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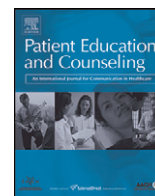
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## Patient Education and Counseling

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## 1 Educational/Counseling Model Health Care

2 The development and evaluation of a nurse led food intolerance clinic  
3 in primary care

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## ABSTRACT

**Objective:** To develop a clinic for patients who believe they have a food intolerance that could be administered by practice nurses with minimal experience of dietary change or food intolerance.

**Methods:** The clinic consisted of 1 week baseline, 2 weeks healthy eating plan (HE), 2 weeks wheat and dairy free plan (WD). Patients were discharged after the HE plan if their symptoms had improved, otherwise they continued onto the WD plan. Following training 4 nurses ran 4 clinics across the UK.

**Results:** 281 patients with perceived food intolerance were recruited. The most common symptoms were bowel symptoms, tiredness, stomach symptoms, and headaches. Of those who completed the programme ( $n = 150$ ), the majority were discharged after the HE plan as their symptoms had improved ( $n = 106, 70.6\%$ ). A third also completed the WD plan ( $n = 44, 29\%$ ). Symptoms, mood and quality of life improved significantly by the end of the intervention. WD showed added value as symptoms showed further improvement.

**Conclusion:** There was a need for the clinic although not on a full time basis. Symptoms improved following both the HE and WD plans.

**Practice implications:** A simple dietary based intervention may help relieve symptoms in those who believe they have a food intolerance.

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7  
8 **1. Introduction**

9 Defining and diagnosing 'food intolerance' is problematic due to  
10 the range of terms used by both lay and scientific communities  
11 including 'adverse reactions to food', 'food allergy' and 'food  
12 intolerance'. Prevalence estimates in the community also range  
13 from 2% to 33% depending on the terms used and the mode of  
14 verification employed [1-5]. Evidence indicates, however, that  
15 'food intolerance' is becoming an increasingly common presenta-  
16 tion in primary care [1-5] with common symptoms including  
17 bowel and stomach problems, headaches and skin problems.  
18 Interviews with GPs, however, suggest that they are uncertain how  
19 to manage food intolerance [3] and patients indicate that health  
20 professionals are often unhelpful and unsympathetic [6]. To date,  
21 the only available services are either specialist allergy services  
22 which tend to prioritise patients with severe allergies or private  
23 medical care which is not accessible to all and raises concerns  
24 around standardisation and control [5,6]. Many individuals  
25 therefore rely on self-diagnosis, self-management or alternative  
26 practitioners which can result in the use of elimination diets that  
27

can be unnecessarily restrictive and even harmful to an individua- 27  
l's nutrition and health [7]. 28

The present study therefore aimed to develop and evaluate a 29  
nurse led food intolerance clinic in primary care. The study used a 30  
pragmatic definition of food intolerance [8] focusing on symptom 31  
experiences rather than the underlying causal mechanisms which 32  
enables a set of criteria to be used in clinical practice which are 33  
derived from clinical observation. To this end the service was 34  
developed for perceived food intolerance and for those patients for 35  
whom other relevant diagnoses had been ruled out. In particular, 36  
the study aimed to assess the impact of the service on patient 37  
outcomes with a focus on symptoms, mood and quality of life. 38

## 2. Methods 39

## 2.1. Design 40

The service consisted of a healthy eating plan (HE) followed by a 41  
wheat and dairy free plan (WD). Measures were taken at the end of 42  
the sessions at baseline (time 1), end of healthy eating plan (time 2) 43  
and end of wheat and dairy free plan (time 3). The clinics ran for 24 44  
months and were administered by 4 nurses in four General 45  
Practices across the UK: Birmingham, South London, Norfolk and 46  
Glasgow. These were identified to provide a heterogenous sample 47  
that varied in terms of geographical location, ethnic mix, social 48

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**Table 1**  
Eating plans: healthy eating (HE) and wheat and dairy (WD) free plans.

	Foods to avoid	Foods to eat	General advice
Healthy eating plan	Caffeine Fizzy drinks Chemicals and additives Alcohol Sugar Highly processed foods Fast foods Takeaways Very spicy foods Less salt Less fat	Starchy foods Fruit and vegetables More fish Drink plenty of water Good intake of fibre Foods rich in vitamins and minerals	Cook more Eat out less
Wheat and dairy free plan	Any food prepared with wheat or dairy	Fresh meat and fish Eggs Oats, rice, rye flour, corn flour, buckwheat, barley Fruit Fresh nuts and seeds Salad Wheat free pasta Wheat free bread	Keep it simple Avoid sauces Detailed meal plans given

49 class and age and provided a combined population of 32,200 (aged  
50 16 and over). Approval was obtained from MREC and the R and D  
51 committees.

## 52 2.2. Participants

53 Patients were included if they were aged 16 and over and  
54 reported experiencing symptoms that they believed may relate to a  
55 food intolerance. They were excluded for the following: diabetes,  
56 renal failure, Coeliac disease, Anorexia Nervosa or Bulimia,  
57 medically undiagnosed weight loss, learning difficulties, psychiat-  
58 ric illness, dementia or language barriers. Participants were  
59 recruited via self-referral either through a postal questionnaire  
60 sent to 20% of the patients at each practice or an advert placed in  
61 the waiting room. GPs also referred some patients directly.  
62 Analysis showed no differences between participants in terms of  
63 means of recruitment.

## 64 2.3. Developing the service

65 The service aimed to be an improvement on the current skill  
66 base in primary care and to offer a degree of expertise that could be  
67 taught to practice nurses with no prior knowledge in this area  
68 within a short time frame. It was also designed to feel personalised  
69 to the individual patient, yet follow a set protocol to ensure that  
70 the clinic procedure was replicable and could be offered as a pre-  
71 designed package to General Practices in the future. The service  
72 was designed in consultation with food intolerance specialists who  
73 advised that although dietary interventions for food intolerance  
74 are often highly individualised, there are some common culprits in  
75 food intolerance that can be identified using a food diary and  
76 detailed interview and are frequently the cause of some of the  
77 more common symptoms.

## 78 2.4. The service

79 The service offered each patient a maximum of four 50 min  
80 sessions over a 5-week period in which they followed a 2-week  
81 healthy eating (HE) plan, followed by a 2-week wheat and dairy  
82 (WD) free plan. Patients were discharged after the HE plan if both  
83 they and the nurse felt that their symptoms had been alleviated  
84 and that no further intervention was required or if they had been  
85 unable to adhere to the HE plan. They continued onto the WD plan  
86 if their symptoms persisted and it was deemed that they needed

further help and dietary change. The dietary plans were devised to  
make them manageable for patients and are shown in Table 1.

## 2.5. Food and symptom diary

Patients were required to keep food and symptom diaries whilst  
they were attending the clinics, which were used as a tool for the  
nurse and patient to discuss the patients' dietary habits and  
possible links to symptoms.

## 2.6. Nurse training

The study employed four practice nurses with only minimal  
experience and knowledge of diet, behaviour change and food  
intolerance who were placed as additional staff into the practices. All  
were registered nurses, two had worked as research nurses, one had  
worked as a practice nurse and one was a district nurse. The nurses  
were recruited and trained by the researchers and a clinician who  
specialises in the management of food intolerance. Training involved  
familiarisation with the clinic procedure, training in food intolerance  
(eg. detection of symptoms, possible causes, common food culprits,  
changing eating behaviour) and role plays to enable the nurses to  
manage patients and offer appropriate advice for food intolerance  
and dietary change. The initial training took place over two days at  
the University. Subsequent follow up training days were then  
provided every six months for the next 2 years which provided an  
opportunity to reflect upon their management of patients, describe  
any consultations they found problematic and have any questions  
answered by the research team and the clinician.

## 2.7. Measures

Participants completed validated measures of demographics,  
clinical history, aspects of symptoms (total no., no. attributed to  
food, frequency, severity), mood (profile of mood states, (POMS);  
GHQ12) and quality of life (physical health, mental health) [9-11]  
at baseline, end of the HE plan and end of the WD plan. Measures  
took about 20 min to complete.

## 2.8. Data analysis

The data were analysed to describe the demographics and  
symptoms of patients attending the clinic and to assess changes in  
symptoms, quality of life and mood following the intervention.

### 3. Results

#### 3.1. Clinic attendance

The study employed four nurses for 24 months. Due to training time, staff changes and competing clinical duties it is estimated that the nurses offered the clinics for a total of 62 months for 3 days a week. This is approximately 37 months of possible full time clinics. Over this period, 281 participants attended the clinics across the four different practices. Of the initial sample of participants who attended the clinics at baseline ( $n = 281$ ) just over half ( $n = 150$ , 53.4%) completed the intervention. Completers and non-completers were matched in terms of all demographic measures and aspects of symptoms. The majority of those who completed the intervention were discharged after the HE plan ( $n = 106$ , 37.7% (70.6% of completers)) as their symptoms were deemed to have improved significantly at this stage. Just under a third ( $n = 52$ , 29.3% (34.6% of completers)) continued on to the WD plan.

#### 3.2. Demographics of those attending the service

Demographics for all participants who attended at least the first session are shown in Table 2.

The mean age of the sample was 41 years, ranging from 18 to 86 years. The majority reported having a degree. Over three quarters of the participants that attended the clinic at baseline were female and over 80% classified themselves as white.

#### 3.3. Symptoms experienced

The most commonly reported symptoms were bowel symptoms, tiredness, stomach symptoms, and headaches. This pattern was fairly consistent for those who did and did not complete the intervention and for those who completed the HE and the WD plans (see Table 3).

#### 3.4. Impact of intervention

Changes from baseline to the end of the intervention are shown in Table 4. For those who only completed the HE plan this was assessed at the end of this plan and for those who progressed onto the WD plan this was assessed after this stage of the intervention had also been completed.

##### 3.4.1. Symptoms

The total number of symptoms, the number of symptoms attributed to food, symptom frequency and symptom severity all

**Table 2**

Patient demographics (whole sample:  $n = 281$ ).

Variable	<i>n</i>	%
Age		
Mean	41.44	
SD	14.55	
Range	18-86	
Gender		
Male	62	(22.1)
Female	219	(77.9)
Educ status		
Degree	114	(43.2)
Higher educ < degree	28	(10.6)
A level and equiv	23	(8.7)
GCSE and equiv	57	(21.6)
None	42	(15.9)
Educ status – 2 levels		
Higher educ	142	(53.8)
School educ	122	(46.2)
Ethnicity		
White	225	(81.2)
Mixed	6	(2.2)
Asian	5	(1.8)
Black	25	(9.0)
Chinese	3	(1.1)
Other	13	(4.7)
Ethnicity – 2 levels		
White	225	(81.2)
Non-white	52	(18.8)

significantly reduced from before to after attending the clinic. The results also show significant time by group interactions for all measures apart from symptom frequency indicating that although all participants showed an improvement this was particularly pronounced in those that completed the WD plan after the HE plan.

##### 3.4.2. Quality of life and mood

Patients reported a significant improvement in quality of life and mood from baseline to the end of the intervention. This improvement was equal across all patients regardless of whether they went onto the WD plan.

##### 3.4.3. Added value of WD plan

Adding the WD plan after the HE plan resulted in significant improvements in symptoms in terms of number of symptoms and symptom frequency. It had no effect on symptom severity, mood or health status ( $ps > 0.05$ ) (see Table 5).

**Table 3**

Type of symptoms reported by all participants at baseline ( $n = 281$ ) and HE group ( $n = 106$ ) and WD group ( $n = 44$ ) ( $n/\%$ ).

Type of symptom	All pts. ( $n = 281$ )	Rank	HE group ( $n = 106$ )	Rank	WD group ( $n = 44$ )	Rank
Bowel symptoms	212 (75.4%)	1	80 (75.5%)	1	39 (88.6%)	1
Tiredness	145 (51.6%)	2	55 (51.9%)	2	27 (61.4%)	2
Stomach symptoms	132 (47%)	3	46 (43.4%)	3	24 (54.5%)	3
Headache	112 (39%)	4	39 (36.8%)	4	19 (43.2%)	4
Skin	89 (31.7%)	5	28 (26.4%)	5	14 (31.8%)	6
Mood symptoms	76 (27%)	6	24 (22.6%)	6	12 (27.3%)	5
Eyes/nose symptoms	60 (21.4%)	7	22 (20.8%)	7	11 (25%)	7
Joint pain	43 (15.3%)	8	14 (13.2%)	8	10 (22.7%)	11
Water retention	38 (13.5%)	9	11 (10.4%)	9	8 (18.2%)	9
Chest symptoms	37 (13.2%)	10	11 (10.4%)	9	7 (15.9%)	8
Mouth symptoms	32 (11.4%)	11	11 (10.4%)	9	4 (9.1%)	10
Mouth ulcers	28 (10%)	12	10 (9.4%)	12	4 (9.1%)	11
Anaphylaxis	7 (2.5%)	13	1 (0.9%)	13	1 (2.3%)	13

**Table 4**  
Q2 Changes in symptoms, quality of life and mood between Time 1 and end point.

	Time 1		End		Main effect time	Main effect group	Time × Group
	HE group (n = 106)	WD group (n = 44)	HE group (n = 106)	WD group (n = 44)			
<b>Symptoms</b>							
Total number of symptoms							
Mean	10.99	12.75	7.03	5.47	F = 188.67	F = 0.09	F = 18.10
(SD)	(4.70)	(4.89)	(4.53)	(3.03)	p < .0005*	p = .76	p = .0005*
Total number of symptoms attributed to food							
Mean	4.09	4.86	2.60	1.78	F = 46.23	F = 0.005	F = 6.62
(SD)	(3.22)	(4.06)	(2.37)	(1.74)	p < .0005*	p = .94	p = .011*
Symptom frequency							
Mean	3.26	3.24	2.91	2.73	F = 45.42	F = 1.80	F = 0.73
(SD)	(0.59)	(0.61)	(0.64)	(0.69)	p < .0005*	p = .18	p = .39
Symptom severity							
Mean	3.06	3.11	2.81	2.65	F = 29.92	F = 0.11	F = 4.82
(SD)	(0.61)	(0.64)	(0.73)	(0.79)	p < .0005*	p = .74	p = .03*
<b>Mood</b>							
POMS							
Mean	17.84	17.80	5.69	6.84	F = 52.10	F = 0.05	F = 0.10
(SD)	19.52	16.94	18.35	13.42	p < .0005*	p = .83	p = .75
GHQ-12							
Mean	11.97	12.9	9.20	8.95	F = 40.13	F = 0.23	F = 0.99
(SD)	4.83	6.43	4.73	2.74	p < .0005*	p = .63	p = .22
<b>Quality of life</b>							
Physical health							
Mean	53.74	53.18	57.78	57.82	F = 22.92	F = 0.05	F = 0.11
(SD)	(8.45)	(10.25)	(7.73)	(6.15)	p < .0005*	p = .83	p = .74
Mental health							
Mean	57.43	54.43	60.17	59.44	F = 21.26	F = 1.71	F = 1.82
(SD)	(9.07)	(9.95)	(9.03)	(8.05)	p < .0005*	p = .19	p = .18

**Table 5**  
Added value of WD: changes in symptom experience.

	Time 2	Time 3	T	df	p
	WD group (n = 44)	WD group (n = 44)			
<b>Total number of symptoms</b>					
Mean	8.56	5.47	4.29	41	<.0005*
(SD)	(4.49)	(3.03)	(CI = 1.67-4.66)		
<b>Total number of symptoms attributed to food</b>					
Mean	3.37	1.78	3.55	39	.001*
(SD)	(3.11)	(1.74)	(CI = 0.72-2.63)		
<b>Symptom frequency</b>					
Mean	2.99	2.73	2.32	41	.025*
(SD)	(0.61)	(0.69)	(CI = 0.04-.55)		
<b>Symptom severity</b>					
Mean	2.81	2.65	1.21	38	.24
(SD)	(0.59)	(0.79)	(CI = -0.09-.36)		

179 **4. Discussion and conclusion**

180 **4.1. Discussion**

181 Over a period of time equivalent to 37 full time months 281  
 182 patients attended the clinic with perceived food intolerance. Of  
 183 these, over half completed the intervention with two thirds of these  
 184 being discharged after the healthy eating plan and a third being  
 185 discharged after the wheat and dairy free plan. The most common  
 186 presenting symptoms were bowel symptoms, tiredness, stomach  
 187 symptoms, and headaches. Following the intervention the results  
 188 showed significant improvement in symptoms, quality of life and  
 189 mood. Completing the wheat and dairy free diet after the healthy  
 190 eating plan added value in terms of symptom improvement but had  
 191 no impact on mood and health status. The present study therefore  
 192 indicates that a simple intervention could be used to improve  
 193 patient symptoms within the framework of a primary care setting.

194 There are however, several problems with the study that need  
 195 to be addressed. First due to the absence of a control group it

remains unclear what aspects of the intervention were effective as  
 it consisted of multiple components including time spent with a  
 dedicated professional, general dietary advice, tailored specific  
 dietary advice, repeated food diaries and time for reflection and  
 discussion. A full scale randomised trial is now needed to explore  
 these issues. Second, changes were only examined during the  
 course of the 5-week programme (maximum). Longer term  
 assessments are needed.

4.2. Conclusions

The present study suggests that a simple nurse led intervention  
 in Primary Care could help to improve a range of symptoms that  
 patient's believe are related to food intolerance.

4.3. Practice implications

Much of the problem with food intolerance rests with issues of  
 definition and distinguishing 'real' food intolerance from the

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211 multitude of other common presenting symptoms such as bowel  
212 and stomach problems and tiredness. This study indicates that as  
213 long as other relevant diagnoses have been ruled out many of these  
214 symptoms may well be successfully managed by encouraging a  
215 more healthy approach to eating with a reduction in common  
216 culprits such as fizzy drinks, processed foods and caffeine. Further,  
217 a more restrictive wheat and dairy free diet made have added  
218 benefit if initial symptoms do not subside as long as this is done  
219 under close supervision. In addition, these changes can be  
220 facilitated by having access to a health professional who has time  
221 to spend with the patient and the use of diaries to promote an  
222 insight both into what a patient is actually eating and how their  
223 diet can be changed. Such an intervention may remain too time  
224 consuming for a GP but could be introduced into the workload of  
225 the Practice Nurse and would help the practice team manage the  
226 many patients who may well have been considered as having  
227 intransigent problems.

### 228 **Conflicts of interest**

229 I confirm all patient/personal identifiers have been removed or  
230 disguised so the patient/person(s) described are not identifiable  
231 and cannot be identified through the details of the story.

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241

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