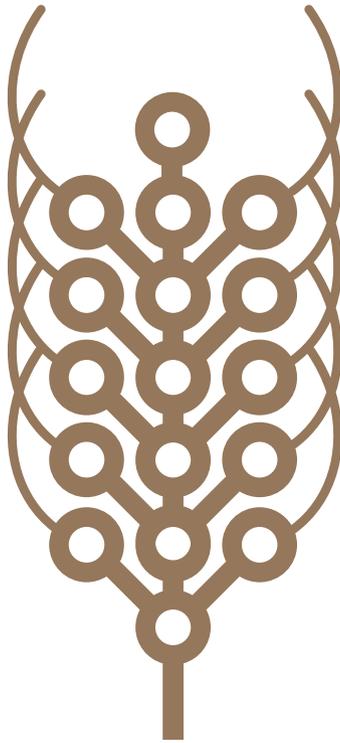




28-DAY REBOOT
NUTRITION AND LIFESTYLE PROGRAM



Background

Freedom Foods Group is an innovative Australian company that has a mission to ‘Make Food Better’ and in this way, to positively influence population health outcomes. In making food better, we focus on the use of wholesome ingredients, using less processing and on retaining greater nutrition benefits with favorable taste profiles. We are working on delivering more than ‘high fiber’ through our product range: we also look to deliver the best mix of quality fiber types, which we now know includes resistant starch, soluble fiber and insoluble fiber.

The Barley⁺ 28-Day Reboot

Barley⁺ is a breakfast Muesli and Muesli Bar range launched recently by the Freedom Foods Group. Barley⁺ is rich in a high fiber, non-genetically engineered, barley cultivar called BARLEYmax™*, which has particularly high levels of resistant starch, soluble fiber and insoluble fiber.

We believe so strongly in the extraordinary health potentiating benefits of the barley in Barley⁺, that we developed The Barley⁺ 28-Day Reboot Nutrition and Lifestyle Program and asked our Freedom Foods family employees to complete the program.

It was conducted over a 28-day period, from early February to early March, 2017 and involved participants substituting their normal daily breakfast with Barley⁺ Muesli and having a Barley⁺ Muesli Bar each day. After 28 days, our participants experienced statistically significant reductions in body weight, body fat and body mass index (BMI), and a significant positive shift in feelings of anger.

***BARLEYmax™ is a non-genetically engineered whole grain that has been developed by Australia’s prestigious research organisation, the CSIRO and contains high levels of resistant starch, soluble fiber and insoluble fiber compared with other conventionally consumed whole grains⁽¹⁻³⁾.**

The Barley⁺ 28-Day Reboot Program protocol

Freedom Foods family participants were asked to consume 50 g Barley⁺ Muesli (Cranberry and Nuts variety) each morning, with a milk of their choice. They were also offered serving ideas, such as “add 100 g natural yogurt to your Barley⁺ breakfast; add a few berries or chopped cashews if there aren’t any nut allergies in your family; add a few slices of a firm banana”. Participants were also asked to enjoy a Barley⁺ Muesli Bar (Cranberry and Almond) each afternoon, with -1 cup water if they were hungry and to continue engaging in 15-20 min of incidental physical activity every day, which includes things like walking the dog, walking with children to school and household chores such as ironing.

Pre- and post-program assessments

Independent and qualified personal trainers (Step into Life Group Outdoor Personal Training) collected pre- and post-program anthropometrical measurements (tricep skinfold thickness, tricep and waist circumference, height and body weight) according to standard protocols⁽⁴⁾. Participants also completed self-administered questionnaires relating to their physical activity (International Physical Activity Questionnaire)⁽⁵⁾ and their overall sense of wellbeing or affective balance of positive versus negative state (Scale of Positive and Negative Experiences questionnaire)⁽⁶⁾. Post-program qualitative information capturing subjective experiences during the program was also collected.

Participants

Anyone with known symptoms of Irritable Bowel Syndrome was excluded. $n=51$ (36 female & 15 male) participants living in Sydney, Australia enrolled (mean age 38.7 years: SD \pm 10.3 years) and undertook pre-program assessments. Five female participants withdrew from the program prior to the completion of the 28 days for personal reasons. Post program measures were taken for $n=40$ participants (26 female & 14 male). Six participants did not undertake post-program testing, due to unavailability.

Participant baseline characteristics

Characteristic	Mean (\pm SD)
BMI (kg/m ²)	26.9 (4.85)
Weight (lb)	169.1 (37.3)
Tricep skinfold (mm)	17.65 (5.47)
Tricep girth (cm)	32.08 (4.29)
Feelings (anger) 1=very rare/never 5=very often/always	2.68 (0.94)
Feelings (pleasant) 1=very rare/never 5=very often/always	3.82 (0.65)
Affective balance of positive vs negative state -24=unhappiest possible +24=happiest possible	9.53 (6.26)
Physical activity (MET)	3124 (3079)

In making our food, we focus on the use of wholesome ingredients using less processing and on retaining greater nutrition benefits with favorable taste profiles.

Data analysis

Independent behavioral scientists (Decision Design Behavioral Consultancy) received all raw data directly from Step into Life, and completed all data analysis. Analysis was conducted using IBM SPSS Statistics (version 20). Prior to conducting the data analysis, participants who either withdrew from the program and/or did not complete the post program assessment were removed from all analysis. Baseline metrics were recalculated and reported only for participants who completed the pre- and post-program assessment.

All pre- and post-measures were assessed independently for significant outliers. No outliers greater than 2 standard deviations were identified. Prior to conducting tests of significance of the mean change in scores, the distribution of changes in pre- and post-average scores were assessed across all variables and outliers above 2 standard deviations were removed from analysis. This resulted in the removal of one participant for the pre/post analysis of triceps skinfold.

The magnitude of change in mean scores (pre- to post-program) on assessed parameters was analyzed for statistical significance using repeated measures t-test.

The Barley⁺ 28-Day Reboot showed that sustained consumption of Barley⁺ Muesli and Muesli Bars resulted in significant reductions in mean body weight, triceps skinfolds, tricep girth and feelings of anger (all $p < 0.05$).

The results

The Barley⁺ 28-Day Reboot showed that sustained consumption of Barley⁺ Muesli and Muesli Bars resulted in significant reductions in mean body weight, triceps skinfolds, tricep girth and feelings of anger (all $p < 0.05$) (Figure 1a-d). There was also a significant reduction in BMI (-0.24 kg/m^2 ; $SD \pm 0.46 \text{ kg/m}^2$, $p < 0.001$). In addition, there were trends towards increased pleasant feelings ($p = 0.06$) and improved overall sense of wellness (i.e. affective balance state) ($p = 0.129$) (Figure 1e-f). There was no change in physical activity levels. The qualitative information revealed that 43% of our participants experienced some level of intestinal gas build-up relative to baseline during the first 2 weeks of the program, which generally subsided by the end of the program.

Group mean changes in key outcomes

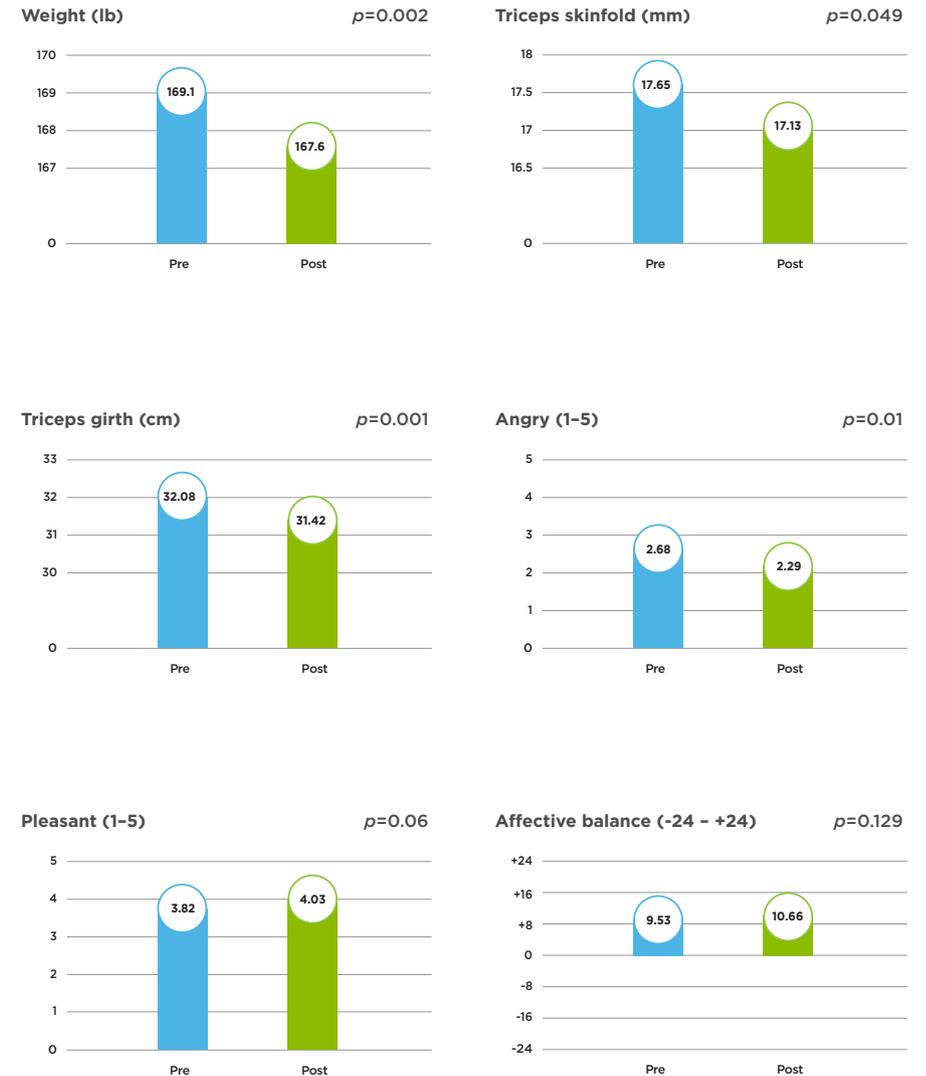


Figure 1a-f: 1a) body weight; 1b) triceps skinfold; 1c) triceps girth; 1d) angry feelings (score range: 1=very rare/never, 5=very often/always); 1e) pleasant feelings (score range: 1=very rare/never, 5=very often/always); 1f) affective balance (score range: -24=unhappiest possible, +24 happiest possible.)

Discussion and conclusion

Our study has shown that sustained daily consumption of Barley⁺ Muesli and Barley⁺ Muesli Bars results in significant reductions in body mass index, body weight, tricep girth and body fat levels. In addition, participants were significantly less angry following their 28 days of consuming Barley⁺. Importantly, the reductions in weight and body fat levels were not due to changes in physical activity levels, as these remained constant throughout the 28-Day Reboot. Additionally, whilst participants were advised to maintain healthy eating habits consistent with the Australian Dietary Guidelines (2013)⁽⁷⁾, no other dietary intervention was undertaken. Therefore, observed changes may be attributable to Barley⁺ intake over the 28-Day Reboot Program.

The Centers for Disease Control and Prevention highlight that people who lose weight gradually and steadily are more successful at keeping weight off⁽⁸⁾. Further, that healthy weight loss involves long-term changes in daily eating and exercise habits, which can be sustained in an ongoing manner⁽⁸⁾. Our study has shown that a small dietary change involving regular Barley⁺ intake positively influences gradual weight loss in a group of healthy Australians over 28 days. Importantly, this weight loss is attributed to body fat loss, indicated by the reduction in both tricep skinfold thickness and tricep girth.

We speculate that the mechanisms mediating these positive changes relate to the prebiotic dietary fiber effects of Barley⁺ and consequent effects on resident gut microflora populations, as recent studies show that obesity is associated with an imbalance in normal gut microbiota^(9, 10) and it is generally acknowledged that alterations in gut microbiota can mediate mood and behavior change in humans^(11, 12).

BARLEYmaxTM, and so Barley⁺, is a rich source of various prebiotic dietary nutrients, including resistant starch, fructans and fructooligosaccharides. Intake of fermentable prebiotic fiber can greatly alter gastrointestinal microbiota profiles and increase specific bacteria numbers in the large bowel, by providing substrate or by supplying short chain fatty acids (SCFA) to other gut microbes and intestinal cells⁽¹³⁻¹⁵⁾. In addition to the SCFA produced by the gastrointestinal bacteria, a number of gasses, including methane, hydrogen and carbon dioxide are produced^(16, 17).

From our study, subjective evidence of shifts in gut microbiota profiles is apparent from the increased intestinal gas reported by 43% of our study participants during the first 2 weeks. Consistent with the results from our study, not all people feel the same level of effects of increased fermentation in the gut, which at least partly depends on visceral hypersensitivity^(18, 19) and for those who do, such responses have been shown to subside after around 1 month of initiating Barley fiber intakes⁽²⁰⁾.

Alternative explanations for the significant weight loss observed in the current program are 2-fold; 1) the lower glycemic index and high whole grain/fermentable fiber content of Barley⁺ may have promoted increased satiety^(21, 22); and 2) Barley whole grains have lower bioavailable energy relative to the more commonly consumed wheat⁽²³⁾.

In conclusion, the changes observed during The Barley⁺ 28-Day Reboot appear sustainable and lead to positive changes in body weight, body fat levels and feelings of wellbeing. This simple and effective dietary change may offer benefits to individuals seeking to make positive and sustainable changes.

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