The Effect of Zespri® SunGold Kiwifruit on gut health function: A randomized cross-over clinical trial

Sarah Eady, Alison Wallace, Chrissy Butts, Duncan Hedderley, Lynley Drummond, Richard Garry
Disclosures

• I have received the following from Zespri International
  – Research funding
  – Advisory board membership
  – Support to attend conferences
Background

• Constipation affects ~17% of global population
• Conventional treatments may be poorly tolerated
• There is a strong demand for natural food interventions to address GI symptoms
• Multiple studies support the use of Zespri® Green Kiwifruit (*Actinidia deliciosa* var. Hayward) to improve bowel function
Primary outcome (green kiwifruit) – CSBM

*P<0.05, **P<0.01; ***P<0.001
Potential mechanisms of action of kiwifruit

- Strong evidence
- More evidence required

- ↑ Permeability (actinidin)
- ↑ Mucous production (actinidin)
- ↓ Inflammation (kissper)
- ↓ Pro-inflammatory cytokines
- ↓ NO production

- ↑ Protein digestion (actinidin)
- ↑ Gastric emptying (actinidin)

- ↓ Transit time

- ↑ Water retention (fibre)
- ↑ Faecal bulk (fibre)
- ↑ Lactobacilli, Bifidobacteria (fibre)
- ↑ SCFA (fibre)

Bayer, Gearry, Drummond, *Critical Reviews in Food Science and Nutrition*, 2017
Aim

• To determine whether daily consumption of three Zespri™ SunGold kiwifruit could alleviate constipation and improve gastrointestinal discomfort in mildly constipated individuals with and without pain.
Study design

- Randomised single-blinded cross-over design
- Powered to show an increase of 1.5 CSBM per week 90% power, 5% significance
Interventions

Three Zespri Gold Kiwifruit

8.5g psyllium
Inclusion / exclusion criteria.

Inclusion

• 18-65 years of age
• BMI 18-35
• IBS-C (20)
• Functional constipation (20)

Exclusion

• GI alarm symptoms
• Significant chronic medical conditions
• Fasting glucose >7.2mmol/L
• Drugs affecting GI motility
• Pregnant / breastfeeding women
• Known kiwifruit or latex allergy
• Not prepared to stop other laxatives
Schedule of assessments.

START OF STUDY

Week 0 2 6 10 14 16

GSRs

Daily Diary

IBS - QoL

Food Diary

Stool Sample

Blood Sample (Vitamin C)

POMS

IBS- SSI

Rome III

Lead-in 2 weeks

Intervention 1 4 weeks

Washout 4 weeks

Intervention 2 4 weeks

Follow-up 2 weeks

BASELINE

START OF STUDY

Week 0 2 6 10 14 16

GSRs

Daily Diary

IBS - QoL

Food Diary

Stool Sample

Blood Sample (Vitamin C)

POMS

IBS- SSI

Rome III

Lead-in 2 weeks

Intervention 1 4 weeks

Washout 4 weeks

Intervention 2 4 weeks

Follow-up 2 weeks
Disposition of study participants

56 Expressions of interest

39 participants screened

35 participants enrolled (10 functional constipation, 25 IBSC)

32 participants completed

17 declined screening

4 participants declined enrollment after screening

2 participants withdrew, 1 withdrawn for non-adherence
Baseline characteristics and demographics

<table>
<thead>
<tr>
<th>Baseline characteristic</th>
<th>Total group (n=32)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>32 (100%)</td>
</tr>
<tr>
<td>NZ European ethnicity</td>
<td>24 (75%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>51 (21-65)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>68 (42-92)</td>
</tr>
<tr>
<td>BMI</td>
<td>25 (20-33)</td>
</tr>
</tbody>
</table>
IBS severity scores for study participants

<table>
<thead>
<tr>
<th></th>
<th>Severity of abdominal pain</th>
<th>Severity of abdominal distension</th>
<th>Bowel habit satisfaction</th>
<th>Effect on quality of life</th>
<th>IBS severity score total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Functional constipation</td>
<td>1.6 (3.7)</td>
<td>10.7 (17.6)</td>
<td>32.4 (21.6)</td>
<td>14.2 (21.9)</td>
<td>58.8 (47.3)</td>
</tr>
<tr>
<td>(n=9)</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>IBS-C</td>
<td>22.1 (20.3)</td>
<td>25.9 (24.4)</td>
<td>66.9 (16.4)</td>
<td>43.8 (23.7)</td>
<td>158.7 (59.3)</td>
</tr>
<tr>
<td>(n=23)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>P value</td>
<td>0.005</td>
<td>0.082</td>
<td>&lt;0.001</td>
<td>0.004</td>
<td>&lt;0.001</td>
</tr>
</tbody>
</table>
Primary outcome – CSBM / week (ITT)

Complete spontaneous bowel movements per week

Δ 3 CSBM/day
Secondary outcomes following 3 Zespri Sungold kiwifruit / day or psyllium

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Lead in period</th>
<th>Zespri Sungold kiwifruit</th>
<th>Psyllium</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. BM/week</td>
<td>7.2 (3.5)</td>
<td>9.1 (4.9)*</td>
<td>8.1 (3.8)</td>
<td>0.02</td>
</tr>
<tr>
<td>No. complete BM/week</td>
<td>4.2 (3.1)</td>
<td>6.9 (4.3)*</td>
<td>5.5 (4.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>No. spontaneous BM/week</td>
<td>6.7 (3.6)</td>
<td>8.6 (5.0)</td>
<td>7.2 (4.5)</td>
<td>0.23</td>
</tr>
<tr>
<td>No. strained BM/week</td>
<td>3.7 (2.6)</td>
<td>1.7 (2.4)*</td>
<td>2.5 (3.4)*</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Bristol stool scale (mean)</td>
<td>3.24 (1.13)</td>
<td>4.15 (1.26)*</td>
<td>3.52 (1.27)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>% BM using laxatives</td>
<td>2.8% (10.9)</td>
<td>5.2% (20.9)</td>
<td>3.4% (17.7)</td>
<td>Not analysed (92% of participants did not use laxatives)</td>
</tr>
</tbody>
</table>
### Changes in GI symptoms from baseline after kiwifruit and psyllium interventions

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Lead in period</th>
<th>Zespri Sungold kiwifruit</th>
<th>P value</th>
<th>Psyllium</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhoea</td>
<td>1.53 (0.71)</td>
<td>1.89 (1.51)</td>
<td>ns</td>
<td>1.44 (0.68)</td>
<td>ns</td>
</tr>
<tr>
<td>Indigestion</td>
<td>2.54 (0.95)</td>
<td>1.87 (0.80)</td>
<td>0.002</td>
<td>2.33 (1.02)</td>
<td>ns</td>
</tr>
<tr>
<td>Constipation</td>
<td>3.11 (1.41)</td>
<td>1.92 (1.16)</td>
<td>&lt;0.001</td>
<td>2.41 (1.43)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>1.88 (0.70)</td>
<td>1.57 (0.61)</td>
<td>&lt;0.05</td>
<td>1.84 (0.91)</td>
<td>ns</td>
</tr>
</tbody>
</table>
Changes to habitual diet during the study

<table>
<thead>
<tr>
<th></th>
<th>Lead in period</th>
<th>Zespri Sungold kiwifruit</th>
<th>P value</th>
<th>Psyllium</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Fruit</strong></td>
<td>1.4 (0.9)</td>
<td>1.0 (0.9)</td>
<td>&lt;0.05</td>
<td>1.2 (0.8)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Meat</strong></td>
<td>1.2 (0.5)</td>
<td>1.2 (0.7)</td>
<td>ns</td>
<td>1.4 (0.6)</td>
<td>ns</td>
</tr>
<tr>
<td><strong>Vegetables</strong></td>
<td>2.8 (1.6)</td>
<td>2.4 (1.7)</td>
<td>ns</td>
<td>2.3 (1.6)</td>
<td>ns</td>
</tr>
</tbody>
</table>
Adverse events

• No adverse events were observed
Conclusions

• Three Zespri SunGold kiwifruit / day are safe & effective in people with IBS-C or FC for:
  – relief of constipation
  – improvement in gastrointestinal discomfort
  – improvement in overall gastrointestinal symptoms

• Results suggest non-inferiority with psyllium
Acknowledgements

• Plant and Food Research

• Lynley Drummond

• Juliet Ansell / Zespri international