

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

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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 Programme³.

Aim

The ComPoD trial (ISRCTN70221670) 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.

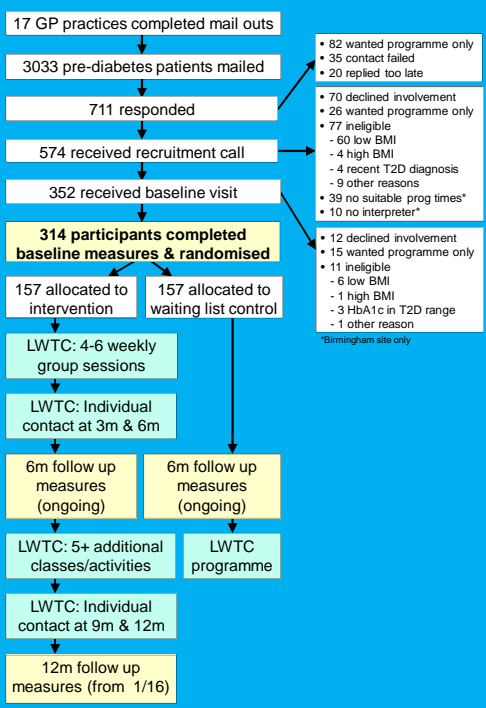


Fig 1 Study overview and participant flow

Living Well, Taking Control

- Big Lottery-funded, with structure, content and delivery designed to be adherent with NICE guidance for diabetes prevention programmes¹.
- Initial 4-6 2-hour group sessions held weekly in local venues, led by trained lifestyle coaches, and adapted to local participants' needs...



- Followed by 3-monthly individual support contacts and attendance at 5+ additional chosen classes or activities up to 12 months, such as...



Progress & findings to date

- Recruitment to target was achieved in June 2015.
- There was a 23% response rate, with participants representing 10% of the target population, and a further 4% referred to LWTC outside the trial (Fig 1).

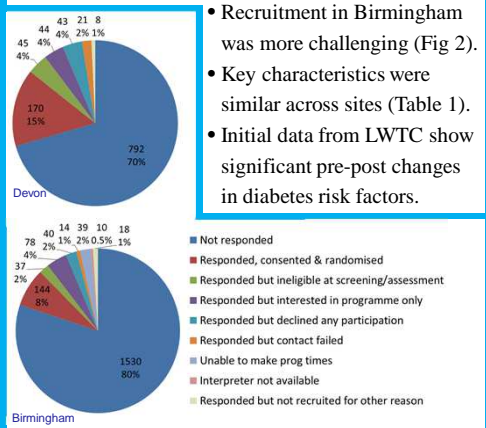


Fig 2 Response & recruitment rates at trial sites

| | Control n=157 | Intervention n=157 | Devon n=170 | Birmingham n=144 | Combined n=314 |
|-------------------------------------|------------------|-----------------------|----------------|---------------------|-------------------|
| Male gender: no. | 68 | 68 | 75 | 61 | 136 |
| % | 43% | 43% | 44% | 42% | 43% |
| Age (yrs): mean | 61.3 | 61.4 | 63.3 | 59.1 | 61 |
| SD | 10.35 | 8.97 | 9.03 | 10.37 | 9.88 |
| range | 29 - 75 | 29 - 75 | 29 - 75 | 29 - 75 | 29 - 75 |
| Weight (kg): mean | 86.8 | 87.7 | 87.9 | 86.5 | 87.3 |
| SD | 17.0 | 13.1 | 13.0 | 17.4 | 15.2 |
| range | 55.7 - 126.7 | 56.8 - 154.2 | 56.8 - 123.8 | 55.7 - 154.2 | 55.7 - 154.2 |
| BMI (kg/m²): mean | 31.7 | 32.0 | 31.6 | 32.1 | 31.8 |
| SD | 5.1 | 4.0 | 4.0 | 5.1 | 4.6 |
| range | 24.3 - 44.8 | 24.2 - 44.6 | 25.0 - 43.9 | 24.2 - 44.8 | 24.2 - 44.8 |

Table 1 Key baseline characteristics of sample

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

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