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

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Declared competing interests of authors: Rod S Taylor is currently co-chief investigator on a National Institute for Health Research (NIHR)-funded programme grant designing and evaluating the clinical effectiveness and cost-effectiveness of a home-based cardiac rehabilitation intervention for patients who have experienced heart failure (RP-PG-1210-12004). He is also a member of the NIHR Priority Research Advisory Methodology Group (August 2015–present). Previous roles include NIHR South West Research for Patient Benefit Committee (2010–14); core group of methodological experts for the NIHR Programme Grants for Applied Research programme (2013–October 2017); NIHR Health Technology Assessment (HTA) Themed Call Board (2012–14); NIHR HTA General Board (2014–June 2017); and chairperson of NIHR Health Services and Delivery Research Researcher-led Panel (March 2014–February 2018). Nanette Mutrie reports a grant from NIHR during the conduct of the study, and personal fees in relation to UK physical activity guidelines revision outside the submitted work. Chloe McAdam reports grants from NIHR and Economic and Social Research Council Impact Acceleration Accounts during the conduct of the study, and is employed by NHS Greater Glasgow and Clyde, which funds and manages the exercise referral scheme involved in this research. Sarah Dean, Wendy M Ingram, Rohini Terry, Lucy Yardley, Nigel Charles and Ben Ainsworth report grants from NIHR during the conduct of the study. The research programme of Lucy Yardley and Mary Steele is partly supported by the NIHR Southampton Biomedical Research Centre. Kate Jolly reports that she is part-funded by NIHR Collaborations for Leadership in Applied Health Research and Care (CLAHRC) West Midlands and is a subpanel chair of the NIHR Programme Grants for Applied Health Research programme. Lisa Price reports personal fees from the University of Plymouth during the conduct of the study and grants from Living Streets (London, UK) outside the submitted work. Ben Ainsworth reports grants from the NIHR School of Primary Care Fellowship (October 2016–October 2018) for RP-PG-1211-20001. Sarah Dean reports grants from NIHR outside the submitted work as she is a co-applicant or named applicant and academic lead on a number of grants. Sarah Dean is partly funded by the South West Peninsula Applied Research Collaboration. Wendy M Ingram reports grants from the NIHR Research for Patient Benefit (RfPB) programme (PB-PG-0215-36142) and the NIHR HTA programme (15/111/01). Rohini Terry reports grants from the NIHR Programme Grants for Applied Research programme. Paul Little was the Programme Director of the Programme Grants for Applied Research (PGfAR) programme (until 31 May 2018), Editor-in-Chief for the PGfAR journal and a member of the NIHR Journals Library Editorial Group.

Published November 2020
DOI: 10.3310/hta24630

Scientific summary

The e-coachER RCT

Health Technology Assessment 2020; Vol. 24: No. 63
DOI: 10.3310/hta24630

NIHR Journals Library www.journalslibrary.nihr.ac.uk

Scientific summary

Background

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

E-health interventions for promoting physical activity have become popular because they offer an opportunity to target a wide range of people at a low cost, but to our knowledge no studies have explored their use alongside exercise referral schemes that offer face-to-face support. We developed a bespoke support system, using the LifeGuide© (LifeGuide version 1.0.7.30, University of Southampton, Southampton, UK) platform, to empower exercise referral scheme 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 'seven 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, a fridge magnet with attached tear-off strips to record daily steps or minutes of moderate and vigorous physical activity, and a user guide with instructions on how to access the web-based support. The e-coachER 'seven steps to health' programme aimed to increase favourable beliefs in the importance of 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 in the exercise referral schemes, 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 have an impact on minutes of moderate and vigorous physical activity, although we recognised that mailing a pedometer could be an effective intervention alone.

Objectives

The overall aim of the study was to determine whether or not adding the e-coachER intervention to usual exercise referral schemes was more effective and cost-effective in increasing physical activity after 1 year, compared with usual exercise referral schemes alone.

Research questions

The specific research questions were:

- Does the e-coachER intervention, when added to usual exercise referral schemes, compared with usual exercise referral schemes alone, increase the total minutes of accelerometer-assessed moderate and vigorous physical activity (in bouts of at least 10 minutes) per week at 12 months post randomisation?

- Does the e-coachER intervention, when added to usual exercise referral schemes, compared with usual exercise referral schemes alone, improve:
  - exercise referral scheme attendance?
  - other accelerometer- and self-reported measures of moderate and vigorous physical activity?
  - quality of life and mental health?
  - process outcomes (e.g. confidence to do and importance of doing physical activity, a sense of autonomy in deciding what physical activity to do and when, a sense of relatedness to others in doing physical activity, and use of self-monitoring and goal-setting)?
- Is the e-coachER intervention, when added to usual exercise referral schemes, compared with usual exercise referral schemes alone, cost-effective?
- Is the effect of the intervention moderated by participant and exercise referral scheme characteristics?
- What are the mechanisms through which the intervention has an impact on the outcomes?

Methods

The study involved an individually randomised, pragmatic, multicentre, two-arm randomised controlled trial with follow-up at 4 and 12 months, with an embedded mixed-methods process evaluation and health economic analysis. Patients were referred to a local exercise referral scheme 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 exercise referral schemes operated.

Participants were aged 16–74 years with a body mass index of 30–40 kg/m^2 and had one or more of the following conditions: hypertension, prediabetes, type 2 diabetes, lower limb osteoarthritis and a current or recent history of treatment for depression. Participants were eligible if they were inactive or moderately inactive (using the General Practice Physical Activity Questionnaire) and were an internet user contactable via e-mail.

The primary outcome was minutes of moderate and vigorous physical activity in ≥ 10-minute bouts measured by accelerometer over 1 week at 12 months, worn ≥ 16 hours per day for ≥ 4 days including ≥ 1 weekend day. Other accelerometer-derived physical activity measures (e.g. not in ≥ 10-minute bouts), self-reported physical activity (7-day recall of physical activity), exercise referral scheme attendance (at initial session with exercise referral scheme practitioner), non-validated process measure survey items and EuroQol-5 Dimensions, five-level version, and Hospital Anxiety and Depression Scale scores were collected at baseline, and then at 4 and 12 months.

Results

The sample ($n = 450$) had a mean body mass index of 32.6 kg/m^2 (standard deviation 4.4 kg/m^2), and the primary participant-reported reasons for referral to the exercise referral schemes 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 comorbidity in the sample. At baseline, only 4% of the sample achieved ≥ 150 minutes of moderate and vigorous physical activity (accumulated in bouts of ≥ 10 minutes) for 1 week at 12 months post randomisation.

Primary analysis

Loss to follow-up and incomplete data reduced the sample size to 232 participants for the primary analysis (intervention, $n = 108$; control, $n = 124$). Intention-to-treat, complete-case-adjusted comparison of groups at 12 months showed a weak indicative effect in favour of the intervention group ($n = 232$; mean difference 11.8 minutes per week, 95% confidence interval −2.1 to 26.0 minutes; $p = 0.10$). 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 and 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 day 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 wear), there remained no significant between-group differences. A complier-average causal effect analysis, with consideration of whether or not participants had completed an a priori definition of adequate intervention dose (i.e. step 5: completed at least one goal review in e-coachER), also revealed no intervention effect.

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

In exploratory analysis of ≥ 10-minute bouts of accelerometer data, with only participants who were included in the intention-to-treat, complete-case-adjusted analysis, the control group showed a significant mean (standard deviation) increase of 8.2 (32.1) minutes of moderate and vigorous physical activity 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 moderate and vigorous physical activity outcomes, with one exception. In an intention-to-treat imputed comparison at 12 months participants in the intervention group were more likely than the control group to self-report that they had achieved 150 minutes of weekly moderate and vigorous physical activity (odds ratio 1.55, 95% confidence interval 0.99 to 2.42; $p = 0.05$). The intervention had no effect on exercise referral scheme attendance: in the control group, 78% of the 223 participants for whom we had exercise referral scheme attendance data attended the exercise referral scheme at least once, compared with 167 (75%) of 223 in the intervention group. The intervention also had no effect on EuroQol-5 Dimensions, five-level version, or Hospital Anxiety and Depression Scale scores at 12 months compared with the control group. In an intention-to-treat imputed comparison at 12 months, the intervention group had lower Hospital Anxiety and Depression Scale depression and anxiety scores than the control group.

Intervention engagement

Among the intervention participants, 64% logged onto the online support at least once, with generally positive feedback on its value. The mean (standard deviation) number of goal reviews was 2.5 (4.5) with a range of 0–24 reviews. The 144 participants who registered logged onto the online support for a mean (standard deviation) 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 completed a goal review, the mean (standard deviation) and median number of reviews was 14.4 (13.8) and 4.5, respectively, with a range of 1–52. Overall, participants who registered online spent a mean (standard deviation) of 6.47 (7.45) minutes and a median of 4.08 minutes each time they logged into the e-coachER website. The engagement data from the LifeGuide platform indicate that reasonable levels of engagement were achieved. The 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, although 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 moderate and vigorous physical activity, compared with usual exercise referral scheme support. Among the participants included in only 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 physical activity (e.g. brisk walk) on at least 5 days per week; confidence in achieving at least 30 minutes of moderate-intensity physical activity on at least 5 days per 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.

Health economics

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

Conclusion

We believe this to be the most rigorous study to date on the clinical effectiveness and cost-effectiveness of adding web-based behavioural support to usual exercise referral schemes. Adding the e-coachER intervention to usual exercise referral schemes led to only a weak indicative effect on objectively assessed moderate and vigorous physical activity at 1 year post randomisation. 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 physical activity measures of moderate and vigorous physical activity, 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 quality-adjusted life-years indicate that e-coachER has a probability of 63% to be a cost-effective intervention at the National Institute for Health and Care Excellence's willingness-to-pay threshold of £30,000 per quality-adjusted life-year. 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 health care

Our findings suggest that clinically meaningful increases in physical activity may not be derived from the e-coachER intervention, but given its additional cost and associated small gains in quality-adjusted life-years (main outcome for the economic evaluation), that such an intervention could still be a cost-effective addition to usual exercise referral schemes (offered in different ways) for increasing physical activity for up to 12 months. In other words, sending patients a pedometer and a fridge magnet with tear-off physical activity self-monitoring strips, and providing access to a website that 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 online e-coachER support suggests that work is needed to understand what factors influenced intervention engagement and how best to further develop low-cost and scalable support to increase exercise referral scheme uptake and maintenance of physical activity. 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 that offers the chance to explore additional questions including the following:

- What were the characteristics of participants that predicted changes in 4- and 12-month physical activity?
- How did different measures of moderate and vigorous physical activity (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 exercise referral schemes?

Trial registration

This trial is registered as ISRCTN15644451.

Funding

This project was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme and will be published in full in *Health Technology Assessment*; Vol. 24, No. 63. See the NIHR Journals Library website for further project information.

Health Technology Assessment

HTA/HTA TAR

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.370

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, the Cochrane Library and Clarivate Analytics Science Citation Index.

This journal is a member of and subscribes to the principles of the Committee on Publication Ethics (COPE) (www.publicationethics.org/).

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 13/25/20. The contractual start date was in January 2015. The draft report began editorial review in January 2019 and was accepted for publication in November 2019. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

This report presents independent research funded by the National Institute for Health Research (NIHR). The views and opinions expressed by authors in this publication are those of the authors and do not necessarily reflect those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care. If there are verbatim quotations included in this publication the views and opinions expressed by the interviewees are those of the interviewees and do not necessarily reflect those of the authors, those of the NHS, the NIHR, NETSCC, the HTA programme or the Department of Health and Social Care.

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