Background and aim:
- We conducted a randomised controlled trial of a very brief (<5 minutes) pedometer-based intervention for physical activity ('Step It Up') targeting adults aged 40-74 years in primary care, and found no evidence of a positive effect on physical activity.
- The aim of this study was to assess fidelity of intervention delivery and examine whether this could illuminate the trial findings.

Methods

**Randomisation**
- 1007 participants from 23 primary care practices in England

**Usual Care**
- N=502
- N=2 per practice

**Step It Up**
- N=505
- N=3 per practice

**Intervention**
- Health Check Only
- Health Check + Step It Up

Audio-recordings

Sub-sample of consultations randomly selected to be audio-recorded

**RESULTS**
- 63 tapes returned by 13 out of 23 practices (Usual Care N=26, Step It Up N=37).
- Inter-rater agreement: good (only one item showed <75% agreement).

**Intervention Duration (Step It Up group):** Mean = 3m 06s (see Table 1).

**Intervention Fidelity (Step It Up group):**
- Mean Fidelity Score = 9/15 items (60%), see Table 1.
- Fidelity varied widely across practices and practitioners (data not shown).
- All interventions delivered in <1m 45s showed <53% fidelity while those delivered in >1m 45s mostly showed >60% fidelity (data not shown).
- Fidelity was <60% for 6 individual items, see Figure 1. These items included giving feedback on PA (Item 1) and items intended to promote participants’ engagement (Items 2, 6, 14 and 15).

**Intervention Contamination (Usual Care group):**
- Mean Contamination Score = 1.6/15 items (10.8%), see Table 1.
- Contamination was >30% for 3 individual items, see Figure 1.

**Table 1:** Average duration of the Step It Up intervention; and average and percentage fidelity/contamination scores for Step It Up Intervention Items (score out of 15) in both the Usual Care group and in the Step It Up group.

<table>
<thead>
<tr>
<th>Intervention Item</th>
<th>Usual Care</th>
<th>Step It Up</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Usual Care</strong></td>
<td>N=502</td>
<td>N=505</td>
</tr>
<tr>
<td><strong>N=2 per practice</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intervention Duration</strong></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
</tr>
<tr>
<td><strong>Min. - Max.</strong></td>
<td>3m 05s (1m 51s)</td>
<td>16s - 8m00s</td>
</tr>
<tr>
<td><strong>Fidelity / Contamination Score</strong></td>
<td>1.6 / 15</td>
<td>9.0 / 15</td>
</tr>
<tr>
<td><strong>(15 %)</strong></td>
<td>(10.8%)</td>
<td>(60.0%)</td>
</tr>
</tbody>
</table>

**Contamination Score**
- GIVES the patient the pedometer
- SHOWS the patient how to wear the pedometer and use it to measure steps/day.
- EMPHASIZES that any activity that elevates heart/breathing rate counts, e.g. brisk walking
- TELLS the patient the recommendations: 10,000 steps a day
- TELLS the patient the recommendations: 30mins on most days
- EXPLAINS how to calculate miles walked (2,000 steps = 1mile)
- ENCOURAGES the patient to start with a smaller goal and try to increase their goal each week
- ASKS if patient has any questions
- EXPLAINS that the rest of the booklet contains other useful tips and information.

**Contamination Score**
- <30% Contamination
- >30% Contamination
- >60% Fidelity
- <60% Fidelity

**Figure 1:** Average fidelity/contamination scores for each individual Step It Up Intervention Item in both the Usual Care group and in the Step It Up group.

Conclusions:
- Obtaining audio-recordings in a pragmatic trial in primary care was challenging, and we do not know whether the sample of tapes was representative.
- Brief physical activity advice in the control group may have diluted any intervention effect. However, contamination was minimal so this explanation is unlikely. Instead, moderate overall fidelity (60%), poor delivery of 6/15 intervention items, and wide variation in fidelity among practices/practitioners may explain the trial findings.
- Practitioner training in intervention delivery was brief (60-90 minutes out of 3hrs total training time) as training in study procedures (online randomisation, taking consent) proved time-consuming and stressful for some practitioners. Consequently, practitioners may have had limited time to master delivery of all intervention items.
- Intention duration was 2mins less than intended. This may be due to practitioners being rushed for time, lacking skills in engaging participants in the discussion, lacking confidence in delivering very brief advice, and perceptions that physical activity advice is ineffective and not valuable.

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