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1 Protocol for a feasibility randomised controlled trial of the use of Physical  
2 ACtivity monitors in an Exercise Referral Setting: The PACERS study.

3

4 *Dr Jemma Hawkins*<sup>1</sup> [hawkinsj10@cardiff.ac.uk](mailto:hawkinsj10@cardiff.ac.uk)

5 *Dr Michelle Edwards*<sup>1</sup> [edwardsm28@cardiff.ac.uk](mailto:edwardsm28@cardiff.ac.uk)

6 *Dr Joanna Charles*<sup>2</sup> [j.charles@bangor.ac.uk](mailto:j.charles@bangor.ac.uk)

7 *Prof Russell Jago*<sup>3</sup> [russ.jago@bristol.ac.uk](mailto:russ.jago@bristol.ac.uk)

8 *Dr Mark Kelson*<sup>4</sup> [kelsonmj@cardiff.ac.uk](mailto:kelsonmj@cardiff.ac.uk)

9 *Dr Kelly Morgan*<sup>1</sup> [morgank22@cardiff.ac.uk](mailto:morgank22@cardiff.ac.uk)

10 *Prof Simon Murphy*<sup>1</sup> [murphys7@cardiff.ac.uk](mailto:murphys7@cardiff.ac.uk)

11 *Dr Emily Oliver*<sup>5</sup> [emily.oliver@durham.ac.uk](mailto:emily.oliver@durham.ac.uk)

12 *Prof Sharon Simpson*<sup>6</sup> [sharon.simpson@glasgow.ac.uk](mailto:sharon.simpson@glasgow.ac.uk)

13 *Prof Rhiannon Tudor Edwards*<sup>2</sup> [r.t.edwards@bangor.ac.uk](mailto:r.t.edwards@bangor.ac.uk)

14 *Dr Graham Moore*<sup>1</sup> [mooreg@cardiff.ac.uk](mailto:mooreg@cardiff.ac.uk)

15

16 1. Centre for the Development and Evaluation of Complex Interventions for Public Health

17 Improvement (DECIPHer), Cardiff University, Cardiff, CF10 3BD, UK

18 2. Centre for Health Economics and Medicines Evaluation, Bangor University, Bangor, LL57 2PZ,

19 UK

20 3. Centre for Exercise, Nutrition and Health Sciences, University of Bristol, Bristol, BS8 1TZ, UK

21 4. Centre for Trials Research, Cardiff University, Cardiff, CF14 4YS, UK

22 5. School of Applied Social Sciences, Durham University, Durham, DH1 3HN, UK

23 6. MRC/CSO Social and Public Health Sciences Unit, University of Glasgow, Glasgow, G2 3QB,

24 UK

25

26 **Corresponding author:** *Dr Jemma Hawkins*

27 **Abstract**

28 **Background:** Exercise referral schemes are recommended by the National Institute for  
29 Clinical Excellence (NICE) for physical activity promotion among inactive patients with  
30 health conditions or risk factors. Whilst there is evidence for the initial effectiveness and  
31 cost-effectiveness of such schemes for increasing physical activity, evidence of long-term  
32 effects is limited. Techniques such as goal setting, self-monitoring and personalised feedback  
33 may support motivation for physical activity. Technologies such as activity monitoring  
34 devices provide an opportunity to enhance delivery of motivational techniques. This paper  
35 describes the PACERS study protocol, which aims to assess the feasibility and acceptability  
36 of implementing an activity monitor within the existing Welsh National Exercise Referral  
37 Scheme (NERS) and proposed evaluation methodology for a full-scale randomised controlled  
38 trial.

39 **Methods/Design:** The PACERS study consists of a pilot randomised controlled trial, process  
40 evaluation and exploratory economic analyses. Participants will be recruited from the generic  
41 pathway of the Welsh NERS and will be randomly assigned to receive the intervention or  
42 usual practice. Usual practice is a 16-week structured exercise programme, the intervention  
43 consists of an accelerometry-based activity monitor (MyWellnessKey) and an associated web  
44 platform (MyWellnessCloud). The primary outcomes are predefined progression criteria  
45 assessing the acceptability and feasibility of the intervention and feasibility of the proposed  
46 evaluation methodology. Postal questionnaires will be completed at baseline (time 0: T0), 16  
47 weeks after T0 (T1), and 12 months after T0 (T2). Routinely collected data will also be  
48 accessed at the same time points. A subsample of intervention participants and exercise  
49 referral staff will be interviewed following initiation of intervention delivery and at the end of  
50 the study.

51 **Discussion:** The PACERS study seeks to assess the feasibility of adding a novel motivational  
52 component to an existing effective intervention in order to enhance effects on physical  
53 activity and support longer-term maintenance. The study will provide insight into the  
54 acceptability of activity monitoring technologies to an exercise referral population and  
55 delivery staff. Data from this study will be used to determine whether and how to proceed to  
56 a full-scale trial of effectiveness of the intervention, including any necessary refinements to  
57 intervention implementation or the proposed evaluation methodology.

58

59 **Trial registration:**

60 ISRCTN85785652

61

62 **Keywords:**

63 Exercise referral, Physical activity, Autonomous motivation, Feasibility studies,  
64 Accelerometer/try, Physical activity monitors, Physical activity trackers, Costs, Economic  
65 evaluation

66

67 **Background**

68 Physical inactivity is a major cause of preventable illness with large costs to the National  
69 Health Service (NHS) [1]. Increasing activity at the population level and among at-risk  
70 groups is a public health priority [2, 3]. Physical activity interventions for at-risk groups often  
71 involve advice and/or signposting from primary care practitioners [4]. Exercise referral  
72 schemes (ERS) are one common model [5], usually involving referral to a community-based  
73 structured exercise program. In Wales, the 16-week National Exercise Referral Scheme  
74 (NERS) has been running since 2007. A previous effectiveness study of the scheme [6]  
75 showed that, at 12 months, NERS was associated with improvements in physical activity for

76 patients at risk of coronary heart disease, but not for those referred for anxiety and  
77 depression, despite an improvement in their mental health [7]. The evaluation also showed  
78 the base-case incremental cost-effectiveness ratio was £12,111 per quality adjusted life year  
79 (QALY), falling to £9741 if participants were to contribute £2 per session [7]. Qualitative  
80 data highlighted a need for post-intervention motivational support to maintain changes [7, 8].  
81 Whilst there is evidence for effectiveness of ERS in increasing physical activity in the short-  
82 term [9-11] evidence of long-term effects is limited. The Department of Health's Quality  
83 Assurance Framework for Exercise Referral [12] highlights the need to understand how to  
84 support long-term maintenance of changes in physical activity.

85

86 On entry to an ERS, patients may be initially motivated by external sources such as GP  
87 advice to attend [13, 14]. However, sustained changes in physical activity are consistently  
88 associated with more internalised, or autonomous, motivation [15-17]. According to Self-  
89 Determination Theory [18], the development of autonomous motivation can be achieved  
90 through supporting psychological needs for autonomy (volitional and self-endorsed  
91 engagement), competence (personal mastery and effectiveness) and relatedness (meaningful  
92 interpersonal connections). Thus, developing ways to support these three needs should help  
93 to maintain changes in physical activity. Support for this notion is provided by the  
94 randomised controlled trial of the Welsh NERS which found increases in autonomous  
95 motivation after scheme exit. This increase explained almost half of the between group  
96 difference in physical activity six months later [19]. Integrating processes to further enhance  
97 and sustain autonomous motivation during and after involvement in an exercise referral  
98 scheme may lead to larger effects and longer-term maintenance of these. Existing evidence  
99 points to potential motivational effects of techniques such as goal setting, monitoring, and  
100 personalised feedback on progress towards goals [20, 21] which may support autonomous

101 motivation by enhancing patients' sense of mastery and competence and are recommended by  
102 NICE as core components of behaviour change interventions [22].

103

104 Technologies such as activity monitors, provide opportunities to enhance delivery of goal  
105 setting and feedback, allowing for more frequent, and automatic feedback on progress toward  
106 activity goals, tailored updating of goals based on achievement, and remote contact with  
107 intervention providers [23]. In addition to addressing psychological needs for competence,  
108 incorporation of social components may support motivation through promoting relatedness to  
109 other service users. Research on such technologies in exercise interventions suggests that use  
110 can be quickly integrated in participants' lives [24] and may increase physical activity levels  
111 [25-29], however overall the evidence is equivocal [23]. Furthermore, little is known about  
112 the acceptability of these technologies to ERS populations or if the benefits will remain once  
113 the initial novelty has ceased. Exercise referral patients are a diverse group with a range of  
114 ages and conditions. For example, although the average age of participants in the evaluation  
115 of the Welsh NERS was 52 years old, the overall ages ranged from 16 to 88. Thus, familiarity  
116 with technology and willingness to use it may differ within the group [30]. In addition,  
117 participant diversity in terms of socioeconomic status and geographic location may result in  
118 differences in access to high speed internet connections or the hardware required for  
119 engaging with some technologies (e.g. personal computer). Hence, prior to a trial of  
120 effectiveness, which may be undermined by difficulties integrating technologies into routine  
121 practice or facilitating uptake by patients, piloting is required to investigate these issues.

122

123 A preliminary investigation [31] tested a protocol for integrating activity monitoring devices  
124 (MyWellnessKey, Technogym) and a linked web platform in one local authority area of the  
125 Welsh NERS. The study showed potential for using the MyWellnessKey (MWK) devices in

126 the scheme; however, further work is required to understand the feasibility and acceptability  
127 of this on a larger scale with a demographically diverse population. In this paper we describe  
128 the protocol of the PACERS study, a pilot trial to assess the feasibility and acceptability of  
129 using the MWK activity monitors to promote maintenance of physical activity within NERS.  
130 The aim of the study is to evaluate the feasibility and acceptability of the intervention (the  
131 MWK) and its proposed evaluation methodology, in order to optimise design and delivery  
132 and evaluate whether a full scale randomised controlled trial of effectiveness is warranted and  
133 feasible.

134

### 135 **Study aim**

136 The primary aim of the study is to assess the feasibility and acceptability of implementing  
137 the MWK activity monitors within the Welsh NERS as well as the proposed evaluation  
138 methodology in order to optimise design and delivery for conducting a definitive evaluation  
139 trial.

140

### 141 **Study objectives**

142 The main objectives for this study are to investigate:

- 143 a) the fidelity of delivery of the intervention and trial methodology including compliance  
144 with study invitation and randomisation processes;
- 145 b) the acceptability of the intervention to participants in terms of its usability and  
146 likelihood of future use;
- 147 c) whether randomisation is acceptable to 50% or more of the participants;
- 148 d) the feasibility of recruiting 20% or more new NERS patients and retaining at least  
149 80% of participants at 12-month follow-up (T2);

- 150 e) contamination, by exploring whether less than 20% of control participants are ~~the~~  
151 exposed to the intervention;
- 152 f) the effect of the intervention on the main hypothesised change mechanism  
153 (autonomous motivation);
- 154 g) the feasibility of collecting the primary, secondary and process outcome measures and  
155 economic evaluation methods.

156

## 157 **Methods**

### 158 **Study design**

159 The study design is an individually randomised pilot randomised controlled trial, plus a  
160 process evaluation and exploratory economic analyses, of implementing the MWK devices  
161 within Welsh NERS standard practice. Data will be collected at three time points: baseline  
162 (time 0 (T0)), at the end of the 16-week NERS programme (T1) and 12-months post-baseline  
163 (T2). Figure 1 shows the study flow diagram. The study was given favourable ethical opinion  
164 for conduct in the NHS on 1<sup>st</sup> December 2015 by the South East Scotland Research Ethics  
165 Committee 02 (REF: 189587).

166

167 Figure. 1 Flow diagram of the PACERS study design

168

### 169 **Setting and participants**

170 The study is being undertaken within the Welsh NERS across leisure centres in eight local  
171 authority areas in Wales, UK. The eight study sites were purposively selected to reflect a  
172 range of urbanisation and geography. Participants are eligible for the study if they; i) are  
173 referred into the NERS generic pathway (see Box 1), and ii) have the capacity to use the  
174 activity monitors (i.e. computer access and an email address).



**Box 1. NERS Generic Pathway Criteria**

For referral into the NERS generic pathway, patients must:

- be aged 16 years or above;
- be sedentary (defined as not moderately active for 3 times per week or deconditioned through age or inactivity);
- have at least one of the following:
  - Raised blood pressure 140/90,
  - BMI >28,
  - Cholesterol >5.0,
  - Controlled diabetes or impaired glucose intolerance,
  - Family history of heart disease or diabetes,
  - At risk of osteoporosis and/or musculoskeletal pain,
  - Mild arthritis or poor mobility,
  - Mild-moderate COPD, asthma, bronchitis, emphysema,
  - Mild anxiety, depression or stress,
  - Multiple sclerosis.

**Recruitment**

Participants will be recruited to the trial using opportunistic invites within the existing scheme structure. NERS exercise professionals will provide information about the study to all new generic pathway clients during their first consultation appointment on the scheme. Exercise professionals will transfer the contact details of clients who are eligible for and interested in joining the study to the research team using a secure electronic form. The research team will send a recruitment pack containing full informed consent materials and the baseline questionnaire to interested clients to be returned by post. Participants who return a signed consent form and completed baseline questionnaire will be entered into randomisation. Participants in the intervention group will be sent information about the process evaluation interviews following randomisation and will be asked to express an interest in taking part in

200 the interviews. From those who express an interest, participants will be selected to provide  
201 variation in local authority area, age, sex, and reason for referral. Where possible we will  
202 interview the same participants at 4-weeks and 12-months. Where not possible, additional  
203 participants matched by demographics (e.g. age and sex) will be recruited for 12-month  
204 interviews. All NERS staff involved in the study will be invited to participate in the process  
205 evaluation interviews. From those who express an interest, two staff members per local  
206 authority area will be selected.

207

### 208 **Randomisation**

209 After completion of baseline measures, study staff will randomly assign participants 1:1 to  
210 receive either the intervention (NERS plus MWK) or the control treatment (NERS standard  
211 practice) via a computer-generated random allocation sequence created by the South East  
212 Wales Trials Unit.

213

### 214 **The Intervention**

#### **Box 2. Features of the MWK activity monitor and MyWellnessCloud web platform**

- Real-time visual feedback via a screen on the activity monitor
- Detailed feedback on activity levels via a web platform to indicate progress towards goals, time spent in different activity intensities and calories burned
- Automatised goal setting via an algorithm which sets goals in a stepwise fashion such that forward progression is mastery-based
- Facilitation of social support for exercise via the web platform (through involvement in group challenges and remote communication with an exercise professional) and smartphone app (the option to share details about activity completed via social media)
- Free access to the web platform and smartphone application following discontinuation of use of the MWK via manual input or by linking the account to another monitoring device.

215 The intervention is an enhanced ERS that includes usual care (NERS standard practice) [6]  
216 plus an accelerometry-based activity monitor (MyWellnessKey; MWK). The MWK can be  
217 used for self-monitoring of physical activity levels in combination with a linked web platform  
218 (MyWellnessCloud) and smartphone application (see box 2). The MWK has been validated  
219 in terms of device accuracy at monitoring physical activity level and intensity [32, 33] and  
220 utility at fostering increased physical activity levels (high concurrent validity with ActiGraph  
221 accelerometer to detect physical activity in laboratory and free living environments) [34].

222 Intervention participants will be provided with a MWK to use for the remaining 12 weeks of  
223 their 16-week NERS programme after receiving it at their 4-week consultation and will be  
224 encouraged to use it for 36 weeks after they exit the scheme, up until their 12-month  
225 consultation when the device will be returned. In current practice conducting an 8-month  
226 telephone consultation to check clients' progress with exercise is an optional part of standard  
227 care. To encourage participants to maintain engagement in the study we have asked for the  
228 telephone consultation to take place with all intervention participants. Table 1 shows how the  
229 intervention will be implemented within the scheme.

230

231 It is anticipated that the intervention will enhance NERS through two key mechanisms; 1)  
232 goal setting and personalised feedback elements of the devices will support a sense of  
233 exercise mastery and perceived competence; 2) the web platform will provide a sense of  
234 relatedness to others via opportunities to communicate remotely with exercise professionals,  
235 other NERS clients and social media contacts. It is anticipated that these mechanisms will  
236 improve autonomous motivation for exercise, leading to greater maintenance of increases in  
237 physical activity, as depicted in the intervention logic model (see Figure 2).

238

239 Figure 2. PACERS logic model

240

241 **Control treatment**

242 Control participants will receive usual care which is NERS standard practice; a 16-week  
243 structured exercise programme which includes consultations with an exercise professional at  
244 the start, 4-weeks, on exiting the scheme (16-weeks) and at 12-month follow-up [6].

245

246 **Primary outcome**

247 The primary outcome will be the feasibility and acceptability of the intervention and its  
248 proposed evaluation methodology, to inform a decision on whether a full randomised  
249 controlled trial is warranted and feasible. This will be assessed against a set of predefined  
250 progression criteria related to recruitment and retention rates, exposure to the intervention in  
251 both intervention and control groups, and acceptability of the intervention, recruitment and  
252 randomisation processes to participants. The criteria were agreed by the Trial Steering  
253 Committee (TSC) and follow a traffic light assessment system (red=stop; amber=discuss with  
254 TSC whether there is enough evidence that sufficient improvements can be made to proceed  
255 to full trial without another feasibility assessment; green=proceed) using quantitative  
256 measures supported by qualitative data. The criteria, their measurement, and assessment  
257 criteria are summarised in Table 2. Qualitative data will provide insights into intervention and  
258 evaluation design features which need to be retained, or where metrics fall into the amber  
259 zone, modifications which may need to be made to improve feasibility and acceptability.

260

261 It is anticipated that in a full trial, the main outcome measure will be objectively measured  
262 physical activity using accelerometry. To examine the feasibility of collecting this data at  
263 follow-up in the NERS population, a sub sample of participants will be recruited to complete

264 the accelerometer measure at 16 months post-randomisation. Participants will wear a GT3X  
265 ActiGraph accelerometer around the waist for seven consecutive days during waking hours.  
266 Data will be processed to identify mean minutes of moderate to vigorous intensity activity per  
267 day and mean accelerometer counts per minute (volume of physical activity) using  
268 established processes [35].

269

### 270 **Secondary outcomes**

271 The effect of the intervention on the main hypothesised change mechanism (autonomous  
272 motivation) will be evaluated. Other secondary outcome measures will be piloted to estimate  
273 key trial parameters (e.g. standard deviation) to inform a future full trial.

274

### 275 *Measures collected routinely in NERS*

276 Data collected routinely within NERS will be obtained for use within the trial from T0, T1  
277 and T2, as follows:

- 278 • Blood pressure and resting heart rate;
- 279 • Body Mass Index;
- 280 • Waist circumference;
- 281 • Self-reported physical activity (Scottish Physical Activity Questionnaire) [36];
- 282 • Health-related quality of life (EQ-5D-5L) [37];
- 283 • Fitness test (Chester fitness test) [38].

284

### 285 *Measures included in PACERS study questionnaire*

286 The following additional measures will be collected at all time-points, which in a full trial  
287 would be used to assess effectiveness of the added intervention component  
288 (MyWellnessKey):

- 289       • Autonomous Motivation (Behavioural Regulation in Exercise Questionnaire 3  
290       (BREQ-3)) [39];
- 291       • Psychological need support (Intrinsic Motivation Inventory) [40];
- 292       • Anxiety and depression (Hospital Anxiety and Depression Scale (HADS)) [41].

293

#### 294 *Economic evaluation outcome measures*

295 The PACERS study questionnaire will include an adapted Client Service Receipt Inventory  
296 (CSRI) based on the previous service use questionnaire used in the NERS evaluation [7] and  
297 examples in the DIRUM database (dirum.org) to capture client health and social care service  
298 use since the last time point (plus a four month retrospective period at baseline). Additional  
299 questions in the 12-month questionnaire will capture wider economic outcomes including  
300 current work status, days off work due to health problems and estimated income lost due to  
301 changes in work during the study period. Willingness to pay for the MWK will also be  
302 explored. Baseline demographic data on housing status and household income will also be  
303 collected in the PACERS study questionnaire for the purpose of the economic analysis.

304

#### 305 **Sample size**

306 The proposed sample size for the study of 286 participants was calculated to allow the  
307 estimation of the feasibility proportions of adherence and retention to within at least plus or  
308 minus 8.2 percentage points using a 95% confidence interval, as well as to provide 80%  
309 power to detect an effect size of 0.4 at the 5% level on the main hypothesised mediator of  
310 autonomous motivation at 12-month follow-up, assuming 30% attrition [7]. The sample size  
311 was also planned to provide an indication of likely response rates, permit estimates of effect  
312 sizes of primary and secondary outcomes in advance of a larger trial, and allow exploration of

313 socio-demographic patterning in uptake and use of the MWKs in order to generate  
314 hypotheses regarding who the intervention might work for and why.

315

### 316 **Data collection**

317 Routinely collected data will be extracted from the NERS database at all T0, T1 and T2. The  
318 PACERS study questionnaire will be mailed to participants at all time-points. Telephone and  
319 email reminders will be made to non-responders. Semi-structured telephone interviews will  
320 be conducted with a sub-sample of intervention participants (n=20) following receipt of the  
321 intervention at 4-weeks and again at 12-months (T2) to explore feasibility and acceptability  
322 of the intervention and study methods. In addition, telephone interviews will be conducted  
323 with a sample of NERS exercise professionals at the same time points to explore feasibility  
324 and acceptability of implementing the intervention and study methods from a professional  
325 perspective. Figure 3 indicates the schedule of enrolment, interventions and assessments.

326

327 Figure 3. PACERS study schedule of enrolment, interventions, and assessments.

328

### 329 **Process evaluation**

330 A detailed process evaluation will examine the acceptability and feasibility of the  
331 intervention and evaluation methods, including intervention delivery and fidelity, potential  
332 contamination and contextual influences. Quantitative and qualitative data will be collected  
333 using a range of methods. Table 3 summarises the process evaluation methods.

334

### 335 **Economic analysis methods**

336 Data will be collected to estimate intervention costs and examine the feasibility of calculating  
337 cost-effectiveness alongside a definitive full pragmatic randomised trial. Health care service  
338 use will be costed using national unit costs [42, 43]. Both arms of the study will be costed,

339 revisiting and revising the costing methodology used in previous economic analysis of the  
340 Welsh NERS [44].

341

342 The additional costs of the intervention will consist of: the cost of the MWK; staff costs  
343 relating to the MWK (e.g. training, implementation and participant follow up support); the  
344 cost of the professional web cloud (e.g. licence fee) and additional staff interactions. These  
345 costs are in addition to the core programme costs (in both arms) including: NERS standard  
346 practice costs and participant contributions. Information about the additional staff resources  
347 required for the use of the MWK and professional web cloud will be derived from qualitative  
348 interviews with staff.

349

## 350 **Data analysis**

### 351 *Quantitative analysis*

352 The main outcomes in this feasibility study are related to the study progression criteria as  
353 outlined in Table 2. The methods of analysis for quantitative data collected for the process  
354 evaluation are summarised in Table 3. Analyses will be largely descriptive, with summary  
355 statistics being presented overall and also by key demographics. Evidence of whether the  
356 intervention could lead to behaviour change will be examined using regression analyses to  
357 quantify effects on autonomous motivation, using the Relative Autonomy Index derived  
358 from the BREQ-3.

359

360 To examine the direction of effect on physical activity Analysis of Covariance models  
361 [ANCOVA] will be used to estimate intervention effects on physical activity at 16 months.  
362 While likely non-significant due to limited power, this should be in the direction of a  
363 favourable intervention effect. Accelerometer data will be processed using standard  
364 procedures; periods of  $\geq 60$  minutes of zero counts will be recorded as “non-wear time” and



365 removed. Participants will be included in the analysis if they provide  $\geq 3$  valid days (i.e. 500  
366 minutes of data between 6am and 11pm). Mean minutes of daily moderate to vigorous  
367 intensity activity will be estimated using a threshold value of  $\geq 2020$  counts per minute with  
368 minutes of light intensity physical activity estimated using thresholds of between 100 and  
369 2019 counts per minute [35]. Sedentary time will be estimated based on a cut-point of less  
370 than 100 counts per minute; mean sedentary minutes per day will be derived.

371

### 372 *Qualitative analysis*

373 Qualitative data from interviews with exercise professionals and intervention participants will  
374 be transcribed verbatim and organised and coded into a thematic framework using NVivo 11  
375 software. An approach to thematic analysis will be used that allows for both a deductive and  
376 inductive approach to data analysis [45]. Data will be initially coded using an a priori coding  
377 scheme of categories which align with the research questions as a means of organising the  
378 data for subsequent interpretation. An element of flexibility will be maintained to account for  
379 the emergence of any new and unexpected themes. The first three transcripts will be  
380 independently coded by two coders in order to develop a shared codebook via consensus.  
381 Any disagreements between coders will be discussed with a third coder. Divergence and  
382 convergence between interviews will be examined and comparisons made of the experiences  
383 of the intervention across and within areas (NERS clients and exercise professionals). We  
384 aim to develop a comprehensive understanding of the intervention acceptability,  
385 implementation and mechanisms of impact.

386

### 387 *Economic Analysis*

388 A pilot cost-consequence analysis will be conducted from a NHS and societal perspective.  
389 Response rates and level of completion of the measures will be reported using descriptive

390 statistics. Variables will be checked for out of range values before analysis begins. As data  
391 are expected to be skewed, non-parametric tests will be used to assess differences across  
392 groups or time points for the outcomes of QALYs (using the EQ-5D) and health and social  
393 care service use. We will bootstrap (5,000 replications) differences in cost and outcomes to  
394 produce a 95% confidence interval around these differences. Ceiling effects on the EQ-5D  
395 will also be assessed, assessing the proportion of participants that state “no problems” on all  
396 five dimensions on the EQ-5D questionnaire. QALY gains (using the EQ-5D) will be  
397 compared to those in similar samples from previous literature (where available).

398

399 A report on the data gathered about service use (from routinely collected data recorded by  
400 healthcare professionals delivering NERS) will explore if future studies could use this or a  
401 different method to the CSRI questionnaire used in the feasibility study. Descriptive statistics  
402 will be used to describe the amount participants are willing to pay for the MWK, both during  
403 the intervention and beyond. Response rates and level of completion of the questions  
404 exploring how best to capture productivity losses will be reported using descriptive statistics.  
405 Sub-group analyses will explore the effect on health related quality of life of socio-  
406 demographics (e.g. gender) and reason for referral. Sensitivity analysis will be conducted in  
407 accordance with NICE guidelines to vary the cost of the device [46], demonstrating what  
408 happened in the feasibility trial and how co-ordination may be varied in a future full-scale  
409 trial.

410

#### 411 **Serious adverse event reporting and monitoring**

412 It is not anticipated that there will be any additional risks to participants over and above  
413 existing NERS standard practice for which standard operating procedures are in place  
414 covering referral into the scheme, provision of exercise instruction and support, and dealing

415 with adverse events. There are no serious adverse events expected to be related to the  
416 intervention. Any serious adverse event occurrence will be reported to the Chief Investigator  
417 within 48 hours of receiving notification. Assignment of causality will be made by the  
418 independent clinician member of the TSC.

419

#### 420 **Project management**

421 A Trial Management Group is responsible for ensuring the appropriate, effective and timely  
422 implementation of the trial including monitoring adherence to standardised research  
423 protocols. The day-to-day operational management of the feasibility study is co-ordinated by  
424 a central project management team which meets weekly to monitor progress and any issues  
425 which may need relaying to the Trial Management Group. An independent TSC provides  
426 overall supervision for the trial and advice through its independent chair and also  
427 encompasses the role of Data Monitoring Committee.

428

#### 429 **Discussion**

430 The PACERS feasibility trial aims to assess the feasibility and acceptability of implementing  
431 a novel motivational component, the MyWellnessKey, into the existing Welsh NERS. In  
432 addition, the trial also aims to determine the acceptability and feasibility of the proposed  
433 evaluation methodology for a definitive trial of the intervention for promoting long-term  
434 maintenance of physical activity. Whilst exercise referral approaches have been shown to be  
435 effective for increasing physical activity levels, evidence of long-term effects is limited [9,  
436 10, 12] and so there is a need to better understand how to support long-term maintenance of  
437 physical activity [3]. The MWK intervention offers a potential mechanism for enhancing and  
438 sustaining autonomous motivation for physical activity via evidence-based techniques

439 including goal setting, self-monitoring and receiving personalised feedback on progress  
440 towards goals [20-22].

441

442 Findings from this study will determine whether progression to a full scale randomised  
443 controlled trial of effectiveness and cost-effectiveness is feasible and warranted, through the  
444 assessment of key progression criteria. The study will assess whether the outcomes being  
445 used are feasible and acceptable to use with the study population. Findings related to the  
446 acceptability and feasibility of implementing the intervention will inform potential refinement  
447 of the implementation processes where necessary. The findings will also allow refinement of  
448 the intervention logic model.

449

#### 450 **List of abbreviations**

451 CSRI: Client Service Receipt Inventory; ERS: Exercise Referral Scheme; MWK: MyWellnessKey;  
452 MWC: MyWellnessCloud; NERS: National Exercise Referral Scheme; NHS: National Health  
453 Service; NICE: National Institute for Clinical Excellence; NRES: National Research Ethics Service;  
454 QALY: Quality Adjusted Life Year; REC: Research Ethics Committee; TSC: Trial Steering  
455 Committee.

456

#### 457 **Ethics approval and consent to participate**

458 The PACERS study was given favourable ethical opinion for conduct in the NHS on 1<sup>st</sup>  
459 December 2015 by the South East Scotland Research Ethics Committee 02 (REF: 189587)  
460 and participants are required to provide written informed consent in order to participate in the  
461 study.

462

#### 463 **Consent for publication**

464 Not applicable, this manuscript does not contain participant data.

465 **Availability of data and material**

466 Not applicable.

467

468 **Competing interests**

469 The authors declare that they have no competing interests.

470

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481

482 **Authors' contributions**

483 JH is the Principal Investigator and responsible for overall management of the PACERS  
484 study. She led the development of the study protocol. ME is the trial manager and responsible  
485 for coordinating the PACERS study. ME was involved in finalising the study protocol and  
486 implementing study processes. GM is the principal co-investigator and was involved in  
487 finalising the study protocol, in particular the process evaluation methods. The first draft of  
488 the manuscript was prepared by ME, JH and GM. EO and SS were involved in finalising the  
489 study protocol, in particular the qualitative methods. RJ and KM were involved in finalising

490 the study protocol, in particular the accelerometry methods. MK was involved in finalising  
491 the study protocol, in particular the statistical considerations. SM was involved in finalising  
492 the study protocol, in particular the trial design. JC and RTE were involved in finalising the  
493 study protocol, in particular the health economics analysis. All authors reviewed, contributed  
494 to and approved the final manuscript.

495

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503

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635 **Figure titles and legends**

636 Figure 1. Flow diagram of the PACERS study design. (page 8)

637

638 Figure 2. PACERS logic model. (page 11)

639

640 Figure 3. PACERS study schedule of enrolment, interventions, and assessments. (page 14)

641 X = study participants, **X = intervention delivery staff**

**Table 1. Implementation of the intervention components**

<b>Time-point</b>	<b>Exercise professionals</b>	<b>Intervention participants</b>
At 4 week review appointment	Set up participants with a MWC account, configure initial activity goals on the MWK and demonstrate how to use the device and web platform.	Take the MWK home, sign into their MWC account on their home computer and connect their MWK to read data and charge it.
Over the study period (48Weeks)	Interact with participants to monitor and adjust their goals, send positive comments and set up group challenges through direct messaging via a linked website called Professional Cloud.	Use the device daily and connect the MWK to a computer at least twice per week to upload data to the MWC, receive feedback and charge the device.  Manually enter information about activity that the device does not readily measure, i.e. swimming, weight training, cycling.
At 8 months from start	Telephone participants to check on their progress with exercising and remind them of the study and encourage use of the MWK, MWC and associated features.	Participants with a MWK continue to use it daily.
At 12 months from start	Exercise professionals will have a consultation with all	Hand the MWK back to the exercise professional.

	participants for usual NERS assessments and to collect the MWK.	
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**Table 2 Summary of progression criteria**

<b>Progression Criteria (PC)</b>	<b>Measures used</b>	<b>Assessment of whether criteria have been met</b>
<p><b>PC1.</b> Feasibility to recruit a sufficient proportion of new NERS patients to participate in the trial, with appropriate retention rates to 12 month follow-up.</p>	<ul style="list-style-type: none"> <li>• The percentage of new NERS patients recruited to the trial, and retained at each subsequent follow-up.</li> <li>• Regression models will be used to identify predictors of loss to follow-up (e.g. demographics or baseline motivation).</li> </ul>	<ul style="list-style-type: none"> <li>• If &gt;20% of new NERS patients recruited = proceed; if &lt;5% = full-scale trial unlikely to be feasible. If 5-20% the TSC will consider the feasibility of proceeding to a full-scale trial bearing in mind the data and feedback presented and representativeness of the recruited sample, and possible steps to increase the recruitment rate.</li> <li>• If &gt;80% retained at 12-months = proceed, if &lt;60% = full-scale trial unlikely to be feasible. If 60-80% the TSC will consider the feasibility of proceeding based on the available data and possible steps to increase retention.</li> </ul>
<p><b>PC2.</b> Intervention and trial methodology delivered as intended</p>	<ul style="list-style-type: none"> <li>• Summary statistics for intervention fidelity measures overall and by area.</li> <li>• Compliance with study invite processes.</li> <li>• Compliance with randomisation processes.</li> </ul>	<ul style="list-style-type: none"> <li>• The TSC will consider the data presented and make a judgement about whether the intervention and trial methodology were delivered as intended.</li> </ul>
<p><b>PC3.</b> At least one of the two intervention</p>	<ul style="list-style-type: none"> <li>• Percentages of participants who report acceptability of the intervention components on four self-report</li> </ul>	<ul style="list-style-type: none"> <li>• The TSC will consider the quantitative and qualitative data and make an overall judgement on whether the intervention is</li> </ul>

<p>components is acceptable to participants</p>	<p>questions.</p> <ul style="list-style-type: none"> <li>• Issues regarding acceptability of, and engagement with, the two intervention components explored in qualitative interviews with a sub-sample of intervention participants.</li> </ul>	<p>acceptable.</p>
<p><b>PC4.</b> Recruitment and randomisation processes acceptable to &gt;50% of recruited participants</p>	<ul style="list-style-type: none"> <li>• Percentages of participants who report acceptability of the recruitment and randomisation processes on patient questionnaires.</li> <li>• Exploration of understanding and acceptability of recruitment and randomisation processes in qualitative interviews.</li> </ul>	<ul style="list-style-type: none"> <li>• &gt;50% of recruited participants report ‘agree’ or ‘strongly agree’ to questions about the acceptability of recruitment and randomisation processes.</li> <li>• The TSC will apply discretion in judging whether this criterion has been met, or could be addressed to improve acceptability in a full-scale trial.</li> </ul>
<p><b>PC5.</b> &lt; 20% of control group exposed to the intervention components</p>	<ul style="list-style-type: none"> <li>• The percentage of participants in intervention and control groups who report that they were provided with a MWK device or accessed the MWC web platform.</li> </ul>	<ul style="list-style-type: none"> <li>• &lt;20% of control participants report that they have used a MWK device during the study period.</li> <li>• &lt;20% of control participants report that they have accessed the MWC during the study period.</li> </ul>

**Table 3. Summary of process evaluation methods**

<b>Fidelity/Feasibility/ Acceptability</b>	<b>Method of data collection</b>	<b>Aims to explore</b>	<b>Method of Analysis / Data to be presented</b>	<b>Participants</b>	<b>Time</b>
Fidelity to trial methodology (PC2)	Audio recordings of NERS initial consultations with participants	The accuracy with which recruitment and consent processes were followed.	A summary score of adherence to the processes (range 0-4) will be calculated for each recording and presented overall and by area	Two participants per exercise professional	T0 (during NERS initial consultation)
Feasibility of implementing the intervention and trial methodology within routine NERS practice	Telephone interviews with NERS staff	Barriers/ facilitators, fit with local context, any adverse effects on usual NERS delivery, differences across settings, additional infrastructure or resources required for a full trial.	Thematic analysis	Two exercise professionals per area	After receipt of the intervention at 4-weeks and at T2
Acceptability of the trial methodology (PC4)	Telephone interviews with NERS staff and intervention participants	Understandings and acceptability of recruitment and randomisation processes.	Thematic analysis	Two exercise professionals per area, 20 intervention participants	After receipt of the intervention at 4-weeks and at T2
	Self-report questions on study questionnaire		Percentages of participants reporting acceptability of the randomisation process	All participants	T1



Acceptability of the intervention (PC3)	Telephone interviews with professionals and participants patients	Perceived acceptability of intervention components, barriers and facilitators in using the devices.	Thematic analysis	Two exercise professionals per area, 20 intervention participants	After receipt of the intervention at 4-weeks and at T2
	Self-report questions on study questionnaire	Frequency of use, ease of use, likelihood of future use.	Percentages of participants reporting that the intervention was easy to use, that they used it, and would do so in the future	All intervention participants	T1 and T2
Feasibility of collecting objective data on physical activity at long-term follow up	ActiGraph accelerometers	The feasibility of obtaining measures of physical activity over a 7 day period	A linear regression model controlling for age, gender, baseline self-reported physical activity and randomisation group will be fitted. Results will be expressed using regression coefficients, 95% confidence intervals, and standardised effect sizes.	100 participants	16 months post-randomisation
Contamination (PC5)	Self-report questions on study questionnaire on awareness of and exposure to intervention components	Assessment of contamination between trial arms.	Percentages of participants in intervention and control arms reporting exposure to the intervention will be presented alongside 95% confidence intervals.	All participants	T1 and T2