Weight Loss Maintenance in Adults: the WILMA trial

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Background

- Few RCTs specifically exploring weight loss maintenance (WLM)
- Approx 1/3 of weight lost during intervention regained in next year
- WLM interventions associated with less weight gain compared to no contact but small differences between intervention & control
- Reviews have identified issues important for maintenance including:
  - physical activity; low calorie/low fat diet; self monitoring; tailoring; internal motivation and self efficacy.

These are central to the intervention being evaluated in this trial.
Design

Design:
- 3 arm individually randomised feasibility trial (intensive, less intensive and control)

Intervention:
- Intensive or less intensive groups will receive a 12 month individually tailored intervention

Population:
- 170 obese adults aged 18-70 (current or previous BMI 30+) who have lost at least 5% body weight (independently verified)
- 4 HB’s in South Wales & England recruited from exercise referral schemes, slimming clubs, GP surgeries and advertising

Follow-up:
- 6 months during the intervention, end of intervention (1yr post-randomisation)
Intervention

Based on 2 key elements: Motivational Interviewing and self monitoring

Intensive Intervention Group:
• 6 one-to-one MI sessions
• 9 telephone MI sessions

Less Intensive Intervention Group:
• 2 one-to-one MI sessions
• 2 telephone MI sessions

Control:
• Leaflet advising on healthy eating & exercise for weight maintenance
Study Objectives

- To assess the feasibility, acceptability, compliance and delivery of a 12 month multi-component intervention based on MI, as well as recruitment and retention.

- To give an indication of effect sizes for a larger trial we evaluated the impact of the intensive and less intensive intervention on participants' BMI one year from randomisation.

- We also assessed the impact of the intervention on a number of secondary outcomes including physical activity, diet, alcohol, smoking status, health related quality of life, binge eating, psychological wellbeing and other resource usage.

- A cost effectiveness evaluation was also undertaken.
Process Evaluation

- Comprehensive process evaluation model looking at 8 elements: context, reach, fidelity, exposure, recruitment, retention, contamination and theory testing.
- We developed a theoretical framework and logic model to explain how the intervention might work and are measuring mediators of intervention effects.
- Key mediators: social support, self efficacy, intrinsic motivation, planning and self-monitoring
Analysis

- Feasibility outcomes assessed descriptively.

- The main effectiveness analysis was intention-to-treat, comparing BMI at 12 months in the intensive intervention arm with the control using analysis of covariance controlling for age, gender, ethnicity, source of recruitment and percentage weight lost.

- Secondary outcomes were analysed using multi-level logistic or linear regression.

- A sensitivity analysis was conducted assuming those lost to follow-up failed to maintain their weight loss.

- A Complier Average Casual Effect (CACE) was estimated using multi-level mixture analysis for the primary outcome to assess the effect of the intervention in those who complied.
Expression of Interest (EOI) received (n=1284)
- GP/nurse (n=921)
- SW (n=82)
- Exercise on referral (n=157)
- Other/advertising (n=124)

Excluded (n=114)
- 5% WL not achieved/evidenced (n=783)
- Not eligible - other (n=61)
- Declined to participate (n=248)
- Trial closed to recruitment (n=22)

Randomised (n=170)
- GP/nurse (n=71)
- SW (n=45)
- Exercise on referral (n=12)
- Other/advertising (n=42)

Control arm (N=60)
- Ineligible excluded n=2

Less intensive arm (n=55)
- Ineligible excluded n=1
- Attended 2 FTF sessions (n=49)
- Attended 1 FTF session (n=2)
- Received no intervention (n=3)

Intensive arm (n=55)
- Ineligible excluded n=1
- Attended > 5 FTF sessions (n=45)
- Attended 1-4 FTF sessions (n=9)
- Received no intervention (n=0)

6m follow-up (n=139)
- N=47
- Lost to follow-up (n=11)
- Withdrawn (n=0)

12m follow-up (n=139)
- N=51
- Lost to follow-up (n=6)
- Withdrawn (n=1)

Analysis
- Analysed (n=51)
- Analysed (n=43)
- Analysed (n=45)
## Baseline demographics

<table>
<thead>
<tr>
<th>Age</th>
<th>Control</th>
<th>Less intensive</th>
<th>Intensive</th>
<th>Total</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 30 N %</td>
<td>6</td>
<td>10.0%</td>
<td>5</td>
<td>9.1%</td>
<td>16</td>
</tr>
<tr>
<td>30 to 59 N %</td>
<td>37</td>
<td>61.7%</td>
<td>33</td>
<td>60.0%</td>
<td>102</td>
</tr>
<tr>
<td>60 and over N %</td>
<td>17</td>
<td>28.3%</td>
<td>17</td>
<td>30.9%</td>
<td>52</td>
</tr>
<tr>
<td>Gender</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male N %</td>
<td>10</td>
<td>16.7%</td>
<td>9</td>
<td>16.4%</td>
<td>29</td>
</tr>
<tr>
<td>Female N %</td>
<td>50</td>
<td>83.3%</td>
<td>46</td>
<td>83.6%</td>
<td>141</td>
</tr>
<tr>
<td>Body Mass Index Mean SD (kg/m²)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>33.7</td>
<td>5.5</td>
<td>34.8</td>
<td>6.1</td>
<td>34.3</td>
</tr>
<tr>
<td>Waist-to-hip ratio Mean SD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.9</td>
<td>0.1</td>
<td>0.9</td>
<td>0.1</td>
<td>0.9</td>
</tr>
<tr>
<td>Smoker</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No N %</td>
<td>54</td>
<td>90.0%</td>
<td>49</td>
<td>89.1%</td>
<td>153</td>
</tr>
<tr>
<td>Yes N %</td>
<td>6</td>
<td>10.0%</td>
<td>6</td>
<td>10.9%</td>
<td>17</td>
</tr>
</tbody>
</table>
Results

- 170 participants were randomised. Retention was good (84%).
- Adherence was excellent (intensive, 83%; less intensive, 91%).
- The intervention was delivered successfully and both practitioners and participants were positive about the support the intervention provided and the impact.
- Between group difference in mean BMI indicated a potential reduction of 1.0kg/m² for the intensive arm relative to controls (95% CI: [-2.2, 0.2]).
- A potential reduction was found for weight (average loss of 2.8kg (95% CI: [-6.1, 0.5])).
- There was evidence that participants in the intensive arm reduced fat intake statistically significantly more than controls.
<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>Less Intensive#</th>
<th>95% CI</th>
<th>Intensive#</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m$^2$)</td>
<td>129</td>
<td>-0.21</td>
<td>[-1.44, 1.03]</td>
<td>-0.96</td>
<td>[-2.16, 0.23]</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>129</td>
<td>-0.70</td>
<td>[-4.10, 2.70]</td>
<td>-2.82</td>
<td>[-6.09, 0.45]</td>
</tr>
<tr>
<td>Waist (cm)*</td>
<td>129</td>
<td>0.15</td>
<td>[-3.34, 3.65]</td>
<td>-0.84</td>
<td>[-4.21, 2.59]</td>
</tr>
<tr>
<td>Waist-to-hip ratio</td>
<td>129</td>
<td>-0.001</td>
<td>[-0.030, 0.027]</td>
<td>-0.012</td>
<td>[-0.039, 0.016]</td>
</tr>
<tr>
<td>DINE Fat*</td>
<td>54</td>
<td>-1.80</td>
<td>[-4.50, 0.54]</td>
<td>-4.68</td>
<td>[-7.44, -2.28]</td>
</tr>
<tr>
<td>DINE Health Eating*</td>
<td>46</td>
<td>-0.30</td>
<td>[-5.73, 5.12]</td>
<td>4.16</td>
<td>[-1.80, 10.14]</td>
</tr>
</tbody>
</table>
Results

- The intensive arm had a potential odds ratio of maintaining on average 43% (OR: 1.4, 95% CI:[0.6,3.5]) higher than controls.

- Sensitivity analyses (assuming that the individuals who we were unable to follow-up, failed to maintain) revealed similar results.
<table>
<thead>
<tr>
<th></th>
<th>n</th>
<th>OR</th>
<th>95% CI</th>
<th>OR</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintaining weight lost</td>
<td>129</td>
<td>0.61</td>
<td>[0.23,1.56]</td>
<td>1.43</td>
<td>[0.59,3.54]</td>
</tr>
<tr>
<td>Sensitivity analysis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>non-responders failed to</td>
<td>166</td>
<td>0.64</td>
<td>[0.27,1.47]</td>
<td>1.34</td>
<td>[0.60,3.01]</td>
</tr>
</tbody>
</table>
Results

- The CACE analysis indicated that attending the intensive intervention led to a potential reduction BMI by 1.23 points, though the 95% confidence interval ranges from a -2.49 reduction to a 0.03 increase (n/s).

- We found that attending the intensive intervention led to a reduction in weight on average by 3.69kg, with a 95% confidence interval ranging from a 7.08kg reduction to a 0.31kg decrease (p = 0.033).

- The other secondary outcomes showed limited evidence of differences between groups other than on the DINE questionnaire.
Mediation Analyses

- Hypothesised mediators assessed using questionnaires and tested via mediation analyses were:
  - self-monitoring;
  - intrinsic motivation;
  - self-efficacy;
  - habits;
  - social support.

- We also considered goal setting, problem solving and planning to be important and explored these and the above in the qualitative work.
Mediation Analyses

- The results did not show any impact of the intervention on the mediators tested.

- However, interpretation of the mediation analyses is limited by,
  - the small sample size,
  - the absence of a statistically significant effect of the intervention on the primary outcome
  - the absence of any statistically significant between group differences in the analyses of mediators.

- Five of the ten mediators had a statistically significant association with BMI in the expected direction.
### Table 21: Relationship between mediators and BMI

<table>
<thead>
<tr>
<th>Mediator</th>
<th>Coefficient**</th>
<th>Lower 95% CI</th>
<th>Upper 95% CI</th>
<th>p-value</th>
<th>Brief interpretation (as mediator increases...)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight Efficacy Lifestyle Questionnaire (WELS)</td>
<td>-0.03</td>
<td>-0.05</td>
<td>-0.02</td>
<td>&lt;0.001</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Exercise Self-Efficacy Scale (ESES)</td>
<td>-0.28</td>
<td>-0.51</td>
<td>-0.05</td>
<td>0.015</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Social Support and Eating Habits survey (SSEH) – sabotage domain</td>
<td>0.08</td>
<td>-0.08</td>
<td>0.24</td>
<td>0.332</td>
<td></td>
</tr>
<tr>
<td>Social Support and Eating Habits survey (SSEH) – encouragement domain</td>
<td>-0.09</td>
<td>-0.37</td>
<td>0.20</td>
<td>0.546</td>
<td></td>
</tr>
<tr>
<td>Social Support and Exercise Survey (SSEX) – participation domain</td>
<td>-0.09</td>
<td>-0.34</td>
<td>0.17</td>
<td>0.491</td>
<td></td>
</tr>
<tr>
<td>Social Support and Exercise Survey (SSEX) – support domain</td>
<td>-0.26</td>
<td>-0.48</td>
<td>-0.04</td>
<td>0.022</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Treatment Self-Regulation Questionnaire Concerning the Motivation for Eating a Healthy Diet (TSRD) – relative autonomy</td>
<td>0.06</td>
<td>-0.28</td>
<td>0.40</td>
<td>0.732</td>
<td></td>
</tr>
<tr>
<td>Treatment Self-Regulation Questionnaire Concerning the Motivation for Exercising Regularly (TSRE) – relative autonomy</td>
<td>-0.23</td>
<td>-0.56</td>
<td>0.11</td>
<td>0.185</td>
<td></td>
</tr>
<tr>
<td>Self-reported habit index (diet) at 12 months</td>
<td>-0.49</td>
<td>-0.85</td>
<td>-0.13</td>
<td>0.007</td>
<td>BMI decreases</td>
</tr>
<tr>
<td>Self-reported habit index (exercise) at 12 months</td>
<td>-0.36</td>
<td>-0.61</td>
<td>-0.12</td>
<td>0.004</td>
<td>BMI decreases</td>
</tr>
</tbody>
</table>

*Mediator collected at six month time point unless specified otherwise.*
Qualitative work

- The qualitative data provided insights into the mediators of intervention effect.
Ongoing Motivation

- Ongoing motivation was seen as central, and was influenced positively and negatively by the support of others including family, friends, and professionals.

0349-LessInt-F-12mnth: He (the MIP) gave me quite a lot of help with motivation, you know, encouragement just to keep going.

- A good professional relationship facilitated motivation by instilling in participants a feeling of ‘wanting to please’, i.e. by being successful in WM.

- This was related to a need for ‘accountability’ whereby they were accountable to an independent party for progress.

- Positive reinforcement was a crucial aspect of support.

- It also appeared to work independently to facilitate self-efficacy and maintain motivation, particularly the reinforcement acquired through continued weight loss or maintenance.

- Improvements in health also acted as a positive reinforcer.
Social Support

- Social support seen as key for WLM. It reduced isolation and provided opportunities for reinforcement, encouragement, feedback, role modelling, instrumental support and comparison as well as learning from others.

- Peer support is distinct from other support because of the shared experience and it also provided opportunities to improve self-efficacy.

- **0053-Cont-F-12mnth:** Everybody that wants to shares phone numbers [does], so there’s always support from someone..... somewhere, by some means. So it’s, you know, even if it’s (...) ‘I’m shopping I want to buy this cream cake somebody stop me’, and generally somebody does.
Social Support

- Support from family and friends was important, particularly if they were committed to maintaining a healthy lifestyle. If they were not then often this led to temptation.

- **0060-LessInt-F-12mntth:** My husband, you know, will eat the same food as I do. My son actually has taken on board some of the healthier things that I’ve tried in the past, things like dry roast potatoes (...) and it’s part of their lives now.
Control

- Control was seen as important; participants indicated that feelings of control were reinforcing and were important in relation to motivation.

- Conversely, loss of control could lead to bingeing and thus demotivation and feelings of failure.

2101-LessInt-F-6mnth: *But I’m quite happy also not to eat tons and tons of food, in fact I’m much better when I’m in control, I feel happier more you know psychologically, I benefit from it all, I feel wonderful when I’m in control.*

- Self-monitoring was seen as important to both weight loss and maintenance, in the form of regular weighing. Self-monitoring was described as helping people feel in control.

0651-Cont-M-12mnth: *You know, it’s a lot easier to lose two pound than it is two stone, and as long as I keep it in short bites then, I can control it a lot easier.*
Habits

- Routine and habit formation were described as important to longer term maintenance of healthy behaviours.

**0073-LessInt-F-12mnth:** *On the other hand there are now a couple of ideas and a couple of habits that are so ingrained that it’s more difficult to not to do them things like the portion control and like the exercise.*

- Those who failed to develop healthy lifestyle habits continued to struggle with their weight management.
Conclusion

- The intervention is feasible and acceptable, and retention and adherence were high.

- The main effectiveness outcome showed promising mean differences for the intensive arm.

- Due to the small sample size we are limited in the conclusions we can draw. However, findings suggest that the intensive intervention may facilitate weight maintenance.

- In terms of mediators of intervention effect there was no support from the quantitative work for the hypothesised pathway of effect but the analyses were underpowered.

- The qualitative work found some support for the theorised mediators as well as identifying other important aspects including control.

- Social support, self-efficacy and habit formation are likely important in WLM.
UK Congress on Obesity 2014

University of Birmingham, Edgbaston Campus
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