A feasibility study to assess the impact of a lifestyle intervention in people with a family history of colorectal or breast cancer

Annie S. Anderson et al

BMJ Open (in press)
Cancer: a genetic-environmental interaction

Nature and Nurture.......
Study Design

Two arm, two-centre, randomised feasibility study of the LivingWELL intervention versus usual care.

- NHS Tayside and NHS Grampian
- Genetic clinic referral for family history of BC or CRC
- Measured BMI $> 25\text{kg/m}^2$

- Exclusion criteria: severe cognitive impairment, conditions where physical activity is contra-indicated
The LivingWELL intervention programme aims

- Weight management (weight loss) 5% weight loss
- Physical activity (toward 225 to 300 minutes of moderate physical activity per week)
- Dietary components (~600 kcals/day)
- Low alcohol intake
Intervention Programme

• One-hour (65 mins) lifestyle coaching session
• 4 follow up phone consultations plus mailed materials
• Over 3 month period

• Goal setting, implementation intentions, self-monitoring, feedback, coping planning

• Web-based support programme
Research methods

Baseline and follow up measures (3 months)

• Anthropometric measures
• Physical activity (objective and subjective)
• Diet (DINE), Alcohol, smoking
• Psychosocial measures
LivingWELL Recruitment

Patients with a family history of breast or colorectal cancer (n=600)

- Approached n= 480 (80%)
- Responded ‘No’ n= 47 (10%)
- Did not respond n= 237 (49%)

- Responded ‘Yes’ n=196 (41%)
  - Changed mind n= 32 (16%)
  - Unable to contact n= 40 (20%)
  - Ineligible n= 46 (24%)

- Randomised n=78 (40%)

University of Dundee
LivingWELL Retention

Randomised n=78 (40%)

Intervention n=39

Completed 12 weeks
n=30 (77%)

Control n=39

Completed 12 weeks
n=29 (74%)

LivingWELL
Implementation and Fidelity

Intervention delivery
Lifestyle coaches self-assessment (n=39 participants)

<table>
<thead>
<tr>
<th>Face to face visit</th>
<th>All</th>
<th>Most</th>
<th>Skipped or cut down some</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coverage of topics</td>
<td>27 (73%)</td>
<td>8 (22%)</td>
<td>2 (5%)</td>
</tr>
</tbody>
</table>

Independent Fidelity assessment – 62% (improved with time)
## Baseline Demographics at Randomisation

<table>
<thead>
<tr>
<th></th>
<th>Intervention (n=36)</th>
<th>Control (n=36)</th>
<th>All (n=78)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age (years) Mean Range</strong></td>
<td>49.1 ± 12.7 22-72</td>
<td>45.1 ± 12.8 18-71</td>
<td>47.1 ± 12.8 18-72</td>
</tr>
<tr>
<td><strong>Male</strong></td>
<td>6 (15%)</td>
<td>3 (8%)</td>
<td>9 (12%)</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td>33 (85%)</td>
<td>36 (92%)</td>
<td>69 (88%)</td>
</tr>
<tr>
<td><em><em>SIMD</em> (quintiles)</em>*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 (most deprived)</td>
<td>4 (11%)</td>
<td>8 (20.5%)</td>
<td>12 (15%)</td>
</tr>
<tr>
<td>2</td>
<td>6 (16%)</td>
<td>3 (8%)</td>
<td>9 (12%)</td>
</tr>
<tr>
<td>3</td>
<td>10 (26%)</td>
<td>7 (18%)</td>
<td>17 (22%)</td>
</tr>
<tr>
<td>4</td>
<td>11 (29%)</td>
<td>8 (20.5%)</td>
<td>19 (25%)</td>
</tr>
<tr>
<td>5 (least deprived)</td>
<td>7 (18%)</td>
<td>13 (33 %)</td>
<td>20 (26%)</td>
</tr>
</tbody>
</table>

Data are mean ± SD or number (%) unless stated otherwise. *Scottish Index of Multiple Deprivation
### Changes in anthropometric measures

| Bodyweight (kg) | Intervention | | | Control | | | | Between group difference Mean (95%CI) |
| --- | --- | --- | --- | --- | --- | --- | --- |
| | n | Mean (SD) | Difference to baseline Mean (95%CI) | n | Mean (SD) | Difference to baseline Mean (95%CI) | |
| Baseline | 39 | 90.9 (17.0) | -3.2 (-4.8 to -1.5) | 39 | 88.2 (15.9) | -0.3 (-1.0 to 0.4) | -2.8 (-4.6 to -1.1) |
| 12 weeks | 30 | 85.9 (16.3) | | 29 | 87.6 (15.6) | | | |
Body Weight Reduction

- % achieving 5% body weight loss
  - Significantly higher in the intervention group than the control group (37% vs. 0%)

- % achieving 10% body weight loss
  - Also higher in the intervention group (10% vs. 0%)
## Changes in Physical Activity - Sensewear

<table>
<thead>
<tr>
<th>Daily average time spent in moderate activity (mins)</th>
<th>Intervention</th>
<th>Control</th>
<th>Between group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean (SD)</td>
<td>Difference to baseline</td>
</tr>
<tr>
<td>Baseline</td>
<td>34</td>
<td>58.1 (49.5)</td>
<td>20.3(-35.2 to -4.4)</td>
</tr>
<tr>
<td>12 week</td>
<td>23</td>
<td>86.8 (62.0)</td>
<td></td>
</tr>
</tbody>
</table>
## Changes in dietary intake

<table>
<thead>
<tr>
<th>Fat consumption score</th>
<th>Intervention</th>
<th>Control</th>
<th>Between group differences</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Mean (SD)</td>
<td>Difference to baseline Mean (95%CI)</td>
</tr>
<tr>
<td>Baseline</td>
<td>39</td>
<td>29.3 (9.0)</td>
<td>-7.8 (5.2 to 10.4)</td>
</tr>
<tr>
<td>12 week</td>
<td>30</td>
<td>20.5 (6.0)</td>
<td></td>
</tr>
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</table>
It has given me more information that I didn't know about

Having a pedometer definitely helped me increase my daily steps

Although my lifestyle was reasonably good before, this helped me at least look at portion size

Pedometer my new addiction checking out steps all day long!

I am now motivated to increase my activity and I do feel better for it

They were always full of good ideas

Literature very helpful especially re portions of different food groups

Best thing that I was ever offered to participate in

I am now motivated to increase my activity and I do feel better for it

Started at 6,000 steps, now 20,000+ and loving it!

Difficult to keep up momentum due to serious illness in family; determined to keep trying

It did make me think more about the food I eat/ate. Need to be more organised food/meals.

Everything is clear and easy. I'm happy with this programme.

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LivingWELL
Conclusions

• It is feasible to recruit and retain people attending FHS services with a FH of BC or CRC

• A weight management programme focussed on diet, physical activity and behaviour change techniques is acceptable to participants

• Indicative results suggest favourable results consistent with cancer risk reduction