Relating process evaluation measures to complex intervention outcomes: findings from the PACE-UP primary care pedometer-based walking trial

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Abstract

Background:

The PACE-UP trial demonstrated positive effects of a pedometer-based walking intervention on objective physical activity (PA) outcomes at 3 and 12 months in 45-75 year old primary care patients, in postal and nurse-supported trial arms compared with controls. We explored associations between process evaluation measures and change in PA outcomes.

Methods:

The MRC framework guided process evaluation. Three quantitative measures (nurse session attendance (dose delivered); PA diary completion (fidelity); and pedometer use (fidelity)), were selected as independent variables in multi-level models estimating intervention effectiveness on PA outcomes (changes in step-counts and time in moderate-to-vigorous PA (MVPA) levels in ≥ 10 minute bouts).

Results:

Dose: attending all 3 nurse sessions compared with 0-2 sessions was associated with an increase in steps/day at 3 and 12-months of 1197 (95% CI 627, 1766) and 605 (95% CI 74, 1137), respectively; and MVPA in bouts (minutes/week) at 3 and 12 months by 74 (95% CI 45, 103) and 30 (95% CI 3, 57), respectively. Fidelity: postal and nurse groups showed strong positive associations of diary return with steps/day at 3 months: postal 1458 (95% CI 854, 2061), nurse 873 (95% CI 190, 1555) and MVPA in bouts (minutes/week) postal 64 (95% CI 33, 94), nurse 50 (95% CI 15, 85) At 12 months only the postal group effects remained statistically significant: steps/day 1114 (95% CI 538, 1689), MVPA 47 (95% CI 18, 75) . Regular pedometer use in the postal group only was associated with higher 3 and 12-month steps/day: 1029 (95% CI 383, 1675) and 606 (95% CI 22, 1190), respectively, and with MVPA in bouts at 3 months 40 (95% CI 6, 73).

Conclusion:

Process evaluation measures demonstrated significant associations with PA outcomes at 3 and 12 months. We cannot infer causality, but the associations between the process measures and PA outcomes suggest that they were important in enabling the trial changes observed and should be considered core components of the PACE-UP nurse and postal interventions. We have shown the MRC framework to be a useful tool for process evaluation of intervention implementation.

Background:

The PACE-UP randomised controlled trial (RCT) is a complex intervention. Randomised controlled trials establish intervention effectiveness, but do not tell us how or why an intervention works, and if it is not successful, why not. Process evaluation provides an assessment of the effective components of an intervention. Without evaluating the processes of the intervention, it is challenging to assess the validity of the contribution of an intervention to the research outcomes. This process evaluation investigates the relationship between the fidelity and quality of implementation, the context of the intervention and the main trial outcomes. The evaluation helped to illustrate replicability and generalisability of the intervention by relating process evaluation measures to objectively measured trial PA outcomes.

The MRC framework, developed in 2014[1], built on the 2008 guidance [2] and on previous less comprehensive frameworks used to assess implementation fidelity alone (e.g., the modified conceptual framework[3] and RE-AIM [4]), offers the first useful tool to evaluate the entire process of a complex intervention. It can be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes.

Matthews et al[5] used the 2014 MRC framework, in combination with guidance from Steckler and Linnan[6]; the RE-AIM framework[4]; and the World Health Organisation,[7] for process evaluation of a walking intervention; however, they did not clearly relate process and outcome measures. Van Bruinessen et al[8] used the MRC framework to complete the PatientTIME web-based intervention process evaluation, and showed significant improvements in perceived efficacy, but no significant association between process and outcome measures. Foley et al[9] found no significant effect of the SWITCH study intervention on main trial outcomes, which could be related to the lack of fidelity in the intervention reported as a result of the process evaluation.

The PACE-UP trial is a large, pedometer-based, complex, walking intervention with two intervention arms (postal and nurse support) and multiple interacting intervention components (pedometer, handbook, physical activity (PA) diary, practice nurse PA consultations and behaviour change techniques (BCTs)). The aim of this process evaluation was to understand how the PACE-UP intervention was delivered and received and which intervention components were associated with the main positive trial PA outcomes.

Methods:

PACE-UP Trial design

PACE-UP was a 3-armed RCT of a 12-week, pedometer-based, walking intervention with and without practice nurse support. 1023 patients aged 45-75 years, from 922 households, with no contradictions to increasing PA were recruited from 7 general practices in South London, UK, and randomised by household (1 or 2 persons per household) to either control (n=338), postal pedometer intervention (n=339) or nurse-supported pedometer intervention (n =346). The main trial outcomes were changes in average daily step-count and weekly time spent in moderate-to-vigorous physical activity (MVPA) (in ≥10min bouts) between baseline and 12 months. The full study design, methods and outcomes are described in detail in the trial protocol[10] and outcome[11] papers. A brief summary of the PACE-UP intervention is provided, followed by the process evaluation methods used.

The PACE-UP interventions

The intervention was designed to gradually increase step-count and MVPA over a 12-week period, with targets based on participants' baseline physical activity levels. Participants' physical activity was objectively measured using accelerometry over 7-day periods at baseline, 3 and 12 months to assess main trial PA outcomes. The two intervention groups received pedometers, 12-week walking programmes, handbook and PA diaries. The nurse group additionally were offered three PA consultations with a practice nurse at weeks 1, 5 and 9. The patient handbook and PA diary received by both intervention groups incorporated several BCTs adapted from the NHS Health Trainers Handbook[12]. Nurse sessions provided further BCTs, including individual goal setting and motivational interviewing. Content delivered in the nurse-support arm was captured with nurse attendance logs completed by the nurses.

Process Evaluation

The process evaluation component of PACE-UP was designed in accordance with the MRC guidance framework 2014[1]. Methods used were selected through the key functions model (figure 1). A mixed-methods (quantitative and qualitative) approach included assessment of all key functions: context; implementation (implementation process, reach, fidelity, dose, adaptations), and mechanisms of impact. Full details will be published in the Health Technology Assessment (HTA) report. Qualitative evaluations of participants[15] and practice nurses[16] are already published.

This paper focuses on implementation fidelity and dose in the nurse group, the dose delivered was fixed for the postal group. The evaluation included three key quantitative elements relating to

implementation of the intervention: Nurse Session attendance (dose delivered), PA diary

completion (implementation fidelity), and pedometer use during the 12-week intervention

(implementation fidelity). Data sources and evaluation measures are identified and summarised in

Table 1. Both intervention groups provided data on PA diary and pedometer use. However, dose

delivered is only available for the nurse group with data on the number of nurse sessions attended.

Table 1

Data Collection

Nurse session attendance - Dose delivered

Dose delivered could fluctuate in the nurse intervention group depending on the number of sessions attended which could range from 0 to 3 (the prescribed number). Data on the number of sessions participants attended was recorded by the nurses and allowed us to explore the relationship between dose delivered, 0,1,2,3 sessions attended, and PA outcomes in this group at 3 and 12 months.

Physical Activity diaries - Intervention Fidelity

12-week PA diaries were provided to both trial intervention groups and returned by participants to the trial team. The diaries provided data on daily step-counts and/or daily walks. A completed diary was defined pragmatically as one with 3 or more completed days for each of the 12 weeks of the intervention, to demonstrate that the diary had been used for the duration of the intervention. The relationships between completed diary return (Y/N) after the intervention (3months) and PA outcomes at 3 months and 12 months were explored.

Pedometer Use - Intervention Fidelity

Participants were asked about their pedometer use during the intervention period via a questionnaire completed at 12 months. Pedometer use was defined as how regularly the participant used the pedometer during the 12 week intervention period. The associations between pedometer use during the intervention (0-3 months) and PA outcomes at 3 months and 12 months, respectively, were explored for both intervention groups using the response to the following question: How often did you wear the pedometer? The most positive responses were identified as reported pedometer use 'every day' or 'most days' and compared this with other less frequent responses.

Analysis

The trial was powered for the analysis of the difference in PA outcome measures between the three trial groups and not for exploration of the effect of the process evaluation measures[10]. Nevertheless, it was important to explore the relationship between dose and intervention fidelity and change in PA outcomes in order to understand how different intervention components may have had their effects. To estimate change we regressed estimated average daily step-count at 12 months on estimated average daily baseline step-count, month of baseline accelerometry, age, gender, general practice, and a group variable using the Stata command xtmixed. A household identifier was included as a random effect to account for clustering by household. The group variable was

included to allow for treatment effects and to estimate differences in response between individuals within a treatment group, with different process measures. Thus for number of nurse sessions attended the group variable had the following 4 categories: Control, Postal, Nurse <3 sessions, Nurse 3 sessions attended. The lincomest post estimation command was then used to provide estimates and confidence limits for the difference between Nurse 3 sessions attended and Nurse < 3 sessions attended. Because we regressed 12 month on baseline step-count, the coefficients for the group variable is a direct measure of change from baseline. Similar analysis were conducted for different time points, MVPA, and the other process measures. Full details of the accelerometry data processing and the statistical models used for the main trial outcomes are provided elsewhere [11].

Results

Main trial outcomes

The main trial outcomes have been published elsewhere[11], but are reported briefly here to provide context; in particular for the later comparison of the impact of process evaluation measures on trial outcomes. The PACE-UP trial recruited 1023 participants, 93% (n=956) of participants provided accelerometry outcome data at 12 months. At 3 months there were significant differences for change in step-counts from baseline between intervention groups and the control group: additional steps/day postal 692 (95% C.I. 363 to 1020), nurse support 1,172 (95% C.I. 844 to 1501). Findings for MVPA showed a similar pattern: additional MVPA in bouts (minutes/week) postal 43 (95% C.I. 26 to 60), nurse-support 61 (95% C.I. 44 to 78). At the main 12 month outcome both intervention groups had increased their PA compared with controls; however, there were now no significant differences between the two intervention groups: additional steps/day postal 642 (95% CI 329 to 955), nurse 677 (95% C.I. 365 to 989), and additional MVPA in bouts (minutes/week) compared with control postal 33 (95% CI 17 to 49); nurse-support 35 (95% CI 19 to 51).

Table 2

Process evaluation measures

Table 2 shows the results for the process evaluation measures relating to implementation that we are using to model against PA outcomes. For dose, over three-quarters of participants in the nurse-support group attended all three nurse sessions, 95% (330/346) attended session 1 and 86% (296/346) attended session 2. Diary return was also high with overall 80% (549/685) returning their diaries and little difference between postal and nurse groups. Regular pedometer use was high during the intervention (0-3 months) in both intervention groups (85% overall); this was higher in nurse-supported than the postal group.

Relationship between process evaluation and physical activity trial outcomes measures

The modelling results relating nurse session attendance, PA diary return and pedometer use to PA outcomes (step-counts and time in MVPA in bouts) at 3 months and 12 months are presented in Table 3.

The nurse intervention group showed significant positive associations with dose of the intervention delivered (number of sessions attended) and step-count and time in MVPA in bouts at both 3 and 12 months. Participants attending all 3 sessions at 3 months increased their step-count significantly by 1197 steps/day (95% CI, 627,1766) more than those attending 0-2 sessions, and at 12 months by 605 steps/day (95% CI, 74, 1137). MVPA in bouts was significantly higher in those attending all 3 nurse

session at both 3 months; 74 minutes/week (95% CI, 45, 103) and 12 months; 30 minutes/week (95% CI, 3, 57).

Both intervention groups at 3 months showed strong positive associations between diary return and PA outcomes. Diary return in the postal intervention group was associated with increased step count by 1458 steps/day (95% CI, 854, 2061) and MVPA in bouts by 64 minutes/week (95% CI, 33, 94) compared to those not returning a diary; and in the nurse intervention group an increase of 873 steps/day (95% CI, 190, 1555) and 50 minutes/week of MVPA in bouts (15, 85). At 12 months only the postal group had sustained this significant association between diary return and increase steps of 1114 steps/day (95% CI, 538, 1689) and 47 minutes/week (95% CI, 18, 75) of MVPA in bouts with diary return. The directions of association were still positive in the nurse group at 12 months between diary return and both step-counts and time in MVPA, but the associations were no longer statistically significant and the differences between the nurse and postal groups were of borderline statistical significance.

Regular pedometer use in the postal intervention group (on either most days or everyday) during the intervention (0-3 months) showed strong significant increases in steps/day at 3 months 1029 (95% CI, 383,1675) and 12 months 606 (95% CI, 22, 1190) compared to those not reporting regular pedometer use; results were similar for MVPA (minutes/week) at 3 months 40 (95% CI, 6,73) and in a positive direction, but not statistically significant at 12 months 26 (95% CI -2, 55). Regular pedometer use in the nurse intervention group during the intervention was not however significantly associated with steps or time in MVPA either at 3 or 12 months, but nor were the effects significantly different from those in the postal group.

Table 3

Discussion

Main findings

Our study results demonstrate the positive association between core components of the intervention and the main trial outcomes. For the nurse group the number of sessions attended was significantly associated with both step-counts and time in MVPA at both 3 and 12 months. For both nurse and postal groups, return of a completed PA diary was positively associated with step-count and time in MVPA at 3 months and for the postal group at 12 months. Regular pedometer use was only associated with PA outcomes for the postal group (step-counts and MVPA at 3 months and step-counts at 12 months). Whilst we cannot infer causality, the strong and consistent associations between nurse appointments, diary return and pedometer use, identify these intervention components as important enabling factors in the main trial effects observed. The somewhat stronger impact seen in the postal group for diary return and pedometer use suggests that possibly the pedometer was a less important component for the nurse group. For the nurse group the number of nurse visits attended seemed to have a greater influence.

Strengths and Limitations:

The study used data collected as part of the trial, this helped to reduce participant burden and optimise data completeness. We used data collected by both practitioners and participants, providing us with a more comprehensive assessment of the intervention. The data were collected longitudinally which allowed any change in intervention delivery over the course of the trial to be detected. The completeness of data sources strengthened the robustness of our findings.

The process evaluation was conducted by the trial team during the trial. This allowed efficient data collection, but as non-independent observers this could have led to bias in evaluation. Bias was minimised by the choice of data collection methods (e.g., nurse session attendance logs, completed by nurses), 12-month pedometer use questionnaires (completed by participants), and return of patient PA diaries, which was not influenced by the researchers. Whilst data was collected from nurses and participants, the number of nurse sessions attended related more to participant responsiveness than to nurse engagement with the trial. This study was not powered to look at the effects of adherence to different aspects of the protocol on trial outcomes, which limits interpretation of these findings. Also, comparisons of those attending / not attending nurse appointments, those returning / not returning PA diaries and those using / not using pedometers were not randomised group comparisons, but within group comparisons, meaning that we can only describe associations between the process evaluation measures and trial outcomes, we cannot attribute causality. But our findings

from the process evaluation on the value of attendance at nurse sessions and use of pedometer and diary are consistent with the qualitative finding from intervention participants[13] and practice nurses,[14] which provided evidence that the pedometer, the recording of steps and PA in the diary and the nurse appointments were all important components of the trial and contributed to its success.

Comparison with other studies

Process evaluation has become an increasingly important component of complex intervention Implementation and evaluation. Studies that have examined intervention implementation fidelity or process evaluation, have used a variety of frameworks and models as a structure to complete this which makes it difficult to draw direct comparisons with this study. Two studies reported analysis of the relationship between process evaluation outcomes and main trial outcomes[8 9], but to our knowledge no trials have reported significant positive associations between process evaluation measures and main trial outcomes. A further novel feature of our study was the inclusion of perspectives from both nurse intervention delivery (no. of sessions) and participant responsiveness (use of diary and pedometer); other studies report on a single perspective only, and most commonly the person delivering the intervention[15-19]. For example Van Bruinessen et al. reported participants' perspectives and found that the intervention significantly improved perceived efficacy[8]; however, the association with outcome measures was not significant, therefore suggesting that the true effect of the intervention could not be identified. Berendsen et al.[20] evaluated both patient and practitioner perspectives, but demonstrated a much wider variation in dose delivered than we observed in PACE-UP, which makes it difficult to identify which of the intervention components were effective. They also reported problems with fidelity: health care professionals deviated from the protocol to reduce drop out from the trial, which had a positive effect on patient satisfaction[20]. Foley et al[9] examined the relationship between process evaluation and trial outcomes in a weight loss trial; the intervention was not effective and investigators identified poor adherence to the intervention protocol as the most likely reason for this. The reduction in PA that we saw between 3 and 12 months, particularly in the nurse intervention group, could be seen as a case of 'declining effect' and directs attention to the maintenance part of the RE-AIM framework[4] and the whole question of intervention sustainability.[21]

The PACE-UP intervention demonstrated that intervention dose (nurse session attendance) was associated with effectiveness of the intervention. Our finding of an association between return of a completed step-count diary and change in PA outcomes is consistent with the finding of a recent systematic review's findings, which suggested that use of a step-count diary was common to many

successful pedometer interventions[22]. We demonstrated that both intervention groups in the PACE-UP trial engaged well with the self-monitoring, using the pedometer and step-count diary. Although it is not possible to infer causality directly with the process evaluation data and the main trial outcomes, the high level of engagement with trial resources suggests that they were important influencing factors to make the PA changes observed. The associations between increased PA levels (steps and MVPA) and session attendance, step-count diary return and pedometer use emphasised that these components were active ingredients of the intervention. The MRC framework provided a useable logical and coherent structure for reporting[1]. The PACE-UP trial had a positive and significant effect on PA outcomes, but had this not been the case, the positive process evaluation with high levels of fidelity would have enabled us to have confidence that any negative trial effect would not have been due to poor trial implementation[3].

Conclusion

The PACE-UP process evaluation demonstrated that the trial was delivered as per protocol with the MRC Framework a useful vehicle for reporting the evaluation. An association between several process evaluation measures and main trial PA outcomes has been demonstrated, suggesting that these components were important in effectiveness and should be considered core components of the PACE-UP nurse and postal interventions.

List of abbreviations

BCT   behaviour change technique

CI   confidence interval

MVPA   moderate to vigorous physical activity

NHS   National Health Service

NIHR   National Institute for Health Research

PA   physical activity

PACE-UP   Pedometer And Consultation Evaluation-UP

RA   research assistant

Declarations

Ethics approval and consent to participate

Consent for publication

Not applicable

Availability of data and material

The dataset used within this study is available from the corresponding author on a reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

CF, TH, and EH conceived the idea for this paper. TH designed the PACE-UP trial and as PI has overall responsibility for the execution of the project. JI and SDW recruited general practices and advised on safety measures in the trial. EH and CF conducted the data collection for this study. EL and DC designed the analysis and EL conducted the analysis for this study. The manuscript was prepared by CF, TH and EH with substantial input from EL,

DC and CW. TH, DC, CV, SK, SI, PW, MU & J F-R conceived the idea and obtained funding for the PACE-UP trial. All of the author team reviewed and approved the manuscript prior to submission.

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Figures:

1. Title: Key functions of process evaluation and relationships amongst them[1]

   Legend: Blue boxes are the key components of a process evaluation. Investigation of these components is formed from intervention description and informs interpretation of outcomes.

Table 1: Components, data sources and measures for evaluating associations between process evaluation measures and trial PA outcome

Process Evaluation Component	Data Source	Trial Groups Evaluated	Measures
Dose	• Nurse session attendance log	Nurse intervention group	• No. of sessions attended (frequencies and percentages)
Fidelity (content and quality)	• PA diaries • Pedometer use questionnaire	Nurse and postal intervention groups	• Return of completed diaries (frequency and percentages). • Pedometer use (frequencies and percentages)

Table 2: Nurse session attendance, diary return and pedometer use in the intervention groups

	Postal N=339		Nurse N=346		Nurse + Postal N=685	
Dose: Attended all 3 nurse sessions	N/A		255	(74%)		
Diary return: Yes	268	(79%)	281	(81%)	549	(80%)
Pedometer use during 12 week intervention: Every day or most days	238	(81%)	269	(89%)	507	(74%)

Footnote:

1. 45 and 43 participants in the Postal and Nurse groups respectively didn't answer the question on pedometer use during the 12 week intervention.

Table 3: PACE-UP modelling results: relating nurse session attendance, step count diary return and pedometer use to physical activity outcomes

	Daily step count						Total weekly minutes of MVPA in ≥10 minute bouts					
	3 months			12 months			3 months			12 months		
	Effect	(95% CI)	*p*-value	Effect	(95% CI)	*p*-value	Effect	(95% CI)	*p*-value	Effect	(95% CI)	*p*-value
Nurse session attendance												
Attended all 3 nurse sessions:												
YES vs NO	1,197	(627, 1766)	<0.001	605	(74, 1137)	0.03	74	(45, 103)	<0.001	30	(3, 57)	0.03
Step count diary return												
Postal group: YES vs NO	1,458	(854, 2061)	<0.001	1,114	(538, 1689)	<0.001	64	(33, 94)	<0.001	47	(18, 75)	0.002
Nurse group: YES vs NO	873	(190, 1555)	0.01	323	(-278, 925)	0.29	50	(15, 85)	0.005	3	(-27, 33)	0.86
Nurse - Postal difference	-585	(-1498, 328)	0.21	-791	(-1624, 42)	0.06	-14	(-60, 33)	0.57	-44	(-85, -2)	0.04
Pedometer use every day or most days during 12 week intervention												
Postal group: YES vs NO	1,029	(383, 1675)	0.002	606	(22, 1190)	0.04	40	(6, 73)	0.02	26	(-2, 55)	0.07
Nurse group: Yes vs NO	337	(-525, 1198)	0.44	394	(-321, 1109)	0.28	24	(-20, 68)	0.28	10	(-25, 45)	0.58
Nurse - Postal difference	-692	(-1772, 387)	0.21	-212	(-1136, 712)	0.65	-16	(-71, 39)	0.58	-16	(-62, 29)	0.48