

Sainsbury, Kirby and Mullan, Barbara and Sharpe, Louise. 2013. A Randomized Controlled Trial of an Online Intervention to Improve Gluten-Free Diet Adherence in Celiac Disease. *The American Journal of Gastroenterology*. 108: pp. 811-817. doi: 10.1038/ajg.2013.47

Title: A randomised controlled trial of an online intervention to improve gluten free diet adherence in coeliac disease

Running title: Online intervention to improve gluten free diet adherence

Authors: Kirby Sainsbury^a, Barbara Mullan^b, and Louise Sharpe^a

a Clinical Psychology Unit, The University of Sydney, Sydney, Australia

b School of Psychology, The University of Sydney, Sydney, Australia

Corresponding author: Barbara Mullan
School of Psychology
The University of Sydney
NSW 2006 Australia
Barbara.mullan@sydney.edu.au
Ph: 612 9351 6811
Fax: 612 9351 2603

Word count: 4072 (excluding title page, abstract, references, tables, figures)

Acknowledgements: The Coeliac Society of NSW, Health Psychology Lab Group,
The University of Sydney

ABSTRACT

Objective: To test the effectiveness of an interactive online intervention to improve gluten free diet adherence in adults with coeliac disease.

Design: Randomised controlled trial. A total of 189 adults with biopsy-confirmed coeliac disease were recruited and randomised to receive the intervention (n = 101) or to a waitlist control condition (n = 88). Post-intervention data was available for 50 intervention and 64 waitlist participants. Three month follow-up data was obtained for 46/50 participants from the intervention group. The primary outcome measure was gluten free diet adherence. Secondary outcomes were gluten free diet knowledge, quality of life, and psychological symptoms.

Results: Results were based on intention-to-treat analyses. The intervention group evidenced significantly improved gluten free diet adherence, and gluten free diet knowledge following the treatment period relative to the waitlist control group. The change in knowledge did not contribute to the change in adherence. These improvements were maintained at three-month follow-up.

Conclusion: The online program was effective in improving adherence and represents a promising resource for individuals with coeliac disease who are struggling to achieve or maintain adequate gluten free diet adherence.

STUDY HIGHLIGHTS

WHAT IS CURRENT KNOWLEDGE

- Gluten free diet adherence in patients with coeliac disease is less than adequate
- Inadequate knowledge about the gluten free diet and increased levels of psychological symptoms have been linked to poorer adherence
- There have been no interventions designed to improve gluten free diet adherence in people with coeliac disease

WHAT IS NEW HERE

- Bread n' Butter... Gluten Free of Course! resulted in significant and clinically meaningful improvements in adherence and knowledge relative to the waitlist control group
- These improvements were maintained at three-month follow-up

INTRODUCTION

Coeliac disease is a chronic autoimmune disorder involving intolerance for dietary gluten, for which the only available treatment is lifelong adherence to a strict gluten free diet (1). If left untreated, coeliac disease has been linked to small but significant increases in the risks for several serious long-term health complications including intestinal and bowel cancers, osteoporosis, and infertility (2). The amount of gluten shown to prevent histological recovery has been reported to be as small as one milligram per day (3), meaning that strict adherence in this population is of the utmost importance.

Despite this, a systematic review found that only 70% (median; range = 36 – 90%) of participants were classified as having strict adherence (4), although the unreliable measurement of adherence that has characterised most studies suggests that true adherence rates are significantly lower (5-7). Indeed, when measured using the only available validated questionnaire: the Coeliac Dietary Adherence Test (6), only half the participants had adequate adherence (8, 9).

Given the seriousness of non-adherence in this population, the development of interventions to improve gluten free diet adherence is a major goal. To date only three intervention studies in coeliac disease have been reported and none of these directly targeted gluten free diet adherence. Addolorato and colleagues (10) reported on a supportive counselling intervention, which targeted depression and anxiety in newly diagnosed/untreated patients with coeliac disease and affective disorders. At the conclusion of the six-month study period the intervention group had significantly reduced depression scores and a lower rate of non-adherence compared to the control group. Importantly though, the direct relationship between adherence and depressive

symptomatology was not assessed and therefore the mechanisms via which depression improved were unable to be established.

Meyer and colleagues (11) found that an interactive computer program successfully improved knowledge about the gluten free diet and transference to scenarios requiring dietary management relative to a control group. The improvements were, however, diminished when measured only three weeks later. Finally, a problem-based learning program was effective in improving psychological wellbeing in women with coeliac disease compared to a control group (12). Unfortunately, neither of these studies included measures of gluten free diet adherence, so it is unclear whether the improvements in knowledge or wellbeing would translate to improvements in actual adherence.

The current paper reports on a randomised controlled trial to assess the effectiveness of the Bread n' Butter... Gluten Free of Course! intervention in improving gluten free diet adherence in a group of adults with biopsy-confirmed coeliac disease. The intervention was developed based on previous research which found that poorer gluten free diet adherence was related to poorer knowledge, higher levels of psychological symptoms – in particular depression – and greater reliance on maladaptive coping strategies (8, 9). It was hypothesised that relative to the waitlist control group, the intervention group would evidence greater improvements in gluten free diet adherence, gluten free diet knowledge, quality of life, and psychological symptoms across the course of the intervention.

METHODS

Design

A randomised, waitlist controlled design was used. After completing the baseline assessment, gluten free diet adherence scores were calculated and

participants were classified into the following adherence categories: excellent or very good; moderate; and fair-to-poor (see materials section for further details; 6). In order to ensure equivalent numbers of good and poor adherers in each condition, three sets of random numbers (one for each adherence category) were generated using an online random number generator. Consistent with a truly random sequence of numbers, it was not specified that there should be an equivalent proportion of participants in each of the two conditions. Participants were then assigned to the intervention or waitlist control condition within their respective adherence category in the order in which they completed the baseline assessment. The intervention was conducted according to the protocol approved by the Human Research Ethics Committee (approved March 2012).

Sample size

A meta-analysis of Internet-delivered health behaviour change interventions found that theory-based interventions had medium effects on behaviour, while the additional use of text messages was associated with large effects on behaviour (13). Therefore anticipating a medium-to-large effect size, an a-priori power analysis (ANCOVA: fixed effects, main effects and interactions; $d_+ = 0.6$; 80% power; $\alpha = 0.05$), indicated that 90 participants (45 per group) would need to complete the baseline and post measurements to detect a statistically significant difference between the two conditions. Allowing for up to 50% attrition in an Internet intervention (14), the desired sample size was 180 people.

Participants and procedure

Participants were recruited from the Coeliac Society of NSW Australia. Initially, the database was screened to identify members who met the following inclusion criteria: biopsy confirmed coeliac disease, gluten free diet duration >3

months, aged >16 years. The decision to include participants with varying levels of adherence at baseline was based on concerns that restricting inclusion to a purely ‘at risk’ sample would lead to the unnecessary exclusion of a large number of participants who could potentially still obtain secondary benefit from the program, therefore limiting the statistical power of the study. Further, evidence suggests that the majority of non-adherence to the gluten free diet is inadvertent and unintentional (4, 8, 9), and that despite poor correlations with objective measures (4-7), the majority of people with coeliac disease report having good adherence (4). Consequently, the inclusion of a varied sample served to enable recruitment of individuals with objectively inadequate adherence who would probably not otherwise volunteer.

Anticipating a 10% response rate, an invitation email which included an introduction to the study and a link to the website to complete the baseline questionnaires was sent to a randomly selected sample of 1500 (of ~4500) members who met the inclusion criteria. Similarly, for the previously outlined reasons the study was advertised as a program designed to help participants better cope with the challenges of the gluten free diet rather than explicitly mentioning adherence.

The assessment questionnaires, and all intervention modules were administered online using LimeSurvey. After providing consent participants completed the baseline questionnaires, which took approximately 20 minutes. Four days later participants randomised to the intervention condition received an email with a link to the study website to complete module 1. Participants randomised to the waitlist control condition received an email informing them that they would be contacted again in eight weeks to complete the post-survey and would be given access to the intervention materials at that time. There were no restrictions placed on the

control group regarding their contact with health professionals during the waitlist period.

Progression through the six modules was managed using automated emails and text messages. Participants had to complete module 1 (the educational component) to continue with the intervention; however, it was then possible to skip a module and remain active in the intervention. To maximise the post-intervention response rate all intervention group participants were sent the post-survey after a specified period of time, even if they had previously discontinued responding to the intervention modules. Due to the automated nature of the module administration reasons for non-responses to modules were not obtained. Three-month follow-up survey emails were automatically sent to intervention group participants who completed the program following a three-month delay. Supplementary Table 1 outlines the structure of the automated emails and text messages.

Table 1 here

The intervention

Development of the intervention occurred over several months in consultation with a group of relevant experts including health psychology researchers, health and clinical psychologists, a specialist coeliac disease dietitian, and several individuals with coeliac disease. Module content was informed by previous theory-driven qualitative and quantitative research, which examined the social-cognitive and psychological predictors of inadequate gluten free diet adherence (8, 9). Decisions regarding the online mode of delivery and adjuncts to the online modules (text messages) were informed by previous successful Internet-based cognitive behaviour therapy (CBT) programs (15, 16) and a meta-analysis of Internet-delivered health

interventions (13). The final version of the intervention consisted of six weekly online modules, each of which took approximately 30 minutes to complete. It included a combination of (a) education, (b) validated behaviour change techniques shown to be effective in modifying health behaviours within the health psychology literature (17, 18), and (c) evidence-based strategies drawn from CBT to treat anxiety and depression and improve coping behaviour (19). Participants completed questions pertaining to the acceptability of the program at the conclusion of each module and in each case the mean scores indicated that the program was well received. Table 1 provides a summary of the content of each module.

Table 1 here

Measures

At baseline (April 2010) participants completed measures of demographic (age; gender; occupational and marital status; and highest level of education) and coeliac disease information (e.g., age at diagnosis; duration of gluten free diet; reason for diagnosis – symptomatic or screen-detected; symptoms; family history; and additional allergies/intolerances). The following questionnaire battery was completed at three time points: baseline, post-intervention (July – August 2012), and three-month follow-up (October – November 2012; intervention group only). Gluten free diet adherence was measured using the Coeliac Dietary Adherence Test (CDAT) (Leffler et al., 2009). Scores range from 7 – 35, with higher scores representing poorer adherence. In addition to being used as a continuous measure, scores were grouped into the following categories: excellent or very good (7 – 12), moderate (13 – 17), and fair-to-poor (18 – 35) (6). The World Health Organisation Quality of Life Assessment BREF (20) was used to measure overall quality of life, and physical and psychological quality of life. Psychological symptoms were assessed using the

Depression, Anxiety, Stress Scale (21) and the Eating Disorders Inventory-3 Eating Disorder Risk Scale (22). Knowledge was assessed using 14 ingredient lists adapted from educational materials used by the Coeliac Society.

Statistical Analysis

All analyses were conducted using SPSS 18.0 on an intention-to treat basis, although the per-protocol analysis yielded an identical pattern of results (not shown). Multivariate analyses of variance and chi-square analyses were used to assess for differences on the baseline continuous and categorical variables respectively between the intervention and waitlist control groups, and between participants who completed the intervention and those who did not. A series of 2 x 2 repeated measures analyses of variance and paired samples t-tests were conducted to assess for differences across the course of the intervention (baseline vs. post) between the intervention and waitlist control conditions. The primary outcome of interest was gluten free diet adherence. To provide an indication of the clinical significance of the improvement, the analysis concerning adherence was repeated on only the subsample of participants showing inadequate adherence at baseline and for whom post-data was available (N = 55). In addition, a chi-square analysis was conducted to assess for differences between the two conditions in adherence category changes. Secondary outcomes were gluten free diet knowledge, overall, physical, and psychological quality of life, and psychological symptoms. Effect sizes (Cohen's d) for each significant between groups outcome were calculated using the means and standard deviations of the change scores from baseline to post-intervention. A Cohen's d of 0.2 indicates a small effect, d = 0.5 indicates a medium effect, and d = 0.8 indicates a large effect size. Regression analyses were conducted to determine whether the observed changes from baseline to post-intervention mediated the effect of the intervention on gluten free diet adherence.

Paired samples t-tests were used to assess whether the improvements observed at immediate post-intervention had been maintained at three-month follow-up.

RESULTS

Response rate and sample characteristics

Two hundred and ten people accessed the website and 189 of them completed the baseline survey. Eighty-eight participants were randomised to the waitlist control condition, while 101 were randomised to the intervention condition. The majority of participants were female (87.3%; mean age = 46.5, $SD = 14.7$) and either married or living with a partner (81%), while the remainder were single or divorced. Overall the sample was well educated, with 77% having completed education beyond year 12. The majority of participants were engaged in full time or part time/casual work (69%), with a small proportion unemployed, retired, or students. Participants had been on a gluten free diet for an average of 4.6 years ($SD = 7.0$; range = 3 months – 50 years).

The mean baseline adherence score (12.2, $SD = 3.4$) fell in the excellent or very good range, although only 58.9% of the sample fell in this category (moderate: 33.2%; fair to poor: 7.9%)(6). Overall quality of life scores were equivalent to Australian population norms, while scores on the physical and psychological quality of life domains fell approximately half a standard deviation below Australian population norms (20). The mean scores on the psychological symptom measures fell in the average or normal ranges (22, 23). The mean percent correct on the knowledge test was 80.5%. Baseline characteristics of the sample have been described in detail elsewhere (24).

Baseline differences between groups

The two groups did not differ at baseline on any of the demographic, adherence, quality of life or psychological variables (all $p > .05$). There were a higher proportion of participants diagnosed as a result of screening (as opposed to symptoms) in the waitlist control group than the intervention group ($p = .02$). There were no differences between symptom-detected and screen-detected participants on the change scores for any of the primary or secondary outcome measures (all $p > .05$) and so this variable was not controlled for in subsequent analyses.

Intervention completion statistics

An adequate dose of the intervention was defined as completion of four or more modules because such participants had completed 4/5 modules containing new content, as module six was a summary module. Of the 101 intervention participants, 50 (49.5%) completed the intervention; 31 (30.7%) were lost to follow-up; and 20 (19.8%) completed the post-survey but had previously stopped responding to the intervention modules (completed only 1 – 3 modules). Post data was obtained from 64/88 waitlist control participants (loss to follow-up = 27.3%). The online nature of data collection prevented any missing values, as it was not possible to submit incomplete responses. Consequently, the intention-to-treat analysis contained data carried forward from baseline for the 31 participants from the intervention group and 24 participants from the waitlist control group who did not complete the post survey. Three-month follow up data was obtained for 46/50 of the intervention group participants who completed the intervention. This represented a loss to follow-up of 8% from immediate post-intervention. Supplementary Figure 1 provides a summary of intervention progress and completion.

Tests of representativeness

The results indicated that there were no differences between completers and non-completers on any of the baseline continuous or categorical variables (all $p > .05$).

Primary outcome: Gluten free diet adherence

There was a significant improvement over time in adherence for both conditions ($F_{1,187} = 8.89, p = .002$); however, the time x condition interaction effect was also significant ($F_{1,187} = 5.67, p = .014$). Paired samples t -tests indicated that the intervention group had improved adherence scores from baseline to post ($t_{100} = 3.83, p < .001$), while the waitlist group's scores remained unchanged ($t_{87} = 0.42, p = .674$). For the total intention-to-treat sample ($N = 189$; intervention: $n = 101$; waitlist: $n = 88$) this represented a small-to-medium effect size (Cohen's $d = 0.35$; see Figure 1a). Based on only the subsample of participants who had inadequate adherence at baseline and for whom post-data was available ($N = 55$; intervention: $n = 26$; waitlist: $n = 29$), the improvement yielded a medium-to-large effect size (Cohen's $d = 0.69$; interaction effect: $F_{1,53} = 6.49, p = .014$; see Figure 1b).

Figures 1a and 1b here

Clinical significance

Forty-three percent of the waitlist control group had inadequate adherence at baseline (moderate or fair-to-poor). Of the 29/38 of these for whom post-measurements were available, 55.2% were still classified as having inadequate adherence; 37.9% had improved their adherence category ($n = 9$ moved from moderate to excellent/very good; $n = 2$ from fair-to-poor to moderate); and 6.9% had a negative change to their adherence category (moved from moderate to fair-to-poor). Thirty-nine percent of the intervention group had inadequate adherence at baseline. Of the 26/39 participants for whom post-data was available, 65.4% had improved

their adherence category (n = 14 moved from moderate to excellent/very good; n = 3 moved from fair-to-poor to moderate), while 34.6% remained in the inadequate category at post-measurement. A chi-square analysis indicated the difference between conditions was significant ($\chi^2_1 = 4.13, p = .042$).

Secondary outcomes

Significant time ($F_{1,187} = 6.45, p = .012$) and time x condition interaction effects were also observed for gluten free diet knowledge ($F_{1,187} = 18.16, p < .001$). Specifically, the intervention group improved (baseline: $M = 79.28, SD = 13.31$; post: $M = 84.09, SD = 12.53; t_{100} = 4.69, p < .001$), while the waitlist control group's scores remained unchanged from baseline (baseline: $M = 81.90, SD = 13.39$; post: $M = 80.68, SD = 13.62; t_{87} = 1.28, p = .205$). This improvement represented a medium effect size (Cohen's $d = .62$).

Significant positive time effects were observed for physical quality of life ($F_{1,187} = 4.43, p = .037$), and psychological quality of life ($F_{1,187} = 28.95, p < .001$). There were no significant time effects or time x condition interaction effects observed on measures of depression, anxiety, stress, eating disorder risk or overall quality of life (all $p > .05$).

Mediation analyses

Regression analyses were conducted to investigate the extent to which change in adherence was mediated by change in secondary outcomes (25). Condition (intervention vs. waitlist control) predicted 8.9% of the variance in the change in knowledge ($\beta = .298, F_{1,187} = 18.16, p < .001$). Knowledge change did not, however, account for significant variance in adherence change ($\beta = .087, F_{1,187} = 1.43, p = .234$). A formal mediation analysis was therefore not conducted, as the assumptions for mediation were not met.

Three-month follow-up

The difference in gluten free diet adherence from baseline to three-month follow-up was significant ($t_{46} = 3.63, p = .001$), while there was no difference between immediate post-intervention and three-month follow-up scores ($t_{46} = 0.53, p = .600$; see Figure 2). Similarly, the difference in knowledge from baseline to three-month follow-up was significant ($t_{46} = 4.39, p < .001$), while there were no differences between immediate post-intervention and three-month follow-up ($t_{46} = .550, p > .05$).

Figure 2 here

DISCUSSION

Bread n' Butter... Gluten Free of Course! is the first intervention specifically designed to improve gluten free diet adherence in coeliac disease. The program resulted in significant improvements in gluten free diet adherence immediately after the intervention relative to the waitlist control group. This difference was clinically as well as statistically meaningful, with the mean score for the participants who had inadequate baseline adherence falling in the excellent or very good range and a greater proportion of intervention participants evidencing a positive change in adherence category at the conclusion of the program. Further, amongst participants who completed the program this improvement was maintained at three-month follow-up. Given the significant consequences of even slight lapses in adherence within this population the findings suggest that the Bread n' Butter... Gluten Free of Course! program is a promising avenue for assisting individuals who are struggling to maintain adherence.

The program also resulted in improvements in gluten free diet knowledge. The findings for improvements in knowledge here are consistent with a previous

intervention, which showed that knowledge could be successfully improved through a targeted online intervention (11). The lack of a significant relationship between the change in knowledge and change in gluten free diet adherence, however, suggests that improvements in knowledge are not sufficient to produce improvements in adherence. The lack of predictive power of knowledge in changing behaviour has been consistently noted within the wider health psychology literature (26, 27); however, this is the first study to confirm the knowledge-behaviour gap specifically within coeliac disease and gluten free diet adherence. In contrast to the knowledge training program reported by Meyer and colleagues (11) improvements in knowledge resulting from the current program were maintained at three-month follow-up.

All participants improved on measures of physical and psychological quality of life and this was not differentially affected by intervention participation. A mere measurement effect (28) may have contributed to the lack of a significant time by condition interaction effect; that is, completing measures of quality of life in the context of a study to improve adherence, coping, and quality of life may have increased the salience of any difficulties, which in turn may have led to changes in the efforts to manage the gluten free diet, with positive flow-on effects to quality of life. Indeed it has been suggested that specifically in the context of Internet-based interventions participants may actively seek out additional e-support following questionnaire completion while remaining on the waitlist (29). No information regarding contact with health professionals or information/support seeking during the trial period was collected and so this possibility cannot be ruled out. Alternatively, for the waitlist control group, knowing that they would be given access to the intervention following a delay may also have been enough to lead to improvements in

wellbeing. Without knowledge of the participant's life circumstances it is not possible to fully explain this finding.

Despite including CBT strategies, the program did not result in significant improvements in psychological symptoms, although this may be reflective of the relatively low levels of psychological symptoms at baseline, with all the mean scores falling in the average or normal ranges. Alternatively, the psychological symptom measures may not have been sensitive enough to detect subtle changes in disease-specific distress that may have resulted from intervention participation.

This study had some limitations. Firstly, the use of a waitlist control group meant that three-month follow-up data could only be obtained for the intervention group. It is therefore unclear whether the differences between groups would have remained significant. Given that the paired samples t-test indicated that the waitlist group did not change from baseline to the post-survey on adherence or knowledge this, however, seems unlikely. Secondly, individuals with varying levels of adherence were recruited to the intervention and as such approximately half the participants were already exhibiting excellent or very good adherence prior to participation. When the analyses were conducted on the reduced sample of participants with inadequate adherence, however, the effect size was actually increased suggesting that there was still adequate power to detect a significant and meaningful effect.

There was a high level attrition from the intervention, which may have resulted in an overestimation of the effectiveness of the program. That is, only ~50% of the intervention group completed the program. This figure is, however, consistent with previous attrition research in internet-based interventions, which has suggested that researchers anticipate an overall 50% attrition rate with the majority of the drop out occurring in the first month (14). There were no differences in baseline

characteristics between completers and non-completers, suggesting that selective attrition did not directly influence the intervention outcome. It is possible that other factors such as the perceived acceptability of the program may have resulted in differential attrition, which may, in turn, have affected the trial outcome. Consistent with the pattern of early drop out following the educational module, qualitative feedback at each stage of the program indicated a perception that the intervention would be of most benefit to people newly diagnosed with coeliac disease. Despite significant drop out, the intention-to-treat analyses, which are generally thought to underestimate treatment effects (30), suggests that the program is likely to effectively improve adherence in people with coeliac disease.

This study showed that access to the Bread n' Butter... Gluten Free of Course! program conferred significant benefits across the sample. These benefits were particularly pronounced for individuals who had compromised adherence at baseline. When combined with the online and automated design, the program represents an inexpensive and evidence-based resource to supplement the services provided by Coeliac Societies, which is likely to improve adherence in those who have been unable to achieve or maintain good adherence. Given the potential negative health effects of even minor breaches to adherence in coeliac disease, the Bread n' Butter... Gluten Free of Course! program is an important and much-needed resource for this population.

REFERENCES

1. Green PHR, Cellier C. Celiac disease. *The New England Journal of Medicine*. 2007;357:1731-43.
2. Green PHR, Jabri B. Coeliac disease. *Lancet*. 2003;362:383-91.
3. Biagi F, Campanella J, Martucci S, Pezzimenti D, Ciclitira PJ, Ellis HJ, et al. A milligram of gluten a day keeps the mucosal recovery away: A case report. *Nutrition Reviews*. 2004;62:360 -3.
4. Hall NJ, Rubin G, Charnock A. Systematic review: Adherence to a gluten-free diet in adult patients with coeliac disease. *Alimentary Pharmacology and Therapeutics*. 2009;30:315-30.
5. Leffler DA, Edwards-George J, Dennis M, Cook EF, Schuppan D, Kelly CP. A prospective comparative study of five measures of gluten-free diet adherence in adults with coeliac disease. *Alimentary Pharmacology and Therapeutics*. 2007;26:1227-35.
6. Leffler DA, Dennis M, Edwards-George J, Jamma S, Magge S, Cook EF, et al. A simple validated gluten-free diet adherence survey for adults with celiac disease. *Clinical Gastroenterology and Hepatology*. 2009;7:530-6.
7. Fera T, Cascio B, Angelini G, Martini S, Guidetti CS. Affective disorders and quality of life in adult coeliac disease patients on gluten-free diet. *European Journal of Gastroenterology & Hepatology*. 2003;15:1287-92.
8. Sainsbury K, Mullan B. Measuring beliefs about gluten free diet adherence in adult coeliac disease using the theory of planned behaviour. *Appetite*. 2011;56:476-83.
9. Sainsbury K, Mullan B, Sharpe L. Gluten free diet adherence in coeliac disease: The role of psychological symptoms in bridging the intention-behaviour gap. *Appetite*. 2013;61:52-8.
10. Addolorato G, De Lorenzi G, Abenavoli L, Leggio L, Capristo E, Gasbarrini G. Psychological support counselling improves gluten-free diet compliance in coeliac patients with affective disorders. *Alimentary Pharmacology and Therapeutics*. 2004;20:777-82.
11. Meyer KG, Fasshauer M, Nebel IT, Paschke R. Comparative analysis of conventional training and a computer-based interactive training program for celiac disease patients. *Patient Education and Counseling*. 2004;54:353-60.
12. Ring Jacobsson L, Friedrichsen M, Goransson A, Hallert C. Does a coeliac school increase psychological well-being in women suffering from coeliac disease, living on a gluten-free diet? *Journal of Clinical Nursing*. 2012;21:766-75.
13. Webb TL, Joseph J, Yardley L, Michie S. Using the internet to promote health behaviour change: A systematic review and meta-analysis of the impact of theoretical basis, use of behaviour change techniques, and mode of delivery on efficacy. *Journal of Medical Internet Research*. 2010;12:e4.
14. Eysenbach G. The law of attrition. *Journal of Medical Internet Research*. 2005;7:e11.
15. Titov N, Dear BF, Schwencke G, Andrews G, Johnston L, Craske MG, et al. Transdiagnostic internet treatment for anxiety and depression: A randomised controlled trial. *Behaviour Research and Therapy*. 2011;49:441-52.
16. Titov N, Andrews G, Davies M, McIntyre K, Robinson E, Solley K. Internet treatment for depression: A randomized controlled trial comparing clinician vs. technician assistance. *PLoS ONE*. 2010;5:e10939.

17. Abraham C, Michie S. A taxonomy of behavior change techniques used in interventions. *Health Psychology*. 2008;27:379-87.
18. Abraham C, Kok G, Schaalma H, Luszczynska A. Health promotion. In: Martin PR, Cheung F, Kyrios M, Littlefield L, Knowles L, Overmier M, et al., editors. *The International Association of Applied Psychology Handbook of Applied Psychology*. Oxford: Wiley-Blackwell; 2010.
19. Butler AC, Chapman JE, Forman EM, Beck AT. The empirical status of cognitive-behavioural therapy: A review of meta-analyses. *Clinical Psychology Review*. 2006;26:17-31.
20. Murphy B, Herrman H, Hawthorne G, Pinzone T, Evert H. *Australian WHOQOL instruments: Users manual and interpretation guide*. Melbourne, Australia: Australian WHOQOL Field Study Centre; 2000.
21. Lovibond PF, Lovibond SH. The structure of negative emotional states: Comparison of the Depression Anxiety Stress Scale (DASS) with the Beck Depression and Anxiety Inventories. *Behaviour Research and Therapy*. 1995;33:335-43.
22. Garner DM. *Eating Disorder Inventory - 3. Professional Manual*. Lutz, Florida: Psychological Assessment Resources, Inc.; 2004.
23. Lovibond SH, Lovibond PF. *Manual for the Depression Anxiety Stress Scales (DASS)*. 2nd ed. Sydney, Australia: Psychology Foundation of Australia; 1995.
24. Sainsbury K. *Adherence to the gluten free diet in coeliac disease: An intervention mapping approach using the theory of planned behaviour and psychological symptoms*. The University of Sydney; 2013.
25. Baron RM, Kenny DA. The moderator–mediator variable distinction in social psychological research: Conceptual, strategic, and statistical considerations. *Journal of Personality and Social Psychology*. 1986;51(6):1173.
26. Hornik R. The knowledge-behaviour gap in public information campaigns: A development communication view. In: Salmon CT, editor. *Information campaigns: Balancing social values and social change*. Newbury Park, CA: Sage; 1989. p. 113-38.
27. Rimal RN. Closing the knowledge-behaviour gap in health promotion: The mediating role of self-efficacy. *Health Communication*. 2000;12:219-37.
28. Godin G, Sheeran P, Conner M, Germain M. Asking questions changes behavior: Mere measurement effects on frequency of blood donation. *Health Psychology*. 2008;27:179-84.
29. Zetterqvist K, Maanmies J, Strom L, Andersson G. Randomized controlled trial of Internet-based stress management. *Cognitive Behaviour Therapy*. 2003;32:151-60.
30. Montori VM, Guyatt GH. Intention-to-treat principle. *Canadian Medical Association Journal*. 2001;165:1339-41.

Guarantor of the article: Kirby Sainsbury

Specific author contributions: Author One designed the intervention and study.

Author One conducted the study, conducted relevant analyses and drafted the article.

Authors Two and Three both reviewed the intervention and article. All authors approved the final version of the paper prior to submission.

Financial support: none

Potential competing interests: none

Clinical trial registration: Australian New Zealand Clinical Trial Registry

(<http://www.ANZCTR.org.au/ACTRN12612001258842.aspx>); protocol number:

ACTRN12612001258842

Full trial protocol: available on request from authors

Table 1. Summary of the Bread n’ Butter... Gluten Free of Course! modules

Module	Content
1: Introduction and information about coeliac disease and the gluten free diet	Definition of coeliac disease, gluten, and the gluten free diet; advantages of following a gluten free diet; label reading rules and exceptions; avoiding cross contamination.
2: Managing the challenges of the gluten free diet	Internal and external barriers to maintaining a gluten free diet; structured problem solving to manage the external barriers to adherence.
3: Communication around the gluten free diet	The communication dilemma (not wanting to draw attention to self and diet vs. needing to communicate in order to receive a safe meal); styles of communication; typical gluten free diet situations where assertiveness may be needed; initial enquiries; unhelpful follow-up responses; steps to assertiveness; communicating about the exceptions to the rules; being assertive with friends and family.
4: Thinking about the gluten free diet	The relationship between thoughts, feelings, and behaviour; reactions to the coeliac disease diagnosis; managing thoughts using cognitive restructuring/reframing; generating alternate thoughts for use in future situations.
5: Balancing life with your gluten free diet	The effects of narrowed focus; achieving balance with the gluten free diet; pleasant activity scheduling; SMART goal setting (specific, measurable,

achievable, relevant, time-limited).

6: Bringing it all together

Summary of skills from the previous six modules:
label reading/avoiding contamination; problem
solving; assertiveness/communication skills;
reframing thoughts; achieving balance and goal
setting.

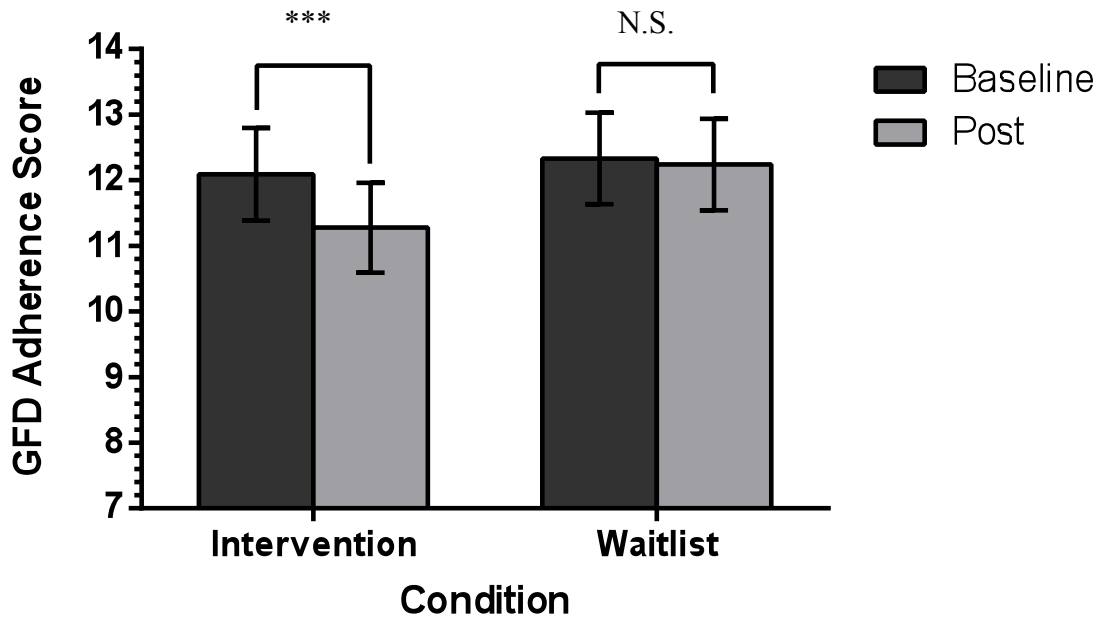


Figure 1a. Time x condition interaction effect for gluten free diet adherence

(intention-to-treat sample)

Note: Analyses based on N = 189 (intervention group: n = 101; waitlist control group: n = 88); interaction effect: $F_{1,187} = 5.67, p = .014$; intervention group: $t_{100} = 3.83, p < .001$; waitlist control group: $t_{87} = 0.42, p = .674$; GFD adherence scores range = 7 – 35; higher scores indicate poorer adherence; inadequate adherence defined as a score of 13 or higher; Cohen’s d = 0.35; *** $p < .001$.

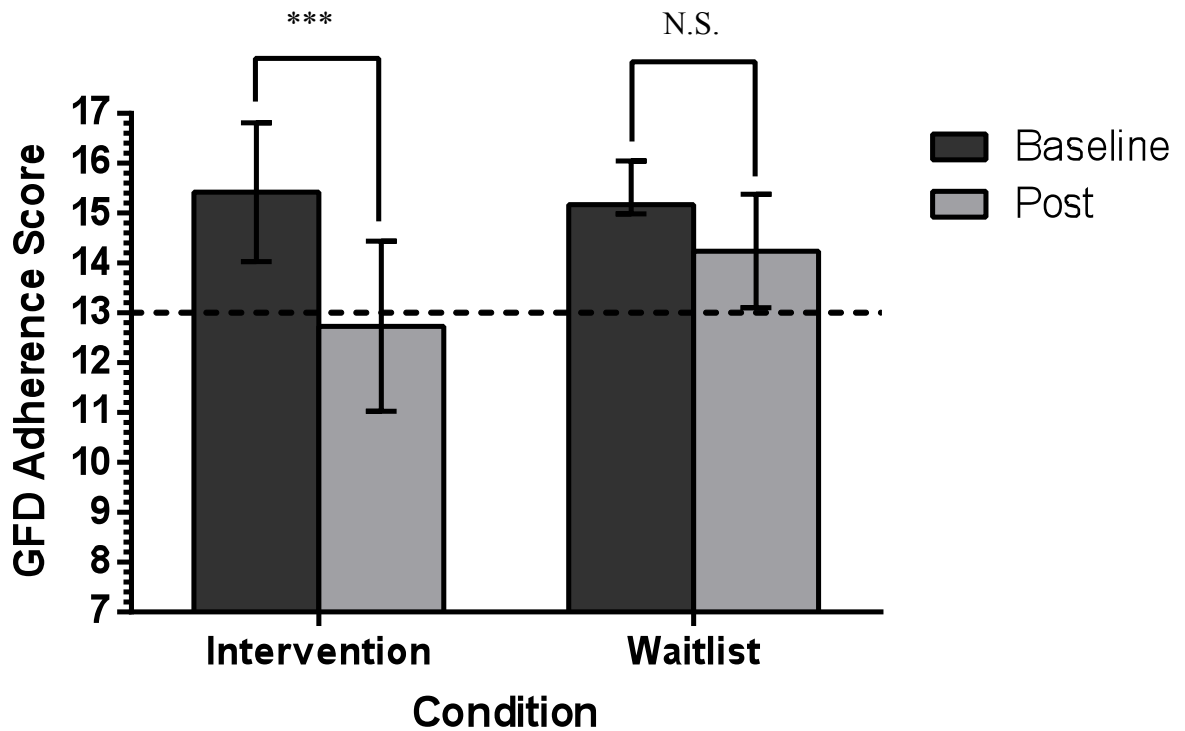


Figure 1b. Time x condition interaction effect for gluten free diet adherence (per-protocol, inadequate adherence at baseline only)

Note: Analysis based on $N = 55$ (intervention group: $n = 26$; waitlist control group: $n = 29$); interaction effect: $F_{1,53} = 6.49, p = .014$; GFD adherence scores range = $7 - 35$; higher scores indicate poorer adherence; inadequate adherence defined as a score of 13 or higher (denoted by dashed line); Cohen's $d = 0.69$; *** $p < .001$.

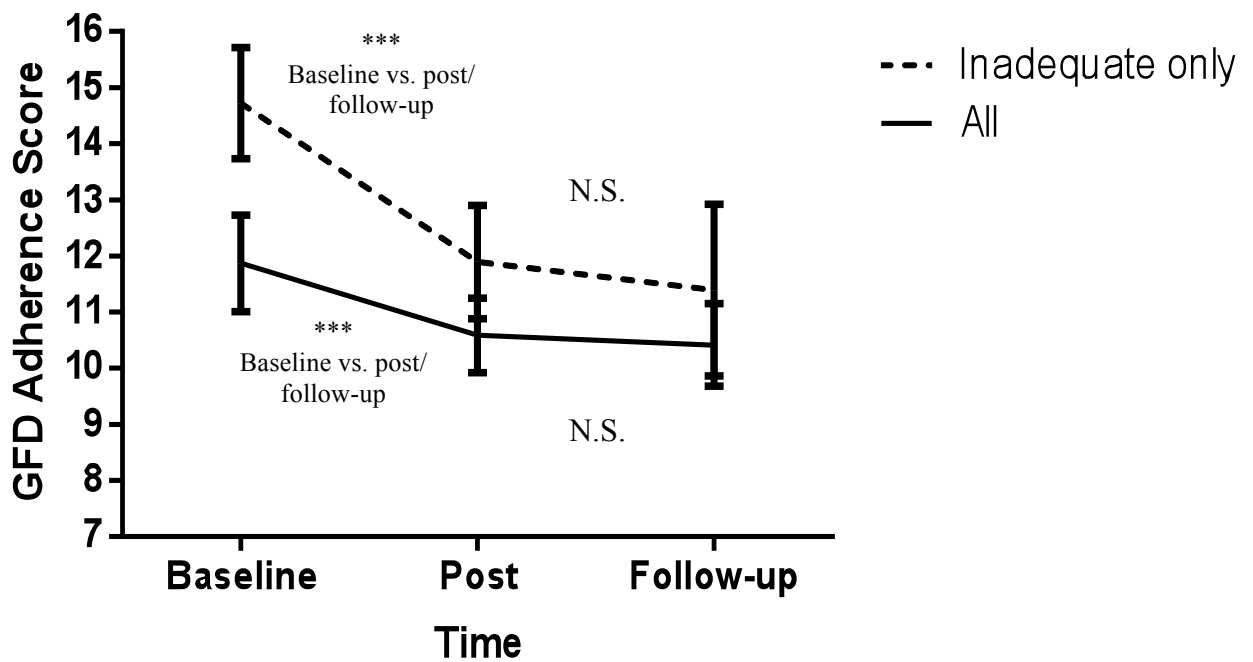


Figure 2. Baseline, post-intervention, and three-month follow-up adherence scores

Note: Fixed line (all) refers to analyses conducted on the sample of intervention group participants who completed the intervention and responded to the three-month follow-up survey ($n = 46$); baseline vs. follow-up: $t_{46} = 3.63, p < .001$; post vs. follow-up: $t_{46} = 0.53, p = .600$; Dashed line (inadequate only) refers to analyses conducted on the sub-sample of intervention participants who had inadequate adherence at baseline and completed the intervention and three-month follow-up survey ($n = 18$); baseline vs. follow-up: $t_{18} = 4.50, p < .001$; post vs. follow-up: $t_{18} = 0.70, p = .497$; GFD adherence scores range = 7 – 35; higher scores indicate poorer adherence; inadequate adherence defined as a score of 13 or higher; *** $p < .001$.