The 10 Top Tips (10TT) Trial: A randomised controlled trial of habit-based advice for weight control in general practice

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Healthy Weight, Healthy Lives identified Primary Care as the ‘first port of call’ for advice about weight control

Advice in the Primary Care setting needs to be:

• Simple to deliver
• Easy for patients to understand
• Help to establish permanent behaviour change
Habit-based intervention

- Habits are (relatively) automatically triggered actions
- Formed through repetition in a consistent context
  = ↑ automaticity
- Can be used to help individuals ‘learn’ healthy lifestyle behaviours
- Require less engagement or motivation
- Less time-consuming to explain
- Promotes long-term maintenance
Ten Top Tips

1. Keep to your meal routine (helps develop habits)
2. Focus on your food (helps to avoid slips)
3. Look at the labels (helps lower calorie choices)
4. Go reduced fat (-200 kcal)
5. Walk off the weight (-100 to 200 kcal)
6. Pack a healthy snack (-100 kcal)
7. Caution with your portions (-100 kcal)
8. Up on your feet (-100 kcal)
9. Think about your drinks (-150 kcal)
10. Don’t forget your 5 a day (-50 Kcal)

Total calorie deficit = 800-900 kcal

No further clinical contact
Design

A two-arm, individually-randomised, controlled trial in obese adults in primary care, comparing weight loss in patients receiving a simple weight control intervention based on habit formation theory (10TT) vs. ‘usual care’

Primary Outcome

Change in body weight over 3 months
Participant flow chart

Number of letters sent (n=3092, from 14 practices)

- Didn’t respond (n=1826)

Number of letters returned (n=1266)

- Declined participation (n=581)

Number agreed to participate (n=685)

- Not eligible (n=31)
  - BMI < 30: 23
  - Didn’t want to participate: 1
  - Gastric band: 1
  - Unable to fill questionnaires: 1

Number assessed (n=568)

Randomised (n=537)

- Attrition(n=71)
  - Withdrawn: 18
  - Unable to contact: 6
  - Nurse error: 4
  - Did not attend appointment
    - Personal reasons: 2
    - Illness: 1
    - No reason given: 25
    - Early/late appointment: 15

Allocated to control (n=270)

Allocated to intervention (n=267)

3 months follow-up (n=199)

72%

3 months follow-up (n=190)

Attrition(n=77)

- Withdrawn: 30
- Unable to contact: 5
- Nurse error: 3
- Did not attend appointment
  - Personal reasons: 1
  - Illness: 1
  - No reason given: 25
  - Early/late appointment: 12
Participant flow chart

6 month follow-up (n=174)

12 month follow-up (n=165)

18 month follow-up (n=145)

24 month follow-up (n=158)

6 month follow-up (n=166)

12 month follow-up (n=153)

18 month follow-up (n=146)

24 month follow-up (n=155)
## Baseline Characteristics: Socio-demographics

<table>
<thead>
<tr>
<th></th>
<th>Control</th>
<th>Intervention</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n=270)</td>
<td>(n=267)</td>
<td>(n=537)</td>
</tr>
<tr>
<td><strong>Age, years (Median, IQR)</strong></td>
<td>60.0</td>
<td>59.1</td>
<td>59.4</td>
</tr>
<tr>
<td></td>
<td>48.9-67.1</td>
<td>48.1-66.1</td>
<td>48.7-66.8</td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>95</td>
<td>89</td>
<td>184</td>
</tr>
<tr>
<td></td>
<td>35.2%</td>
<td>33.3%</td>
<td>34.3%</td>
</tr>
<tr>
<td>Female</td>
<td>175</td>
<td>178</td>
<td>353</td>
</tr>
<tr>
<td></td>
<td>64.8%</td>
<td>66.7%</td>
<td>65.7%</td>
</tr>
<tr>
<td><strong>Ethnic origin (n=534)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>255</td>
<td>252</td>
<td>507</td>
</tr>
<tr>
<td></td>
<td>95.2%</td>
<td>94.7%</td>
<td>94.9%</td>
</tr>
<tr>
<td>Non-white</td>
<td>13</td>
<td>14</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>4.9%</td>
<td>5.3%</td>
<td>5.1%</td>
</tr>
<tr>
<td><strong>Deprivation (IMD) quintiles (n=526)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 - Most deprived</td>
<td>18</td>
<td>11</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>6.7%</td>
<td>4.3%</td>
<td>5.5%</td>
</tr>
<tr>
<td>2</td>
<td>54</td>
<td>45</td>
<td>99</td>
</tr>
<tr>
<td></td>
<td>20.2%</td>
<td>17.4%</td>
<td>18.8%</td>
</tr>
<tr>
<td>3</td>
<td>77</td>
<td>83</td>
<td>160</td>
</tr>
<tr>
<td></td>
<td>28.8%</td>
<td>32.1%</td>
<td>30.4%</td>
</tr>
<tr>
<td>4</td>
<td>66</td>
<td>49</td>
<td>115</td>
</tr>
<tr>
<td></td>
<td>24.7%</td>
<td>18.9%</td>
<td>21.9%</td>
</tr>
<tr>
<td>5 – Least deprived</td>
<td>52</td>
<td>71</td>
<td>123</td>
</tr>
<tr>
<td></td>
<td>19.5%</td>
<td>27.4%</td>
<td>23.4%</td>
</tr>
</tbody>
</table>
A brief intervention for weight control based on habit-formation theory delivered through primary care: results from a randomised controlled trial

RJ Beeken¹, B Leurent², V Vickerstaff³, R Wilson¹, H Croker¹, S Morris¹, RZ Omar³, I Nazareth³ and J Wardle³

- 10TT reduced weight significantly more than usual care at 3 months by an adjusted average of 0.87kg (p=0.004)

- 16% achieved clinically significant weight loss (≥5%)
Missing data

- Adjusting for predictors of missingness

<table>
<thead>
<tr>
<th>Model</th>
<th>Difference</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adjusted for predictors of missingness</td>
<td>-0.94</td>
<td>[-1.55, -0.33]</td>
<td>0.003</td>
</tr>
</tbody>
</table>

- Multiple imputation of the missing weight at 3 months (M imputation = 100)

<table>
<thead>
<tr>
<th>Model</th>
<th>Difference</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MI</td>
<td>-1.03</td>
<td>[-1.77, -0.30]</td>
<td>0.006</td>
</tr>
</tbody>
</table>

- Baseline observation carried forward

<table>
<thead>
<tr>
<th>Model</th>
<th>Difference</th>
<th>95% CI</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOCF imputation</td>
<td>-0.58</td>
<td>[-1.02, -0.14]</td>
<td>0.010</td>
</tr>
</tbody>
</table>

- MNAR analysis demonstrated a significant difference in most scenarios
## Secondary outcomes:
### Clinical outcomes at 3 months

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control</th>
<th>Intervention</th>
<th>Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (SD)</td>
<td>Mean (SD)</td>
<td>N</td>
</tr>
<tr>
<td>Change in systolic blood</td>
<td>-0.97 (16.15)</td>
<td>-3.59 (15.9)</td>
<td>368</td>
</tr>
<tr>
<td>pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in diastolic blood</td>
<td>-2.70 (9.84)</td>
<td>-2.61 (10.5)</td>
<td>368</td>
</tr>
<tr>
<td>pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in total cholesterol</td>
<td>-0.21 (0.80)</td>
<td>-0.12 (0.74)</td>
<td>331</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in LDL cholesterol</td>
<td>-0.14 (0.62)</td>
<td>-0.07 (0.53)</td>
<td>169</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Change in glucose level</td>
<td>0.06 (2.85)</td>
<td>0.00 (1.79)</td>
<td>330</td>
</tr>
</tbody>
</table>
Secondary outcomes: Automaticity of targeted behaviours

![Bar chart showing mean automaticity change for Usual Care (n=85) and 10TT (n=78).]
Mediation analyses

- **Group condition**
  - $\beta = -.12, p = .014$

- **Self-regulation changes**
  - Total effect: $\beta = .117, p = .018$
  - Direct effect: $\beta = -.037, p = .430$
  - $\beta = -.462, p < .001$

- **Automaticity changes**
  - $\beta = -.137, p = .007$

- **Weight changes**
  - $\beta = -.262, p < .001$

Sobel test: Self-regulation: $z = 2.42, p = .01$; Automaticity: $z = 2.39, p = .01$
At 24 months, the patients who were given 10TT had maintained their weight loss from 3 months, with a mean weight loss of 2·15kg (SD=5·75) at the end of the trial.

27% achieved clinically significant weight loss (≥5%)
Conclusions

- The 10TT leaflet delivered through primary care is more effective than usual care in the short-term and a low-intensity option over the longer term that’s as cost effective as usual care.

- It is the first habit-based intervention to be used in a health service setting by health care professionals.

- The first RCT to demonstrate the effectiveness of a leaflet for weight loss.

- The intervention supports patients to develop habits and these changes appear to be an important mechanism behind the observed weight loss.
Limitations

- Opt in
- Limited impact on clinical outcomes (only measured at 3 months)
- Only powered for primary outcome
- Self-report measure of automaticity
- Lack of clear data on the uptake of the various usual care strategies post-referral
Thank you

- Jane Wardle (PI)
- Co-investigators
  - Helen Croker, Stephen Morris, Irwin Nazareth
- Statisticians/Health economists
  - Baptiste Leurent, Rumana Omar, Victoria Vickerstaff, Nishma Patel
- Study Team
  - Rose Wilson, Laura Fildes
- Nathalie Kliemann (PhD student)
- The National Prevention Research Initiative (NPRI) Funding Partners
- Participating practices and their nurses, GPs, practice managers, health professionals and patients
### Missing Not at Random

<table>
<thead>
<tr>
<th>MNAR delta control group (kg)</th>
<th>0</th>
<th>1.02</th>
<th>2.03</th>
<th>3.05</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-0.88 [-1.50 to -0.27]</td>
<td>-0.58 [-1.19 to 0.03]</td>
<td>-0.28 [-0.9 to 0.34]</td>
<td>0.02 [-0.61 to 0.66]</td>
</tr>
<tr>
<td>1.02</td>
<td>-1.17 [-1.78 to -0.55]</td>
<td>-0.86 [-1.48 to -0.25]</td>
<td>-0.56 [-1.19 to 0.06]</td>
<td>-0.26 [-0.89 to 0.38]</td>
</tr>
<tr>
<td>2.03</td>
<td>-1.45 [-2.07 to -0.82]</td>
<td>-1.14 [-1.77 to -0.52]</td>
<td>-0.84 [-1.47 to -0.21]</td>
<td>-0.54 [-1.18 to 0.10]</td>
</tr>
<tr>
<td>3.05</td>
<td>-1.73 [-2.36 to -1.1]</td>
<td>-1.43 [-2.06 to -0.79]</td>
<td>-1.13 [-1.77 to -0.48]</td>
<td>-0.82 [-1.47 to -0.17]</td>
</tr>
</tbody>
</table>