The VBI Studies

Jo Mitchell on behalf of the Very Brief Interventions Programme Team
Physical inactivity is the fourth leading risk factor for death worldwide\textsuperscript{1,2}; in the UK, it has an estimated direct cost to the NHS of £8.2 billion\textsuperscript{3}

Need for scalable interventions that are cost-effective in primary care setting

Evidence suggests that interventions given in a primary care setting could increase physical activity\textsuperscript{4}

However, little is known about ‘very brief’ interventions (up to 5 minutes)

NHS Health Checks provides us with an ideal opportunity to deliver very brief advice to a large population

\textsuperscript{1} WHO 2010  
\textsuperscript{2} Lee \textit{et al.} The Lancet, 2012.  
\textsuperscript{4} NICE 2012
VBI Programme: Aims

- To develop and evaluate very brief interventions (VBI) to increase physical activity that could be delivered by a practice nurse or health care assistant (HCA) in an NHS Health Check (HC) or other primary care consultation.
VBI Development: Method

Sources of Evidence Informing Each of the Four Selection Criteria

**Effectiveness**
- Evidence Synthesis
- Scoping Review of BCTs
- Team Discussion
- Expert Consultation (Round 1)

**Feasibility**
- Qualitative Study
- Team Discussion
- Expert Consultation (Round 1)

**Acceptability**
- Qualitative Study
- Team Discussion
- Expert Consultation (Round 1)

**Cost**
- Cost-effectiveness research
- Team Discussion

For each VBI, experts were asked to rate their agreement with Likert items and answer open-ended questions addressing each of the four selection criteria – **effectiveness**, **feasibility**, **acceptability**, and **cost**.

VBI Piloting
VBI Development: Results

Four Short-listed VBIs

ALL Interventions Included:
- Physical Activity Assessment;
- PA recommendations;
- Face-to-face discussion;
- Written materials

VBI 1: Motivational
- Benefits of PA
- Ways of increasing PA
- Signposting to local resources, etc.

VBI 2: Action Planning
- Ways of increasing PA
- Planning Activity (What, When, Where, & With Whom)

VBI 3: Pedometer
- 10,000 steps goal
- Verbal instruction to record steps
- Pedometer

VBI 4: PA Diary
- Ways of increasing PA
- Record daily activity
- Compare activity and goals
- Review/set new goals each week
The Feasibility Study

- From this development work
  - 4 VBIs were tested in 2 GP surgeries with 68 participants

- The measures used to assess feasibility were:
  - Health Check (plus VBI) Recordings [fidelity and feasibility]
  - Participant Interviews [feasibility and acceptability]
  - Practitioner Interviews and on-going feedback [feasibility and acceptability]

- Results from this study found
  - Mean duration for each VBI was approximately 5 mins
  - The VBIs were acceptable to practitioners and patients

- 3 VBIs were selected for further evaluation in a larger trial.
## Very Brief Interventions (VBIs)

### Face-to-Face Discussion
- Feedback on current physical activity (PA)
- Physical activity recommendations

### Motivational
#### Face-to-Face Discussion
- Benefits of Increasing PA
- Importance and Confidence
- Making a Plan & Keeping a Diary

#### Motivational Booklet
- PA Recommendations
- Benefits of Increasing PA
- Importance and Confidence
- Making a Plan & Keeping a Diary
- Tips for increasing PA
- Tips for staying motivated
- Signposting

### Pedometer
#### Face-to-Face Discussion
- 10,000 steps recommendation
- How to use the pedometer
- Daily step goal and self-monitoring

#### Pedometer Booklet & Step Chart
- PA Recommendations
- 10,000 steps recommendation
- How to use the pedometer
- Daily step goal and self-monitoring
- Tips for increasing steps

### Combined
#### Face-to-Face Discussion
[Combination of Motivational and Pedometer]

#### Motivational Booklet & Step Chart
[Combination of Motivation and Pedometer]
The Pilot Study of the Shortlisted VBIs

- Randomised Controlled Trial (RCT)
- Randomisation was by weeks
- 394 participants
- 8 GP surgeries
- Between April 2013 and February 2014
- VBIs were tested against the “Usual” Health Check
Measures

- **Potential Efficacy**
  - Average accelerometer counts per day [ActiGraph GT3X+]
  - Total physical activity energy expenditure (PAEE) [validated RPAQ version 8]

- **Feasibility**
  - Intervention duration (mins, secs) [consultation audio-recordings]
  - Intervention fidelity (%) [consultation audio-recordings]

- **Acceptability**
  - Transcripts of participant interviews
  - Transcripts of practitioner interviews

- **Cost**
  - Per-participant cost, based on cost of materials and estimated cost of practitioner time
Results: Participants

- 394 participants recruited and randomised between April 2013 and Feb 2014
- Demographics show participants were comparable across arms

<table>
<thead>
<tr>
<th></th>
<th>Total Sample (n=394)</th>
<th>Motivational (n=83)</th>
<th>Pedometer (n=74)</th>
<th>Combined (n=80)</th>
<th>Usual Care (n=157)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean Age (SD), years</td>
<td>53 (9.1)</td>
<td>52.1 (8.1)</td>
<td>53.3 (8.4)</td>
<td>51.3 (8.4)</td>
<td>53.9 (10.1)</td>
</tr>
<tr>
<td>Gender % female</td>
<td>59</td>
<td>54</td>
<td>61</td>
<td>62</td>
<td>59</td>
</tr>
<tr>
<td>Ethnicity % white</td>
<td>92</td>
<td>92</td>
<td>97</td>
<td>96</td>
<td>94</td>
</tr>
<tr>
<td>Occupation % employed</td>
<td>72</td>
<td>70</td>
<td>79</td>
<td>76</td>
<td>68</td>
</tr>
</tbody>
</table>
Comparisons are presented unadjusted. Conclusions were unchanged on adjustment for age.

### Objective PA (accelerometer)

<table>
<thead>
<tr>
<th></th>
<th>Control Mean (95% CI)</th>
<th>Motivational Mean (95% CI)</th>
<th>Pedometer Mean (95% CI)</th>
<th>Combined Mean 95% (CI)</th>
<th>Motivational Relative to Control: Comparison of means (95% CI)§</th>
<th>Pedometer Relative to Control: Comparison of means (95% CI)§</th>
<th>Combined Relative to Control: Comparison of means (95% CI)§</th>
</tr>
</thead>
<tbody>
<tr>
<td>Activity (counts per minute)</td>
<td>636 (597, 674)</td>
<td>656 (600, 712)</td>
<td>659 (581, 738)</td>
<td>632 (590, 675)</td>
<td>+20.3 (-45.0, +85.7)</td>
<td>+23.5 (-51.3, +98.3)</td>
<td>-3.1 (-69.3, +63.1)</td>
</tr>
</tbody>
</table>

### Self-report PA measures (RPAQ)

| PAEE Physical activity energy expenditure (kJ/kg/day) | 32.2 (28.2, 36.9) | 39.2 (31.5, 48.9) | 32.2 (26.7, 38.8) | 33.0 (28.3, 38.5) | +21.7% (-2.9%, +52.5%) | -0.2% (-22.4%, +28.4%) | +2.4% (-18.3%, +28.3%) |

§ Comparisons are presented unadjusted. Conclusions were unchanged on adjustment for age

- Posterior probability of positive effect was estimated to be 73% for both the motivational and pedometer interventions, and 46% for the combined intervention.
# Feasibility: Duration and Fidelity

- The pedometer intervention was the shortest on average
- All interventions were delivered relatively well

<table>
<thead>
<tr>
<th></th>
<th>Motivational (n=11)</th>
<th>Pedometer (n=13)</th>
<th>Combined (n=16)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean VBI Duration</strong></td>
<td>6m 48s (1m 51s)</td>
<td>5m 00s (2m 14s)</td>
<td>9m 35s (2m 49s)</td>
</tr>
<tr>
<td><strong>Overall Fidelity (%)</strong></td>
<td>62% (18%)</td>
<td>72% (16%)</td>
<td>74% (10%)</td>
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</table>
The pedometer intervention was favoured by practitioners, due to its brevity, the ease of delivery and perceived response from participants.

All interventions were acceptable to participants.

- **Pedometer** intervention was the easiest and quickest to deliver.
- The **motivational** intervention is least likely to be effective.
- Most confident delivering the **pedometer** and the **combined** intervention.
- Patients responded best to the **pedometer** and **combined** intervention.
- Advice was a good reminder of what was already known—reinforcing/motivating.
- **Pedometer** will be interesting, to see how many steps already take on a normal day.
- Physical activity advice with **motivational** and **pedometer** intervention more generic.
Cost

- All interventions were of low cost
- Cost was higher for both the pedometer and combined intervention, due to the added cost of the pedometer

<table>
<thead>
<tr>
<th></th>
<th>Motivational</th>
<th>Pedometer</th>
<th>Combined</th>
</tr>
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<tbody>
<tr>
<td>Estimated cost of practitioner time*</td>
<td>£4.99</td>
<td>£3.67</td>
<td>£7.03</td>
</tr>
<tr>
<td>Actual cost of printed materials</td>
<td>£1.84</td>
<td>£1.42</td>
<td>£1.95</td>
</tr>
<tr>
<td>Actual cost of pedometer</td>
<td>£0</td>
<td>£12.00</td>
<td>£12.00</td>
</tr>
<tr>
<td>Total cost of VBI per participant</td>
<td>£6.83</td>
<td>£17.09</td>
<td>£20.98</td>
</tr>
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*Practitioner time valued at £0.732 per minute.
The VBI RCT Pilot Work

- Individual Randomisation is the “Gold Standard” method for RCTs but is it feasible to do during Health Checks?
  - Would it increase the risk of patients getting the wrong study procedure?
  - Would it increase the risk of bits of the VBI to be given during the usual Health Check (i.e. contaminating the control condition)?
- Having a standardised control would also be the Gold Standard but is this possible to achieve?
- Measuring change over time is the preferred method of assessing efficacy by many scientists but how feasible is that to do in real life settings?
The RCT Pilot Work

Target recruitment of 24 patients from each of 4 GP practices.

- Surgery A: Individual randomisation
- Surgery B: Randomising by weeks
- Surgery C: The “Best-bet” Intervention
- Surgery C: The feasibility of collecting baseline measurements
The RCT Pilot Work Measures

- Feasibility of Individual randomisation
  - Intervention fidelity (%) [consultation audio-recordings]

- Feasibility of collecting baseline Measurements
  - % of patients dropping out at each stage of the process

- Acceptability of study procedures
  - Participant interviews
  - Practitioner interviews
RCT Pilot Work Results: Feasibility

- It was both acceptable and feasible to randomise patients during the Health Check.
  - Intervention fidelity was good.
  - Patients did not react negatively to the decision that was made by the randomisation tool.
  - Nurses and HCAs experienced no difficulty in using the randomisation tool.
RCT Pilot Work Results: Collecting baseline measures

Baseline randomisation

Health Checks

Received Accelerometer (N=11)  64%

No Accelerometer (n=11)  73%

Completed Follow Up Measurement  67%
The VBI RCT: The Final Stage

- Sample size 1140 participants from 23 GP practices
- Patients are individually randomised during the Health Check
- The intervention we selected as the “best-bet” was the pedometer based intervention.
- 3 month follow up period
How far have we got?

- Surgeries identified: 23
- Surgeries trained: 17
- Actively recruiting: 12
How far have we got?
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Thank You!

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