	217 8.7 (4.6)	214 8.6 (5.1)	164 8.5 (4.8)	146 7.5 (5.0)	156 8.4 (4.8)	139 7.6 (5.2)

ª fulfil the criteria of includable PA data

Primary outcomes

Primary outcome - ITT complete case analysis showed a weak indicative effect in favour of the intervention group in the primary outcome at 12 months (11.8 weekly minutes of MVPA, 95% CI: -2.1 to 26.0, P=0.10) (see Table 12). A plot of the repeated measure model estimates for the primary outcome over time for intervention and control groups are shown in Appendix 3. Although the alternative model P-values varied somewhat, a similar pattern of results was seen across alternative post-hoc models. In interpreting these results, it is important to recognise the limitations of all these models – lack of fit of the pre-defined primary and post-hoc models, and the need to assume data as counts with both negative binomial and zero-inflated binomial models.

Table 12 Comparison of Intervention and control groups – primary analyses

Models adjusted for stratification variables and age and gender and baseline scores and random effects for site & fulfil the criteria of includable PA data.

	Primary analysis ITT complete case comparison at 12 months N Coefficient[a] (95% CI), P-value	Secondary analysis ITT imputed comparison at 12 months N Coefficient[a] (95% CI) P-value	Secondary analysis Complete case comparison at all follow up points P-value for interaction between intervention effect and time
Primary outcome			
Total weekly minutes of MVPA in ≥ 10-minute bouts	232 11.8 (-2.1 to 26.0), 0.10[b] 223 2.5 (-5.8 to 10.7), 0.55[c] 232 1.2 (0.8 to 1.5), 0.27[d] 232 Rate ratio: 1.90 (0.90 to 4.00), 0.09[e] 232 Rate ratio: 1.59 (1.13 to 2.25), 0.01[f]	Not calculated	0.63

[a] *Mean difference in weekly minutes unless otherwise stated*

[b] *Primary analysis mixed effects model (mean difference)*

[c] *Post-hoc model 1 with outliers [>200] dropped (mean difference)*

[d] *Post-hoc model 2 log with constant of 5 added (exponentiated mean difference)*

[e] *Post hoc model 3 negative binomial model (rate ratio)*

[f] *Post-hoc model 4 zero-inflated negative binomial model (ratio ratio)*

The results of the CACE analysis for the primary outcome were consistent with the ITT results (Table 13). In other words, when controlling for whether or not intervention participants completed a pre-specified 'dose' of the intervention (i.e., they completed a goal review – reached Step 5) this made no difference to the findings, although qualitatively the difference between the intervention and control group did appear to be larger (in favour of the intervention).

Table 13 CACE analysis of primary outcome at 12 months

Model adjusted for stratification variables and age and gender and baseline scores and random effects for site & fulfil the criteria of includable PA data

	Between group difference N Coefficient (95% CI), P-value
Total weekly minutes of MVPA in ≥10 minute bouts	232 Mean difference: 22.9 weekly minutes (-3.4 to 47.8) 0.09

As Table 14 shows, there was no evidence of any interactions between stratification variables and age and gender with the intervention effect for the primary outcome at 12 months. The ITT complete case model was adjusted for stratification variables, age and gender and baseline scores and random effects for site and fulfil the criteria of includable PA data.

Table 14 Subgroup analyses on primary outcome at 12 months

	Interaction p-value Subgroup coefficient (95% CI)
Age	0.10
	-0.9 (-1.2 to 0.2)[1]
Gender	0.91
Male	16.7 (-5.2 to 38.7)
Female	10.3 (-7.8 to 17.9)
Trial site	0.20
Plymouth	4.3 (-15.2 to 23.9)
Birmingham	19.4 (-9.8 to 48.8)
Glasgow	9.0 (-9.8 to 27.8)
Participant's perception of main medical referral reason	0.33
Control diabetes	11.9 (-0.1 to 24.1)
Weight loss	7.3 (-9.5 to 24.2)
Lower blood pressure	20.6 (-5.9 to 27.2)
Manage lower limb osteoarthritis symptoms	21.1 (-8.1 to 32.2)
Manage mood/depression;	25.1 (-32.4 to 82.7)
IT literacy level	0.59
Lower confidence	2.3 (-6.4 to 11.0)
Higher confidence	13.5 (-2.2 to 29.2)

[1] Per year of age increase

Table 15 shows the descriptive data for participants included in the primary analysis (N=232). Data shown for the 4 month assessment is from participants who were included in the primary analysis and also had complete data at 4 months. The intervention group had qualitatively greater mean weekly minutes of MVPA than the control at baseline.

Table 15 Accelerometer recorded mean weekly MVPA minutes (in ≥ 10 minute bouts) amongst participants with complete data at baseline and 12 months.

	Baseline		4 Month		12 Month	
	Control group N Mean (SD)	Intervention group N Mean (SD)	Control group N Mean (SD)	Intervention group N Mean (SD)	Control group N Mean (SD)	Intervention group N Mean (SD)
MVPA mins (in ≥ 10 minute bouts)	124 22.6 (60.0)	108 33.5 (53.8)	95 31.7 (67.3)	77 41.8 (82.4)	124 17.6 (35.4)	108 36.1 (78.9)

Note: Data from participants included as per primary analysis with 232 participants providing data at baseline and 12 months, and of these, from the 172 who provided data at 4 months.

In analyses of complete data available at both baseline and 4 months, Table 16 shows the control group significantly increased MVPA up to 4 months, while the intervention did not. Between baseline and 12 months there were no changes in either group, though qualitatively the control group had reduced their MVPA.

Table 16 Changes in mean weekly MVPA minutes (recorded in ≥ 10 minute bouts) in both trial groups from baseline to follow-up assessments

	Control group Mean Difference N Mean (SD) [95% CI] p-value	Intervention group Mean Difference Mean (SD) [95% CI] p-value
Baseline vs month 4	118 8.2 (32.1) [2.4,14.1] p=0.006	105 6.4 (68.1) [-6.7,19.6] p=0.334
Baseline vs month 12	124 -5.0 (52.2) [-14.3,4.3] p=0.288	108 2.6 (74.5) [-11.6,16.8] p=0.721

Secondary outcomes

Results of the complete case, imputed ITT and repeated measures analyses (including both 4 and 12 months follow up) for the PA secondary outcomes appeared consistent with the analysis for the primary outcome (see Table 12). As Table 17 shows, there were no significant between group differences in ITT complete case analyses for any of the secondary outcomes at 12 months. Models adjusted for stratification variables and age and gender and baseline scores and random effects for site & fulfil the criteria of includable PA data. The coefficient is mean difference unless otherwise stated.

The ITT imputed comparison at 12 months showed the intervention group had a greater proportion of participants achieving ≥ 150 minutes of self-reported MVPA (P=0.05). In the repeated measures analyses (including both 4 and 12 months follow up) a greater proportion of intervention participants achieved ≥ 150 minutes of accelerometer recorded MVPA (in ≥10-minute bouts). As Table 17 shows, in the control and intervention groups, there were 2% and 6% of the participants who achieved this at 4 months, and 2% and 5% at 12 months, respectively.

There were no significant between group differences in ITT complete case or in the imputed comparison analyses for EQ-5D-5L scores or for the HADS anxiety and depression scores at 12 months. In complete case repeated measures analyses (including both 4 and 12 months follow up) the intervention participants reported lower depression (p <0.05) and anxiety (p = 0.05) scores compared with the control group.

ERS uptake was derived from records held by the ERS service provider, with imputed participant-reported attendance at 4 weeks and/or 4 months where the ERS service data were missing. Data were not available via any of the three sources for four participants (control group n=3; intervention group n=1), resulting in 223 participants in each group with ERS uptake data. One hundred and seventy-three (78%) participants in the control group attended the ERS at least once compared with 167 (75%) in the intervention group.

Table 17 Comparison of Intervention and control groups – secondary outcome analyses

	Primary analysis ITT complete case comparison at 12 months N Coefficient (95% CI), p-value	Secondary analysis ITT imputed comparison at 12 months N Coefficient (95% CI), p-value	Secondary analysis Complete case comparison at all follow up points p-value (for interaction between intervention effect and time)
Average daily minutes of accelerometer recorded MVPA	232 1.9 (-3.8 to 7.7), 0.51	Not calculated	0.68
Weekly achievement of ≥ 150 minutes of accelerometer recorded MVPA in ≥10-minute bouts	232 Odds ratio: 3.80 (0.16 to 20.92), 0.12	Not calculated	0.03
Weekly achievement of ≥ 150 minutes of accelerometer recorded MVPA	232 Odds ratio: 1.67 (0.82 to 3.42), 0.16	Not calculated	0.23
Weekly achievement of ≥ 150 minutes of self-reported MVPA	324 Odds ratio: 1.23 (0.79 to 1.90), 0.36	450 Odds ratio: 1.55 (0.99 to 2.42), 0.05	0.39
Average daily diurnal inactivity	226 0.6 (0.5 to 0.7), <0.0001	Not calculated	0.66
Average daily sleep	226 0.3 (-0.1 to 0.6), 0.11	Not calculated	0.18

ERS attendance	446 Odds ratio: 1.13 (0.72 to 1.79), 0.58	450 Odds ratio: 1.09 (0.70 to 1.71), 0.70	-
EQ-5D-5L Devlin measure	290 0.00 (-0.4 to 0.05) 0.89	450 0.01 (-0.03 to 0.04), 0.70	0.99
HADS-D	289 -0.2 (-1.0 to 0.6), 0.44	450 -0.2 (-0.9 to 0.6), 0.63	0.02
HADS-A	289 -0.5 (-1.2 to 0.2), 0.20	450 -0.2 (-1.0 to 0.5), 0.52	0.05

Adverse events

In total, 42 Serious Adverse Events (SAEs) were reported in 35 participants as reported in Appendix 4, which were all deemed to be either 'not related' or 'unlikely to be related' to the trial. In the control group there were 26 SAEs among 21 participants, and in the intervention group there were 16 SAEs among 14 participants. One SAE was reported as a life-threatening event (asthma attack), all other SAEs were hospitalisations. SAEs were consistent with the patient population.

Chapter 4: Mixed methods process evaluation

This chapter presents the findings from both qualitative and quantitative methods, and brings the two together to help understand and explain the findings from the main analyses presented in Chapter 3.

Introduction

The overarching aim of the e-coachER trial was to determine if adding support to usual ERS would be more effective and cost-effective than usual ERS alone for supporting increases in PA in inactive patients referred to ERS with a range of chronic conditions. The qualitative part of this chapter will explore participants' and e-coachER researchers' views and experiences of the support package and how it did or did not contribute to changes in PA. The quantitative part of the chapter will seek to understand if specific survey process measures were changed by the intervention, compared with usual ERS, as predicted from our Logic Model (see Figure 5). Finally we explore if changes in the process outcomes mediated intervention effects on the primary outcome.

Previous research has quantitatively and qualitatively explored the barriers and facilitators[19, 51] to engaging in ERS, and the moderators of ERS engagement.[15, 52, 53] The e-coachER intervention was designed to help overcome many of the reported barriers and enhance the use of facilitators to either attend ERS or become physically active in other ways, or both, through this primary care based intervention.[54]

The e-coachER intervention is theoretically underpinned by Self-Determination Theory (SDT),[31] which asserts that all humans possess three innate basic psychological needs (autonomy, competence and relatedness). When met, these needs foster intrinsic-motivation resulting in personal growth and satisfaction. A range of behaviour change techniques (BCTs)[35] based on SDT were employed within e-coachER's seven 'Steps to Health' (

Table 1), so this process evaluation seeks to establish if the intervention influenced basic psychological needs and behaviour change processes.

A mixed methods process evaluation seeks to best understand how participants engaged in the intervention (and trial methods) and what the consequences were with respect to our Logic Model.

Qualitative process evaluation

The Logic Model shown Figure 1 has been adapted to show the causal pathways proposed to contribute to behaviour change and intervention outcomes and the objectives for the qualitative work (see Figure 5).

Figure 5*: *The e-coachER Logic Model, adapted to show relationship with qualitative research objectives.

INTERVENTION COMPONENTS

Initial package includes free pedometer, fridge magnet and access to e-coachER; a web-site to promote PA via specific behaviour change techniques (BCTs):

Step 1: Information about physical and mental health consequences Understand benefits of exercise and PA goal setting; How to manage setbacks.

Step 2: Social support Seek support from friends and families/exercise coach to implement & maintain PA regimen.

Step 3: Self-monitoring of behaviour Monitor steps/PA.

Step 4: Goal setting Set weekly step & PA goals.

Step 5: Action planning Making plans to achieve goals.

CONTEXT: Participants' engagement with e-coachER may be moderated by participant socio-demographic and health characteristics, type and location of ERS scheme and relationship with ERS coach. Participant motivation and PA might also be moderated by the same contextual factors. Quantitative data on contextual factors from questionnaires in both trial arms. Qualitative interviews with intervention group only (**Objective 1)**

INTERVENTION DELIVERY

Participants progress through e-coachER. Quantitative data on BCT delivery in intervention arm (via LifeGuide(c)). Qualitative data on participant experiences in intervention arm. (**Objectives 1 & 2**)

CHANGES TO MOTIVATION & BEHAVIOUR

Participant motivation for PA is mediated by autonomy, competence and relatedness. Participant autonomy, competence and relatedness is enhanced by using the web-site and implementing BCTs. Quantitative measures of autonomy, competence and relatedness in both trial arms. Qualitative data on processes of change in intervention arm. (**Objective 2**)

LONG-TERM OUTCOMES

Health and economic benefits. Quantitative outcome data in both trial arms, including weight, quality of life.

SHORT-TERM OUTCOMES

MVPA increases, sedentary time decreases. Quantitative outcome data in both trial arms.

FEEDBACK LOOP

Increased use of website and BCTs, motivation, achievement of PA goals reinforce each other (e.g. motivation is enhanced as levels of PA increase). Quantitative modelling of interactions in one or both arms. Qualitative data on these interactions. (**Objective 2**)

Aims and objectives

The qualitative interviews primarily aimed to explore how participants experienced and engaged with the e-coachER intervention.

The objectives were to:

1) Explore whether the impact of the intervention is moderated by medical condition, age, gender and socioeconomic status, IT literacy or ERS characteristics.
2) Explore the mechanisms through which the intervention may impact on the outcomes.

The implementation and delivery of the trial and recommendations for future research in this area were also explored with participants – and additionally with the trial Research Assistants who provided their views on e-coachER and their role in the study.

Methods

Recruitment

Semi-structured interviews were originally planned with a purposeful sampling framework (considering gender, age, underlying health condition and trial site). The trial sample size was subsequently reduced with a corresponding reduction in the number of interview participants and a change to focus the sampling from across the three sites. All participants who had logged on to the website (at least once) were approached by the CTU team to take part in a qualitative interview. Those expressing an interest were then telephoned or emailed by the researcher (NC or RT) who explained the interview purpose and process. Participants were invited to take part in an initial interview and to give permission to be contacted for follow-up telephone interviews (up to three were planned) over the course of the intervention period. Participants provided informed consent to participate in the qualitative interview (in addition to prior consent to take part in the RCT). Since most interviews were carried out by telephone, the Informed Consent Form for the qualitative interview component was read point-by-point to the participant and signed by the researcher. Interviews were recorded transcribed verbatim and anonymised.

Interviews with researchers at each research site were carried out following the completion of recruitment.

Interviews

Interviews with participants

Interviews were conducted at different stages of participation in the trial as it was anticipated that not everyone allocated to the intervention would progress through all Steps to Health. Each individual was invited to participate in an interview and further follow-up interviews, which enabled interviews to be conducted over the whole duration of the e-coachER intervention period (with online support available for up to 12 months).

The interview topic guide for participants (Appendix 5) focussed on each of the Steps to Health. Participants were also asked their views on the Welcome Pack, the overall online support and the pedometer. Participants were asked to identify if and how they thought e-coachER provided support for ERS, and for maintaining PA over and above maintaining their ERS. Participants were also asked to put forward any suggestions to improve or modify e-coachER.

The topic guide was also designed to gauge the participant's development of self-regulatory skills (e.g. self-monitoring, goal setting) and the extent to which the intervention enhanced a sense of autonomy (control), competence and relatedness. However these terms were not used explicitly, rather the researchers used their knowledge of the guiding principles of the e-coachER intervention to prompt the participant to expand on their responses to the broader topic guide questions.

Interviews with Research Assistants

The interview topic guide (Appendix 5) focussed on exploring issues surrounding the delivery of the trial, including recruitment and an exploration of processes which worked well, and what and where improvements could be made.

Analysis procedure

Interviews were audio-recorded, transcribed verbatim and anonymised, with any personal data or ways of identifying participants removed. Transcripts were imported into NVivo Version 11 for data management and coded by one researcher (RT) following an initial period of coding by NC. A thematic analysis was performed to identify key findings initially focussing on 'top level' themes reflected in the Logic Model (Figure 5). Additional in-depth analysis took place to further explore the

data. RT, JL and SD discussed the emerging codes and themes and a consensus about these was reached. Further more in-depth analysis was also undertaken and this will be fully reported in a forthcoming manuscript as the main publication arising from the qualitative research. Results are reported firstly to address the objectives and secondly to give findings emergent from the data.

Results

Participant sample and interviews

Of the 144 participants approached for interview, 36 (25%) participants expressed an initial interest in taking part. Thereafter 6 participants who had initially expressed an interest did not respond to the invitation for interview. It was not possible to make contact with a further 3 participants. Hence, 26 (18%) participants who had logged on to e-coachER at least once were recruited to take part in the qualitative interview. Nineteen participants completed a single interview. Seven completed more than one interview several weeks apart, one participant completing four interviews, three participants completing three interviews, and three participants completing two interviews. Therefore 38 interviews were carried out in total, each lasting between 16 and 80 minutes; the average interview length was approximately 48 minutes. In total, 11 participants from Plymouth took part in a qualitative interview, nine from Birmingham and six participants from Glasgow. Participants had, at a minimum, logged on to e-coachER once. The majority had progressed to the point that they were automatically locked out of the website for the first time (*i.e*. prior to Step 2). At the time of the initial interview being conducted, participants may not have engaged with or progressed through all of the Steps to Health. Interviewing at these points, and as participants progressed through the steps, was intentional as it was important to obtain the experiences of those who did not progress as well as those who did. Interviews were also conducted with three Research Assistants, one from each site.

Table 18 provides a summary of interviewed participant demographics, including gender, health condition, age, confidence using internet/IT, geographical location and access to IT facilities.

Table 18 Participant characteristics (n=26) involved in interviews

Characteristic	Category	
Gender (n)	Female	20
	Male	6
Health condition (n)	Weight loss only	5
	Weight loss plus other morbidities but not low mood	4
	Weight loss and low mood only	7
	Low mood only	2
	Low mood and other morbidity but not weight loss	1
	Weight loss plus low mood and other morbidities	5
	No low mood, not weight loss, other physiological conditions	2
Age range (years)	Female	28-69
	Male	39-72
Confidence using internet/IT (n)	Low	0
	High	26
Participants at each research site (n)	Plymouth	11
	Birmingham	9
	Glasgow	6
Access to IT facilities (n)	Home/work access/mobile	22
	Mobile not home access	3
	Public only, not mobile access	1

Exploring the extent to which the impact of the intervention is moderated by medical condition, age, gender and socioeconomic status, IT literacy or ERS characteristics

A number of factors were identified as possibly affecting participant engagement with e-coachER and/or the impact of the intervention. These reasons included ill-health, issues related to time, and other issues specific to the individuals' circumstances.

In some cases illness and comorbidities (e.g. stroke) made it harder for them to fully engage with e-coachER.

"I have put some goals in there erm but as I think I hope you are aware erm I had a stroke a while ago about ten weeks ago erm so I'm being a bit slow a bit cautious at the moment and I'm not going to I can't think of the word erm I'm not making my goals too high" [P09]

For some participants, other unexpected life events made it difficult to engage with, or experience benefits from e-coachER:

"Yeah I mean, again, I had the motivation to do it it's just I've had things going on that have forced my hand into stopping. But now I have - I do genuinely have the intention to re-start and keep it up definitely [….] I have an illness and a loss in the family [….] It's stopped everything in all honesty [….] Everything in my life [….] Has been ground to a halt virtually." [P08]

In contrast, other participants found that if their health condition had negatively impacted on their motivation or ability to exercise e-coachER provided reassurance and fostered their sense of competence:

"in a way that's saying look you haven't achieved everything that you said you were going to that's fine, but there are reasons for it and do you know what, that's ok. If you're too sore that you couldn't do it. If you're ill you couldn't do it. You know if you were in a particularly low mood that day like if you're in a low mood 'here's a little bit of information for you' and that little bit of information on the low mood- I suffer from depression so the low mood one is really part of it" [P05]

Access to IT facilities was generally good, and participants had high levels of confidence using the internet. A number of participants reported IT related difficulties which may have impacted upon e-coachER engagement and use, and some felt that other apps or similar support provided more in terms of functionality:

"I didn't feel it was that user friendly especially 'cos I had used sort of My Fitness Pal and things like that in the past. And as I was comparing the two sort of the design of it I didn't find e-coachER that great just the white and the green. I also was using the My Wellness app and I found that one a lot better because I was able to keep track of exactly what I was doing in a lot more of an easier way than that" [P22]

Exploring the mechanisms through which the intervention may impact on the outcomes

Most participants found that e-coachER was an easy to understand, flexible and supportive resource:

> *"… it's [the e-coachER website] given me support as well and there's always, as I say, sometimes there's information there to look at. […] it's changed my attitude to exercising because as I say I was not very eager to do it but now I've done it and I'm enjoying it and I have enjoyed it from the start because it's just I've seen the results basically and that's really given me a boost."* [P02]

Most reported the package, or aspects of it, to be of some utility, for example acting as a prompt to increase PA:

> *"I suppose really it is a reminder to actually do it"* [P13]

The e-coachER intervention was also described as providing an "*incentive*" [P02] "*a bit of a lift*" [p09], or "*pat on the back*" [P11] and that simply having access to e-coachER was motivating:

> *"My initial issue was the motivation and confidence that were missing to go and get started which e-coachER has been very instrumental in and then once I was started now I've got that and I've got the benchmark of doing this*" [p16]

The goal setting aspects of e-coachER support package, particularly in conjunction with the pedometer and setting step count goals, using either the e-coachER website or the tear off slips on the fridge magnet, were particularly important components of the package. They acted as a catalyst in helping participants consider new ways to increase their PA:

> *"fascinating […] Erm well just really interesting to find out what I do every day and if I do, do something different what impact that has, what the result of that is and it does encourage me to think erm right I'll get up and go and do whatever anything erm and it makes me think in a different way about doing things"* [P09]

> *"A erm and it makes me think in a different way about doing things because - for instance, my doctor's is [err] a bus ride, it's awkward for me to say to my family 'can you take me' - I'm sort of now starting to think since I've got a bit more energy - my [erm] my legs are working better if you like, I'm starting to think along the lines of, well I can catch a bus and then walk the rest of the way, I don't need somebody to take me and it will - that will certainly increase my steps…"* [P09]

Whilst the aim of achieving or exceeding step goals was motivating, the desire to avoid not meeting these goals, was also motivating and participants would set their goals to avoid feelings of failure and/or guilt, with one participant using paper based goal setting to avoid setting goals online with e-coachER:

> *"Yeah about like I say like you keep them realistic don't you so you don't you don't set yourself up to fail".* [P04]

> *"I haven't as yet put anything down on e-coachER simply because I put down on a piece of paper what I hope to do on a given week and failed miserably to do them so I thought I didn't want to start to put them down erm until I knew that they were reasonable goals that could be achieved not pipe dreams that have got no chance of being achieved"* [P01]

Participants generally felt that e-coachER provided a reminder to think about being more physically active, for example from the fridge magnet with tear off PA recording strips and use of the pedometer:

> *"every day I well at the end of every day I look at the pedometer and say "oh ok you've exceeded your goal"* [P04]

> *"It's just it's another tool that you can use to you know either monitor or encourage or you know everyone works differently I suppose and I didn't, what I needed was something concrete goal-wise to do and to achieve and like I say you know once I'd set that goal then and if I don't reach it well shame on me kind of thing".* [16]

However it became clear these aspects of the intervention were often only used initially and then some people switched to using their phones or other devices to record activity:

> *"I would say so even though I'm not doing it on the erm website now 'cos I monitor my step counts through my phone"* [P15]

Some participants felt that the e-coachER package was instrumental in helping to ameliorate any feelings of guilt experienced when participants perceived their efforts to increase PA were in some way unsatisfactory. For example, the reiteration that failing to meet set goals is normal and something that should be expected that occurred later in the Steps to Health (the 'slips, trips and falls') were particularly helpful for some:

> *"Being someone who suffers from depression I understand about triggers and setbacks […] But you know this part of the system is explaining to you that it's ok, don't worry about it,*

there are always going to be times in your life where you're not going to be able to do this and you shouldn't beat yourself up too badly about it" [P01]

Participants reported that being able to choose their preferred level of engagement with e-coachER was a valuable feature and allowed participants autonomy over their exercise choices:

"Oh definitely recommend it. Like I say I know that I haven't engaged with it as well as I could have but the point still stands that it was instrumental in that motivation at the beginning of going and doing it and doing exercise referral and setting those goals and trying to maintain achieving those goals each day and then obviously upping them and it's definitely worth it." [P16]

Use of e-coachER also had the potential to help participants to develop or expand social networks conducive to augmenting PA:

"it gives you different tips and tells you who to ask and different sites to get in touch with. I went to an osteoporosis meeting and they do an exercise thing and you can actually become a teacher with a qualification eventually but like I say I can't do anything like that at the moment. [...] they give monthly talks and they have someone come to visit to give a talk who works and specialises in osteoporosis and [...] and they do an exercise group once a week.[...] so it's quite good really."[P06]

However, in contrast, many participants felt that they already had an adequate social support network:

"I've already got quite a good support network so I just utilised my work colleagues." [P14]

Improvements to e-coachER

Many participants felt that e-coachER could offer more in terms of functionality and that it did not provide as much information or as many features as could readily be obtained from other 'App' based packages. For example, some participants felt the package was not interesting, or did not provide enough information and some were disappointed by these shortcomings. Some felt that e-coachER did not work in the way that they had expected, or were frustrated by being locked out of the website rather than being able to progress on to the next stage when they were ready to do so:

"I think you know [erm] the website is useful [erm] albeit frustrating at times but once [...] I get past step seven I might have a different view about that because I won't be locked out then or I would think not, I don't know." [P12]

Others found that the e-coachER website was "*not that inspiring*" [P12], "*drab*" [P03] and one participant referred to it as "*death by PowerPoint*" [P04]. A number of participants described the website or aspects of it as "confusing" [P02], "annoying and irritating" [P07] or not "smart" enough [P04]. Participants went on to offer suggestions for improvements to e-coachER which are summarised in Table 19.

Table 19 Suggestions for improvements to e-coachER

Topic	Summary of problem and/or suggestions for improvements	Participant quotes
Welcome pack	The lack of language options in the information pack and the lack of options regarding disabilities was highlighted. Although straightforward in terms of ease of understanding and clarity, some felt that it did not look interesting or engaging.	"I don't see any foreign language on it. In terms of diversity I don't see any Arabic, Chinese, Punjabi erm…Whatever so you can have this leaflet in X, Y or Z." [P04] "User Manual should be made more visual […] It didn't inspire me to turn the page. … It is I mean it's not a huge criticism when I say that, I don't mean that as it perhaps sounds it's not a huge criticism - it is a bit dull erm […] I mean I read it because I had to but I didn't enjoy it erm and you know, I wonder if how many people are skipping over it." [P05] "… I suppose really it's got to be generic but … if you're a woman I would like it sort of a little bit more interesting just – […] it just may be needed to be a little bit more eye-catching I think I'm trying to say." [P18]

Website design Logging on/access and navigation and lock-out	Although many found site-coachER easy to navigate and use, many found the layout of the package and being logged out a certain predefined points frustrating and found navigation difficult and restrictive.	"… I thought it would be very helpful if you could see what every stage was and then go back to where you were rather than having the situation where you're in a stage and you can't go onto the next one. [….] but at the moment of course you can't move on without being locked out […] with the website, you know, I'm not technically in control of what's on the other end so it's sort of going in and having a good look round and seeing what you can and can't do." [P01]
	More tailored website was suggested e.g. could be split up into different categories of condition for referral.	"I think at the front end of the e-coachER it might be a wider remit and then take it out from the tree stem and then branch off so that if it's obesity you can look at different goals, if its diabetes again and if its mental health but it's splitting them up from each other." [P04] so I think again that would be something to say if you are having trouble if you use I don't know iPads, Mac other things just click on the link and it will take you to it." [P04]
	A minority of participants experienced IT related problems, logging on, passwords, accessing e-coachER etc. These were not difficult to resolve and logging on was straightforward for most. Some commented that logging on could have been made easier as participants had to go through the original email link. Some felt that further developments regarding mobile access would have improved e-coachER. Some differences in the experience of e-coachER using different platforms e.g., one participant reported not being	"it was suggested that "well you've got to do it through Microsoft, you've got to do it through this, you've got to do it through that" […] I don't know if it would actually work with a Mac." [P04]

	able to access links using an iPad.	
Stage 1 Quiz	Many felt that the quiz did not offer new information.	"No I mean I'm not putting myself up as a genius but some of it is at quite simplistic level." [P03]

"Erm going through the quiz saying you know did you realise that ah but you know if you did this – it did feel rather high school-ish." [P05] |
| Stage 2 links to finding support | Some found links for external and additional support out of date or irrelevant. Although some found the links thought-provoking, few directly benefited from using these links. | "some of the information that I was looking at was actually dated for last year and all the classes weren't up to date." [P18] |
| Pedometer | The pedometer did not always tally with other devices.

Some found the pedometer difficult to open, some found it difficult to wear. | "the pedometer seemed to just do its own thing. It stopped logging them properly […] again the next day it was the same sort of thing." [P06]

"The other thing I've found quite tricky was getting it placed properly… Sometimes it was a bit uncomfortable. [P04] I am using my own FitBit anyway just purely because I think I said to you before with the pedometer it suggests that you put it on your waistband well women and maybe for men I don't know, don't always wear things that are suitable for the pedometer and so it would be easier if you could use whatever other means you have if you have that." [P24] |

Entering step count onto e-coacher website	Inputting steps on website required participants to round up or round down, which may negate the message perceived by many that 'every little helps'. Some felt that the step count should accurately reflect the number of steps achieved.	"I think it would be quite useful if you could put in the actual steps you've done rather than erm rounding it to the five hundred. Because I well this morning I put mine in and I'm a very honest person and if I've only done 3,200 I'm not going to put in 3,500. I'm going to put in 3,000 but that in itself can be a little bit erm disappointing because you think well actually I've done a bit more than that." [P09]
Reminder emails	Did not factor highly as a necessary component of e-coachER; some found these reminders unhelpful or did not reflect their actual engagement	"Erm well I've been logging in every few days but erm apparently I kept getting emails to say erm where have I been and "it's been four weeks since we heard from you". [P06] "The next day I'll get one 'oh we noticed you haven't logged in for one week' and what would help is perhaps when one sets one's goals that a date was inserted so there's no argument about that." [P03]
Later steps – setting goals and dealing with setbacks	Later steps used less frequently. Those who engaged with the later stages of e-coachER found that goals were not always saved.	" what I found frustrating […] it completely wiped what I'd put the week before […] for me once I get into the routine I can generally do the same activities just adding more in and virtually review them but you have to input absolutely everything again plus the extra stuff that you were doing that week . And I don't I think you know it wouldn't take much for that information to pull through and you just amend it. Rather than re-write it each week and if you're going to set up completely new goals that's absolutely fine but actually you know you should be able to, it would be better to pull it through and amend it …." [P14]
	One participant suggested that support regarding 'slips trips and falls' may be better placed at an earlier step.	"that message coming at the end if you like although I know it's not the end of e-coachER but it's the end of the steps. If it was in earlier…." [P13]

	Goal setting sections could be more 'inspirational'.	"It's good to have inspirational stuff to help you along [...] It wasn't inspirational in any way the site you know because you can have goals and you can have inspiration sort of pushing you towards the goals." [P07]
General	Lack of interaction with health professional or 'real person'.	"Yes yeah maybe I don't know two or three weeks or even four weeks down the line you know a conversation with somebody just even if it's just to see how they're getting on. 'How are you getting on, how are you finding it?' [...] if somebody is struggling and they've thought "oh no I can't do this" in the early days then you would have picked them up already, do you get what I mean? ...Just to have somebody there as well as on the computer sort of thing have a bit more of an input earlier on that's great. As much as we are embracing the technology of life and all the rest of it there is nothing more valuable than a voice and like talking to you." [p21]

E-coachER as a support for ERS use and uptake or as an alternative to ERS

The aim of the e-coachER package was to support and enhance the uptake of ERS:

> *"And I think what […] e-coachER did was it acted like a prompt. So I suppose in terms of my own personality I don't like to let people or anybody down so if I had an appointment with the practitioner I would make sure I got there or try my damnedest you know what I mean."* [P19]

One participant described a lack of support from the ERS and that e-coachER was able to mitigate the effects of this:

> *"Because with the exercise referral scheme [….] I had to do things myself, if that makes sense and I went and I had my induction, she, there was - there was no come back to say "how are you getting on, how are you finding things?". The person that did the induction with me hasn't been in touch with me again whereas at least with the e-coachER I can refer back to it.*

I can look at it at my leisure and go back and be inspired again. Whereas I had, I've not had that contact with the person at the gym." [P21]

While the combined use of ERS and e-coachER was noted, a number of participants reported that they found the ERS difficult to commit to, perhaps more so than other self-selected activities whilst others expressed a lack of interest in the types of exercise being offered. There were other difficulties for some participants in accessing the facilities or services being offered by the ERS scheme. These included geographical location, transport issues, gym costs and the participants' working patterns or problems with ERS over-subscription, delays in the referral process or staffing levels. Finally, other barriers to ERS attendance stemmed from unforeseen individual circumstances (e.g. bereavement, injury and other health issues). E-coachER was therefore an important alternative or seen as separate to ERS:

"It just feels like they're two different things because I don't always see my instructor all that much and I don't know what - how that works" [P18]

Trial Research Assistants' experiences and role in recruiting and supporting participants through e-coachER

Research Assistants' suggestions for improvements to trial recruitment processes

Researchers suggested a more direct approach to recruitment would improve rates, for example, (1) using more refined criteria for identifying possible participants and (2) using study researchers to carry out this task:

"they looked at the databases and contacted like hundreds of patients who they thought were eligible for e-coachER and they had a really poor return. I think to be cost effective we're going to have to be very clear and definite about finding the right criteria. […]So I feel that that's going to be a big way forward is the clinical research network or somebody in the research field is going to be able to, have to go into practices and have access to the databases and pull, going, doing that directly rather than asking the GP to spend part of his valuable few moments that he has with patients trying to encourage them to take part in a research study. That's not going to happen, they just, although they are willing to do it they just don't have time to do it." [RA02]

Broadly, simplifying the referral and paperwork, streamlining the referral system, contacting participants via the ERS rather than via the GP, or contacting the participants directly about the study after the ERS practitioner had sought permission to pass on contact details to the researcher were found to be helpful:

"we had approval to go straight to the exercise referrer who was receiving the exercise referral from the GP and then ask the staff there to help us identify the people that would be suitable for our study looking at our study criteria and then approach them to either get, give consent for the patient to pass on their telephone details to me as the RA and then I would either approach them directly or she would give them out the patient, the trial information pack and then the patient could contact me if they were interested in taking part and that was really successful." [RA01]

Similarly, at another research site, opportunistic sampling via general practice was slow. Engaging the ERS team to help meant little chance for the researcher-participant interaction, but a significant improvement in recruitment rates:

"So opportunistic recruitment didn't work well at any point for us but the ERS, using the ERS system mail out to potential participants that worked really well. I mean we really, we kind of went from way behind to meeting our recruitment targets from the ERS so they were really helpful/"Opportunistic recruitment it was very slow and it was also, I was constantly kind of chasing and reminding the GPs. Whereas with the ERS it was one of the data team who was sending out the packs and she you know she just had to input the data and it was really a small job for her just to send out a letter to any potential participants. So it was really it worked much better it was much more fluid". [RA03]

Research Assistants' views of key issues to consider for future trials

Research Assistants considered good communication to be a key issue in keeping participants *engaged in the trial:*

"I did think keeping the communication as open as possible is the best step for that to make them feel involved"[RA02]

The participants using e-coachER often described the importance of social support, and at times either explicitly or implicitly mentioned the support obtained from the researchers (including the *qualitative interviewers). The study researchers also highlighted the importance of social contact:*

"A lot of participants said it was nice to have me on the phone to contact so it's not just online." [RA03]

Research Assistants' suggestions for improvements to the e-coachER package

Like the study participants, researchers felt that there was some scope to refine e-coachER in terms of *functionality:*

> " I guess I mean there was a couple of people that had said that the website should have
> been a little more - I don't know - maybe all singing all dancing sort of thing. I think the
> competition is now with all these devices, apps and things that are out there a lot of people
> were maybe well not a lot a couple of people had flagged up that they were disappointed
> with how basic the website is. On the flipside of that it does need to be basic because a lot of
> people aren't computer literate but I guess that's a downside with the competition now from
> all the apps and so many things that are out there that it maybe does look less appealing."
> (RA02)

Research Assistants' views of participants' attitude towards the trial

The researchers felt that most participants were already highly motivated to take part in something (the research) that would help them to make lifestyle changes and increase PA although it was less clear that they had understood why they had been referred to ERS, and there was some confusion regarding being contacted about the research study and being referred to ERS:

> "I think they were all quite positive really. There were obviously some people who just
> weren't interested but the main thing that came out when I've been looking into it, there was
> a lot of confusion over what they'd actually been referred to. So there was a lot of the times I
> had to explain that they'd been referred by their GP and that it was the [ER] Scheme and I
> had to explain what that was but generally once they kind of knew what we were doing in
> conjunction with that they were very positive [....]I think they were all interested in doing
> something that helped them and a couple of them were even you know I think also the
> voucher obviously that was a nice bonus to have but yeah they were all very positive about
> doing it." [RA03]

One further finding relating to participant experiences of being in the research trial arises from both the research assistant interviews and from a final follow-up interview with one of the participants, who remarked that just having the interview was *"motivational" [P13]* as it was:

> "…..another reminder that I need to go back to e-coachER to keep it there so you're you [the
> research interviewer] are part of the motivation". [P13]

The research assistants also noted that participants using e-coachER often described the importance of social support, and at times either explicitly or implicitly mentioned the support obtained from the researchers (including the qualitative interviewers). Two of the researchers commented:

"Again it wasn't something that we have discussions with because it wasn't part of my role however I did get some emails from a lot of people who just felt that they wanted to tell someone that they were logging their steps. Although they didn't have to, a few participants have done that it was a very important aspect to them." [RA02]

"A lot of participants said it was nice to have me on the phone to contact so it's not just online………I think a lot of the people when they fill in the website they phoned me after to say why they haven't been as active […] this week because, this month because they'd been you know had an injury or they'd been busy and I think it was just that, that kind of option to explain that they don't get via the website." [RA03]

Discussion

The qualitative component of the process evaluation helped to develop a better understanding of the participants' experience of and engagement with e-coachER and to explore how factors both related and unrelated to the e-coachER contents, impacted on participant's engagement with ERS and the e- coacher website itself. A further element was to understand the experiences of the researchers working on the e-coachER trial. The findings are also of relevance beyond the e-coachER RCT, in particular, regarding the role of support, self-monitoring, goal setting, and feedback from IT support tools. Interviews with members of the trial site teams involved in recruitment provided further information regarding trial implementation and delivery.

The e-coachER intervention went through substantial initial piloting with public and patient input prior to going live within the trial and some specific features of the intervention were designed for a purpose. For example, the lock out feature of the intervention was aimed to prevent participants going through all 7 Steps to Health at the same session (which would leave less reason to return to the website at a later date). It was inevitable that some participants found this frustrating or worthy of comment such as the useful suggestion that relapse management ('slips, trips and falls') would have been helpful at an earlier step. Strategies that prevent existing, or developing, competencies from being undermined were an important feature of e-coachER's design and the 'slips trips and falls' step was instrumental in helping participants to develop and maintain competence rather than experience failure. However, potential benefits of and opportunities to develop competence by engaging in these later steps were often not realised as participants found these stages less 'user

friendly' than earlier steps or were not able to proceed onto these steps when they wanted to, having been automatically locked out in the earlier stages. Being locked out of the package may have provoked annoyance and disengagement and may have negatively impacted on the control/autonomy dimension of SDT. It should be noted that these findings arise from the relatively few participants interviewed who reached these end steps.

We also designed the intervention to engage with participants with a range of levels of IT literacy. However, for those interviewed it was clear that most were competent IT users meaning that, for some participants, e-coachER provided insufficient content and functionality. Similarly, information provided in e-coachER was designed to be straightforward and accessible for all, for example the quiz, sometimes described as a 'useful reminder' seemed to serve as a prompt to remind participants what they 'should' be doing. Thus whilst little of the information was considered to be new, the re-iteration appeared to be valuable and some felt the links provided useful information but others found it too basic, perhaps offering insufficient challenge to allow the development of a sense of competence around using e-coachER. It is clear that while some appreciated the information provided there is scope to add further levels of information and advice as this would allow both tailoring for specific conditions and help create a sense of progression (of information detail) within e-coachER. It is possible that the efficacy of the intervention may vary depending on the condition for which the participant was referred for, and many had multiple comorbidities. More tailored information which could be selected if relevant may have added to the functionality of e-coachER and provided further opportunities for the user to develop feelings of competence regarding undertaking more PA with their underlying health condition. In future the intervention could be refined to include more explicit statements about the intervention design features (e.g. the purpose of the lock-out, that the pedometer is only a basic monitoring tool) as well as provide more optional levels of information content related to specific health conditions.

Interviewed participants identified two main 'active ingredients' of e-coachER. Firstly the skills training and opportunity to set goals and to monitor progress by using the pedometer. This encouraged participants to reach or exceed their personal goals. Goal setting and self-monitoring have been found to facilitate the ability to initiate and maintain behaviour change.[29] The participants who were interviewed did seem to set their goals realistically and were broadly 'SMART' (specific, measurable, achievable, realistic and time-bound), they 'set their pace' and mentioned how setting and attempting to meet these goals were positive aspects of the intervention and participants particularly valued the step count activities. Donnachie et al[55] also described how pedometers can providing tangible evidence of progress, demonstrating enhanced competence with the device being seen as an 'ally' to meeting goals. It was clear that participants appreciated receiving the pedometer (and fridge magnet) and recent research has shown that providing primary

care patients with a pedometer by mail is effective in increasing PA,[56] so this finding was not surprising. However, although most were very enthusiastic about obtaining feedback from the pedometer some were disappointed by the quality of the device and wondered if the step count was accurate. Whether or not these limitations acted as barriers to engagement with either e-coachER or PA (or both) is unclear, although previous research suggested that mistrust of monitoring equipment may be detrimental.[54]

Secondly the provision of support, for example, by providing a virtual 'reminder' or 'pat on the back' was regarded as an important aspect of e-coachER. These features provided opportunities for social interaction and/or the support of social interaction where social interaction had been in some way lacking. The e-coachER intervention, grounded in SDT, sought to build a sense of connection or relatedness with others. Throughout the interviews, participants referred to the importance of social support, and how this was met to varying degrees through e-coachER. Step Two of e-coachER encouraged participants to seek social support, highlighting opportunities for joining groups, communities, discussion forums etc. Although designed to be specific to the participant's geographic area, some felt these were not relevant to their needs, or could be improved in other ways. For other participants, however, e-coachER did help to facilitate an open discussion about health within the participants' social network and provide them with an initial starting point or 'trigger' to try new things. The concept of competence refers to an individual's need to master tasks or to learn new or different skills[31] and some participants described how e-coachER helped them to develop the confidence to engage more with PA.

In general most participants reported at least some benefits of using e-coachER; participants often felt that its use was 'motivating' but when asked to explain more they were less clear in identifying which specific aspects had this motivating effect. A qualitative study evaluating the effects of a walking intervention found that many participants reported benefits of trial participation, even when objective quantitative measures of PA did not increase.[54] Whilst satisfied with the e-coachER website providing a 'starting point' for their plans to increase PA, many found the limitations inherent to the e-coachER package to be frustrating. For example, it is possible that the e-coachER prompts (if inappropriately timed) undermined intrinsic motivation, and this may have been compounded by a reduced sense of control arising from being locked out of e-coachER for predefined periods of time.

A number of participants felt that components of e-coachER were limited or could be improved, however they often described the package as a valuable resource. This may be because participants were already motivated to make changes and e-coachER provided additional support to do this. Many of the participants had actively sought to attend ERS and described a pre-existing motivation

or readiness to change.[57] Those who reported few benefits from e-coachER may not have been at a stage where they were ready to make changes and it is also possible that over the duration of the engagement with e-coachER, participants progressed non-linearly through stages of readiness to change. None of the participants explicitly stated that they were not motivated to increase their PA and most were positive about their involvement in the trial. They felt supported by an intervention which was designed to help them to achieve greater levels of PA and felt that e-coachER consolidated, directed and focussed their desire to make changes.

Strengths and Limitations

Interviewing participants at different stages of engagement with the intervention, and the follow-up interviews with seven participants, allowed us to tap into experiences at particular stages of e-coachER and, for those giving repeat interviews, how perceptions may have changed as engagement progressed.

The present findings were prepared blind to overall trial findings before being presented at a trial management meeting. This strengthens the findings from the qualitative research as the main trial results did not influence the interpretation of the qualitative findings.

One limitation is that it is unclear the extent to which the interviews and the support provided by the RAs may have affected the participants' interaction with e-coachER. However most of those interviewed only did one interview (n = 19), and these contacts were relatively early on in the intervention period Furthermore we could find no obvious differentiation between interviewees who had multiple interviews regarding their comments about engagement with the other intervention components. Also, given the absence of a difference in the primary outcome and most other outcomes in the trial, it is unlikely that a few additional interviews had any influence on the findings.

It is also unclear whether the participants' appreciation of being in the 'additional' intervention arm affected their responses to the interview questions and to e-coachER as well. Some were apologetic about being critical of the intervention components and participants may have felt obliged to modify their criticism.

None of the 16% of the total e-coachER study sample (N=450) who were classified as having low IT literacy (as a stratification variable) were interviewed and this may have limited our ability to understand how the web-based support helped or did not help these participants. This is a limitation but does not necessarily mean we only interviewed those with very strong IT skills.

We did not interview any participants who were not in the e-coachER group of the trial about their experiences of ERS. We therefore do not know how trial control group participants felt about not being selected for the intervention group or about their experiences of ERS. A further limitation is that we did not interview any participants at the end of their time in the trial, for example, at about 12 months post enrolment, to explore their experiences over the longer term and whether e-coachER had helped them maintain PA. Interviewing at this time point may have provided a clearer picture of the extent to which any behaviour change achieved during interactions with e-coachER were sustained. However, undertaking such late stage interviews could have compounded the co-intervention effects already mentioned and resources were not available to conduct such interviews after the primary end-point of the main trial.

Conclusions

There has been considerable literature on the barriers and facilitators to ERS so our qualitative work focused mainly on if and how the e-coachER intervention complemented usual ERS. The e-coachER intervention was acceptable and was positively experienced by many of the interviewed participants; it did 'do what it said on the tin' in terms of enhancing competence, autonomy, and relatedness for many, but not all of the interviewed participants, with several areas for enhancement and augmentation identified. Engaging in self-monitoring and progressive goal setting helped to build a sense of competence to increase PA. In doing so, participants appreciated the opportunity to make personal decisions about the types of activities they engaged in and how often. The website encouraged participants to get personal support from the ERS and this worked for some but not others, for example, those who had other competing demands on their time. We were not able to identify specific examples in the interviews of how the website had brought people together to share PA experiences. There were positive and negative experiences of e-coachER but these were not necessarily of equal impact. For example, finding e-coachER a useful reminder to exercise may have more positive impact than the dislike of the web page layout or colour scheme. Instead of focusing only on individual positive and negative experiences of e-coachER itself it is perhaps more important to place the findings from the interview study into the wider context; this was a complex intervention and as such may be more, or less, effective for individuals depending on their morbidities or co-morbidities, complex personal circumstances or whether they were (or not) ready to increase PA.

For future trials, it is important to ensure that recruitment and referral pathways are as direct, targeted and straightforward as possible (i.e. not dependent upon busy general practices). Future trials could be resourced sufficiently to allow any parallel qualitative study to be balanced across trial arms.

Quantitative Process Evaluation

Aims and objectives of quantitative process evaluation

Within our Logic Model we expected that the e-coachER support package would more favourably influence some key theoretical components (i.e. a sense of competence, autonomy and relatedness, and heightened value or importance attached to the behaviour) and behaviour change processes (i.e. action planning, self-monitoring, enlisting social support) known to be involved in health behaviour change.

The objectives were to:

1) Explore whether the e-coachER intervention led to more favourable process outcomes, compared with usual ERS alone at 4 and 12 months.

2) Explore if any changes in the process outcomes between baseline and 4 months (during which intervention engagement was expected to predominantly take place) mediated any intervention effects on the primary outcome (i.e., minutes of accelerometer recorded MVPA (in bouts of ≥10 minutes) at 12 months.

Methods

The survey used to capture the process outcomes was described in Chapter 2. Briefly, items were derived from extensive reviews of the literature to ensure they matched our expected changes within our Logic Model but also were fit for purpose within a randomised trial. In other words, they had to make sense for a responder whether or not they did any PA, and they had to have some sensitivity to identify change. In response to PPI input we also had to maximize the participant completion rates so ensured the questions were easy to interpret and the response format was clear. The items and respective scales are supplied as a supplementary file.

Questions about importance and confidence are single items using an 11-point scale. The remaining items were chosen to represent specific constructs and create composite scores. Confirmatory factor analysis revealed support for adding survey items to assess: perceived competence in being regularly physically active (4 items); autonomous in decisions about PA (4 items); availability of support (3 items); frequency of support (3 items); action planning (5 items); and self-monitoring (2 items). The Cronbach alpha coefficient of all factors were found to be in excess of 0.77, indicating good internal consistency of each. Composite scores were calculated and used in the analysis.

Using a model adjusted for age, gender, stratification variables and baseline scores, and random effects for centre, with only participants included in the primary analysis (i.e. based on complete accelerometer data and had completed the respective survey items), we compared each of the eight process outcomes by group at both 4 and 12 months. We restricted the analysis to outcome data deemed valid, with no more than 200 minutes spent in 10 minute bouts of MVPA, as per the primary analysis.

The size and significance of any mediating effects was evaluated through the product-of-coefficients method.[58] This was performed irrespective of the results from the main analysis, as mediation may still be possible without having detected a significant effect of the intervention on the primary outcome.[59] Referring to causal diagram in Figure 6 , the coefficient, *a*, for the intervention effect on process measures in path A was derived from the mixed model of changes in process measures regressed on the intervention, adjusted for age, gender, stratifications variables, and random effects for centre. Utilising the same adjustment variables, the coefficient, *b*, for the change in process measures on the primary outcome in path B was obtained by modelling the outcome on the process measure change, also adjusting for the effect of the intervention. The coefficient of the mediating effect was, therefore, calculated as the product *a*b*. The confidence intervals were calculated through the Sobel test[60], dividing the coefficient product by the estimated standard error used: $SE_{ab} = \sqrt{(a^2 * SE_b^2 + b^2 * SE_a^2)}$.

Results

Descriptive data are shown in Table 20 for each of the 8 outcomes at baseline and 4 and 12 months, by trial group.

Table 20 Descriptive data for all the process measures only among those included in the primary analysis

Note: Greater values reflect more positive beliefs.

1. Perceived importance of doing at least 30 minutes of moderate intensity PA (e.g. brisk walk) on at least 5 days a week (Using 0-10 scale: 1 item); 2. Confidence in achieving at least 30 minutes of moderate intensity PA (e.g. brisk walk) on at least 5 days a week (Using 0-10 scale; 1 item); 3. Perceived competence in being regularly physically active (Using 1-5 scale – 4 items). 4. Autonomous in decisions about PA (Using 1-5 scale – 4 items); 5. Availability of support (Using 1-5 scale – 3 items); 6. Frequency of support (Using 1-5 scale – 3 items); 7. Action planning (Using 1-5 scale – 5 items); 8. Self-monitoring (Using 1-5 scale – 2 items).

Mediators	Baseline		Month 4		Month 12	
	Control	Intervention	Control	Intervention	Control	Intervention
	N Mean (SD)	N Mean (SD)	N Mean (SD)	N Mean (SD)	N Mean (SD)	N Mean (SD)
1 Importance	121 5.49 (2.90)	96 5.58 (2.58)	117 6.53 (2.76)	95 7.55 (2.22)	122 6.34 (2.77)	100 7.14 (2.55)
2 Confidence	121 5.60 (3.10)	97 6.06 (2.73)	117 5.56 (3.28)	95 6.72 (2.82)	122 5.44 (3.28)	100 6.07 (2.94)
3. Competence	123 13.14 (3.65)	97 13.74 (3.46)	113 12.69 (3.92)	93 14.27 (3.64)	118 12.51 (3.94)	99 13.40 (4.09)
4. Autonomy	121 14.26 (3.48)	98 14.54 (3.18)	116 14.69 (3.64)	93 15.31 (3.31)	121 14.53 (3.45)	96 15.32 (3.41)
5. Support availability	122 9.89 (3.39)	97 10.47 (2.93)	115 9.77 (3.38)	94 10.80 (2.87)	121 9.69 (3.30)	97 10.36 (3.18)
6. Support frequency	122 7.01 (3.50)	99 7.61 (3.17)	116 7.58 (3.62)	94 8.03 (3.41)	120 6.97 (3.62)	100 7.70 (3.38)
7. Use of action planning	117 12.99 (5.25)	97 13.13 (5.03)	114 16.10 (5.00)	92 17.09 (4.67)	120 14.84 (5.19)	97 15.88 (4.91)

8. Use of self-monitoring	121 5.17 (2.16)	98 5.70 (1.97)	115 6.60 (2.02)	94 7.36 (2.03)	121 6.32 (1.95)	99 6.70 (2.09)

Analysis of the intervention effect on the process outcomes among participants meeting the minimum accelerometer wear times as specified for the primary analysis indicated that intervention participants reported greater change in beliefs from baseline to 4 months for PA beliefs about importance, confidence and competence, compared with the control group (Table 21). By 12 months there was no longer evidence of differences in change in beliefs among the intervention group compared with the control group.

Table 21 Intervention effects on changes in process outcomes from baseline to 4 and 12 months

Mediators	Month 4				Month 12			
	N	coefficient	p-value	95% CI	N	coefficient	p-value	95% CI
1 Importance	208	0.888	0.013	(0.184, 1.592)	218	0.705	0.098	(-0.129, 1.540)
2 Confidence	209	1.041	0.007	(0.287, 1.794)	219	0.393	0.332	(-0.401, 1.187)
3. Competence	205	1.214	0.024	(0.158, 2.269)	216	0.571	0.337	(-0.593, 1.735)
4. Autonomy	207	0.51	0.306	(-0.466, 1.486)	216	0.495	0.335	(-0.511, 1.500)
5. Support availability	208	0.399	0.318	(-0.384, 1.182)	216	0.026	0.951	(-0.818, 0.870)
6. Support frequency	211	-0.072	0.889	(-1.090, 0.945)	220	0.115	0.831	(-0.947, 1.178)
7. Use of action planning	200	1.249	0.18	(-0.575, 3.073)	210	1.042	0.239	(-0.694, 2.777)
8. Use of self-monitoring	209	0.293	0.45	(-0.468, 1.054)	218	-0.102	0.774	(-0.798, 0.594)

Figure 6 shows the a priori model to be tested in the mediation analysis.

Figure 6 a prior path model for testing mediation effects
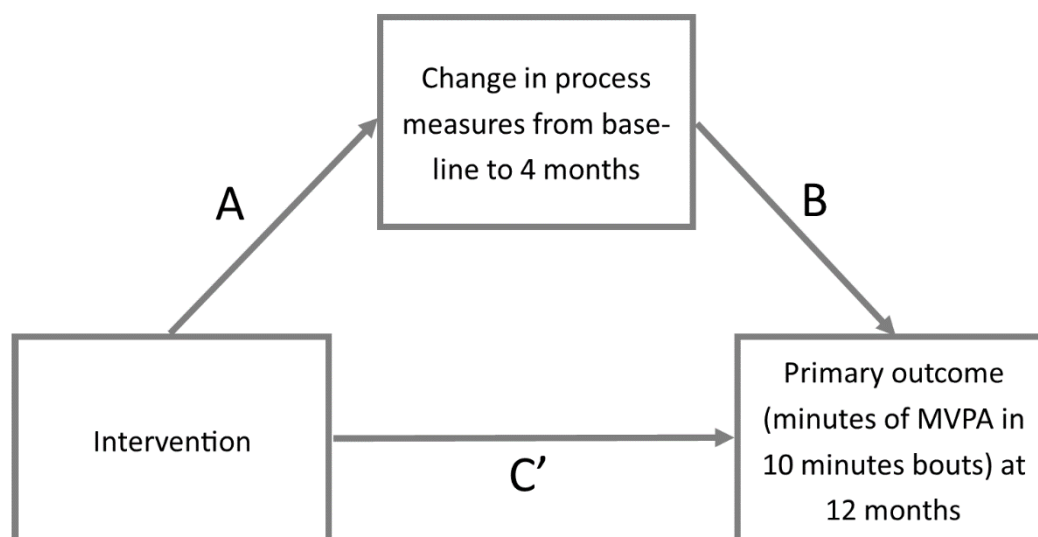
Table 22 shows the analysis of mediating effects of change in the process outcomes (from baseline to 4 months) on the primary outcome at 12 months, using only participants included in the primary analysis. There were no significant mediation effects. Despite there being significant intervention effects on change in beliefs about importance, confidence and competence at 4 months, these changes in beliefs did not translate into increases in MVPA minutes at 12 months. A possible explanation is that the intervention effects on the primary outcome were insufficient to fully test the mediating effects, especially given the distributions, with many participants recording zero for minutes accumulated in bouts of ≥10 minutes. Another explanation may be that the 10 point scales used to assess importance and confidence were more sensitive to identify change, compared with a 5-point scale used for the other outcomes.

Nevertheless, according to analysis of the B path in the mediation diagram, the primary outcome did appear to be sensitive to changes (from baseline to 4 months) in importance, the frequency of support, action planning and self-monitoring. However, in all but importance, there were insufficient changes in the process measures between baseline and 4 months, to assume a mediating effect. With regards to importance, although paths A and B were individually significant, the

combined change in this process measure and its effect on the primary outcome according to the Sobel test, was insufficient to produce a significant mediating effect.

Table 22 Mediation effects for the process outcomes

Mediators	N	A path		B path		Mediated effect	
		coefficient (SE)	p-value	coefficient (SE)	p-value	coefficient (SE)	95%CI
Importance	204	0.919 (0.365)	0.012	2.483 (0.924)	0.007	2.282 (1.242)	(-0.152,4.716
Confidence	205	1.056 (0.392)	0.007	1.433 (0.832)	0.085	1.513 (1.043)	(-0.531,3.557
Competence	201	1.139 (0.547)	0.037	0.267 (0.614)	0.664	0.304 (0.714)	(-1.095,1.704
Autonomous	203	0.478 (0.508)	0.347	0.437 (0.679)	0.520	0.209 (0.393)	(-0.561,0.979
Support availability	204	0.419 (0.407)	0.303	-0.104 (0.820)	0.899	-0.044 (0.346)	(-0.722,0.635
Support frequency	207	-0.065 (0.527)	0.903	1.568 (0.598)	0.009	-0.102 (0.827)	(-1.723,1.519
Use of action planning	196	1.198 (0.938)	0.201	1.012 (0.362)	0.005	1.212 (1.044)	(-0.834,3.259
Use of self-monitoring	205	0.235 (0.389)	0.545	2.533 (0.828)	0.002	0.595 (1.004)	(-1.373,2.563

Chapter summary

Our mixed methods approach to understanding if and how the intervention worked for some participants provided interesting insights into engagement with a novel technology-based support system and how that complemented the available support from usual ERS. Both the qualitative and quantitative approaches were conducted independently. The interviews highlighted the role of developing self-monitoring and SMART goal setting skills to increase confidence, which featured strongly in being physically active on a regular basis. The survey process outcomes confirmed that the intervention increased importance and confidence up to 4 months but the effects (compared with usual ERS) had dissipated by 12 months.

The qualitative interviews were mostly not able to follow intervention participants for long. The lack of intervention effects on changes in other process outcomes (e.g. action planning and self-monitoring) was surprising given that 36% participants reached Step 5 (completed a goal review). Some participants continued to complete goal reviews for up to 12 months but it would appear that insufficient participants did so, and most had stopped completing goal reviews long before completing the 4 month follow-up assessment. This was also despite periodic reminders from the online system to log in.

The interviews provided a little information on how e-coachER had prompted intervention participants to find and use social support to increase PA. (e.g. Support to get active - Step 2). Although designed to be specific to the participant's geographic area, some felt the e-coachER links to other PA opportunities were not relevant to their needs. For other participants, however, e-coachER did help to facilitate an open discussion about health within the participants' social network. It is possible that simply talking about being in the e-coachER study (i.e. an opportunity to connect) would have been done by participants in both arms of the trial, and few actually got around to joining groups or setting plans to exercise with others. Hence, this may explain why the intervention had no effects on the process outcomes, namely identifying and using social support.

In this pragmatic trial the aim was to determine if there were intervention effects in addition to usual ERS. An alternative explanation to null intervention effects on some of the process outcomes is that usual ERS has sufficient positive effects on PA beliefs to make additional effects unlikely. The Glasgow ERS differed from the other ERS involved in the trial in that the exercise professional supported participants with behaviour change counselling and signposting to different PA options. In this sense the Glasgow ERS may have been expected to build a sense of autonomy, and the e-coachER support may not have added much. Further analysis is needed to explore differences in intervention effects on process outcomes by site, although site did not interact with the intervention effects on the primary outcome. Health interventions, including ERS, are notorious for having short

term effects on health behaviour which dissipates with time. Given that ERS can provide barriers to engagement and sometimes may not promote a range of sustainable PA option we designed e-coachER to have more lasting appeal and to develop self-regulatory skills and the intrinsic motivation to be physically active for managing chronic conditions, above and beyond usual ERS. Some key processes did change as a result of e-coachER engagement in the short-term but these were not sustained, which is consistent with the absence of any mediating effects of change in these measures on intervention effects on the objective primary outcome of MVPA.

Chapter 5: Economic Evaluation

Introduction

This chapter reports the economic analysis of an augmented ERS with web-based behavioural support (e-coachER) versus ERS alone. Comparing the costs and consequences of alternative approaches to promoting health care is key to facilitating efficient allocation of resources.[61]

Whilst economic evidence on ERS exists (mostly compared with usual care), although unclear[17], little is known about the value for money of an augmented ERS with online behavioural support. A review of reviews (n=3) conducted by Pavey et al[49] found one review[62] showing ERS to be cost effective, another one[63] reporting mixed findings, and the third[64] found limited evidence of effectiveness but higher cost. In an analysis of 21 economic evaluation studies published by NICE from 2006 to 2010, Owen et al[65] found ERSs to be cost effective at the NICE threshold of £20,000 to £30,000. Vijay et al,[66] in a systemic review of economic evaluations, reported three studies showing a cost per Disability Adjusted Life Years (DALY)/QALY estimate below £10,000 for exercise prescriptions.

The most recent NICE guideline development on ERS identified two key gaps in knowledge.[67] First, there is paucity of cost effectiveness evidence on alternative models of ERS. Second, information on the cost effectiveness of ERS on people with comorbidities is lacking. We are aware of an ongoing multi country, multi centre RCT examining the cost effectiveness of ERS enhanced plus self-management strategies compared with ERS alone among inactive.[68]

This chapter addresses the gaps in the literature by estimating the cost-effectiveness of e-coachER compared with ERS alone, in adults with range of chronic conditions. The analysis uses one year time horizon (from baseline to 12 months post randomisation) and is conducted from the viewpoint of NHS, personal social services, and patients. The base case analysis covered NHS and personal social services perspectives.

Methods

The intervention and control population are as defined in Chapter 2. In line with the effectiveness analysis, the sample for base case analyses are participants who provided accelerometry data. Sensitivity analysis explored the impact of using the whole sample.

Measurement and valuation of cost

Total costs was expressed per participant and calculated by multiplying resource use with each relevant unit cost and summing across the range of resource use possibilities across the 12 months of the study.

Resource use, including those 'in kind', associated with both intervention and control was identified through discussions with the management team of the trial. Following this, resources were measured and valued without research-driven resource use. The range of resource use covered: (a) set up and design of the intervention, (b) delivery of the intervention including handbooks, pedometers, guide for using LifeGuide© platform, technical support and maintenance of website, (c) consultation provided by exercise specialist and staff support to participants, (f) primary and secondary health service use: GP, nurse, social worker, care worker, physio consultations (both home and practice visits), prescriptions, hospital admissions, A&E visits, and other (e.g. podiatrist visits); (g) time and money expenses borne by participants in relation to participation in the intervention (time spent on web platform), visit to exercise specialist, and PA (e.g. membership fees for gym or sports club). Data on resource use was collected using the trial administrative records, key informant interviews (e.g. trial manager), review of trial management records and participants' questionnaires at baseline, 4 and 12 months

Resources were valued using national tariffs (eg PSSRU 2017,[69] NHS Reference cost 2016,[70] ONS 2017[71]) to increase generalisability. In the absence of available national costs, unit costs came from trial administrative records. Appendix 6 provides details of unit costs. The unit cost of capital costs (i.e. pedometer) was calculated pro-rata (costs were spread over their expected lifetime)because its use can occur beyond the time-period of this analysis.[72] Costs were expressed in 2017/18 pounds sterling, using the Hospital & Community Health Service (HCHS) inflation index where appropriate (PSSRU 2017). No discounting was done as the time horizon of the analysis is one year.

Measurement and Valuation of Outcomes

Two types of outcomes were used for estimating cost-effectiveness; physical units (PA indicator) and QALYs. The PA measure is the primary outcome measure of the trial (as described in Chapter 2), total weekly minutes of MVPA in ≥10 minute bouts, recorded objectively by accelerometer. QALYs were estimated by converting EQ-5D-5L utilities using area under the curve method. EQ-5D-5L questionnaires were completed by trial participants at baseline, 4 and 12 months. In line with NICE (2018) recommendation,[61] utility weight based on the cross walk function[73] was used to assign utility weights. Sensitivity analysis explored the impact of using other valuation sets.

Methods of analysis

Missing data analysis

Multiple imputation was employed to replace missing values as it incorporates uncertainty around imputed estimates. Imputed values are drawn from a regression model fitted for each variable with missing data. Multiple Imputation by Chained Equations (MICE) was used and not Multivariate Normal (MVN) imputation as the variables with missing data includes binary and categorical variables, and these are not suitable with the MVN.

Five imputations were used.[74] The standard approach was followed in building the imputation model as we ensured the imputation model match the model used for the analysis whilst including the predictors of missingness as possible. Second, the dependent variable was included in the imputation model to ensure that the imputed values have the same relationship to the dependent variable as the observed values.[75]

As the purpose of the multiple imputations was to replace missing values for raw data to allow the generation of derived variables, a point estimate was required not its variance per se. In line with Rubin's rules,[76] we derived the overall point estimate for the imputations by averaging the estimates of the multiply imputed data. For categorical data, the overall point estimate was rounded up to the nearest decimal point as relevant. The mean of multiple imputations is an unbiased estimate of the missing value, and their contributions to increased variance in subsequent analysis viewed as an estimate of the added uncertainty due to data missingness.[76]

Incremental analyses

The within trial analyses were two-fold: (a) incremental cost utility analysis: this was the primary analysis of the economic evaluation and used QALY as the effectiveness measure. The outcome of

the analysis was cost per QALY; (b) incremental cost effectiveness analysis: analysis generated cost per change in MVPA minutes based on accelerometer data indicated in Chapter 3.

Descriptive statistics based on means (standard deviation) were conducted for the costs components and quality of life measure. Estimations of the outcomes used regression models fitted separately for costs, QALYs and MVPA minutes. Details of the estimation of MVPA minutes is presented in Chapter 2. Generalised linear models (GLM) fitted with gamma and binomial 1 (equivalent to beta regression) distributional families were fitted for the costs and QALY's analyses, respectively[77][78]). The modified Park test was used to select the appropriate distributional family.[77] Regression models adjusted for covariates, as recommended, including baseline QALYs (as appropriate), and potential correlates of the dependent variables: age, gender, ethnicity, health condition. Models specification was tested using the link test. All analyses accounted for cluster effect (based on site ID) through clustered standard errors. Sample means and incremental values for costs and QALYs were estimated using the margins method[77] to improve precision of estimates. The estimation of standard error and confidence intervals also accounted for the cluster design.[79]

Uncertainty in estimations was analyzed using deterministic analyses to examine the impact of; (i)using the whole sample (all randomized people) for analysis; (ii) changing perspective of analysis to include costs incurred by participants; (iii)excluding costs of health and social service use; (iv) using different value sets[80] to estimate quality of life, (v)complete case analysis (excluding missing data), and (vi) worst case scenario -combination of 'i' and 'iv'. In addition, sub group analyses were conducted to explore whether the cost effectiveness of the intervention differed across different types of disease groups reported as the reason for referral to the ERS (hypertension, low mood, type 2 diabetes, weight loss, and osteoarthritis).

Probabilistic uncertainty was assessed through nonparametric bootstrapping (n=2000 replications). To ensure the observations within the resampled clusters are independent in each bootstrap replication, the bootstrap estimation was fitted with unique identifiers inter and intra clusters.[56] Based on the bootstrap samples, cost-effectiveness planes (CEPs) and acceptability curves (CEACs) were constructed using the *bsceaprogs* program code.[77]

Results

Summary statistics (unadjusted for baseline differences) on costs to both providers and participants, and quality of life are provided in Table 23 (see Appendix 7, Appendix 8 and Appendix 9). At 12 months, the cost to providers per participant was higher in intervention group (£1730). The biggest component of the cost borne by providers was health and social service use cost (91%) and the least

was cost associated with the provision of support to participants (<1%, 60p per participant). In terms of cost to participants, the pattern was different as participants in the control group incurred an average cost of £298 compared to £255 in the intervention group. The vast majority of this cost was due to cost related to participation in PA (69%). Fees paid for child/dependent care during exercise specialist visit was the least (<1%, 20p per participant). The intervention group experienced higher quality of life at 12 months with a quality adjusted life year of 0.662 (Table 23).

Table 23 Descriptive statistics of costs (2017/2018) and quality of life per participant (with accelerometry data)

	Control (n=133)	e-coachER (n=110)
	Mean (SD)	
Cost to providers at 12 months (£)		
Total costs to providers	1385 (2177)	1730 (1707)
Set up cost	0	182 (0)
Delivery cost	0	29 (0)
Cost of participants' consultation with exercise specialist	30 (45)	29 (45)
Cost of attendance to ERS centre	3.1 (4)	2.5 (3)
Number of ERS attendances[1]	11(12)	7(9)
Cost associated with general support to participants	0.3 (1)	1 (2)
Costs of health and social service use	1352 (2180)	1487 (1691)
Cost to participants at 12 months (£)		
Total costs to participants	298 (1252)	255 (347)
Travel cost to visit the exercise specialist	13 (23)	14 (29)
Time cost in consultation with exercise specialist	43 (64)	42 (66)
Fees paid for child/dependent care during exercise specialist visit	0.3 (2)	0.1 (1)
Other expenses related to exercise specialist visit	2 (8)	4 (20)

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[1] Mean imputed attendance rates (over the period of an ERS varied across the different sites from 15 in Plymouth to 7 in Birmingham and 3 in Glasgow, Numbers reflect different schemes (see description of schemes elsewhere in the Report) and challenges in capturing data, rather than participant interest and success of schemes.

	Control (n=133)	e-coachER (n=110)
	Mean (SD)	
Time cost using the e-coachER web platform	0	10 (12)
Cost of attendance to ERS centre	27 (34)	18 (26)
Costs related to PA participation	213 (1253)	168 (311)
Quality of life		
QALY (1 year)	0.637 (0.245)	0.662 (0.261)
EQ 5D index - baseline	0.656 (0.240)	0.663 (0.261)
EQ 5D index - 4 months	0.642 (0.257)	0.672 (0.279)
EQ 5D index -12 months	0.620 (0.286)	0.641 (0.305)

Table 24 shows the main results based on regression estimates that adjusted for baseline differences. Consistent with the pattern observed in the unadjusted estimates, the average cost per participant was £1355 (95% CI £701, £2008) and £1793 (95% CI £1635, £1952) in the control and intervention group respectively. This represents an additional cost of £439 (95% CI £-182, £1060) in the intervention group although the difference is not statistically significant. The intervention led to a weak indicative effect on total weekly minutes of MVPA in bouts of ≥10 minutes (11.8 minutes, 95% CI -2.1 to 26, compared with the control group. In terms of quality of life outcome, the intervention group (0.663; 95% CI 0.625, 0.701) had more QALYs than the control group (0.637; 95% CI 0.585, 0.688) (Table 24). The difference in QALYs (0.026; 95% CI 0.013, 0.040) among the two groups was statistically significant. The cost utility ratio shows that compared with control, the intervention cost an additional £16,885 per QALY. This is below the NICE threshold of £20,000-£30,000/QALY.

Table 24 Costs, effects and cost-effectiveness at 12 months

For incremental analyses, the comparison is e-coachER vs control.

	Control		e-coachER	
	Mean	(95% CI)	Mean	(95% CI)
Within trial analysis **Costs and effects over 12 months**				
Total cost per participant (£)	1355	(701 to 2008)	1793	(1635 to 1952)
Incremental cost (£)	-		439	(-182 to 1060)
Total QALYs per participant	0.637	(0.585 to 0.688)	0.663	(0.625 to 0.701)
Incremental QALYs	-		0.026	(0.013 to 0.040)
Incremental total weekly minutes of MVPA in bouts of ≥10 minutes	-		11.8	(-2.1 to 26)
Within trial analysis **Incremental cost-effectiveness/utility ratio (ICER) at 12 months**				
Cost per additional QALY (£)	-		16,885	
Cost per additional minute of MVPA in a bout of ≥10 minutes (£)	-		37.20	

Table 25 shows the results of the deterministic sensitivity analyses. The base case finding was robust to deterministic sensitivity analyses with a few exceptions. The intervention was found to be more expensive but produced more QALYs. Excluding health and social service use costs, or changing the perspective of analysis, improved the cost effectiveness of e-coachER with ICERs ranging between £9,000 and £15,885. Using estimates based on the whole sample (all randomised) was decisionally significant. It produced a worse cost effectiveness ratio, with the intervention becoming not-cost effective (£43,900 per QALY).

Compared with the base case findings, sub group analysis showed the intervention to be more cost effective in groups who reported that hypertension (dominates control) or osteoarthritis (£12,389 per QALY) or type 2 diabetes (£14,886) was the primary reason for referral. Among individuals who reported that being overweight was the primary reason for referral, e-coachER was still cost effective but a higher ICER value (£18,421 per QALY). In the group who reported that low mood was the primary reason for referral, the intervention was not cost-effective (dominated by the control).

Table 25 Sensitivity analyses

Parameter	Incremental cost(£)		Incremental QALY		ICER (£)
	Mean	(95% CI)	Mean	(95% CI)	
Base case	439	(124 to 754)	0.026	(0.013 to 0.040)	16,885
Whole sample (all randomised)	439	(124 to 754)	0.010	(-0.005 to 0.024)	43,900
Changing cost perspective (both participants and NHS&PSS costs)	413	(-266 to 1093)	0.026	(0.013 to 0.040)	15,885
Excluding all health and social care use cost (cost directly related to intervention)	234	(216 to 251)	0.026	0.013 to 0.040	9,000
Complete case analysis (exclude missing data)	529	(-166 to 1223)	0.035	(0.010 to 0.059)	15,114
Changing the values for measuring QALYs (based on EQ 5D value set from Devlin et al[80]	439	(-182 to 1060)	0.030	(0.022 to 0.039)	14,633
Participants with hypertension (n=37)	-46	(-1260 to 1168)	0.009	(-0.020 to 0.038)	Intervention dominates control

Parameter	Incremental cost(£)		Incremental QALY		ICER (£)
	Mean	(95% CI)	Mean	(95% CI)	
Participants with low mood (n=84)	989	(637 to 1341)	-0.056	(-0.098 to -0.014)	Control dominates intervention (Less expensive and more effective)
People with type 2 diabetes (n=49)	655	(-187 to 1497)	0.044	(-0.021 to 0.110)	14,886
Participants who were overweight (n=227)	350	(-44 to 745)	0.019	(-0.035 to 0.072)	18,421
Participants with osteoarthritis (n=53)	223	(-781 to 1228)	0.018	(-0.016 to 0.052)	12,389

Figure 7 shows the cost-effectiveness plane for the intervention compared with control. The majority of the cloud of points (representing mean differences in costs and QALYs) are located in the north-east quadrant of the plane. This indicates that the intervention has high likelihood of generating more QALYs but at higher costs. The probability of the intervention being cost- effective (compared with control) at multiple willingness to pay per QALY values is presented in Figure 8. At £10,000 per QALY, the intervention has about 30% chance of being cost effective compared with the control. The likelihood of cost-effectiveness nearly doubles (51%) at the £20,000/QALY threshold and increases further to 63% at £30,000 threshold.

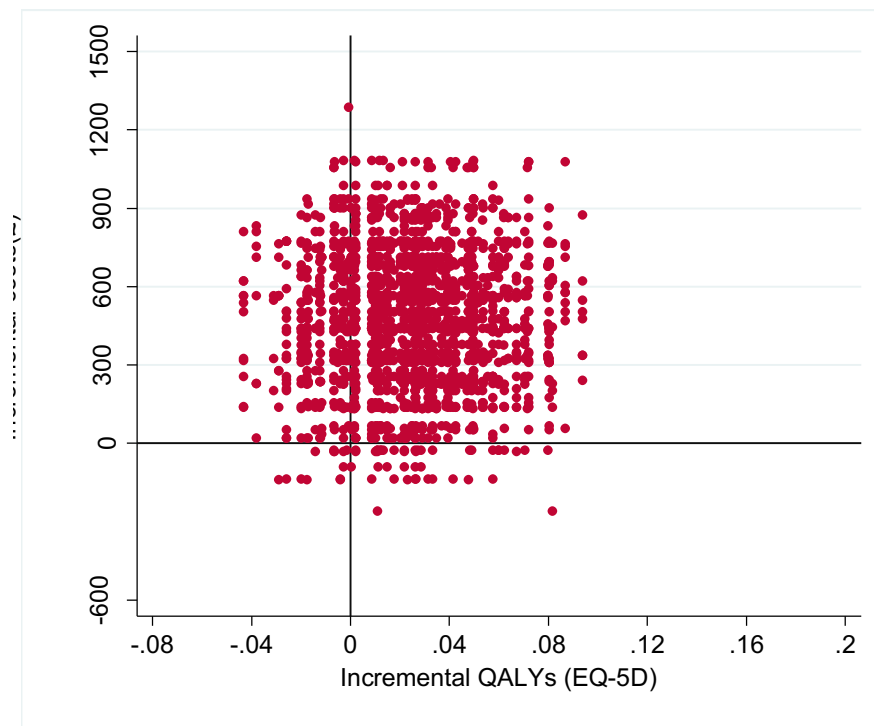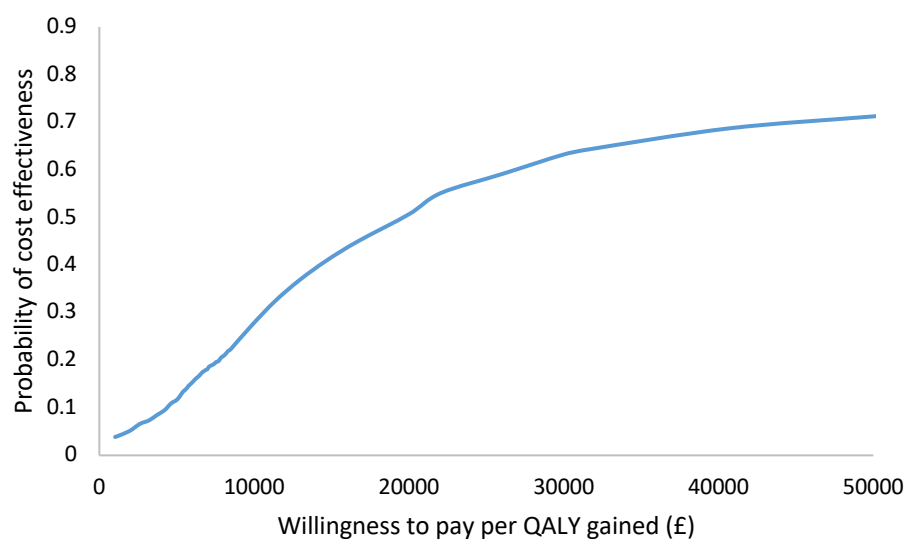**Figure 7 Cost-effectiveness plane for intervention vs control at 12 months**

Figure 8 Cost-effectiveness acceptability curve showing the probability of within trial cost-effectiveness for intervention vs control at different willingness to pay per QALY threshold levels

Discussion

This study shows that providing online behavioural support for participants of ERS cost providers £1793 per person. Whilst the intervention costs £439 more than offering ERS alone, it leads to better quality of life outcomes (0.026 more QALYs per person) and increased participation in PA (12 minutes more weekly minutes of MVPA in ≥10 minute bouts per person). Whilst the differences were mostly not statistically significant, it is important to note that this is not sufficient proof of no significant effect, as the clinical trial was not powered to identify the changes in the economic outcomes (cost and QALY) particularly given the small number of observations in the sub group analysis. Compared with the control, the intervention cost an additional £37 to gain a minute increase in weekly MVPA (in ≥10 minute bouts) and £16,885 per QALY gain per person. Based on the NICE threshold of £20,000-£30,000 per QALY, e-coachER could be considered more cost-effective than ERS alone. If decision makers are willing to pay £30,000 for a QALY, e-coachER has a 63% probability of being cost-effective. The findings were robust to sensitivity analysis including when the cost of participants are added to total costs of the programmes. Exploratory sub group analysis found the intervention to be cost effective among participants who reported that hypertension, osteoarthritis, with type 2 diabetes or overweight problems was the primary reason for referral but not cost effective among those who reported that low mood was the primary reason.

The novelty of e-coachER, its comparison with usual ERS and the disease specific population makes it complicated to relate the findings here meaningfully to the existing economic literature on ERS. We identified one comparable study. Murphy et al,[17] a pragmatic RCT, assessed the cost effectiveness of The Wales National Exercise Referral Scheme (NERS) in Wales, a 16-week programme including motivational interviewing, goal setting and relapse prevention compared with usual care. Participants were inactive people with depression, or/and coronary heart disease risk. The intervention was showed to be cost effective at 12 months, with a cost per QALY estimate of £12,111 and 89% likelihood at £30,000 threshold per QALY.

Our analysis found costs associated with health and social service to constitute the largest proportion of total costs. Although the impact on cost-effectiveness was not decisionally insignificant, an important consideration is why the intervention group had higher health service use cost (mean cost of £135) compared with the control. Particularly given the intervention was more effective and led to increases in both PA and quality of life outcomes. Further exploration shows that in the first four months of the trial, on average, the intervention group had health service cost of £819 and the control group £639 (Appendix 9). In terms of the sub-components of health service use cost collected in this study (n=13), the intervention had higher costs in all except two (A&E visits

and hospital visits-out patients). The reverse pattern was, however, observed from 5 to 12 months - the control group had more health service cost (£713 vs. £668). Similarly, the control had higher cost for all sub cost components apart from prescriptions and care worker visits. A systematic review on injury consequences of PA found that although relatively minor; increased activity could lead to adverse health consequences.[81] However, for older adults, improved participation reduces the risk of fall related injuries.[82] Future studies are required to investigate further the impact of adverse effects on cost effectiveness of PA programmes.

This study feeds into a limited evidence base around the efficiency of different models of ERS. To the best of our knowledge, this is the first study to demonstrate the cost effectiveness of online support for ERS, and in a population with common chronic conditions. The strengths of this study include the use of robust effectiveness data from a large multicentre trial, rigorous analyses to determine the impact variant measures of quality of life and participant perspective, sub group analysis among different disease groups, comprehensive coverage of health service and social care use cost. A key limitation, however, is the short term perspective of the analysis herein. Modelling of the long term costs and effects is important where benefits and costs extend beyond the end of a trial. It is of particular relevance to this trial, where the benefits or costs could be experienced in the future too (as resource savings from reduced disease and therefore benefits in terms of increased quality of life). We expect the impact of the long term effects may have underestimated the cost effectiveness of e-coachER.

There is currently limited national public health guidance on the implementation of ERS enhanced with online support for participants. The results herein suggest that augmented ERS could be a cost effective strategy to improve the PA rates in UK among adults with chronic conditions. Guidance on ERS ought to be revised to account for this new evidence. To strengthen the economic case, future studies are recommended to examine the long term cost effectiveness of the e-coachER and ascertain the impact of the trajectory of activity levels on future health service and future quality of life.

Chapter 6: Discussion

Summary of findings

The 450 trial participants were 64% female (n=290), had an average age of 50 years, a BMI of 32.6, 65% and 35% were classified as inactive (n=293) and moderately inactive (n=157), respectively, and 50% reported that weight loss was the primary reason for referral (n=225), followed by low mood (n=85, 19%), osteoarthritis (n=54, 12%), diabetes or pre-diabetes (n=49, 11%) and high blood pressure (n=36, 8%). Participants also noted that weight loss (n=364 81%), low mood (n=243, 54%), high blood pressure (n=149, 33%), diabetes or pre-diabetes (n=117 26%) and osteoarthritis (n=108, 24%) may have been one of the reasons for referral.

The e-coachER support package was developed which included mailing participants a pedometer, a fridge magnet with attached tear-off strips to record daily PA, and a bespoke website to overcome barriers for some people who are not willing or able to engage in an ERS. The e-coachER intervention demonstrated a mixed level of engagement. About one-third of participants did not register on-line and about one-third did what we thought would be an adequate 'dose' of at least 5 of the 7 Step, involving at least setting a PA goal and reviewing it a week later.

The results show that compared with usual ERS, the e-coachER intervention group did slightly more, but not significantly, accelerometer recorded minutes of MVPA (recorded in bouts of ≥10 minutes) at 12 months. The pattern was similar when considering the level of intervention engagement, with a slightly larger difference in favour of the intervention group. Applying the same approach as in the primary analysis, there were no between group differences at 12 months in any of the other accelerometer derived or self-reported MVPA outcomes, with one exception. The intervention group had significantly more day-time sedentary time (accumulated in blocks of ≥5 minutes) at 12 months. In ITT imputed comparison at 12 months the intervention group were more likely to self-report report that they had achieved 150 minutes of weekly MVPA (OR 1.55; (0.99, 2.42), P = 0.05), compared with the control group. The intervention also had no effect on ERS attendance (78% v 75% in control and intervention, respectively), or EQ-5D-5L or HADS scores at 12 months, compared with the control group. In ITT imputed comparison at 12 months the intervention group had lower HADS depression and anxiety scores than the control group. The proportion of participants adding the ERS was comparable with findings from a review[15] which reported the average ERS uptake was 81% in RCTs.

Economic evaluation

Over the 12 months follow up, the average cost per participant was £1,355 (95% CI £701, £2,008) and £1,793 (95% CI £1,635, £1,952) in the control and intervention groups respectively. Compared to control, the intervention group incurred an additional mean cost of £439 (95% CI £-182, £1,060) but generated more mean quality adjusted life year (QALYs); (0.026, 95% CI 0.013, 0.040) with an incremental cost effective ratio of additional £16,885 per QALY.

Although insignificant, an important consideration is why the intervention group had higher health service use cost (mean cost of £135) compared with control group given the intervention was effective and led to increases in both PA and health related quality of life. The difference in the cost, which was not statistically significant, was observed irrespective of the central measure of tendency, mean or median (see Appendix 9). Further exploration shows that in the four months of the trial, on average, the intervention group had health service cost of £819 and the control group £639. In terms of the sub-components of health service use cost collected in this study (n=13), the intervention had higher costs in all except two components (A&E visits and hospital visits-out patients). The reverse pattern was, however, observed from 5 to 12 months; with the control group qualitatively having more health service cost (£713 vs. £668). Similarly, the control group had higher cost for all sub cost components apart from prescriptions and care worker visits.

Effectiveness and engagement in the intervention

One of the criticisms of e- and m-health interventions is that engagement is not appealing to enough people and can be rather short-lived.[23] The 9 month work in developing the intervention, building on other effective LifeGuide© interventions and with public and patient involvement, aimed to maximise engagement to theoretically have the greatest impact on MVPA outcomes at 12 month follow-up. Automated periodic e-mails were sent to intervention participants right up to 12 months. The intervention included evidence-based and theory driven components as well as a pragmatic approach to enhance engagement. Pedometers and recording sheets attached to fridge magnets were provided in the initial introductory pack as very basic tools for self-monitoring PA, setting and reviewing SMART goals. These may have been sufficient to get some of the 36% of intervention participants who never registered to think about behavioural self-regulatory processes to increase PA for managing their chronic condition(s). Attending the ERS may also have provided sufficient support to become more physically active, without the use of the pedometer or web-based support. Other participants may also have regarded the pedometer as rather basic and decided to use a more sophisticated app on their smart phone.

That 64% of participants did register on-line and completed their first Step, with 36% going on for over 4 weeks to complete a goal review provided us with some assurance that the e-coachER

intervention was acceptable for a reasonable proportion of participants. There is evidence from previous research with LifeGuide© interventions that even limited on-line engagement can be effective and there is no clear 'adequate dose' to optimise behavioural change. Our CACE analysis confirmed that completing our pre-specified intervention engagement level (Step 5) did not lead to significantly greater 12 month objectively recorded minutes of MVPA, recorded in ≥10 min bouts, compared with the control group, although the between group differences were qualitatively greater (22.9 v 11.8 minutes).

Our Logic Model predicted that e-coachER engagement would strengthen various beliefs that would in turn translate into increases in MVPA, compared with usual ERS support. Among only the participants included in the primary analysis, the intervention did increase the following compared with the control group: perceived importance of doing at least 30 minutes of moderate intensity PA (e.g. brisk walk) on at least 5 days a week; confidence in achieving at least 30 minutes of moderate intensity PA (e.g. brisk walk) on at least 5 days a week; and perceived competence in being regularly physically active at 4 months (but not 12 months). Changes (from baseline to 4 months) in these process outcomes did not mediate changes in the primary outcome at 12 months.

In our qualitative part of our process evaluation 12% of intervention participants were interviewed. Overall, e-coachER was acceptable and positively experienced and did "do what it said on the tin" in terms of enhancing autonomy, competence and relatedness for many participants. Inevitably, since the web-based support was available to support participants with a range of levels of IT literacy and chronic conditions, some of the content did not appeal to everyone. That said, the idea that the support aimed to facilitate engagement with the self-monitoring process and then encourage them to move on to using more sophisticated devices to self-monitor PA for example, was overlooked by some participants, but not all. Similarly we tried to help participants to find any source of social support to support increases in PA and a preferred form of PA they could enjoy, whether or not that involved the ERS, and that overarching intent 'may have been lost' by some of those interviewed. The User Guide sent to intervention participants initially could have spelled out some aims of the support more explicitly and if this had been understood then some comments from participant interviews may not have been made. That said, some interviewees did note they had a strong IT background and acknowledged that their comments were personal and acknowledged the need to appeal to those with a lower level of IT literacy than themselves.

Strengths and limitations

Sample characteristics

We believe this to be the first study to recruit inactive participants with chronic conditions into a trial involving ERS, and follow then them up at 12 months to assess objectively measured PA. We

had planned to conduct separate analyses for different chronic conditions, to explore the possibility of establishing an evidence-based case for disease specific ERS pathways, but the study findings have clearly confirmed the extent of multi-morbidity. Nevertheless, when considering the participant reported primary reason for referral, in sensitivity analysis there was no interaction between this reason and the overall intervention effects on the 12 month MVPA primary outcome.

During the course of the study we recalculated the sample size to recruit 430 participants (down from original funding application sample size of 900) allowing for 20% attrition for the primary outcome at 12 months. We actually recruited 450 participants, but partly because we set a very rigorous primary outcome threshold (wear time of at least 4 days a week, including one weekend day, with data from at least 16 hours per day) the primary analysis was based on data from 232 participants. Further analysis explored if more lenient thresholds, which resulted in more participants being involved in the analysis, influenced the findings. The overall findings remained consistent.

ERS context

The e-coachER intervention was designed with considerable public and patient input to ensure it would support patients with a wide range of IT expertise. We categorised 16% of trial participants as having low IT literacy, and further analysis revealed that IT literacy did not impact on the primary analysis.

ERS are delivered in various formats across the UK and we were keen to ensure the trial produced findings with good generalisability. In other words, we wanted to know if adding the e-coachER intervention improve long-term levels of MVPA in patients with chronic conditions. The three sites in which recruitment took place offered quite different types of ERS, which have been described elsewhere.[1] For example, in Glasgow the ERS involves initial contact with an ERS practitioner who provides some behavioural support to increase MVPA and also helps to sign-post participants to preferred and appropriate PA opportunities, with following consultations available at 6 and 12 months. In contrast, the schemes in Birmingham and the South West are more traditional ERS with support provided by an ERS professional in an exercise facility. Within the trial we examined the impact of site on the primary analysis and found no different effects of the intervention across sites.

A further strength of the study was the use of an evidence-based, theory driven intervention which allowed us to identify website usage. The LifeGuide© system provided data on number of visits (and duration) to the website and which Steps were completed. Our detailed mixed methods process evaluation allowed us to collate this information and explore the impact of engagement on cognitive

and behaviour processes we had proposed within our logic model. In turn we were able to explore if changes in these process outcomes mediated changes in the primary outcome.

Accelerometer measures at 12 months

This is the first trial of an ERS to objectively assess MVPA at follow-up. Only one previous trial has involved a 12 month follow-up to assess the long-term effects of an ERS intervention on PA, and that was based on self-reported measures. Due to the very low levels of MVPA in the present sample, relative to other studies, new challenges have appeared for data analysis. We pre-specified our primary outcome and the research team, TSC and DMC have been involved in lengthy discussions about the most appropriate approach to data analysis. The Statistical Analysis Plan was agreed and signed before seeing the data. In our primary analysis we present various scenarios from extensive exploratory modelling, and also sensitivity analysis using different thresholds for analysing raw accelerometer data. These analyses, and those of the self-reported MVPA data, will provide valuable insights into how best to examine within trial PA data. At the time of writing we understand that national and international guidelines for completing moderate and vigorous PA weekly minutes are expected to no longer mention the need to accumulate MVPA in at least 10 minute bouts. Our analyses provide a broad range of findings which will contribute to the understanding of past and future evidence and research.

The accelerometer findings were broadly similar to self-report measures in terms of between group differences but levels of activity were strongly influenced by the way the data was collected and processed. Only participants classified as inactive or moderately inactive according to the GPPAQ were included in the study but at baseline self-reported data revealed that 36% met the 150 minutes per week MVPA guideline, and accelerometer data revealed that 80% met the guideline from non-bouted activity and only 4% met it from activity recorded in bouts of ≥10 minutes. Others have also shown lower levels of accelerometer recorded MVPA minutes when data are processed using ≥ 10 minute bouts compared with bouts of at least 1 minute.[50] Current national and international guidelines do not fully reflect this variability due to measurement method.

Given the over-dispersion and high frequency of zero counts, the primary statistical model was found to poorly fit and post-hoc analysis models were therefore also explored. For example, for the primary outcome of total weekly minutes of MVPA in ≥10-minute bouts, 142/243 (58%) participants at 12 months had zero scores and the standard deviation (60.0) was more than two-times the mean value (26.2). It is important to recognise the limitations of all these models. These include lack of fit of the models and the need to assume data as counts for some models. However, reassuringly, the interpretation of the impact of the intervention on primary outcome analysis was insensitive to the choice of statistical model.

While the effectiveness findings show only a weak indicative effect on MVPA at 12 month follow-up, these changes were found to have a 63% probability of being cost-effective based on a UK threshold of £30,000/QALY.

The mixed methods process evaluation indicated that the intervention was generally acceptable and of value to patients with a variety of physical and mental health conditions. The intervention resulted in changes in some but not all behaviour change processes that we designed the intervention to change. Notably, the perception of importance in being physically active was greater as a result of the intervention, compared with the control group, at both 4 and 12 months. Step 1 in the intervention involved a quiz about the benefits of PA for health generally and also specific chronic conditions. In other Steps we encouraged participants to feel the broader value of being active for both physical and mental well-being. By supporting change in MVPA it is likely that intervention participants learned to place greater value and importance on being physically active but improvements in confidence to be physically active and a perception of importance of being more physically active did not mediate any effects of the intervention on MVPA at 12 months.

Implications for health care

Offering e-coachER support had only small but non-significant effects on objectively recorded MVPA, compared with usual ERS, at 12 months, but the cost utility ratio shows that compared with control, the intervention cost an additional £16,885 per QALY and has a 63% probability of being cost-effective. for increasing MVPA, compared with usual ERS.

As a result of usual ERS alone (i.e., in the control group), across the sites, there was only weak evidence of a change in accelerometer recorded MVPA at 4 months, but none at 12 months, albeit without comparison with no ERS. If anything there were small but non-significant reductions in MVPA among only those engaging in usual ERS. The rationale for conducting the present study was that by offering an additional 'package' of support (e-coachER) aimed at developing self-determined PA alongside usual ERS or instead of usual ERS, our intervention would, if shown to add additional benefit, would be available to primary care professionals to offer to inactive patients, with a range of physical and mental health conditions, at the time of also making a referral to a local scheme.

Providing web-based behavioural support to participants of ERS offers an additional strategy to augment usual ERS to promote PA. There are a few small aspects of the intervention we would change, based on participant feedback, but the intervention could also be extended to be suitable for use by patients with other chronic conditions (e.g., cancer). There was reasonable engagement in e-coachER support, for participants with a range of confidence in using IT, indicating that if implemented it would have low costs and moderate value in promoting PA, in addition to usual ERS.

Our process evaluation indicated that there were changes in some of the measures we collected to assess key components of the logic model. For example, the intervention led to improvements up to 4 months in confidence and competence in doing PA, perceived importance of PA, a sense of availability of support, action planning and self-monitoring, compared with the control group. But these intervention effects were only sustained at 12 months for perceived importance of PA. In our exploration of whether any of the changes between 0–4 months mediated any intervention effects on the primary outcome (accelerometer recorded minutes of MVPA in bouts of ≥10 minutes) at 12 months, there was no evidence that this was the case. Our ability to detect these mediation effects may have been limited by the overall intervention effects on MVPA at 12 months.

The present study found that 36% of participants did not log into the on-line e-coachER support but did receive a pedometer and a fridge magnet to record MVPA. We will further analyse the data to determine if this was sufficient to increase MVPA, compared with usual ERS. Other evidence suggests that providing primary care patients with a pedometer to self-monitor PA is effective[56] in changing objectively recorded MVPA. It would be relatively easy to provide patients with a pedometer at the same time as referring them to an ERS.

The LifeGuide© platform has been used to deliver evidence-based and theory driven interventions online to support change in a wide range of health behaviours. One of its strengths is the ability to capture intervention engagement to help understand fidelity issues and add to the literature on how people change as a result of e-health interventions. While LifeGuide© delivered interventions do these things well and have been shown to be effective in supporting change in a range of health behaviours and weight loss, other more sophisticated technological innovations are rapidly taking over. Indeed, feedback captured within our process evaluation noted that the e-coachER support was rather clunky, and the idea of typing in step counts or minutes of MVPA accumulated in the past week into a website and getting feedback on whether or not goals had been achieved can undoubtedly be done on a range of more sophisticated devices which are embracing digital technology and artificial intelligence. For these reasons, the LifeGuide© platform will no longer support digital interventions from 2021.

We hoped that the intervention would encourage participants to go to the local ERS they had been referred to but this did not happen. Almost 25% of referred participants did not attend any sessions.

Future research implications

Previous research has compared usual ERS with an enhanced ERS scheme, involving additional exercise practitioner training, but showed no additional effect[20] on PA. The present trial provides no clear support for adding a web-based support package to usual ERS, to increase long-term MVPA.

Our process evaluation revealed that some improvements to the web-support could be made, such as mobile options with phone apps for self-monitoring and goal setting.

The modest engagement in the on-line e-coachER support, suggests work is needed to understand what factors influenced intervention engagement and how best to further develop low-cost and scalable support to increase ERS uptake and maintenance of PA. Once this has been done, further research could examine the effects of a modified e-coachER type intervention for participants with chronic conditions involved in the present study and others (e.g. with cancer, back pain and in cardiac rehabilitation).

The e-coachER study has provided a rich data set which offers the chance to explore additional questions including the following:

What were the characteristics of participants that predicted changes in 4 and 12 month PA?

How did different measures of MVPA (self-report and accelerometer-derived) influence the findings, beyond what we present here?

What other aspects of intervention engagement (derived from the LifeGuide© platform) were used, and did any influence changes in process and behavioural outcomes?

Among subsets of the sample (e.g. those with low mood), what changes in quality of life, depression and anxiety occurred as a result of the intervention versus usual ERS?

Conclusions

With modest engagement in the evidence-based and theory driven e-coachER intervention, which was captured by the web-based system, the intervention effects on a rigorously defined, objectively assessed, PA primary outcome at 12 months were only small and not significant, and because of a smaller sample size than intended should be treated with caution.

In the cost-effectiveness analyses the cost utility ratio shows that compared with ERS alone, ERS + the e-coachER intervention cost an additional £16,885 per QALY and has a 63% probability of being cost-effective based on the UK threshold of £30,000/QALY.

Ms Jennie King was the lead research assistant and **Ms Lucy Hughes** was the research assistant at the Birmingham site.

Dr Wendy Ingram and **Mr Douglas Webb** were the trial managers.

Mr Chris Cavanagh was the Patient and Public Involvement representative.

All authors critically revised successive drafts of the manuscript and approved the final version.

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Appendices

Appendix 1 Illustrative screenshots from the e-coachER website

e-coachER
Web support for exercise referrals

Making Your Step Plans
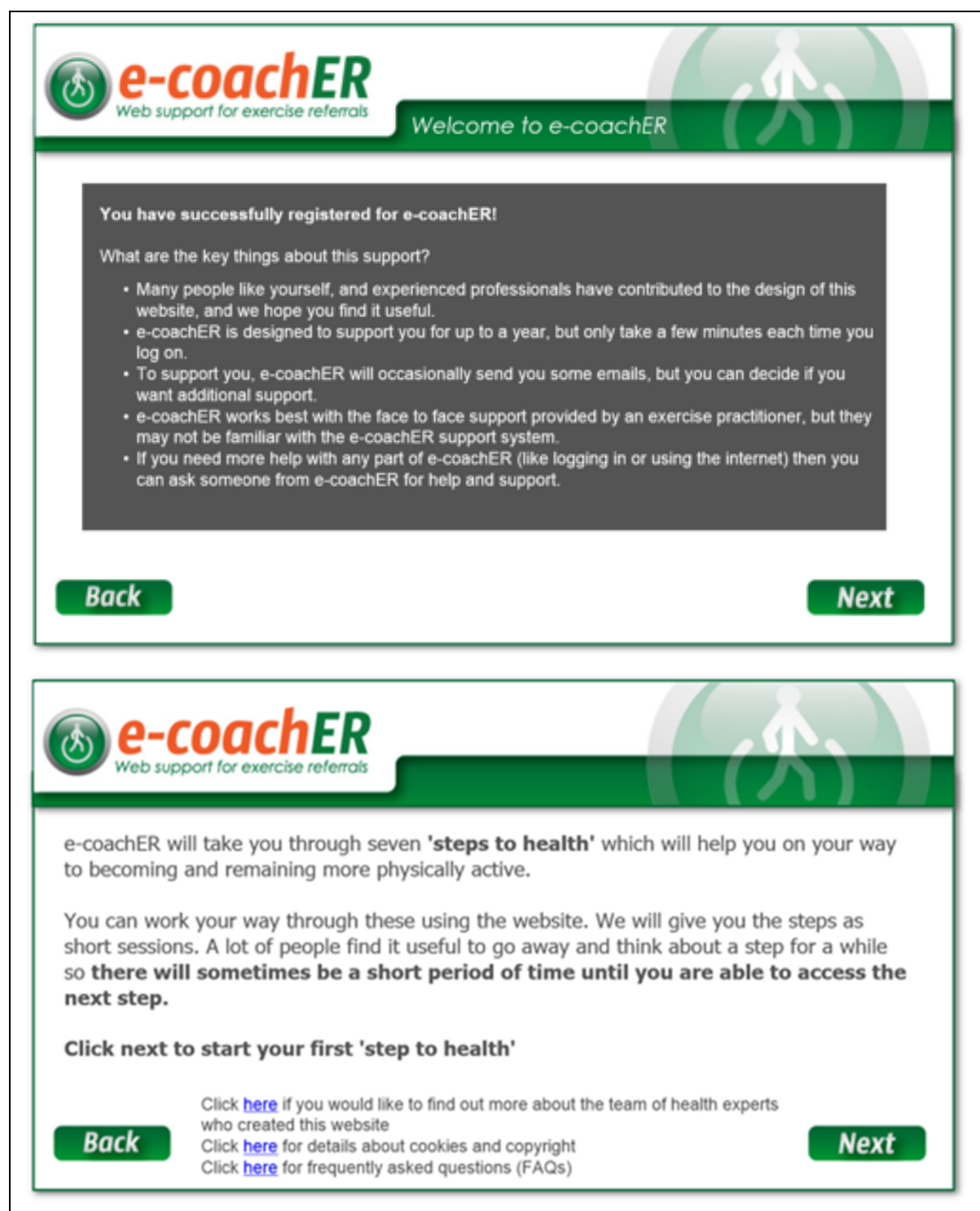
Your step goal!

Now you have some information about the benefits of setting small step goals and some tips on how to achieve them, why not try bringing it together and set your own step goal? Your **Exercise Referral Practitioner** may be able to help with this.

On average, people usually walk between 2000 and 4000 steps a day, just in their everyday activities.

The aim is to increase your step count very gradually without needing to make a special effort.

Why not try setting **your own step goal** using the drop down box below?

For the next week my goal is to walk [0 ▾] Steps per day

Back

Next

Appendix 2 CONSORT (detailed)

Responded to invitation to participate (n=831)

Declined (n=61)

No reason given n=29

No time to devote to ERS/trial n=10

Other reason n=9

ERS/trial is not useful n=8

Ill-health n=5

Ineligible (n=11)

No email/internet n=4

Other reason n=3

Age outside range n=1

Doesn't meet ERS criteria n=1

No clinical condition of interest n=1

Too active (physically active occupation) n=1

Patient not contactable (n=4)

Interested (n=755)

Patient not contactable (n=26)

Ineligible (n=23)

No email/internet n=9

Other reason n=6

Doesn't meet ERS criteria n=4

Unable to use trial materials in English & no translator n=2

Age outside range n=1

Too active (physically active occupation) n=1

Declined (n=15)

No reason given n=5

No time to devote to ERS/trial n=4

Other reason n=2

ERS/trial is not useful n=2

Ill health n=2

Assessed for eligibility (n=691)

Ineligible at screening (n=201)

BMI outside range n=104

Too active on GPPAQ n=46

No clinical condition of interest n=26

Age outside range n=10

No email/internet n=6

Substance abuse problem n=3

Other reason n=3

Doesn't meet ERS criteria n=2

BP outside range n=1

Declined (n=12)

Other reason n=5

No reason given n=3

Ill-health n=2

ERS/trial is not useful n=1

No time to devote to ERS/trial n=1

Patient not contactable (n=1)

Eligible and consented (n=477)

Did not return baseline accel (n=15)

Declined (n=9)

No reason given n=5

Other reason n=3

Ill-health n=1

Patient not contactable (n=3)

Randomised (n=450)

Intervention (ERS plus e-coachER)
(n=224)

Accelerometer returned (n=224)

  Wear-time criteria met (n=207)

  Wear-time criteria not met (n=17)

Control (ERS) (n=226)

Accelerometer returned (n=226)

  Wear-time criteria met (n=201)

  Wear-time criteria not met (n=25)

Received intervention (n=144)

(Logged in to the e-coachER

website one or more times)

Lost to follow-up (n=20)

Declined (n=8)

  No time for ERS/trial (n=4)

  ERS/trial is not useful (n=1)

  Ill-health (n=1)

  Other reason (n=2)

Participant not contactable

(n=12)

Lost to follow-up (n=13)

Declined (n=4)

  No time for ERS/trial (n=3)

  Ill-health (n=1)

Participant not contactable (n=9)

4 month follow-up

Accelerometer returned (n=183)

  Wear-time criteria met (n=109)

  Wear-time criteria not met (n=74)

Accelerometer not returned (n=20)

Analysed (n=109)

4 month follow-up

Accelerometer returned (n=190)

  Wear-time criteria met (n=128)

  Wear-time criteria not met (n=62)

Accelerometer not returned (n=23)

Analysed (n=128)

Lost to follow-up (n=32)

Lost to follow-up (n=29)

Declined (n=18)

    No reason given (n=8)

    No time for ERS/trial (n=3)

    ERS/trial is not useful (n=3)

    Other reason (n=2)

    Ill-health (n=1)

    Rash due to accelerometer

    (n=1)

Participant not contactable

(n=14)

Declined (n=17)

    No reason given (n=7)

    No time for ERS/trial (n=4)

    Other reason (n=3)

    Ill-health (n=2)

    ERS/trial is not useful n=1

Participant not contactable

(n=12)

12 month follow-up

Accelerometer returned (n=160)

    Wear-time criteria met (n=110)

    Wear-time criteria not met (n=50)

Accelerometer not returned (n=12)

Analysed (n=110)

12 month follow-up

Accelerometer returned (n=169)

    Wear-time criteria met (n=133)

    Wear-time criteria not met (n=36)

Accelerometer not returned (n=15)

Analysed (n=133)

Appendix 3 Estimates for repeated measures model for the primary outcome

Appendix 4 Serious Adverse Events

Serious Adverse Events (SAE) reported in the control group

SAEs were hospitalisations, with the exception of: SAE010029/001 (Morton's neuroma) which was categorised as 'persistent/significant disability/incapacity'

Site	SAE Log Number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary description of event
03	SAE030003/**002**	Recovered with sequelae	Not related	Neoplasms (2)	Diagnosed with chronic myeloid leukaemia.
03	SAE030210/**002**	Recovered	Not related	Neoplasms (2)	Prolonged hospitalisation due to recurrence of breast cancer.
03	SAE030184/001	Ongoing	Unlikely	Psychiatric (7)	Inpatient stay on mental health ward.
03	SAE030210/001	Recovered	Not related	Psychiatric (7)	Hospitalised for depression.
01	SAE010029/001	Ongoing	Not related	Nervous system (8)	Morton's Neuroma.
01	SAE010081/001	Recovered	Unlikely	Respiratory (13)	Treated in hospital for fluid on the lungs.
03	SAE030157/001	Recovered	Not related	Gastrointestinal (14)	Varices of gastrointestinal tract. Prolonged inpatient stay due to major organ system involvement.
02	SAE020261/001	Recovered	Not related	Musculoskeletal (17)	Admitted to hospital because unable to walk
02	SAE020194/001	Recovered	Not related	Pregnancy (19)	Childbirth and post-natal inpatient stay.

Site	SAE Log Number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary description of event
03	SAE030157/**002**	Recovered	Not related	Investigations (23)	Admitted to hospital with symptoms of meningitis.
02	SAE020193/001	Recovered with sequelae	Not related	Investigations (23)	Collapse. No diagnosis made.
01	SAE010007/001	Recovered	Not related	Surgical/medical (25)	Planned admission for femorodistal bypass (peripheral vascular disease), subsequent infection/abscess behind knee.
03	SAE030003/001	Recovered	Not related	Surgical/medical (25)	Hospitalised for treatment of boils in groin.
01	SAE010139/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for bunion removal.
01	SAE010139/**002**	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for bunion removal
03	SAE030065/001	Recovered	Unlikely	Surgical/medical (25)	Hospital admission for treatment for diverticular bleeding.
02	SAE020342/001	Recovered	Not related	Surgical/medical (25)	Injury to foot led to planned admission for partial amputation of left great toe.
01	SAE010088/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for right hip replacement.
03	SAE030171/001	Recovered	Not related	Surgical/medical (25)	Planned hospitalisation for total hip replacement.
01	SAE010098/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for total knee replacement.

Site	SAE Log Number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary description of event
02	SAE020111/001	Recovered	Not related	Surgical/medical (25)	Pre-planned hospitalisation for knee surgery due to osteoarthritis.
02	SAE020195/001	Recovered with sequelae	Not related	Surgical/medical (25)	Planned admission for total right knee replacement.
02	SAE020195/**002**	Recovered with sequelae	Not related	Surgical/medical (25)	Planned admission following infected right knee joint - continuing physio and using crutches.
02	SAE020313/001	Recovered	Not related	Surgical/medical (25)	Hospitalisation for emergency operation on knee following a number of falls and pre-existing weakness in knee.
01	SAE010063/001	Recovered	Not related	Surgical/medical (25)	Hospital admission for surgical repair of bulging disc in lower back.
02	SAE020185/001	Recovered	Not related	Surgical/medical (25)	Hospitalised due to complications from type-2 diabetes and heart failure.

Serious Adverse Events (SAE) reported in the intervention group

SAEs were hospitalisations, with the exception of: SAE010011/001 (asthma attack, which was categorised as a life-threatening event.

Site	SAE Log Number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary Description of Event
01	SAE010104/001	Recovered	Not related	Cardiac (11)	Admitted to hospital with abnormal ECG. Diagnosis: Paroxysmal Atrial Fibrillation
03	SAE030240/001	Recovered	Not related	Cardiac (11)	Hospitalised due to heart attack
03	SAE030134/001	Recovered	Unlikely	Vascular (12)	Hospitalised due to minor stroke.
01	SAE010011/001	Recovered	Not related	Respiratory (13)	Asthma attack.
01	SAE010119/001	Recovered	Not related	Investigations (23)	Hospital admission ?meningitis. No formal diagnosis made. Symptoms attributed to adverse effects of prescription medication.
01	SAE010159/001	Recovered	Not related	Investigations (23)	Fall resulting in fracture of left radius. Admitted for investigations of reasons for the fall.
01	SAE010160/**002**	Recovered	Not related	Surgical/medical (25)	Admitted to hospital following fall with fracture to right ankle and trauma to right knee
01	SAE010115/**002**	Recovered	Not related	Surgical/medical (25)	Preplanned hospital admission for abdominal surgery

Site	SAE Log Number	Outcome	Relationship of the event to the study processes	MedDRA organ system	Summary Description of Event
03	SAE030078/001	Recovered	Not related	Surgical/medical (25)	Planned hospitalisation for operation on right ankle
02	SAE020290/001	Recovered	Not related	Surgical/medical (25)	Admitted to hospital for 1 day (day case) due to osteoarthritis
01	SAE010201/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for tendon surgery on hand related to rheumatoid arthritis
03	SAE030049/001	Recovered	Unlikely	Surgical/medical (25)	Hospital admission for treatment of rheumatoid arthritis flare-up.
02	SAE020354/001	Recovered	Not related	Surgical/medical (25)	Inpatient stay for removal of Bartholin's cyst
01	SAE010115/001	Recovered	Not related	Surgical/medical (25)	Planned hospital admission for knee replacement.
01	SAE010160/001	Recovered	Not related	Surgical/medical (25)	Planned admission for partial right knee replacement
03	SAE030102/001	Recovered	Not related	Surgical/medical (25)	Hospitalised for surgery on both knees, as treatment for long-standing osteoarthritis.

Appendix 5 Participant Telephone Interview Topic Guide

Participant telephone interview schedule

Preamble script

Thank you very much for agreeing to participate in this phone interview in order to help us understand what it has been like to be part of the e-coachER study, we really appreciate your time.

Just to recap on the information we sent you, the purpose of this interview is to understand your experience of e-coachER and any impact it may have had so that we can learn for future development. Please say anything you wish, we want to hear all types of feedback and are keen to hear your views on how things might be done differently to improve the study.

The interview will take around 45 minutes and will be audio taped to ensure that we do not miss anything. All information you provide will be anonymised; if we use any quotes from you we will not give your name but use a false name.

Before we begin do you have any questions about doing the interview?

Are you therefore willing to give consent to do this interview…..thank you.

When we are ready to start I will switch the recorder on, say your name and the date; is that OK?

OK so the recorder is now going on….

Take verbal consent

Background
Can you begin by telling me about why you were prescribed the Exercise Referral scheme?
How did you hear about e-coachER?
Have you been referred to an exercise centre? -Which one? Has a program been devised for you?
You should have received a welcome pack in the post - What did you think of the welcome pack
How did you find the user guide?
Is there anything you'd recommend we changed about the user guide?
Did Register on e-coachER website? If no:
It isn't a problem that you decided not to visit the website; but we are keen to find out your reasons so we can change things for the better in the future….so please will you tell me a little bit more about why you didn't go to the website? Were there any technical barriers / problems…..was something else putting you off….. **Now go to **** below**

In general what did you think of the website? (Prompt – what were your first impressions? -we will go through it in more detail in a minute)

So did you register? How was it to do this?…is there anything that could be changed to help make registering easier?

There was also an e-coachER facilitator to help you with the technology…did you make use of this?……in what ways was this helpful? Tell me more about the help you received….or would have liked to have been given?

In Step 1 there was a quiz

    do you remember doing this?

    What did you think about the quiz?

    What were its key messages about the benefits of activity for someone with your condition?

In Step 2 you were encouraged to find support to get physically active. Can you tell me more about how you used this part of e-coachER?

Did you involve family or friends?

In Step 2 you were also introduced to the 'Links' pages on the web-site which gives information about local Exercise Referral Schemes and other local support for becoming physically active. These pages also provided general information about becoming physically active.

- Did you use the links?

- What did you think about the information provided?

- Were the links page useful?

- What links were most helpful?

- How did you use this support?

In Step 3 you were asked to use the pedometer to count your steps. This is the little device you wear on your belt.

How did you get on with using this?

In what ways was it useful for you to use the pedometer?

In what ways was the pedometer difficult to use?

Is there anything else you'd like to say about the pedometer, anything we should do differently?

In Step 4 you were asked to set step count goals.

What did you understand about the purpose / usefulness of setting these goals?

Tell me more about your goal setting:

was it easy to set step count goals that were…..specific….achievable….realistic…..

In what ways was the pedometer helpful for achieving your step count goals

…it was useful (for measuring /seeing progress)

…it wasn't helpful because?

In the welcome pack there was a fridge magnet with tear off strips to record your steps.

Did you use these?

Did you put them up on your fridge (or elsewhere)?

How have you used these strips to record your steps

How have you found these strips useful or not useful

In Step 5 you were asked to make some physical activity plans

Did you use this step to make plans for moderate physical activity?

In what ways was it easy or hard to set weekly goals?

How did you find the advice about setting SMART goals helpful or unhelpful?

In what ways was it easy or hard to keep to a weekly goal?

In what ways was it easy or hard to review your weekly goals?

In what ways was reviewing your step goals helpful or unhelpful?

In this step there was some advice on other opportunities to be physically active, for example, travel, leisure time, household chores. Did you find this advice helpful or useful

What did you think about the progress graph?…..

What did you think about the personalised feedback?…was the praise….encouragement helpful?

What was it like not to achieve your goals?

To what extent have you used e-coachER to set yourself new step goals each week?

In Step 6 you were asked about finding ways to help you achieve your physical activity plans. Dealing with the influences in your environment on your physical activity

did you use this part of the website? How helpful did you find the advice

please tell me a little more about what you did?

Did you make any changes, for example to your daily routine in order to meet your goals

what did you find most motivating?

did you make use of the motivational messages / text /emails?

In Step 7 you were asked to identify any barriers or obstacles to carrying on with your physical activity plans….how did you get on with this task?

Were you able to identify any causes of stopping your activity programme (something to do with your health condition……holidays…sickness...change at work / caring etc)

In what way have you found it easy – or not - to challenge negative thoughts about not doing your planned physical activity.

Do you feel you have learned how to plan and avoid lapses in physical activity in the future?

I would like to ask you some more general questions about e-coachER

How relevant was it for you?

Overall, how did it help you to set and manage your own goals to increase your physical activity?

To what extent did it provide you with new information?

How well were you able to engage with e-coachER?

How easy was e-coachER to navigate? (e.g. layout of 'steps to health'/main menu, goals)

How was the general tone of the website? (Was the language appropriate? Was it supportive? Were the success stories relevant/helpful?)

What did you think about the structure/look of the website? (e/g/ font size, colour, length of sessions, ability to unlock sessions after set time period).

When did you use e-coachER – where were you? / what were you doing?

What was the most useful aspect of the e-coachER support package?

Is there anything else that we haven't talked about that you would like to discuss about e-coachER

Did using e-coachER support you in the ERS

Was e-coachER useful on its own

Thank participant for their time etc.

Interview Topic Guide for e-coachER study Research Assistants

Thank you very much for taking part in an interview to talk about your experiences of working on e-coachER. The aim of the interview is hear your views and experiences of what worked well and what could be done differently if a full trial were to be carried out. Additionally, it is hoped that your experiences and views can help to develop a clearer understanding of 'general' issues related to the research process, particularly recruitment of patients to a trial.

Topic	Specific questions and prompts
Background	Can you begin by telling me about your role in the e-coacher trial?
Recruitment /your role in supporting patients through e-coachER	How have you been involved in recruiting participants? Has your role changed during the study? After addressing the earlier recruitment issues, can you tell me about things that worked well in the recruitment process? Anything that did not work so well, even in the later stages of recruitment? What further improvements do you feel could be made to the recruitment process? Is there anything else that you feel is important to consider in relation to recruitment to e-coachER? More generally, to a trial? Could you tell me about the role you played in supporting participants after they had logged on and begun using e-coachER

About the Patients	How do you feel patients have felt about (or reacted to) being invited to participate in the study?
	What do you feel are the main reasons why patients agreed to participate in e-coachER? In a Trial?
	What do you feel have been the main barriers for patients to participating in e-coachER? (Also in relation to invite, reply slips, registration process, logging on?)
	What do we know about patients opening the information pack and reading the contents? What else could be done to encourage this (for e-coachER, more generally)?
	After the changes had been made to the protocol, do you feel that anything could/has put participants off i) opening info pack ii) returning the reply slips? How can these issues be resolved?
	What do we know about patients who are signing up for the study but not logging on to e-coachER? What might have put them off?
	Have you had any feedback from patients about the benefits of e-coachER support/Participating in a trial?
	Is there anything else you feel is important in relation to what patients have told you about e-coachER/participating in the study? Anything that could have been done differently?
About primary care/ERS	Which Primary care/ERS staff were involved in recruitment? How did they recruit to e-coachER?
	Can you tell me about any feedback you have had from primary care/ERS staff about in the study?
	Can you tell me about any specific issues faced by different PC and ERS staff groups when recruiting to e-coachER?
Finishing up	What do you feel is the most beneficial aspect of e-coachER for participants? Least beneficial aspect of the package?

	What do you feel are the main 'lessons learned' from working on e-coachER, in general and for a larger e-coachER trial?
	Anything else you feel is important for future recruiting to a trial i) generally, ii) for e-coachER?

Appendix 6 Economic evaluation: Overview of unit cost

Type of resource	Unit cost Adjusted to 2017/18 prices as appropriate	Source
GP visit at practice (9.22 minutes)	£37	PSSRU 2017
Nurse visit at practice (15.5 minutes)	£11	PSSRU 2017
A&E visit Weighted average accounting for activity	£158	NHS reference cost (2015/2016)
Social worker visit (30 minutes)	£29.5	PSSRU 2017
Prescriptions	£8	PSSRU 2017
Hospital visit (as outpatient) Weighted average accounting for activity	£137	PSSRU 2017
GP home visit	£135	PSSRU 2010
Nurse home visit	£23	PSSRU 2010
Physiotherapy appointment (I hour appointment)	£33	PSSRU 2017
Care worker/advisor visit (30 minutes)	£13	PSSRU 2017
Hospital visit (as day case) Weighted average accounting for activity	£727	PSSRU 2017
Hospital visit (as inpatient)	£1478	NHS reference cost (2015/2016)

Weighted average accounting for activity		
Mental health support (DBT assessment/counsellor)	£9	PSSRU 2017
Dentist	£127	PSSRU 2017
Occupational therapist (I hour)	£35	PSSRU 2017
Psychiatrist (I hour)	£108	PSSRU 2017
Psychologist (I hour)	£53	PSSRU 2017
Podiatrist (I hour)	£33	PSSRU 2017
Ambulance service	£119	PSSRU 2017
Fitness instructor	£7.46	https://www.payscale.com/research/UK/Job=Fitness_Instructor/Hourly_Rate
Wage rate per hour for participants Time of employed participants was valued at the full wage rate , and for not employed participants we apply half of that estimate[83]	Employed (18-21 years-£8.77; 22-29 years-£12.76; 30-39 years - £16.83; 40-49 years- £18.29; 50-59 years-£17.69; 60+ years- £15.69); Not employed (18-21 years-£4.39; 22-29 years-£6.38; 30-39 years - £8.42; 40-49 years- £9.15; 50-59 years-£8.85; 60+ years- £7.85)	ONS (2017)

Appendix 7 Economic evaluation: Resource use associated with set up cost of intervention

Design was included as these activities may happen in the future following further learning from this trial.

Activity	Resource Discussions with Chief Investigator and trial manager, review of trial records, diaries, and routine administrative records	Total Quantity	Cost per participant Unit cost values are omitted to maintain confidentiality
Design			
Designing of intervention (welcome pack contents)	Time (in hours) spent by:		
	Assistant Trial Manager	20	£8.90
	Professor	20	
	PPI rep (in kind)	20	
Designing of website	Time (in hours)spent by:		
	Technical specialists	960	£172.01
	Professor	48	
Publicity campaigns/identification of participants			
Community based publicity campaigns/identification of participants	Time (in hours) spent by:		
	PPI reps (in kind)	21	£8.21
	Research Assistants	84	

	Centre administrators	9	
	Money costs of travel:		
	Car trips	150 miles	£0.30
	Advertising:		
	Posters	150 posters	£10.00
	Newspaper advert	3 adverts	£3.33
Total cost per participant			£180.91

Appendix 8 Economic evaluation: Resource use associated with delivery cost of intervention

Activity	Resource (from trial records)[a]	Total quantity of resource items	Unit cost (from invoice & trial records)	Cost per patient
Handbooks for participants	Number of handbooks	225	£0.04	£0.04
Welcome pack boxes	Number of Welcome Pack unit boxes	225	£0.28	£0.28
Pedometer	Number of pedometer	225	£4.05	£4.05
Recording sheets for weekly PA activity (a fridge magnet)	Number of sheets	225	£1.01	£1.01
Guide for using e-coachER website	Number of website guides	225	£0.04	£0.04
Postage/packaging of welcome pack	Number of postage pack	225	£10.33	£10.33
Maintenance/technical support (for participants) of e-coachER website	Time spent (in hours) by:			
	Technical specialist	128	n/a	£13.43
	Research Assistants	16		
Total cost per participant				£29.17

Appendix 9 Economic evaluation: Costs of health and social service use

	Whole sample (n=243)	Control (n=133)	e-coachER intervention (n=110)	Which group had higher cost?
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Costs at 4 months				
Cost of GP practice visit	85(89)	84.5(96)	85(80)	Intervention
Cost of Nurse practice visit	15(33)	13(18)	17 (44)	Intervention
Cost of AE visit	31(57)	37(64)	25(47)	Control
Cost of social worker visit	6(61)	3(26)	10(85)	Intervention
Cost of prescriptions	33(68)	32(86)	35(38)	Intervention
Cost of hospital – outpatients	133(184)	136(189)	130(178)	Control
Cost of GP home visit	3(14)	2(14)	3(15)	Intervention
Cost of Nurse home visit	3(13)	2(14)	3(13)	Intervention
Cost of Physio visit	27(75)	22(44)	32(101)	Intervention
Cost of Care Worker visit	3(17)	0.6(4)	5(25)	Intervention
Cost of hospital day case	185(375)	158(351)	218(402)	Intervention
Cost of hospital – Inpatient	190(595)	144(442)	245(738)	Intervention
Costs of other health service	8(57)	4(34)	12(77)	Intervention
Total cost (4 months)	721(952)	639(842)	819(1065)	Intervention
Costs at 5-12 months				
Cost of GP practice visit	111(139)	114(170)	108(89)	Control

	Whole sample (n=243)	Control (n=133)	e-coachER intervention (n=110)	Which group had higher cost?
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)
Cost of Nurse practice visit	16(18)	16(21)	15 (14)	Control
Cost of AE visit	24(65)	27(74)	20(53)	Control
Cost of social worker visit	2(11)	3(14)	1 (6)	Control
Cost of prescriptions	43(189)	28(31)	60(279)	Intervention
Cost of hospital – outpatients	132(221)	136(250)	128(180)	Control
Cost of GP home visit	1(9)	2(12)	0.5(4)	Control
Cost of Nurse home visit	1(12)	0.6(4)	2(18)	Intervention
Cost of Physio visit	24(62)	24(64)	23(60)	Control
Cost of Care Worker visit	5(29)	4(20)	6(37)	Intervention
Cost of hospital day case	204(885)	224(1119)	180(472)	Control
Cost of hospital – Inpatient	128(528)	131(573)	124(469)	Control
Costs of other health service	2(19)	3(24)	1(11)	Control
Total cost (5-12 months after the study)	692(1432)	713(1761)	668(891)	Control
Total costs at 12 months	1413(1971)	1352(2180)	1487(1691)	Intervention