Two RCTs to increase walking in the elderly and middle-aged

PACE-lift

PACE-UP

New proof (23/11/2011)

RCT of a complex intervention by primary care nurses to increase walking in patients aged 60-74 yrs

PACE-Lift trial

Pedometer Accelerometer Consultation Evaluation - Lift

Funded by Research for Patient Benefit NIHR 250k

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Public health importance of physical activity in older people

- Prevention of disease
- Maintenance of independence
- Preventing falls
- Preventing social isolation
- Improving emotional well-being

Physical activity recommendations

All adults (and older adults) should achieve at least 30 minutes each day
on 5 or more days each week
of at least moderate intensity physical activity

Importance of regular walking

How much PA do older UK adults do?

- In HSE 2008 PA was objectively assessed using accelerometers, as well as by self-report.

- Amongst those aged ≥ 65 years: 16% of men and 12% of women self-reported achieving the recommended PA levels, but only 5% men and 0% of women achieved recommended levels using accelerometer measures.

- Most older people not walking are able to do so (Simonsick et al 2005)

How can older adults increase their PA?

Home rather than gym based programmes[1,2]

Cognitive behavioural strategies rather than health education alone[1,2]

Start low and go slow (gradually increasing to moderate intensity)[2]

Incorporate interventions into daily routine (eg walking)[2]

Monitor intensity for progression[2]

Use of activity monitors?

Systematic review found pedometers increased steps by approx 2500 per day but limited information on older people and beyond 12 weeks[3].

Recent trials of older people: Croteau et al showed increase of 1320 steps/day at 12 weeks[4], McMurdo et al showed no effect at 6 months[5]

[1]King et al Am J Prev Med 1998, [2]Cress et al J Aging Phys Act 2005
[3]Bravata at al JAMA 2007 [4]Croteau et al Res Quart Ex Sport 2007
[5]McMurdo et al JAGS 2010

PACE pilot study

PACE-Lift trial

Design:

RCT with intervention and control arms and qualitative evaluation

Participants:

300 people aged 60-74 yrs registered with 3 practices within Oxfordshire PCT, with no contraindications to increasing their PA levels

Intervention:

3 month pedometer and accelerometer based walking intervention with 4 practice nurse PA consultations.

Outcomes:

Change in average daily steps between baseline, 3m & 12 months

Change in time spent in at least moderate intensity PA weekly between baseline, 3m and 12 months

Qualitative evaluations will explore reasons for trial non-participation and the intervention's acceptability

PACE-Lift trial – sample size

Previous study that showed an increase of >1000 steps/day at 3 months.

120 participants per arm would allow a difference of 850 steps to be detected between the groups with 90% power and 1% significance, using sd of 1705 steps/day from pilot work.

However we plan to randomise households . Assuming intra-cluster correlation of 0.5 and that 30% of households recruited are couples, the design effect is 1.15 and we need to analyse 138 people (105 households) at 3m to achieve the same power. Allowing for 10% attrition at 3m we aim to randomise 150 people (120 households) into each arm giving a total of 300 people.

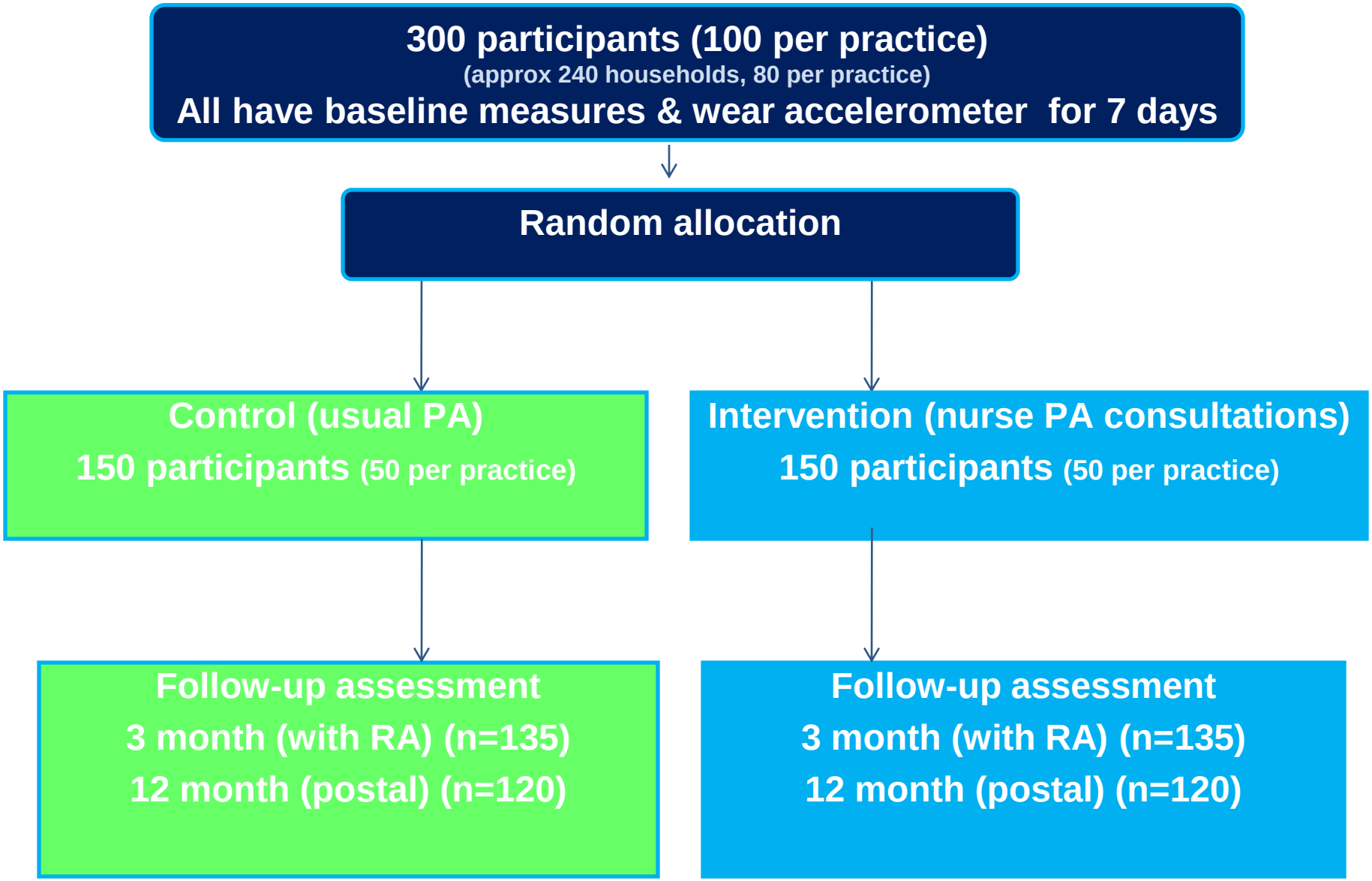
100 people from each of 3 practices will be recruited over 12 months, a target of 9 patients per month per practice.

Baseline and outcome measures

- Questionnaire measures
  - Health, pain, disability, chronic diseases, falls, depression, anxiety, quality of life, exercise self-efficacy, self-reported physical activity, socio-demographic

- Physical assessment
  - Weight, height, BMI, waist circumference, body fat Bio-impedance

- Accelerometer measures
  - 7 day baseline recording of usual physical activity
  - Average daily step-count & average time spent in at least moderate intensity PA weekly


300 participants (100 per practice)
(approx 240 households, 80 per practice)
All have baseline measures & wear accelerometer for 7 days
Random allocation
Control (usual PA)
150 participants (50 per practice)
Intervention (nurse PA consultations)
150 participants (50 per practice)
Follow-up assessment
3 month (with RA) (n=135)
12 month (postal) (n=120)
Follow-up assessment
3 month (with RA) (n=135)
12 month (postal) (n=120)

Physical activity (PA) intervention

4 PA consultations (weeks 1, 3, 7, 11)

Wear accelerometer & pedometer and keep PA diary for week before each consultation, then review results with nurse

PA plan combining health information, average daily steps, time spent at different PA intensities, goal setting, self-monitoring, boosting self-efficacy, relapse prevention etc.

Patient handbook, four sections, one for each session, based on NHS Health Trainer Handbook, adapted to focus on PA only.

Where are we now and current challenges

Currently:

Sponsorship ✓

Ethics approval ✓

R&D approval ✓

Contract between DH & Oxfordshire PCT & SGUL + others ✓

Patient handbook completed ✓

Nurse training ✓

Study started 1/4/2011 recruiting patients from 1/10/2011

Challenges:

Time and money!

Liaising with PCT and funding body

Funding channelled through PCT

Recruitment of practices (then nurses and patients)

Training nurses to download & display accelerometer data

St George's University of London

PACE-UP

New proof (23/11/2011)

RCT of a pedometer-based walking intervention with and without practice nurse support in primary care patients aged 45-74 years

Funded by HTA (NIHR) £1.1 million

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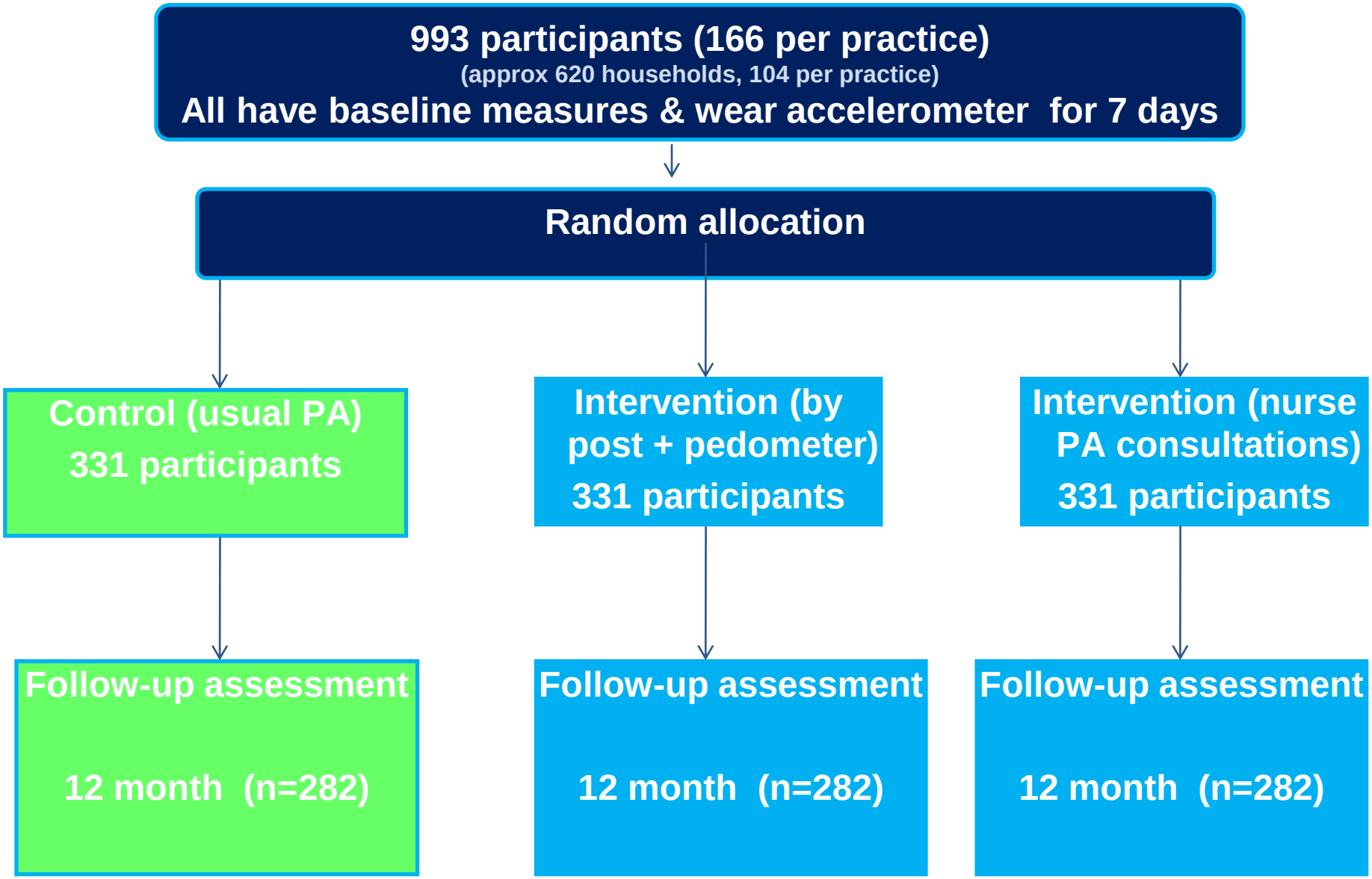
993 participants (166 per practice)
(approx 620 households, 104 per practice)
All have baseline measures & wear accelerometer for 7 days
Random allocation
Control (usual PA)
331 participants
Intervention (by post + pedometer)
331 participants
Intervention (nurse PA consultations)
331 participants
Follow-up assessment
12 month (n=282)
Follow-up assessment
12 month (n=282)
Follow-up assessment
12 month (n=282)

Key differences

- South West London
- Multi-cultural, multi-ethnic
- No accelerometry in intervention
- Problems negotiating excess treatment costs