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Adding web-based support to exercise referral schemes improves symptoms of depression and anxiety in people with elevated depressive symptoms: a secondary analysis of the e-coachER randomised controlled trial.

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Abstract

Background: Exercise referral schemes (ERS) reduce depression but the additional effect on mental health from web-based behavioural support is unknown. The e-coachER trial reported no effect of augmenting usual ERS with theory-driven web-based behavioural support on moderate to vigorous physical activity (MVPA) at 12 months for patients with chronic physical and mental health conditions. The present study reports the effects of the ecoachER intervention on depression, anxiety and MVPA only among participants with elevated depressive symptoms and investigates whether these were mediated by changes in MVPA and hypothesised cognitive and behavioural processes.

Methods: Of the original 450 adults recruited into the e-coachER trial, 205 had at least mild depression, based on the Hospital Anxiety and Depression Scale (HADS), and were included in the present analysis. Data collected included the HADS, accelerometer measured and self-reported MVPA and survey process measures on physical activity action planning, self-monitoring and goal reviewing, and perceived importance, confidence, competence, autonomy and support. Linear mixed models were used to compare groups for change in depression and anxiety at 4 and 12 months using intention-to-treat complete case analysis, controlling for baseline. We also examined whether changes in physical activity and process variables at 4 months mediated changes in depression and anxiety at 12 months.

Results: Of the 205 participants, 138 (67%) provided follow-up data at four months and 126 (61%) at 12 months. For those that provided follow-up data, those randomised to e-coachER reported improved levels of depression (-1.36, 95% CI: -2.55 to -0.18) but not anxiety, or MVPA, compared with controls at four months. No differences were observed at 12 months for depression, anxiety or MVPA. Intervention effects on accelerometer-measured or self-reported MVPA did not mediate improvements in depression or anxiety. However, intervention effects on confidence, competence and self-monitoring at four months significantly mediated the reduction in depression scores at four months. Intervention effects on competence and self-monitoring at four months also significantly mediated improvements in anxiety scores at four months.

Interpretation: Adding web-based support to usual ERS leads to reductions in depression but not anxiety at four months. Changes in depression and anxiety were influenced by changing people's motivational regulations toward physical activity. The benefit of adding web-based support to usual ERS on mental health appears to be from increasing a sense of confidence and competence, and self-monitoring rather than from increasing physical activity in people with elevated depression. Usual ERS should focus more on strengthening motivational regulations than just doing more exercise.

Trial registration: ISRCTN15644451

Keywords: Exercise referral scheme, physical activity, chronic conditions, web-based support, self-determination theory.

Background

Depression and anxiety are common mood disorders, with 7.8% of people in the UK estimated to meet clinical diagnostic criteria (NICE, 2018) with a substantial proportion of mental health care taking place within primary care (Park & Zarate, 2019). Depression is also co-morbid with a range of chronic physical conditions including type 2 diabetes, hypertension, osteoarthritis, and obesity (Pilling et al., 2009), so promoting physical activity to patients has multiple benefits (Cooney, 2018). For patients with depression, physical activity is an evidence-based intervention, which is just as effective as anti-depressants and psychological therapies, with the added benefit of treating many chronic physical conditions (Cooney et al., 2013; Heissel et al., 2023; Rebar et al., 2015; Stubbs et al., 2017). Physical activity has also been shown to be an effective treatment for anxiety (Heissel et al., 2023).

Providing support to increase physical activity within primary care is challenging, especially among patients with poor mental health. Patients with poor mental health often have unique barriers to engaging in physical activity (e.g., low mood, pain, fear, low self-efficacy (perceived ability to be active) and low motivation (Busch et al., 2016; Rebar & Taylor, 2017). Behavioural and psychological support to increase physical activity within primary care can be effective (Harris et al., 2015) but often GPs are unlikely to have enough time to deliver the support needed (Lowe et al., 2022), especially if patients have multiple physical and mental health conditions. Group-based physical activity is also currently recommended by the National Institute for Health and Care Excellence (NICE, 2022) for depression, but not for anxiety (NICE, 2011).

Exercise Referral Schemes (ERS), historically hosted in leisure centres and gyms and more recently through behavioural community support, are common within UK primary care for patients with physical and mental health conditions. There is currently no single model for ERSs in the UK, but the predominant mode of delivery involves 10–12 weeks of structured, supervised exercise at a local exercise facility or a counselling approach to support patients to engage in a variety of types of PA (Taylor et al., 2020). A recent study found that at least

half of those attending exercise referral schemes were referred for low mood (Taylor et al., 2021). Exercise referral schemes are also potentially effective for people with mental health conditions: A systematic review of randomised controlled trials (RCTs) found large effects size in favour of exercise referral schemes for depression (pooled standardised mean difference -0.82 , 95% CI -1.28 to -0.35) when compared to usual care (Pavey et al., 2011). However, another recent review found that uptake and adherence to exercise referral schemes tended to be lower for those referred for mental health conditions (Tomlinson-Perez et al., 2022). One way to overcome the challenge of adherence in people with mental health conditions is through theory-informed approaches.

Self Determination Theory (SDT), a theory of human motivation, posits that increasing a person's sense of competence, autonomy, and relatedness will increase their autonomous motivation. SDT also states that more autonomously motivated individuals are more likely to persevere and achieve their desired goals whilst experiencing more positive mental health outcomes (Deci & Ryan, 2012; Rouse et al., 2011). SDT has been tested extensively, with systematic reviews showing a consistent positive relationship between more autonomous forms of motivation and well-being. Exercise referral schemes grounded in SDT have also been shown to generate improvements in mental health outcomes (Duda et al., 2014).

Web-based interventions, when complementing usual ERS are potentially effective at supporting short-term improvements in physical activity in a range of clinical conditions (Taylor et al., 2021). Web-based interventions promoting physical activity may also improve symptoms of depression and anxiety in people with depression in the community (Lambert et al., 2018), but the evidence is fairly limited (Carneiro et al., 2022) and none examined the effects of augmenting an exercise scheme with web-based support. Web-based interventions promoting physical activity offer a potentially inexpensive and scalable option for people with depression and anxiety (Carneiro et al., 2022). For a group of people who may be referred to an exercise programme, and who may find it more difficult to maintain engagement, an augmented virtual support system that fosters improvements in self-

determination constructs may be particularly valuable. Therefore, understanding the effects of existing web-based interventions targeting physical activity on depression and anxiety may offer important insights into whether a web-based physical activity intervention could offer augmented support, particularly for people with depression.

Exercise referral schemes provide an ideal context to evaluate the effects of web-based support to increase physical activity for people with depression and anxiety. The e-coachER RCT investigated whether adding interactive weekly web-based behavioural support to usual exercise referral schemes could increase accelerometer-measured moderate to vigorous physical activity (MVPA) over exercise referral schemes alone at 12 months post-randomisation. The e-coachER intervention, compared with exercise referral schemes alone showed only a small non-significant effect on accelerometer-measured MVPA at 12 months (Taylor et al., 2021). However, e-coachER led to some short-term changes in most process outcomes, some of which also appeared to mediate e-coachER effects on changes in MVPA (Lambert et al., 2022).

The research questions for this secondary analysis of people with elevated symptoms of depression within the e-coachER trial were:

1. Does e-coachER + exercise referral improve symptoms of depression and anxiety compared to exercise referral alone at 4 and 12 months?
2. Does e-coachER + exercise referral increase accelerometer-measured and self-reported MVPA compared to exercise referral schemes alone at 4 and 12 months?
3. Are improvements in symptoms of depression and anxiety at 4 and 12 months mediated by changes in accelerometer-measured and self-reported MVPA at 4 months?
4. Are improvements in symptoms of depression and anxiety at 4 and 12 months mediated by changes in the e-coachER processes (as defined by the logic model) at 4 months?

Methods

Study design and participants

This secondary analysis utilises data from participants in the e-coachER multi-centre RCT with a score of ≥ 8 on the Hospital Anxiety and Depression Scale (HADS), indicating at least mild depression. The e-coachER RCT recruited 450 adults from Greater Glasgow, Birmingham or Plymouth and adjacent rural areas, who had been or were about to be referred by a primary care practitioner to their local ERS. Participants registered with a general practitioner (GP) surgery with one or more of the following: obesity (body mass index (BMI), 30–40), a diagnosis of hypertension, prediabetes, type 2 diabetes, lower limb osteoarthritis or having a history of treatment for depression were eligible for inclusion in the trial. Participants also needed to be categorised as ‘inactive’ or ‘moderately inactive’ (i.e. some activity but < 1 hour per week and in a sedentary occupation, according to the General Practice Physical Activity Questionnaire (GPPAQ) (Ahmad et al., 2015). Participants were excluded if they did not meet the eligibility criteria for their local ERS, had an unstable, severe and enduring mental health condition, 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.

Participants were randomly allocated 1:1 to either usual exercise referral schemes alone (control arm) or usual exercise referral schemes plus e-coachER (intervention arm) using a secure, password-protected web-based system created and managed by the Peninsula Clinical Trials Unit (CTU). Randomisation was stratified by site. The participant’s perceived main reason for their referral to the exercise referral schemes (i.e., chronic condition) and self-reported IT literacy/confidence (using a 10-point scale) were used as minimisation variables to ensure balanced participant characteristics in each group.

The randomisation sequence was generated by researchers in the University of Plymouth Medical Statistics department independent of the e-coachER RCT. The trial statistician,

health economist and analyst handling the accelerometer data conducted their analyses blinded to allocation. Exercise referral practitioners were not aware of which group participants were randomised. Those involved with the qualitative process evaluation were not blinded. Due to the nature of the intervention, it was not possible to blind participants. The protocol for the study has been published elsewhere (Ingram et al., 2018). The study was approved by the National Research Ethics Committee North West—Preston (15/NW/0347).

Participants in both arms of the trial were offered the usual primary care ERS. Participants randomised to the intervention arm were also offered the e-coachER package in addition to their usual ERS. The intervention has previously been described in detail elsewhere (Ingram et al., 2018; Taylor et al., 2020, 2021). In brief, e-coachER was a web-based support package using the LifeGuide© platform (<https://www.lifeguideonline.org/>), informed by SDT, with behaviour change techniques (BCTs) specifically selected to target the basic psychological needs of autonomy, competence and relatedness (Teixeira et al., 2020). Participants allocated to the intervention group received a small box through the mail containing a user guide for accessing the e-coachER web-based support system, a pedometer (step-counter) and a fridge magnet with tear-off sheets to record weekly step counts or minutes of MVPA. Participants were able to use the e-coachER intervention throughout the entire duration of the study. See Appendix 1 for the e-coachER logic model. Participants were sent an accelerometer and questionnaire booklet by post, and a prepaid envelope to return to Peninsula CTU at baseline, 4 months and 12 months post-randomisation. Weekly minutes of MVPA, recorded in bouts of at least 10 minutes were collected using GENEActiv accelerometers (Activinsights; <https://www.geneactiv.org/>), over 1 week at 4 months and 12 months post-randomisation.

Outcomes

The focus of the present study was the change in symptoms and depression and anxiety self-reported by participants using the HADS. The HADS is a 14-item, 4-point scale, used to

identify possible and probable cases of anxiety and depression among patients in nonpsychiatric hospital clinics. The HADS is divided into both anxiety and depression subscales. A score of 8-10 indicates mild depression or anxiety and 11 to 21 indicates moderate to severe depression or anxiety (Stern, 2014). The HADS performs well in assessing the symptom severity and clinical presence of anxiety and depression in primary care patients and the general population. Mediators included baseline to 4-month change in accelerometer-measured physical activity and process variables. Accelerometer measured physical activity was assessed by counting the number of weekly minutes of MVPA (both in 10-minute bouts and continuous), using GENEActiv accelerometers. Self-reported MVPA over one week was measured using the 7-day recall of PA (7-day Physical Activity Recall questionnaire) at 4 and 12 months (Blair et al., 1985). Process variables were selected to capture key psychological processes for changing physical activity behaviour, as specified by the underlying logic model (Appendix 1). They reflected theoretical mechanisms of change and enactment (i.e., participant use of the BCTs in day-to-day settings). Briefly, items were derived from extensive reviews of the literature to ensure they matched the theoretical constructs specified by the logic model, but also were fit for purpose within a randomised trial and were acceptable and easy to understand according to our Public and Patient Involvement advisory group. Process variables included the following:

Perceived importance to be physically active (single item, 11-point scale). Example question: “Doing at least 30 min of moderate intensity physical activity (e.g., brisk walk) on at least 5 days a week is important to me”

Perceived confidence to be physically active (single item, 11-point scale). Example question: “I am confident that I can do at least 30 min of moderate intensity physical activity (e.g., brisk walk) on at least 5 days a week”

Perceived competence in being regularly physically active (4 item, 5-point scale). Example question: “I am able to meet the challenge of being physically active regularly”

Autonomous in decisions about PA (4 items, 5-point scale). Example question: “I feel free to be physically active in my own way”

Availability of support (3 item, 5-point scale). Example question: “There are others in my life with whom I can be physically active”

Frequency of support (3 item, 5-point scale). Example question: “In the last 30 days how often did others discuss physical activity with me?”

Action planning (5 item, 5-point scale). Example question: “In the last 30 days I have regularly made weekly plans for when to be physically active”

Self-monitoring (2 item, 5-point scale). Example question: “In the last 30 days I have consistently monitored the amount of physical activity I do”

A full report of the outcome and process measures is reported elsewhere (Lambert et al., 2022; Taylor et al., 2020). The participant’s perception of the reason for referral to the exercise referral schemes (i.e., clinical condition) was collected. If multiple conditions were stated, the participant’s most important reason for referral was used as a minimisation variable. The level of engagement in the online e-coachER intervention was captured from the LifeGuide© platform.

Statistical analysis

All models were adjusted for baseline outcome values and stratification variables (by site) and minimisation variables (participant’s perception of the main medical reason for referral to the ERS and IT literacy level) age and gender. Baseline descriptive statistics were presented by the randomisation arm. To investigate the effect of the intervention on the HADS and PA outcomes at 4 and 12 months, according to aims 1 and 2, between-group differences were compared, using complete case data following intention-to-treat (ITT) principles, applying linear mixed-effects models to allow for clustering by the centre. This was followed by secondary per-protocol analysis using a complier average causal effect (CACE) approach,

with robust standard errors clustered by centre, to examine the respective impact of participants registering for e-coachER and of participants completing ‘Step 5’ (i.e., setting a goal and reviewing a goal online). For the mediation analyses in aims 3 and 4, linear mixed effects models, clustered by the centre, were fitted and the product of coefficients in the path analysis (Alwin & Hauser, 1975) (figure 1) of the mediating effects of accelerometer-measured MVPA (both in ≥ 10 -minute bouts and continuous), self-reported MVPA and process variables at 4 months. Mediation analysis was not contingent on the significance of results from the main analysis, as a mediated effect could still be possible without a significant net effect of the intervention on the primary outcome (Cerin & MacKinnon, 2009). Confidence intervals for the mediated path were estimated through the bootstrap resampling method, with 1000 replications. Only those with valid accelerometer data were included in the analysis for the mediating effect of accelerometer-measured physical activity.

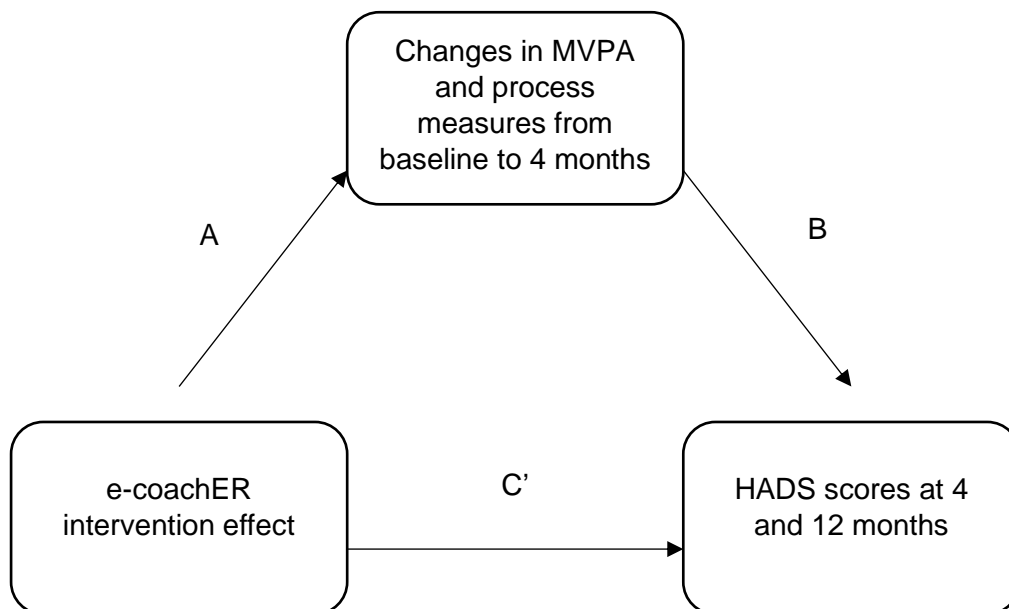


Figure 1 A priori path model for testing mediation effects

Results

At baseline, 205 of the 450 patients randomised to the trial had a score of ≥ 8 on the HADS-D indicating at least mild depression, 69 had a score ranging from 11 to 14 indicating moderate depression and 36 had a score ranging from 15 to 21 indicating severe depression. For anxiety, 178 had a score of ≥ 8 on the HADS-A, indicated mild anxiety, 73 had a score ranging from 11 to 14 indicating moderate anxiety and 52 had a score ranging from 15 to 21 indicating severe anxiety. Of the baseline sample, 138 (67%) provided follow-up HADS scores at 4 months and 126 (61%) provided follow-up HADS scores at 12 months. The groups were well balanced at baseline with no statistically significant differences (Table 1). For accelerometer-measured, bouts physical activity, 187 (91%) provided usable accelerometer data at baseline, 108 (53%) at 4 months and 100 (49%) at 12 months. For self-reported physical activity, 205 provided usable data at baseline, 154 (75%) at 4 months and 138 (67%) at 12 months. Those who did not attend their first ERS session were significantly less likely to have 4-month follow-up data ($p > 0.05$). Overall mean age and BMI was 47.6 years (SD 12.7) and 32.7kg/m² (SD 4.4) respectively. Descriptive data for the whole sample (N=450) have been described previously (Taylor et al., 2020, 2021).

Table 1. Baseline demographic and clinical characteristics

| | Intervention | | | Control | | | Total | | |
|---------------|--------------|--------|-------|---------|--------|-------|-------|--------|-------|
| | N | Mean/n | SD/% | N | Mean/n | SD/% | N | Mean/n | SD/% |
| Gender | 95 | | | 110 | | | 205 | | |
| Female | | 68 | 71.58 | | 73 | 66.36 | | 141 | 68.78 |
| Male | | 27 | 28.42 | | 37 | 33.64 | | 64 | 31.22 |
| Age (years) | 95 | 47.33 | 12.75 | 110 | 47.77 | 12.71 | 205 | 47.57 | 12.70 |
| BMI | 95 | 32.36 | 4.41 | 110 | 33.01 | 4.47 | 205 | 32.71 | 4.44 |
| IT confidence | 95 | | | 110 | | | 205 | | |
| High | | 76 | 80.00 | | 94 | 85.45 | | 170 | 82.93 |
| Low | | 19 | 20.00 | | 16 | 14.55 | | 35 | 17.07 |
| GPPAQ Score | 95 | | | 110 | | | 205 | | |
| 2 | | 69 | 72.63 | | 66 | 60.00 | | 135 | 65.85 |
| 3 | | 26 | 27.37 | | 44 | 40.00 | | 70 | 34.15 |
| Yes | | 65 | 69.15 | | 84 | 77.78 | | 149 | 73.76 |
| No | | 29 | 30.85 | | 24 | 22.22 | | 53 | 26.24 |

Notes: N varies due to invalid wear-time for PA, or non-completion of a full set of measures. *Exercise referral scheme

There was a significant between-group difference of -1.36, (95% Confidence Interval (CI): -2.55 to -0.18, $p < 0.05$) for depression at 4 months post-randomisation in favour of the e-coachER arm (table 2). There were no significant differences in anxiety at 4 months or for depression and anxiety at 12 months (Table 2). There were no significant differences in physical activity at any time point (Table 3).

For the CACE analysis, greater between group differences in depression at 4-months were observed for participants who registered for e-coachER (-1.98, 95% CI: -2.55 to -1.40, $p < 0.001$) or completed a goal review (-2.89, 95% CI: -3.70 to -2.09, $p < 0.001$). Greater between group differences in self-reported physical activity at 12-months were also observed for participants who registered for e-coachER (125.54, 95% CI: 84.47 to 166.60, $p < 0.001$) or

completed a goal review (199.18, 95% CI: 132.13 to 266.24, $p < 0.001$). See appendix 2 for full CACE analysis.

Table 2. Summary of HADS outcome data at baseline and 4- and 12 months follow-up and estimated between-group differences

| | Intervention | | | Control | | | Coefficient (95% CI) | P |
|---------------|--------------|-------|------|---------|-------|------|------------------------|-------|
| | N | Mean | SD | N | Mean | SD | | |
| HADS-D | | | | | | | | |
| Baseline | 95 | 11.66 | 3.23 | 110 | 11.28 | 2.80 | | |
| Month 4 | 57 | 9.35 | 4.58 | 81 | 10.31 | 4.34 | -1.36 (-2.55 to -0.18) | 0.024 |
| Month 12 | 51 | 10.32 | 5.04 | 75 | 9.93 | 4.57 | -0.10 (-1.57 to 1.37) | 0.893 |
| HADS-A | | | | | | | | |
| Baseline | 95 | 12.14 | 3.86 | 110 | 11.40 | 4.04 | | |
| Month 4 | 57 | 10.46 | 4.50 | 81 | 10.94 | 4.34 | -1.00 (-2.21 to 0.21) | 0.105 |
| Month 12 | 51 | 11.33 | 4.44 | 75 | 10.83 | 4.34 | -0.06 (-1.39 to 1.27) | 0.933 |

Table 3. Summary of MVPA measured by accelerometer at 4 and 12 months and estimated between group-differences

| | Intervention | | | Control | | | Coefficient (95% CI) | P |
|----------------------|--------------|--------|--------|---------|--------|--------|---------------------------|-------|
| | N | Mean | SD | N | Mean | SD | | |
| Bouted | | | | | | | | |
| MVPA | | | | | | | | |
| Baseline | 86 | 26.28 | 44.88 | 97 | 17.30 | 35.78 | | |
| Month 4 | 42 | 25.47 | 42.57 | 66 | 21.89 | 32.08 | 1.71 (-11.03 to 14.44) | 0.793 |
| Month 12 | 41 | 16.95 | 39.77 | 59 | 13.73 | 29.42 | 2.92 (-10.69 to 16.52) | 0.674 |
| Continuous | | | | | | | | |
| MVPA | | | | | | | | |
| Baseline | 89 | 387.29 | 265.21 | 98 | 332.40 | 231.71 | | |
| Month 4 | 43 | 379.30 | 207.98 | 67 | 341.52 | 264.79 | 1.36 (-49.25 to 51.96) | 0.958 |
| Month 12 | 44 | 333.16 | 263.46 | 59 | 328.45 | 224.11 | -26.45 (-96.18 to 43.29) | 0.457 |
| Self-reported | | | | | | | | |
| MVPA | | | | | | | | |
| Baseline | 95 | 160.59 | 338.12 | 110 | 167.91 | 296.35 | | |
| Month 4 | 64 | 244.13 | 338.82 | 90 | 333.12 | 579.82 | -17.5 (-163.31 to 128.31) | 0.814 |
| Month 12 | 59 | 222.69 | 442.43 | 79 | 182.90 | 420.58 | 84.7 (-55.92 to 225.38) | 0.238 |

Notes: N varies due to invalid wear-time for PA, or non-completion of a full set of measures.

Mediation analyses revealed no mediation effect of change in weekly minutes of accelerometer-measured MVPA or self-reported MVPA on depression and anxiety at 4- and 12 months post-randomisation (Appendices 3 to 6).

Intervention effects on confidence, competence and self-monitoring at 4 months significantly mediated the effect of e-coachER in lowering depression at 4 months (mediated effect, Table 4). All remaining processes were not significant. There were direct effects of e-coachER on depression scores at 4 months when controlling for changes in all the process

measures apart from confidence and competence (direct C' -path in Table 8). There were no significant mediating effects or direct effects at 12 months for any of the process measures (Appendix 7).

Table 4. Mediation effects for intervention effects on processes at 4 months on depression at 4 months

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|------------------|-----|----------------|-------|-----------------|-------|-----------------|--------------|-----------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95% CI | β (SE) | P |
| Importance | 132 | 0.55 (0.43) | 0.203 | -0.04 (0.10) | 0.672 | -0.02 (0.08) | -0.24, 0.12 | -1.35 (0.62) | 0.030 |
| Confidence | 133 | 1.08 (0.51) | 0.033 | -0.37 (0.09) | 0 | -0.40 (0.20) | -0.82, -0.04 | -0.98 (0.59) | 0.097 |
| Competence | 127 | 1.37 (0.62) | 0.027 | -0.24 (0.08) | 0.002 | -0.33 (0.21) | -0.82, 0.00 | -0.92 (0.63) | 0.146 |
| Autonomy | 130 | 0.48 (0.60) | 0.424 | -0.23 (0.07) | 0.002 | -0.11 (0.15) | -0.41, 0.16 | -1.23 (0.57) | 0.031 |
| Freq of support | 134 | 0.69 (0.59) | 0.247 | -0.01 (0.08) | 0.875 | -0.01 (0.08) | -0.16, 0.16 | -1.36 (0.62) | 0.028 |
| Avail of support | 133 | 0.19 (0.48) | 0.693 | -0.06 (0.10) | 0.555 | -0.01 (0.06) | -0.13, 0.12 | -1.37 (0.62) | 0.026 |
| Action planning | 125 | 0.48 (0.85) | 0.573 | -0.15 (0.04) | 0 | -0.07 (0.13) | -0.34, 0.20 | -1.37 (0.60) | 0.022 |
| Self-monitoring | 131 | 0.86 (0.36) | 0.016 | -0.34 (0.11) | 0.002 | -0.29 (0.16) | -0.65, -0.02 | -1.40 (0.58) | 0.015 |

Notes: N varies due to lack of valid wear-time for PA, or non-completion of full set of measures.

No direct effects of e-coachER on anxiety scores at 4 or 12 months were observed when controlling for changes in the process measures (c' -path, Table 5 and Appendix 8). Change in competence and self-monitoring at 4 months significantly mediated the effect of e-

coachER in reducing anxiety scores at 4 (mediated effect, Table 5) but not 12 months (mediated effect, Appendix 8).

Table 5. Mediation effects for intervention effects on processes at 4 months on anxiety at 4 months

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|------------------|-----|----------------|-------|-----------------|-------|-----------------|--------------|-----------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95%CI | β (SE) | P |
| Importance | 132 | 0.55 (0.43) | 0.203 | -0.24 (0.11) | 0.025 | -0.13 (0.13) | -0.42, 0.07 | -0.96 (0.62) | 0.125 |
| Confidence | 133 | 1.08 (0.51) | 0.033 | -0.17 (0.10) | 0.09 | -0.18 (0.15) | -0.49, 0.07 | -0.81 (0.63) | 0.201 |
| Competence | 127 | 1.37 (0.62) | 0.027 | -0.24 (0.08) | 0.002 | -0.33 (0.19) | -0.77, -0.02 | -0.75 (0.63) | 0.238 |
| Autonomy | 130 | 0.48 (0.60) | 0.424 | -0.10 (0.08) | 0.21 | -0.05 (0.08) | -0.23, 0.10 | -1.05 (0.61) | 0.083 |
| Freq of support | 134 | 0.69 (0.59) | 0.247 | -0.11 (0.08) | 0.153 | -0.08 (0.09) | -0.31, 0.07 | -1.03 (0.63) | 0.102 |
| Avail of support | 133 | 0.19 (0.48) | 0.693 | -0.08 (0.10) | 0.456 | -0.01 (0.07) | -0.19, 0.12 | -1.19 (0.62) | 0.055 |
| Action planning | 125 | 0.48 (0.85) | 0.573 | -0.09 (0.04) | 0.036 | -0.04 (0.09) | -0.26, 0.13 | -1.11 (0.60) | 0.066 |
| Self-monitoring | 131 | 0.86 (0.36) | 0.016 | -0.30 (0.11) | 0.009 | -0.26 (0.16) | -0.61, -0.02 | -1.03 (0.61) | 0.091 |

Notes: N varies due to lack of valid wear-time for PA, or non-completion of full set of measures

Discussion

When added to usual ERS, e-coachER led to significant between-group improvements in symptoms of depression at 4 months (which became larger for participants who registered versus didn't or completed an e-coachER goal review versus didn't), but not at the 12-month follow-up. However, no significant differences were observed for anxiety at 4 or 12 months. No differences were observed for any of the MVPA outcomes. However, differences in self-reported MVPA at 12 months for participants who registered or completed an e-coachER

goal review. MVPA did not mediate the relationship between e-coachER and depression or anxiety and 4 or 12 months follow-up. However, self-reported competence and confidence to engage in physical activity and self-reported use of self-monitoring of physical activity positively partially mediated the effects of e-coachER on the reduction in depression symptoms at 4 months. Competence and use of self-monitoring positively and partially mediated changes in symptoms of anxiety at 4-month follow-up. These results suggest that adding a web-based behavioural support programme to exercise referral schemes yields additional mental health benefits for patients and that these benefits are partly derived from changes in patients' competence and confidence to engage in physical activity and self-reported use of self-monitoring of physical activity, irrespective of whether changes in MVPA were achieved. The present study is the first to evaluate whether adding a web-based behavioural support programme to exercise referral schemes can lead to changes in symptoms of depression and anxiety. Furthermore, the present study is one of the few to evaluate the mediational effects of accelerometer-measured physical activity on depression or anxiety in the context of an RCT.

Relation to other literature

Previous RCTs of web-based behavioural support for MVPA have also observed improvements in depression but not changes in self-reported or accelerometer-measured MVPA. For example, one RCT of 48 people with depression found that a web-based supported intervention targeting physical activity led to changes in depression but not self-reported physical activity (Ström et al., 2013). Similarly, a 3-arm RCT (n=501) observed significant reductions in depression and stress (at 3 months) and anxiety (at 9 months) but no changes in accelerometer-measured MVPA when comparing web-based video-tailored and text-tailored physical activity intervention to a control group (Vandelanotte et al., 2022). However, Vandelanotte et al., (2022) did not solely include people with elevated baseline depression symptoms. Another study compared the effects of an individually tailored, mailed print PA intervention for Latinas (n=266) on symptoms of depression vs a wellness control at

12 months. They found no direct effects of the intervention on symptoms of depression. However, improvements in self-reported MVPA at 12 months appeared to mediate intervention effects on depression at 12 months (Mendoza-Vasconez et al., 2019). This is contrary to our findings despite employing similar behavioural strategies (e.g., goal-setting and self-monitoring). One reason for this could be the differences in the mode of delivery. For example, the e-coachER study used a printed, tailored approach which addressed specific PA barriers identified by Latinas in focus groups and the literature (Marcus et al., 2013). To note, none of the above studies took place within ERS, limiting their comparability with e-coachER.

Our findings also build on previous research investigating the effect of exercise referral schemes grounded in SDT on mental health. A previous cluster RCT compared exercise referral, grounded in SDT vs exercise referral alone and found significant decreases in anxiety but not depression at 6 months in favour of the intervention arm (Duda et al., 2014). However, no differences in participant perceptions of autonomy support from the health and fitness advisor (HFA). The authors attributed the lack of findings to a possible lack of training and support for the HFAs assigned to the SDT arm (Duda et al., 2014). Lack of training can directly impact delivery fidelity, as outlined in the treatment fidelity framework provided by the NIH's Behavioral Change Consortium (BCC) (Borrelli et al., 2005). Therefore, this lack of training may have led to a lack of delivery fidelity to the protocol from the HFA which led to sub-optimal outcomes. In e-coachER, the SDT content was standardised, fixed, and delivered directly to the participant, avoiding this breakdown in fidelity (Watkins et al., 2016) and potentially explaining why we observed further changes in key processes related to SDT and mental health.

There are several possible reasons explaining why we observed reductions in depression but not MVPA. First, increases in perceived autonomy/developing a sense of competence, control or relatedness might be more important than changes in physical activity for improving mood (Nyström et al., 2015). SDT posits that if a person's basic psychological

need for competence, autonomy and relatedness are met, they should experience improvements in mental health via increased autonomous motivation (Deci & Ryan, 2012). The present study found that increases in self-monitoring, competence and confidence towards physical activity mediated the effects of e-coachER on improvements in depression and anxiety at 4 months. This aligns with previous studies which have consistently found self-efficacy to be a strong candidate mechanism for the relationship between physical activity and depression (Haller et al., 2018; Howarter et al., 2014; Kandola et al., 2019; Miller et al., 2019; White et al., 2009). However, self-efficacy refers to confidence in carrying out a behaviour under challenging circumstances, rather than just competence to carry out a behaviour (Rodgers et al., 2014). Previous research has shown that people who demonstrate greater internalisation of their reasons for engaging with PA also exhibit more positive mental health outcomes (Fortier et al., 2012). This is consistent with SDT self-determination theory which shows that autonomously regulated behaviours can translate into enhanced psychological wellness (Teixeira et al., 2012) with less autonomous regulations (e.g., identified regulation) only predicting wellbeing contingent on behavioural performance (Burton et al., 2006). It could be that participant's reasons for engaging in PA in the e-coachER arm were more internalised, leading to decreases in depression and anxiety. It may therefore be more important to focus on activities that are intrinsically motivating to the patient, rather than focusing on frequency, intensity and type of MVPA (Nyström et al., 2015).

Second, e-coachER could be improving symptoms through the same mechanism of behavioural activation (BA). BA reduces depression through increasing exposure to positive reinforcement and reducing negative reinforcement in the environment (Hopko et al., 2003; Lejuez et al., 2001). BA is also compatible with SDT sharing many techniques including providing a rationale, graded tasks, self-monitoring and goal setting, action planning and goal review (Lambert et al., 2017; Teixeira et al., 2020). e-coachER may have supported people to increase their engagement in routine pleasurable and necessary activities that

don't necessarily involve MVPA. For example, a 2-arm pilot RCT using BA to promote PA to people with depression found significant reductions in depression and anxiety at 2 months despite no observed changes in MVPA (Lambert et al., 2018). In another 5-arm RCT, encouraging people to gradually increase their degree of PA over weekly treatment modules (using self-monitoring and providing a rationale for their depression) led to decreases in depressive symptoms when compared with a waiting list control group (Nyström et al., 2017).

Third, the present analysis did not account for the co-dependence of sedentary behaviour and physical activity. A prospective cohort study of 60,235 UK Biobank participants used compositional data analysis methods to assess the impact of replacing daily time spent in sedentary behaviours with sleep, light, or moderate to vigorous physical activity on depression and anxiety symptoms. A 12.5%, 7.6% and 1.3% reduction in depressive symptoms at 2-year follow-up was found when replacing 60 minutes of sedentary behaviour with MVPA, sleep, or light PA, respectively (Kandola et al., 2021). As there is a finite period in the day, it could be that, rather than increasing MVPA, e-coachER led to changes in depression by replacing sedentary behaviour with MVPA, light activity or sleep.

Strengths and limitations

This study had several strengths. First, this secondary analysis was part of a large RCT with a large overall sample size and included people with a range of health conditions, making the findings relevant to patients presenting at primary care who might fit the criteria for exercise referral. Second, the use of accelerometer-measured MVPA is a key strength considering the trial participants were not blinded to their assignment to usual ERS or augmented e-coachER. Third, it followed patients after 4 and 12 months. Fourth it employed mediation analysis to investigate the indirect effects of e-coachER on depression and anxiety via processes of change and MVPA.

Several limitations need to be acknowledged. First, e-coachER struggled with loss to follow-up at 4 and 12 months limiting the level of confidence in the findings. The e-coachER qualitative analysis also showed that participants reported IT-related difficulties and a lack of support from the exercise referral schemes which may have impacted their confidence to use e-coachER (Taylor et al., 2020). Second, we did not use multiple imputation analysis to address the missing data since multiple imputation in trials with a large amount of missing data may introduce bias (Jakobsen et al., 2017). Instead, since we have reported an exploratory analysis, a complete case analysis was used. Third, the sub-sampling from the main trial could have introduced some selection bias. However, both groups were reasonably well matched in key demographic and clinical characteristics.

Directions for future research

This study provides support for SDT underpinning web-based interventions to reduce mental health issues, at least in the short term. Future research could replicate this work by employing a more person-centred approach focussing on people with elevated depression in the intervention design process (e.g., by using the person-based approach) (Yardley et al., 2015). This could enhance the effects of the intervention by making it more specific and relevant for people with depression. Another avenue for future research could be to use compositional data analysis methods on existing RCTs which have collected accelerometer-measured physical activity to see whether displacement of sedentary time with other activities leads to changes in mental health.

In summary, for participants with depression, adding web-based support to usual ERS leads to significantly greater reductions in depression at 4 months compared to ERS alone, but the effects were not sustained at 12 months. The intervention had no effect on physical activity within the study. However, changes in depression can be influenced by changing people's motivational regulations toward physical activity. e-coachER may represent a low-cost option to further reduce depression in the context of ERS. Furthermore, this research provides evidence that web-based interventions promoting physical activity, but without a specific

focus on mental health, have the potential to alleviate depressive symptoms, even in the absence of increasing physical activity. Simply engaging in processes linked to self-determination (e.g., gaining a sense of competence and control) and physical activity can reduce depression. These findings have clear implications for future web-based interventions highlighting the need to capture mental health outcomes and design them to target people with mental health issues. Our mediational analyses also provide insight into how key theoretical components embedded within the intervention can impact depression and anxiety over the short term, further extending the applicability of SDT beyond behavioural engagement into the realm of health and wellbeing (Teixeira et al., 2012). Further research is needed to help to understand how web-based physical activity interventions can be used to facilitate longer-term benefits for people with a mental health condition.

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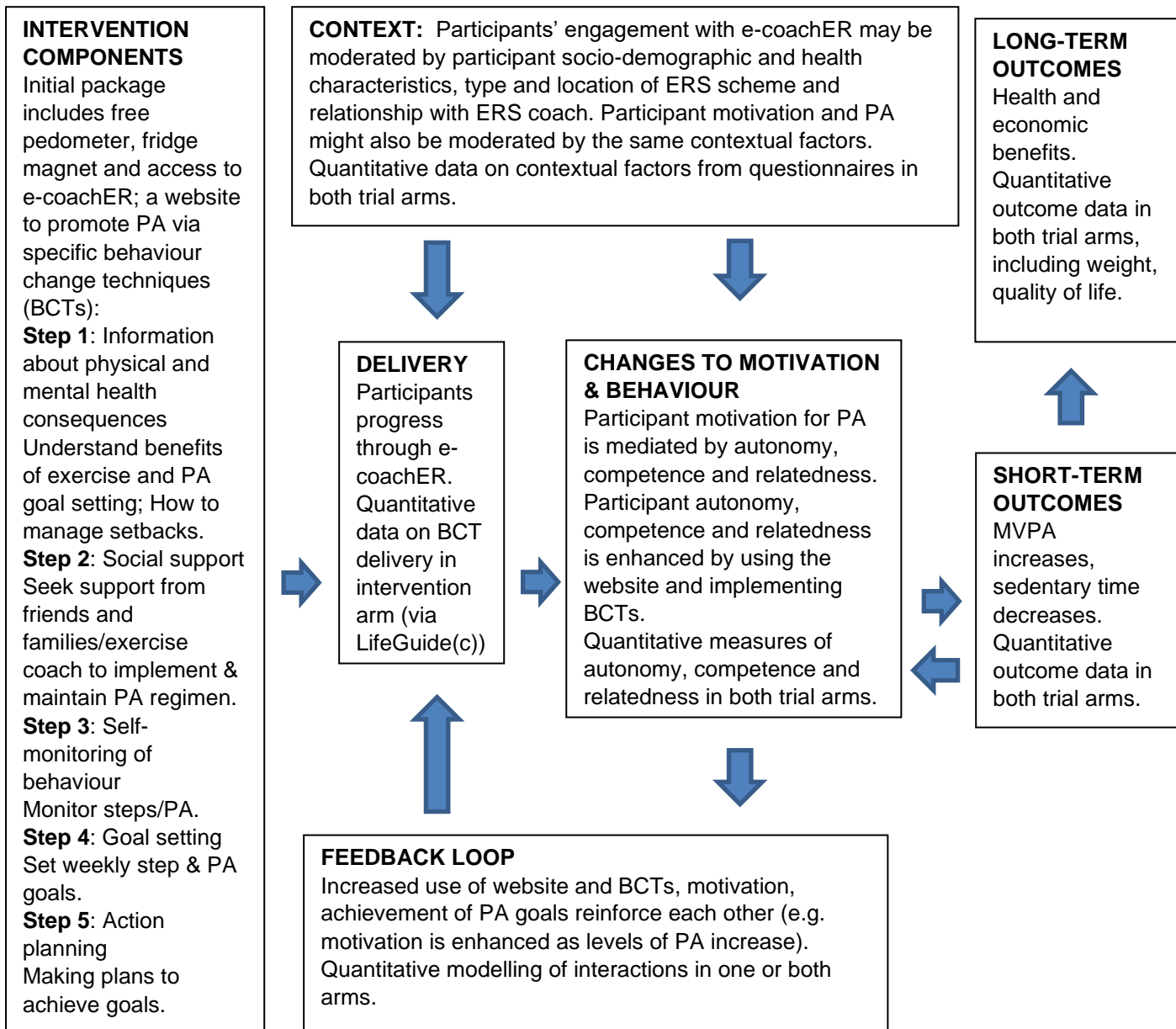
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Appendix 1 The e-coachER Logic model



Appendix 2. Complier-average casual effect (CACE) analysis of all outcomes at 4 and 12 months

| | Coefficient | 95% CI Lower | 95% CI Upper | P value |
|------------------------------------|-------------|--------------|--------------|---------|
| HADS-D Month 4 | | | | |
| Registered | -1.98 | -2.55 | -1.40 | 0.000 |
| Step 5 | -2.89 | -3.70 | -2.09 | 0.000 |
| HADS-D Month 12 | | | | |
| Registered | -0.24 | -0.62 | 0.13 | 0.205 |
| Step 5 | -0.36 | -0.88 | 0.16 | 0.170 |
| HADS-A Month 4 | | | | |
| Registered | -1.37 | -3.20 | 0.45 | 0.140 |
| Step 5 | -2.02 | -4.76 | 0.73 | 0.150 |
| HADS-A Month 12 | | | | |
| Registered | -0.07 | -1.23 | 1.08 | 0.900 |
| Step 5 | -0.11 | -1.84 | 1.62 | 0.899 |
| Bouted MVPA month 4 | | | | |
| Registered | 2.09 | -10.75 | 14.93 | 0.750 |
| Step 5 | 3.08 | -15.47 | 21.63 | 0.745 |
| Bouted MVPA month 12 | | | | |
| Registered | 3.51 | -1.45 | 8.46 | 0.166 |
| Step 5 | 5.04 | -2.07 | 12.15 | 0.165 |
| Continuous MVPA month 4 | | | | |
| Registered | -5.45 | -18.77 | 7.87 | 0.423 |
| Step 5 | -7.85 | -26.00 | 10.30 | 0.397 |
| Continuous MVPA month 12 | | | | |
| Registered | -34.28 | -89.37 | 20.81 | 0.223 |
| Step 5 | -48.87 | -125.58 | 27.85 | 0.212 |
| Self-reported MVPA month 4 | | | | |
| Registered | -33.20 | -171.00 | 104.60 | 0.637 |
| Step 5 | -51.01 | -256.22 | 154.20 | 0.626 |
| Self-reported MVPA month 12 | | | | |
| Registered | 125.54 | 84.47 | 166.60 | 0.000 |
| Step 5 | 199.18 | 132.13 | 266.24 | 0.000 |

Appendix 3. Mediation effects of changes in accelerometer measured and self-reported MVPA at 4 months on the intervention effect on depression at 4 months

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|---------------|-----|--------------|-------|--------------|-------|-----------------|-------------|--------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95%CI | β (SE) | P |
| Bouted | 100 | 1.71 | 0.793 | 0.00 | 0.803 | 0.00 | -0.17, 0.20 | -1.38 | 0.047 |
| MVPA | | (6.50) | | (0.01) | | (0.09) | | (0.70) | |
| Continuous | 104 | 1.36 | 0.958 | 0.00 | 0.919 | 0.00 | -0.22, 0.22 | -1.55 | 0.027 |
| MVPA | | (25.82) | | (0.00) | | (0.10) | | (0.70) | |
| Self-reported | 306 | 22.77 | 0.602 | 0.00 | 0.098 | -0.02 | -0.20, 0.03 | -1.09 | 0.002 |
| MVPA | | (43.61) | | (0.00) | | (0.06) | | (0.36) | |

N varies due to invalid wear-time for PA, or non-completion of a full set of measures.

Appendix 4. Mediation effects of changes in accelerometer measured and self-reported MVPA at 4 months on the intervention effect on depression at 12 months.

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|---------------|-----|--------------|-------|--------------|-------|-----------------|----------------|--------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95%CI | β (SE) | P |
| Bouted | 89 | 1.705 | 0.793 | 0.000 | 0.982 | 0.000 | (-0.251,0.197) | -0.147 | 0.874 |
| MVPA | | (6.499) | | (0.012) | | (0.107) | | (0.926) | |
| Continuous | 92 | 1.356 | 0.958 | -0.003 | 0.401 | -0.004 | (-0.329,0.247) | -0.222 | 0.809 |
| MVPA | | (25.819) | | (0.003) | | (0.130) | | (0.921) | |
| Self-reported | 275 | 22.766 | 0.602 | -0.001 | 0.11 | -0.023 | (-0.209,0.034) | -0.107 | 0.798 |
| MVPA | | (43.607) | | (0.000) | | (0.065) | | (0.419) | |

Notes: N varies due to invalid wear-time for PA, or non-completion of a full set of measures.

Appendix 5. Mediation effects of changes in accelerometer measured and self-reported MVPA at 4 months on the intervention effect on anxiety at 4 months.

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|---------------|-----|--------------|-------|--------------|-------|-----------------|----------------|--------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95%CI | β (SE) | P |
| Bouted | 100 | 1.705 | 0.793 | -0.000 | 0.964 | 0.000 | (-0.194,0.149) | -0.670 | 0.357 |
| MVPA | | (6.499) | | (0.009) | | (0.084) | | (0.728) | |
| Continuous | 104 | 1.356 | 0.958 | -0.001 | 0.782 | -0.001 | (-0.165,0.153) | -0.857 | 0.223 |
| MVPA | | (25.819) | | (0.003) | | (0.078) | | (0.702) | |
| Self-reported | 138 | -17.497 | 0.814 | 0.000 | 0.625 | 0.000 | (-0.157,0.042) | -0.988 | 0.11 |
| MVPA | | (74.394) | | (0.001) | | (0.052) | | (0.618) | |

Notes: N varies due to invalid wear-time for PA, or non-completion of a full set of measures.

Appendix 6. Mediation effects of changes in accelerometer measured and self-reported MVPA at 4 months on the intervention effect on anxiety at 12 months.

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|---------------|-----|--------------|-------|--------------|-------|-----------------|----------------|--------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95%CI | β (SE) | P |
| Bouted | 89 | 1.705 | 0.793 | -0.007 | 0.475 | -0.012 | (-0.309,0.135) | 0.270 | 0.728 |
| MVPA | | (6.499) | | (0.010) | | (0.103) | | (0.777) | |
| Continuous | 92 | 1.356 | 0.958 | -0.004 | 0.117 | -0.005 | (-0.437,0.307) | -0.042 | 0.956 |
| MVPA | | (25.819) | | (0.003) | | (0.158) | | (0.758) | |
| Self-reported | 119 | -17.497 | 0.814 | 0.000 | 0.962 | 0.000 | (-0.167,0.144) | 0.083 | 0.909 |
| MVPA | | (74.394) | | (0.001) | | (0.066) | | (0.722) | |

Notes: N varies due to invalid wear-time for PA, or non-completion of a full set of measures.

Appendix 7. Mediation effects for intervention effects on processes at 4 months on depression at 12 months

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|------------------|-----|------------------|-------|-------------------|-------|-------------------|----------------|-------------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95%CI | β (SE) | P |
| Importance | 112 | 0.545 (0.428) | 0.203 | -0.136 (0.134) | 0.308 | -0.074 (0.112) | (-0.350,0.120) | -0.368 (0.824) | 0.655 |
| Confidence | 113 | 1.075 (0.505) | 0.033 | -0.410 (0.124) | 0.001 | -0.441 (0.265) | (-1.024,0.018) | 0.218 (0.802) | 0.785 |
| Competence | 108 | 1.370 (0.621) | 0.027 | -0.242 (0.100) | 0.016 | -0.332 (0.221) | (-0.873,0.001) | 0.343 (0.808) | 0.671 |
| Autonomy | 111 | 0.481 (0.602) | 0.424 | -0.292 (0.103) | 0.004 | -0.140 (0.197) | (-0.551,0.246) | -0.132 (0.798) | 0.868 |
| Freq of support | 113 | 0.685 (0.592) | 0.247 | -0.095 (0.101) | 0.347 | -0.065 (0.113) | (-0.324,0.129) | -0.283 (0.804) | 0.725 |
| Avail of support | 112 | 0.187 (0.475) | 0.693 | -0.077 (0.133) | 0.56 | -0.014 (0.089) | (-0.173,0.197) | -0.241 (0.808) | 0.766 |
| Action planning | 105 | 0.480 (0.851) | 0.573 | -0.122 (0.061) | 0.045 | -0.059 (0.114) | (-0.318,0.181) | -0.408 (0.821) | 0.619 |
| Self-monitoring | 111 | 0.863 (0.358) | 0.016 | -0.256 (0.152) | 0.093 | -0.221 (0.181) | (-0.611,0.084) | -0.274 (0.811) | 0.735 |

Notes: N varies due to non-completion of full set of measures.

Appendix 8. Mediation effects for intervention effects on processes at 4 months on anxiety at 12 months

| Mediators | N | A path | | B path | | Mediated effect | | C' path | |
|------------------|-----|------------------|-------|-------------------|-------|-------------------|----------------|-------------------|-------|
| | | β (SE) | P | β (SE) | P | β (SE) | 95%CI | β (SE) | P |
| Importance | 112 | 0.545 (0.428) | 0.203 | -0.117 (0.119) | 0.328 | -0.064 (0.098) | (-0.319,0.072) | -0.150 (0.724) | 0.836 |
| Confidence | 113 | 1.075 (0.505) | 0.033 | -0.121 (0.114) | 0.287 | -0.130 (0.155) | (-0.509,0.119) | 0.044 (0.738) | 0.953 |
| Competence | 108 | 1.370 (0.621) | 0.027 | -0.079 (0.092) | 0.392 | -0.108 (0.145) | (-0.438,0.147) | 0.236 (0.736) | 0.748 |
| Autonomy | 111 | 0.481 (0.602) | 0.424 | -0.119 (0.096) | 0.214 | -0.057 (0.099) | (-0.265,0.136) | 0.148 (0.745) | 0.843 |
| Freq of support | 113 | 0.685 (0.592) | 0.247 | -0.070 (0.090) | 0.439 | -0.048 (0.097) | (-0.267,0.132) | -0.146 (0.725) | 0.841 |
| Avail of support | 112 | 0.187 (0.475) | 0.693 | -0.122 (0.119) | 0.308 | -0.023 (0.082) | (-0.193,0.165) | -0.069 (0.720) | 0.923 |
| Action planning | 105 | 0.480 (0.851) | 0.573 | -0.041 (0.054) | 0.448 | -0.020 (0.063) | (-0.158,0.100) | -0.197 (0.725) | 0.786 |
| Self-monitoring | 111 | 0.863 (0.358) | 0.016 | -0.050 (0.143) | 0.729 | -0.043 (0.155) | (-0.359,0.282) | -0.118 (0.739) | 0.873 |

Notes: N varies due to non-completion of full set of measures.