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

Jane Smith¹, Colin Greaves¹, Janice L Thompson², Matthew Jones³, Rosy Armstrong¹, Sarah Coleman², Emma Solomon-Moore⁴, Michele Kok³, Alexis Walsh⁵, Leon Sewell⁶, Jaine Keable⁵, Sue Turton⁶, Ruby King⁵, Amy Clarke⁵, Rod Taylor¹, Charles Abraham¹

¹University of Exeter Medical School; ²University of Birmingham; ³University of the West of England; 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, few robustly evaluated ‘real-world’ diabetes prevention programmes in the UK
ComPoD trial  www.isrctn.com/ISRCTN70221670

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

Design:
• 6m randomised, waiting list controlled trial across 2 of 4 delivery sites (Devon, Birmingham)
• 12m observational follow up of intervention group
• Wider before-after service & process evaluation
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
  – excluding those in diabetes range at baseline

• Resident in eligible Devon or Birmingham postcodes

• BMI ≥25 kg/m² (≥23 for certain ethnic minority groups) and less than ≤45 kg/m²
Outcomes

• 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)

• Wider before-after data on generalisability, process measures e.g. population, provider, participant characteristics; prog. uptake, delivery
Living Well, Taking Control

• Big Lottery-funded with structure, content, and delivery adherent with 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…
3033 pre-diabetes patients mailed from 17 GP practices

711 (23%) responded

574 received recruitment call

352 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

LWTC: Individual contact at 3m & 6m

192 completed 6m follow up up to 30/11 (ongoing to 1/16)

LWTC: 5+ additional classes/activities

LWTC: Individual contact at 9m & 12m

12m follow up measures (from 1/16)

• 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
• 11 ineligible

*Birmingham site only

• 11 withdrawals to date
• 7 lost to follow up to date
## Preliminary baseline characteristics

<table>
<thead>
<tr>
<th></th>
<th>Control (n=157)</th>
<th>Intervention (n=157)</th>
<th>Exeter (n=170)</th>
<th>Birmingham (n=144*)</th>
<th>Combined (n=314)</th>
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<tbody>
<tr>
<td><strong>Male gender</strong></td>
<td></td>
<td></td>
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<tr>
<td>No.</td>
<td>68</td>
<td>68</td>
<td>75</td>
<td>61</td>
<td>136</td>
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<tr>
<td>%</td>
<td>43%</td>
<td>43%</td>
<td>44%</td>
<td>42%</td>
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<tr>
<td><strong>Age (yrs)</strong></td>
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<tr>
<td>Mean</td>
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<tr>
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<td>9.03</td>
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<tr>
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<td>29 - 75</td>
<td>29 - 75</td>
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<tr>
<td><strong>Weight (kg)</strong></td>
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<tr>
<td>Mean</td>
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<td>56.8 - 123.8</td>
<td>55.7 - 154.2</td>
<td>55.7 - 154.2</td>
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<tr>
<td><strong>BMI (kg/m²)</strong></td>
<td></td>
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<tr>
<td>Mean</td>
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<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 data

• 722 participants with pre-diabetes entered LWTC across 2 sites up to July 2015
• 6m follow up data collected by providers on 191 overweight participants to July 2015
• Significant pre-post changes in diabetes risk factors:
  – 1.77kg weight loss (p<0.01)
  – 1.85mmol reduction in HbA1c (p<0.01)
  – dietary behaviours for fat & fibre intake (p<0.001)
• Significant improvements in depressive symptoms (p<0.001)
• Further data collection and 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 effects of LWTC on diabetes risk

• Process data and trial results due early 2016 will provide timely, more definitive evidence on effectiveness and implementation to feed into proposed National Diabetes Prevention Programme
Acknowledgements

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School for Public Health Research

National Institute for 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 commencing Jan 2016:

“Mechanisms of Action in Group-based Interventions”

For more information/to express interest contact:

Aleksandra Borek (a.borek@exeter.ac.uk)  
or Jane Smith (jane.smith@exeter.ac.uk)