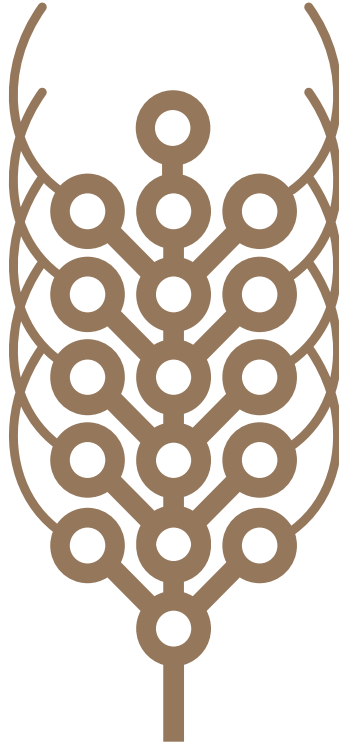




28-DAY REBOOT
NUTRITION AND LIFESTYLE PROGRAM



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 favourable taste profiles. We are working on delivering more than 'high fibre' through our product range: we also look to deliver the best mix of quality fibre types, which we now know includes resistant starch, soluble fibre and insoluble fibre.

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 fibre, non-genetically modified, barley cultivar called BARLEYmax^{TM*}, which has particularly high levels of resistant starch, soluble fibre and insoluble fibre.

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.

***BARLEYmaxTM is a non-genetically modified whole grain that has been developed by Australia's prestigious research organisation, the CSIRO and contains high levels of resistant starch, soluble fibre and insoluble fibre 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, mid-upper arm circumference 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 (kg)	76.7 (16.9)
Tricep skinfold (mm)	17.65 (5.47)
Mid-upper arm circumference (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 favourable taste profiles.

Data analysis

Independent behavioural scientists (Decision Design Behavioural 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 analysed for statistical significance using repeated measures t-tests.

The Barley⁺ 28-Day Reboot showed that sustained consumption of Barley⁺ Muesli and Muesli Bars resulted in significant reductions in mean body weight, triceps skinfold, mid-upper arm circumference 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 skinfold, mid-upper arm circumference and feelings of anger (all $p < 0.05$) (Figure 1a-d). There was also a significant reduction in BMI (-0.24 kg/m^2 ; $\text{SD} \pm 0.46 \text{ kg/m}^2$, $p < 0.001$). 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) mid-upper arm circumference; 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, mid-upper arm circumference 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 were not due to changes in physical activity, 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.

Australia's National Health and Medical Research Council advises that “*even small amounts of weight loss improve health and wellbeing*”⁽⁸⁾, while the American Centers for Disease Control and Prevention highlight that people who lose weight gradually and steadily are more successful at keeping weight off⁽⁹⁾. Further, that healthy weight loss involves long-term changes in daily eating and exercise habits, which can be sustained in an ongoing manner⁽⁹⁾. 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 triceps skinfold thickness and mid-upper arm circumference.

We speculate that the mechanisms mediating these positive changes relate to the prebiotic dietary fibre effects of Barley⁺ and consequent effects on resident gut bacteria populations and their short chain fatty acid (SCFA) production, as recent studies show that obesity is associated with an imbalance in normal gut microbiota^(10, 11)

and it is generally acknowledged that alterations in gut microbiota can mediate mood and behaviour change in humans^(12, 13).

BARLEYmax[™], and so Barley⁺, is a rich source of various prebiotic dietary nutrients, including resistant starch, fructans and fructooligosaccharides. Intake of fermentable prebiotic fibre can greatly alter gastrointestinal microbiota profiles and increase specific bacteria numbers in the large bowel, by providing substrate or by increasing SCFA supply to other gut microbes and intestinal cells⁽¹⁴⁻¹⁶⁾. In addition to the SCFA produced by the gastrointestinal bacteria, a number of gasses, including methane, hydrogen and carbon dioxide are produced^(17, 18).

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^(19, 20) and for those who do, such responses have been shown to subside after around 1 month of initiating barley fibre intakes⁽²¹⁾.

Alternative explanations for the significant weight loss observed in the current program are twofold; 1) the lower glycemic index and high whole grain/fermentable fibre content of Barley⁺ may have promoted increased satiety^(22, 23); and 2) barley whole grains have lower bioavailable energy relative to the more commonly consumed wheat⁽²⁴⁾.

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.

References

1. The BARLEYmax[™] Better Nutrition Report 2009. BARLEYmax[™] Joint Venture representing CSIRO and Australian Capital Ventures Ltd.
2. Commonwealth of Australia. Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes. Dietary Fibre. 2006:45-9.
3. Fuller S, Beck E, Salman H, Tapsell L. New Horizons for the Study of Dietary Fibre and Health: A Review. Plant Foods Hum Nutr. 2016;71(1):1-12.
4. Norton K, Olds T. Anthropometric: A Textbook of Body Measurement for Sports and Health Courses. Australia: UNSW Press Ltd; 2004.
5. Craig CL, Marshall AL, Sjoström M, et al. International physical activity questionnaire: 12-country reliability and validity. Med Sci Sports Exer. 2003;35(8):1381-95.
6. Diener HC, Wirtz D, Tov W, et al. New Well-being Measures: Short Scales to Assess Flourishing and Positive and Negative Feelings. Soc Indic Res 2010;97:143-56.
7. National Health and Medical Research Council, Department of Health and Ageing. Australian Dietary Guidelines, 2013. Canberra: Australian Government. <https://www.nhmrc.gov.au/_files_nhmrc/file/publications/n55_australian_dietary_guidelines1.pdf> Last accessed 19/04/2017.
8. National Health and Medical Research Council, 2013 Summary Guide for the Management of Overweight and Obesity in Primary Care. Melbourne: National Health and Medical Research Council. <https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/n57b_obesity_guidelines_summary_guide_131219.pdf> Last accessed 19/04/2017.
9. Centers for Disease Control and Prevention. Division of Nutrition Physical Activity and Obesity. National Center for Chronic Disease Prevention and Health Promotion (2015). Losing Weight. <https://www.cdc.gov/healthyweight/losing_weight/> Last accessed 25/04/2017.
10. Ley RE, Turnbaugh PJ, Klein S, Gordon JI. Microbial ecology: human gut microbes associated with obesity. Nature. 2006;444(7122):1022-3.
11. Turnbaugh PJ, Hamady M, Yatsunenko T, et al. A core gut microbiome in obese and lean twins. Nature. 2009;457(7228):480-4.
12. Distrutti E, Monaldi L, Ricci P, Fiorucci S. Gut microbiota role in irritable bowel syndrome: New therapeutic strategies. W J Gastro. 2016;22(7):2219-41.
13. Mayer EA, Knight R, Mazmanian SK, et al. Gut microbes and the brain: paradigm shift in neuroscience. J of Neuroscience. 2014;34(46):15490-6.
14. Kleessen B, Sykura B, Zunft HJ, Blaut M. Effects of inulin and lactose on fecal microflora, microbial activity, and bowel habit in elderly constipated persons. AJCN. 1997;65(5):1397-402.
15. Topping DL, Clifton PM. Short-chain fatty acids and human colonic function: roles of resistant starch and nonstarch polysaccharides. Physiological reviews. 2001;81(3):1031-64.
16. Ohkusa T, Ozaki Y, Sato C, et al. Long-term ingestion of lactosucrose increases Bifidobacterium sp. in human fecal flora. Digestion. 1995;56(5):415-20.
17. Cummings JH, Macfarlane GT. The control and consequences of bacterial fermentation in the human colon. The Journal of applied bacteriology. 1991;70(6):443-59. Epub 1991/06/01.
18. Cummings JH, Macfarlane GT, Englyst HN. Prebiotic digestion and fermentation. AJCN. 2001;73(2 Suppl):415S-20S.
19. Camilleri M, Coulie B, Tack JF. Visceral hypersensitivity: facts, speculations, and challenges. Gut. 2001;48(1):125-31.
20. Iovino P, Bucci C, Tremolaterra F, et al. Bloating and functional gastro-intestinal disorders: where are we and where are we going? W J Gastro. 2014;20(39):14407-19.
21. Turunen K, Tsouvelakidou E, Nomikos T, et al. Impact of beta-glucan on the faecal microbiota of polypectomized patients: a pilot study. Anaerobe. 2011;17(6):403-6.
22. Ford H, Frost G. Glycaemic index, appetite and body weight. Proc Nut Soc. 2010;69(2):199-203.
23. McMillan-Price J, Brand-Miller J. Low-glycaemic index diets and body weight regulation. Int J Obes. 2006;30:S40-S6.
24. Aman P, Hesselman K. Analysis of starch and other main constituents of cereal grains. Swed J Agric Res. 1984;14:135-9.



FREEDOM FOODS GROUP LIMITED
80 BOX RD
TAREN POINT NSW 2229

HEALTHPROFESSIONALS@FREEDOMFOODS.COM.AU
WWW.BARLEYPLUS.COM.AU/HEALTHPROFESSIONALS

Disclaimer: The information contained within this document is intended for healthcare professionals and should not be taken as professional medical advice nor as any health claim associated with consuming Barley+.

V101/06/17