Effectiveness and cost-effectiveness of a very brief pedometer-based intervention: The VBI randomised control trial

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on behalf of the Very Brief Interventions Team

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VBI VERY BRIEF INTERVENTIONS
Very brief interventions to promote physical activity in primary care

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Background

Physical inactivity is the 4th leading risk factor for death worldwide[1,2]

Important modifiable risk factor for chronic diseases[3]

Estimated cost to the NHS £1.06 billion/year[4] and $53.8 billion to healthcare systems worldwide[5]

Majority of adults in England do not meet current guidelines[6]

[1] *WHO (2010) Global Recommendations on Physical Activity for Health*
[2] *Lee et al. (2012) Effect of physical inactivity on major non-communicable diseases worldwide: an analysis of burden of disease and life expectancy. Lancet.*
[3] *The Lancet Series. Physical Activity series 2012. http://www.thelancet.com/series/physical-activity*
[4] *Allender et al. (2007) The burden of physical activity-related ill health in the UK. J Epidemiol Community Health*
[5] *Ding et al. (2016) The economic burden of physical inactivity: a global analysis of major non-communicable diseases. Lancet.*
[6] *Chaudhury & Esliger (2008) Health survey for England. The Health and Social Care Information Centre, Leeds.*

Brief interventions

<30 mins

Potentially effective[7,8]

Very brief interventions (VBIs)

<5 mins

- Inexpensive
- Scalable
- Large reach
- May have substantial public health impact

[7] *NICE 2013. Physical activity: brief advice for adults in primary care. NICE public health guidance 44.*

[8] *Vijay GC et al. Are brief interventions to increase physical activity cost-effective? A systematic review. BJSM 50(7):408-17*

Aim of the VBI trial

To assess the effectiveness and cost-effectiveness of a very brief pedometer-based intervention "Step It Up"

Step It Up based on:

- Development work
- Feasibility testing
- Preliminary trial including extensive process evaluation[9,10]

[9] *Pears et al. (2015) Development and feasibility study of very brief interventions for physical activity in primary care. BMC Public Health. 15:333.*
[10] *Pears et al. (2016) A randomised controlled trial of three very brief interventions for physical activity in primary care. BMC Public Health.* ***16****:1033.*

Trial design

Primary care setting

- NHS Health Check
  - Preventative consultation
  - Adults 40-74 years

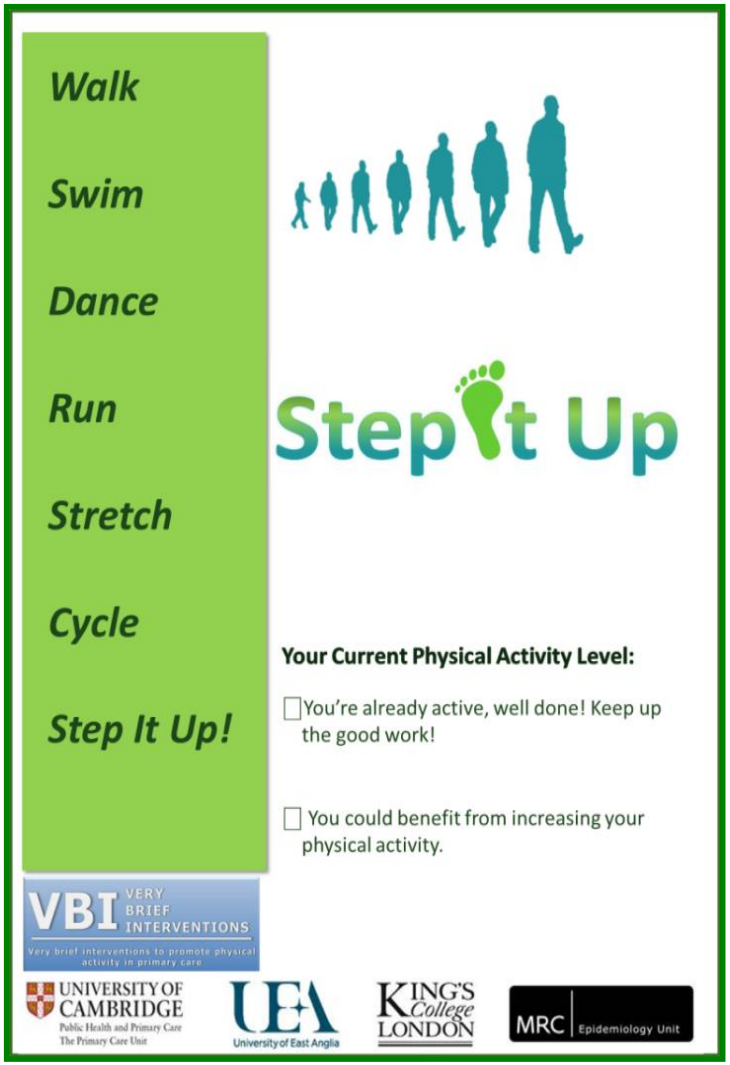
Two parallel-group RCT with 1:1 individual allocation

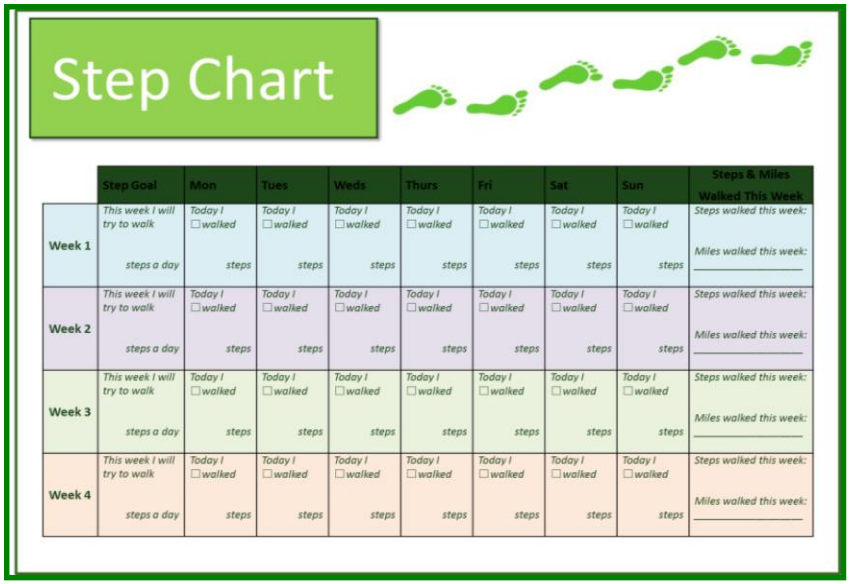
- NHS Health Check
- NHS Health Check + Step It Up

1,007 participants from 23 practices in the East of England

3 months follow up

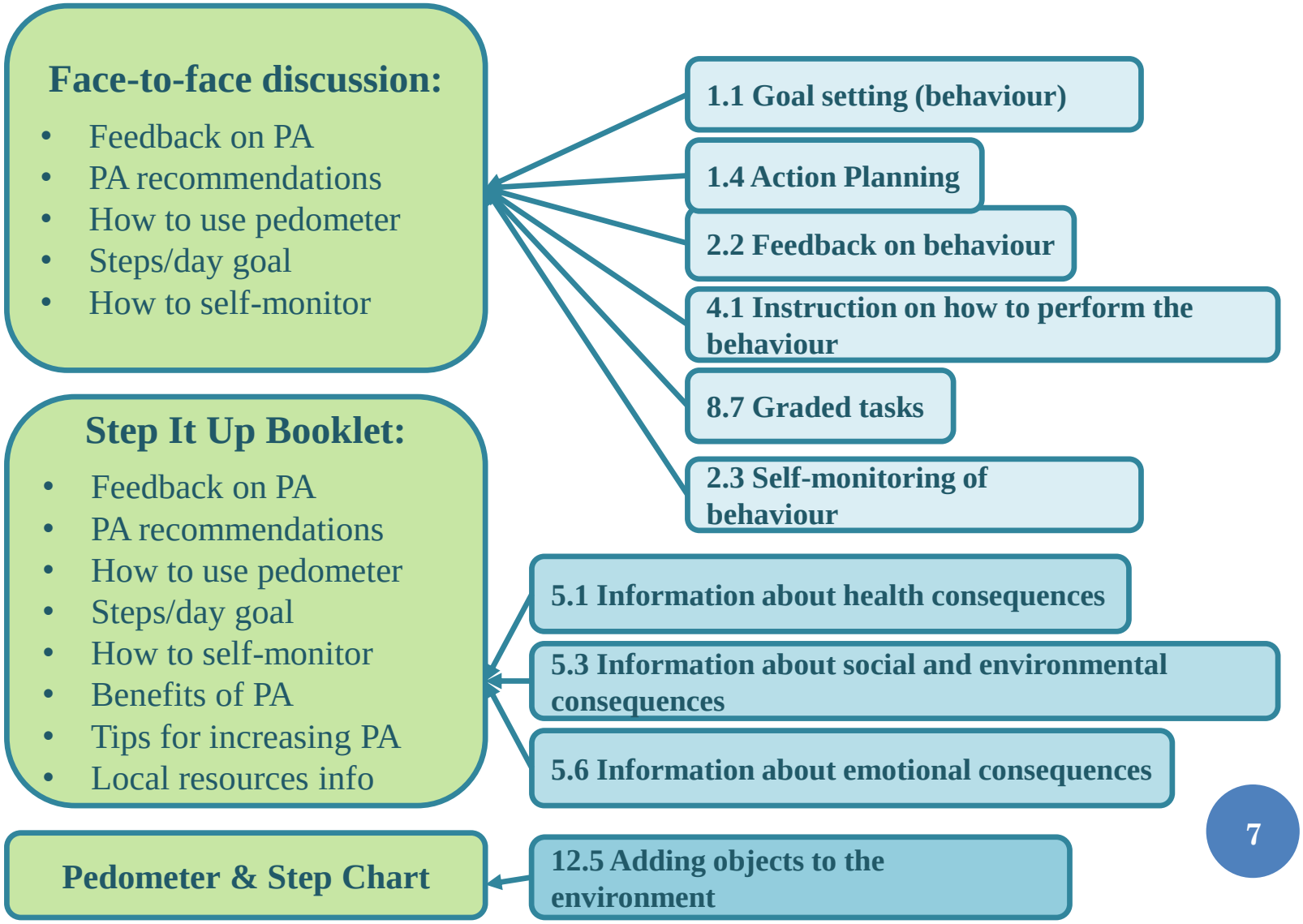
STEP IT UP

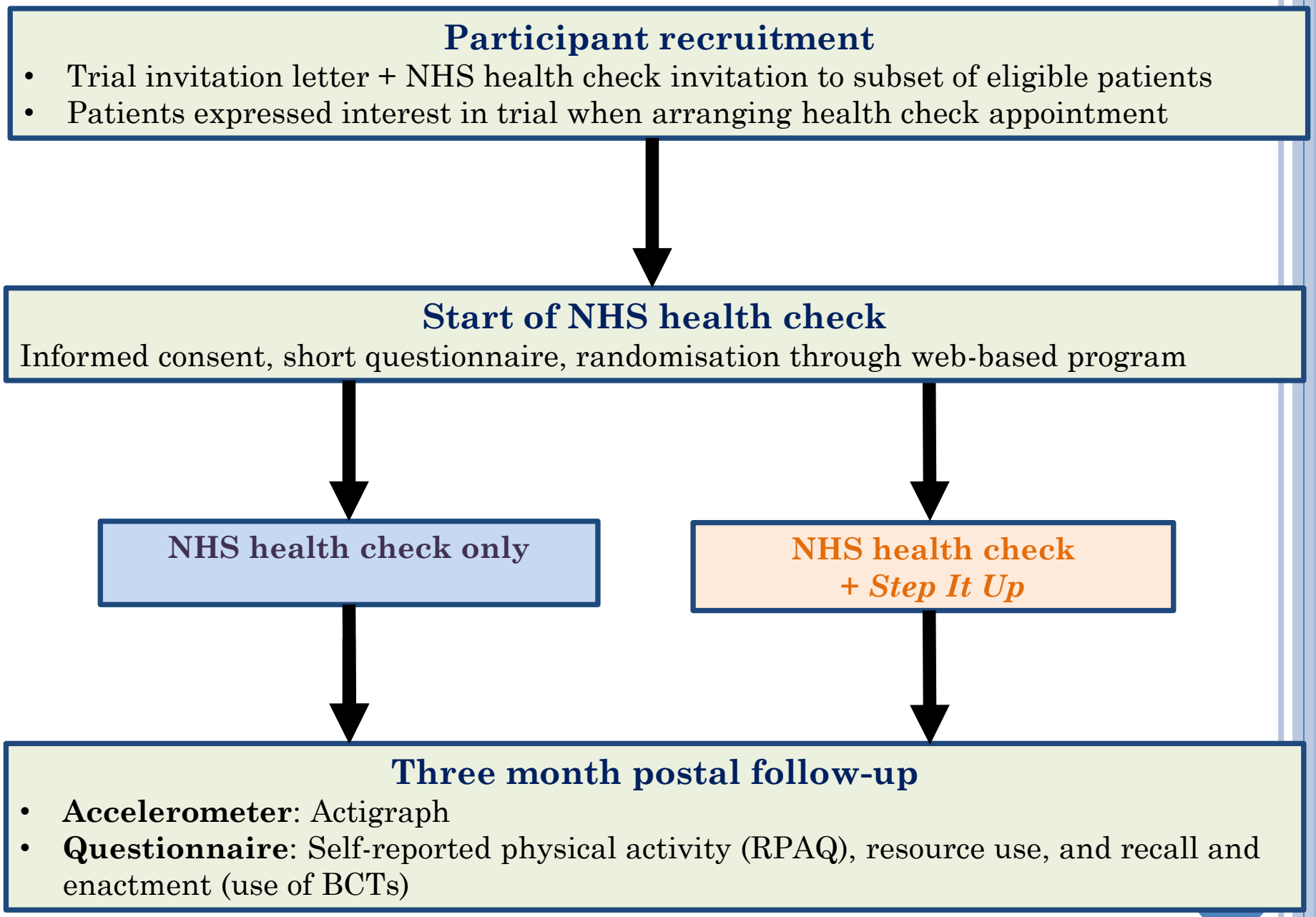




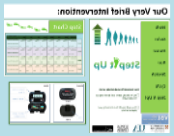
	Step Goal	Mon	Tues	Weds	Thurs	Fri	Sat	Sun	Steps & Miles Walked This Week
Week 1	This week I will try to walk steps a day	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Steps walked this week: Miles walked this week:
Week 2	This week I will try to walk steps a day	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Steps walked this week: Miles walked this week:
Week 3	This week I will try to walk steps a day	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Steps walked this week: Miles walked this week:
Week 4	This week I will try to walk steps a day	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Today I ☐walked steps	Steps walked this week: Miles walked this week:

STEP IT UP


Face-to-face discussion:
Feedback on PA
PA recommendations
How to use pedometer
Steps/day goal
How to self-monitor
Step It Up Booklet:
Feedback on PA
PA recommendations
How to use pedometer
Steps/day goal
How to self-monitor
Benefits of PA
Tips for increasing PA
Local resources info
Pedometer & Step Chart
1.1 Goal setting (behaviour)
1.4 Action Planning
2.2 Feedback on behaviour
4.1 Instruction on how to perform the behaviour
8.7 Graded tasks
2.3 Self-monitoring of behaviour
5.1 Information about health consequences
5.3 Information about social and environmental consequences
5.6 Information about emotional consequences
12.5 Adding objects to the environment


Participant recruitment
• Trial invitation letter + NHS health check invitation to subset of eligible patients
• Patients expressed interest in trial when arranging health check appointment
Start of NHS health check
Informed consent, short questionnaire, randomisation through web-based program
NHS health check only
NHS health check
+ Step It Up
Three month postal follow-up
• Accelerometer: Actigraph
• Questionnaire: Self-reported physical activity (RPAQ), resource use, and recall and enactment (use of BCTs)

CONSORT DIAGRAM

Invited	**n=6200**	
Randomised	**n=1007**	
Allocation	 **Intention to treat n=502**	  **Intention to treat n=505**
Follow-up at 3 months	**Lost to follow up (n=58)**	**Lost to follow up (n=84)**
Analysis	**n=442** Excluded from analysis (n=2)	**n=417** Excluded from analysis (n=4)

Baseline characteristics

	Control N=502	Intervention N=505
% Female	61%	63%
Age [mean (SD)]	56.5 (9.4)	55.7 (9.6)
Ethnicity % White	95% (476/502)	96% (484/505)
Occupational group		
% Manual	24% (71/295)	27% (84/314)
% Non-manual	68% (200/295)	65% (203/314)
% Other	8% (24/295)	9% (27/314)
Work Status		
% Paid work	61% (286/472)	62% (301/482)
% Unemployed/homemaker	6% (29/472)	6% (28/482)
% Full-time student	0% (0/472)	0% (1/482)
% Retired	32% (152/472)	31% (148/482)
% Other	1% (4/472)	1% (4/482)

31% reported being inactive or moderately inactive

Results: Objectively measured PA

	Control N=442 (88% response)	Intervention N=417 (83% response)	Intervention compared to Control
	Mean ++ (95% CI)	Mean ++ (95% CI)	Adjusted difference in means (95% CI)
Accelerometer counts per minute (primary outcome)	660 (641, 679)	668 (648, 689)	8.8 (-18.7, 36.3) p=0.53
Step counts per day (adjusted)	8191 (7911, 8471)	8419 (8110, 8729)	242 (-172, 656) p=0.25

Results: Self reported PA

Self-report PA measures (RPAQ)	Control		Intervention		Intervention relative to Control
	N	Mean+ (95% CI)	N	Mean+ (95% CI)	Comparison of means (95% CI)
PAEE Physical activity energy expenditure (kJ/kg/day)	440	28.0 (26.0, 30.0)	418	29.5 (27.5, 31.7)	5.4% (-4.2%, 16.0%) p=0.28
Home based PAEE (kJ/kg/day)	439	2.7 (2.5, 2.9)	418	2.9 (2.7, 3.1)	6.3% (-5.3%, 19.3%) p=0.30
Work based PAEE (kJ/kg/day)	273	11.8 (10.6, 13.2)	269	13.3 (11.8, 15.0)	9.0% (-6.5%, 27.1%) p=0.27
Leisure based PAEE (kJ/kg/day)	440	12.0 (10.7, 13.4)	416	12.0 (10.8, 13.4)	0.7% (-13.7%, 17.5%) p=0.93
Commuting PAEE (kJ/kg/day)	266	0.60 (0.50, 0.80)	257	0.60 (0.40, 0.70)	-10.0% (-34.0%, 22.6%) p=0.50
Screen/TV time (hours/day)	439	2.80 (2.60, 2.90)	418	2.80 (2.60, 2.90)	0.005 (-0.20, 0.20) p=0.96

+ Means are geometric means for skewed PAEE outcomes and compared as percentage increase of the intervention group to the control group

Strengths & limitations

Strengths

- Large pedometer based intervention
- Well-balanced sample
- 85% retention
- Objective measure of PA

Limitations

- Objective baseline measurement
- Generalisability

Conclusion

Step It Up did not lead to higher levels of physical activity at 3 months than the NHS Health Check alone

- Potential explanations:
  - Insufficient fidelity of delivery (in progress)
  - Already physically active sample[11]
  - Insufficient intensity

[11] *Harris et al. (2015) A primary care pedometer-based walking intervention with and without practice nurse support: PACE-UP cluster-randomised controlled trial. Lancet*

But…

- Step It Up
  - Very small positive effect
  - Low-cost (£18.04)

Better than doing nothing?

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