The Community-based Prevention of Diabetes (ComPoD) trial and service evaluation of the Living Well, Taking Control programme

Jane R Smith¹, Colin Greaves¹, Matthew Jones², Michele Kok², Janice L Thompson³, Rosy Armstrong¹, Sarah Coleman³, Emma Solomon-Moore⁴, Alexis Walsh⁵, Leon Sewell⁶, Jaine Keable⁵, Sue Turton⁶, Rod Taylor¹, Charles Abraham¹

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

- Type 2 diabetes is a serious, expensive & growing public health challenge (~10% of NHS budget)
- NICE guidance recommends diabetes prevention in people at high risk (e.g. with “pre-diabetes”) via intensive lifestyle interventions for weight loss
- One-to-one US & Finnish diabetes prevention programmes reduced risk by ~60%
- BUT, limited evidence on ‘real-world’ diabetes prevention programmes in the UK
Living Well, Taking Control

• Big Lottery-funded voluntary sector-led, with structure, content, delivery as per NICE guidance

• Initial 4-6 2-hour weekly group sessions
  – covering diabetes risk, diet, PA, well-being
  – led by trained lifestyle coaches in local venues
  – adapted to local participants’ needs…

Westbank group, Devon

Health Exchange group, Birmingham
Living Well, Taking Control (cont)

• Followed by 3-monthly individual support contacts, attendance at 5+ additional chosen classes or activities up to 12 months…
“Pre-diabetes” participants

• Aged 18-74 years
• Considered on basis of test in last year at high risk for type 2 diabetes according to NICE criteria:
  – Fasting Plasma Glucose 6.1-6.9 mmol/l, or
  – HbA1c 42-47 mmol/mol
• Resident in eligible Devon/Birmingham postcodes
• BMI ≥25 kg/m² (≥23 for certain ethnic minority groups) and <45 kg/m² (for trial)
UWE evaluation of LWTC

Pre-post outcome evaluation
• Changes over time in provider measured and self-reported outcomes

Process evaluation
• Implementation, interpretation, service integration
• Uptake, attendance, retention, generalisability
• Fidelity of delivery (see Kok et al poster)
• Impact of “dose”, provider, participant characteristics
• Mechanisms of change (motivation, behaviours)

Social return on investment
Evaluation measures

- Demographic, socio-economic, clinical characteristics
- Weight assessed as part of programme
- Self-reported physical activity (NZPAQ)
- Dietary behaviour (Fat & Fibre Questionnaire)
- Health status (EuroQol EQ5D)
- Mental health (CES-D7)
- Psychological well-being (Warwick-Edinburgh MWS)
- Motivation re: PA & diet (importance, confidence)
- Sub-sample: objective PA (accelerometers), HbA1c
ComPoD trial  www.isrctn.com/ISRCTN70221670

Aim:
To evaluate the clinical and cost-effectiveness of the existing community-based diabetes prevention programme (Living Well, Taking Control) being delivered by voluntary sector providers

Design:
• 6m randomised, waiting list controlled trial across 2 sites (Devon, Birmingham)
• 12m observational follow up of intervention group
• Will link to process evaluation data
Trial outcomes & analyses

• Changes at 6m, intervention maintenance at 12m in:
  – objectively-measured **weight** (primary outcome)
  – **physical activity** (via accelerometers)
  – **blood glucose** (HbA1c via point of care testing)
  – self-reported **diet, health and well-being**

• **Cost-effectiveness**, including modelling long-term costs and consequences (Sheffield SPHR model)

• Use of wider pre-post evaluation data to explore **moderators** (e.g. participant characteristics) and **mediators** of effectiveness, **generalisability** of findings
3033 pre-diabetes patients mailed from 17 GP practices

- 711 (23%) responded
- 574 (19%) received recruitment call
- 352 (12%) received baseline visit

314 participants (10%) completed baseline measures & randomised

157 allocated to intervention
157 to waiting list control

LWTC: 4-6 weekly group sessions, 3m & 6m contacts

- 141 (90%) completed 6m follow up (+6 SR weight)
- LWTC: 5+ additional classes, 9m & 12m contacts
- 25 completed 12m follow up to end Feb

144 (92%) completed 6m follow up (+2 SR)

LWTC programme

- 11 withdrawals
- 10 lost to follow up

* Birmingham site only

- 82 wanted prog. only
- 35 contact failed
- 20 replied too late
- 70 declined involvement
- 26 wanted prog. only
- 77 ineligible
- 39 no suitable prog times*
- 10 no interpreter*
- 12 declined involvement
- 15 wanted prog. only
- 12 ineligible

* Birmingham site only
## Trial baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
<th>Exeter</th>
<th>Birmingham</th>
<th>Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=157</td>
<td>n=157</td>
<td>n=170</td>
<td>n=144*</td>
<td>n=314</td>
</tr>
<tr>
<td>Male gender No.</td>
<td>68</td>
<td>68</td>
<td>75</td>
<td>61</td>
<td>136</td>
</tr>
<tr>
<td>%</td>
<td>43%</td>
<td>43%</td>
<td>44%</td>
<td>42%</td>
<td>43%</td>
</tr>
<tr>
<td>Age (yrs) Mean</td>
<td>61.32</td>
<td>61.42</td>
<td>63.32</td>
<td>59.07</td>
<td>61.0</td>
</tr>
<tr>
<td>SD</td>
<td>10.35</td>
<td>8.97</td>
<td>9.03</td>
<td>10.37</td>
<td>9.88</td>
</tr>
<tr>
<td>Range</td>
<td>29 - 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>86.8</td>
<td>87.7</td>
<td>87.9</td>
<td>86.5</td>
<td>87.3</td>
</tr>
<tr>
<td>SD</td>
<td>17.0</td>
<td>13.1</td>
<td>13.0</td>
<td>17.4</td>
<td>15.2</td>
</tr>
<tr>
<td>Range</td>
<td>55.7 - 126.7</td>
<td>56.8 - 154.2</td>
<td>56.8 - 123.8</td>
<td>55.7 - 154.2</td>
<td>55.7 - 154.2</td>
</tr>
<tr>
<td>BMI (kg/m²) Mean</td>
<td>31.7</td>
<td>32.0</td>
<td>31.6</td>
<td>32.1</td>
<td>31.8</td>
</tr>
<tr>
<td>SD</td>
<td>5.1</td>
<td>4.0</td>
<td>4.0</td>
<td>5.1</td>
<td>4.6</td>
</tr>
<tr>
<td>Range</td>
<td>24.3 - 44.8</td>
<td>24.2 - 44.6</td>
<td>25.0 - 43.9</td>
<td>24.2 - 44.8</td>
<td>24.2 - 44.8</td>
</tr>
</tbody>
</table>

*Nearly 50% estimated to be from ethnic minority*
Initial pre-post evaluation findings

- 592 participants with pre-diabetes entered LWTC across 2 sites up to April 2015
- Providers collected 6m follow up data on 237 overweight participants (40%) to Oct 2015
- Significant pre-post changes in diabetes risk factors:
  - 1.84kg weight loss (p<0.001)
  - 1.52mmol reduction in HbA1c (p<0.01)
  - increase in % doing 150mins/week PA (p<0.05)
  - increased fat & fibre intake (p<0.001)
- Significant improvements in depression (p<0.001)
- Further analyses ongoing
Conclusion

- Innovative example of robust evaluation of an existing intervention involving collaboration between multiple academic & third-sector partners
- Initial observational data suggest potential positive changes in diabetes risk factors alongside LWTC
- Process data and trial results due shortly will provide timely, more definitive evidence on effectiveness and implementation to feed into National Diabetes Prevention Programme
Acknowledgements

The LWTC programme and evaluation were funded by the Big Lottery

ComPoD is funded by the NIHR School for Public Health Research Public Health Practice Evaluation Scheme(\url{http://sphr.nihr.ac.uk/})

The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health

National Institute for Health Research

School for Public Health Research
Request for help!

Do you have expertise in the design or delivery of group-based interventions for diet, physical activity, weight loss (or potentially other behaviours)?

We are seeking expert advisors and examples of intervention manuals for NIHR/MRC EME funded study which commenced Jan 2016:

“Mechanisms of Action in Group Interventions”
http://www.nets.nihr.ac.uk/projects/eme/1420203

For more information/to express interest contact:
Aleksandra Borek (a.borek@exeter.ac.uk)
or Jane Smith (jane.smith@exeter.ac.uk)