Community-based Prevention of Diabetes (ComPoD): a randomised, waiting list controlled trial of the voluntary sector-led Living Well, Taking Control programme

Jane Smith1, Colin Greaves1, Janice Thompson2, Matthew Jones3, Alexis Walsh4, Leon Sewell5, Jaime Keable4, Sue Turton2, Rosy Armstrong1, Sarah Coleman2, Michele Kok3, Emma Solomon6, Ruby King4, Amy Clarke4, Rod Taylor4, Charles Abraham1

1University of Exeter Medical School; 2University of Birmingham; 3University of the West of England; 4Westbank Healthy Living Centre, Devon; 5Health Exchange, Birmingham; 6University of Bristol

Background
• Type 2 diabetes is a serious, expensive and growing public health challenge.
• NICE guidance1 recommends diabetes prevention in people at high risk via intensive lifestyle interventions promoting weight loss.
• There are few robustly evaluated ‘real-world’ diabetes prevention programmes in the UK2.
• Immediate evidence on the effectiveness, cost-effectiveness and deliverability of such programmes is needed to inform the proposed UK National Diabetes Prevention Programme1.

Aim
The ComPoD trial (ISRCTN70231670) is evaluating the clinical and cost-effectiveness of a community-based diabetes prevention programme (“Living Well, Taking Control”, LWTC) already being delivered by voluntary sector providers.

Methods
Design:
• Six month randomised, waiting list controlled trial across 2 sites (Devon, Birmingham).
• Further 12-month observational follow up of intervention group participants.

Sample:
• Target of 312 adults aged up to 75 years.
• At high risk of Type 2 diabetes due to a recent blood glucose test in “pre-diabetes” range and BMI >25kg/m² (23 for certain ethnic minorities).
• Recruited via GPs and allocated to receive LWTC programme immediately (intervention) or after 6 months (waiting list control).

Outcomes:
• Changes at 6 months in objectively-measured weight (primary outcome), physical activity (via accelerometers) and blood glucose (HbA1c), and self-reported diet, health and well-being.
• 12 month follow up in the intervention group will establish maintenance of any changes.

Costs:
• Assessment of cost-effectiveness, including modelling of long-term costs and consequences4.

Process measures:
• A parallel before-after service and process evaluation of the wider LWTC programme across 4 sites will provide an indication of the likely generalisability of trial results and data on population, provider and participant characteristics influencing programme uptake, delivery, effectiveness and cost-effectiveness.

Progress & findings to date
• Recruitment to target was achieved in June 2015.
• There was a 2.3% response rate, with participants representing 10% of the target population, and a further 4% referred to LWTC outside the trial (Fig 1).
• Recruitment in Birmingham was more challenging (Fig 2).
• Key characteristics were similar across sites (Table 1).
• Initial data from LWTC show significant pre-post changes in diabetes risk factors.

Conclusions
• This is an innovative example of a robust evaluation of an existing intervention involving collaboration between multiple academic and third-sector partners.
• Initial observational data suggest potential positive effects of LWTC on diabetes risk.
• Process data and initial trial results due early 2016 will provide timely, more definitive evidence on effectiveness and implementation to feed into the proposed National Diabetes Prevention programme.

References

Table 1 Key baseline characteristics of sample

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control</th>
<th>Intervention</th>
<th>Devon</th>
<th>Combined</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>No.</td>
<td>118</td>
<td>159</td>
<td>170</td>
<td>447</td>
<td>565</td>
</tr>
<tr>
<td>Male gender: no.</td>
<td>58</td>
<td>68</td>
<td>75</td>
<td>131</td>
<td>159</td>
</tr>
<tr>
<td>%</td>
<td>43%</td>
<td>42%</td>
<td>44%</td>
<td>43%</td>
<td>42%</td>
</tr>
<tr>
<td>Age (yrs): mean</td>
<td>51.3</td>
<td>61.9</td>
<td>62.3</td>
<td>62.6</td>
<td>62.0</td>
</tr>
<tr>
<td>SD</td>
<td>13.05</td>
<td>10.97</td>
<td>10.8</td>
<td>11.0</td>
<td>10.9</td>
</tr>
<tr>
<td>Range</td>
<td>25 - 75</td>
<td>29-75</td>
<td>29-75</td>
<td>29-75</td>
<td>29-75</td>
</tr>
<tr>
<td>Weight (kg): mean</td>
<td>87.9</td>
<td>96.0</td>
<td>97.9</td>
<td>94.7</td>
<td>94.3</td>
</tr>
<tr>
<td>SD</td>
<td>17.0</td>
<td>13.1</td>
<td>13.0</td>
<td>14.5</td>
<td>14.0</td>
</tr>
<tr>
<td>Range</td>
<td>55.7 - 158.7</td>
<td>59-142</td>
<td>58-128.4</td>
<td>54.2 -158.7</td>
<td>58-142.4</td>
</tr>
<tr>
<td>BMI (kg/m²): mean</td>
<td>31.1</td>
<td>32.0</td>
<td>32.1</td>
<td>31.8</td>
<td>31.4</td>
</tr>
<tr>
<td>SD</td>
<td>4.9</td>
<td>4.9</td>
<td>4.9</td>
<td>4.9</td>
<td>4.9</td>
</tr>
<tr>
<td>Range</td>
<td>24.3 - 44.8</td>
<td>24.2 - 44.5</td>
<td>24.5 - 43.8</td>
<td>24.2 - 44.3</td>
<td>24.2 - 44.3</td>
</tr>
</tbody>
</table>

Table 1 Key baseline characteristics of sample