Is Peer Support in Group Clinics as Effective as Traditional Individual Appointments? The First Study in Patients With Celiac Disease

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INTRODUCTION: **Celiac disease (CD) is common, affecting approximately 1% of the population. The cornerstone of management is a gluten-free diet, with dietetic advice being the key to aiding implementation. The aim of the study was to assess group clinics in comparison with traditional individual appointments.**

METHODS: **Patients with a new diagnosis of CD, confirmed histologically, were prospectively recruited over 18 months in Sheffield, United Kingdom. Patients received either a group clinic or traditional one-to-one appointment, led by a dietitian. Quality-of-life questionnaires were completed at baseline, as well as biochemical parameters being recorded. Patients were followed up at 3 months, where adherence scores were assessed as well as biochemical parameters and quality of life questionnaires being completed.**

RESULTS: **Sixty patients with CD were prospectively recruited and received either an individual (n = 30) or group clinic (n = 30). A statistically significant reduction in tissue transglutaminase was noted following group clinics (mean 58.5, SD 43.4 U/mL vs mean 13.2, SD 5.7 U/mL, $P < 0.01$). No significant differences in baseline and follow-up biochemical parameters between one-to-one and group clinics were noted. At follow-up, there was no statistically significant difference between mean gluten-free diet adherence scores (mean 3.1, SD 0.4 vs mean 3.1, SD 0.7, $P = 0.66$) between one-to-one and group clinics.**

DISCUSSION: **This first study assessing group clinics in CD demonstrates they are as effective as traditional one-to-one clinics, with the added benefits of peer support and greater efficiency, with an estimated 54% reduction of dietetic resources.**

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INTRODUCTION

Celiac disease (CD) is a chronic immune-mediated enteropathy, which is triggered by gluten ingestion in genetically susceptible individuals (1). CD is common, with a prevalence of approximately 1% (2,3). However, many individuals with CD remain undiagnosed. In the United States, more than 80% of individuals with CD were undiagnosed in 2009, although this has decreased to below 50% in 2013–2014 (4). There has been a rise in the diagnosis of CD over recent decades, with almost a four-fold increase in the incidence rate in the United Kingdom between 1990 and 2011, from 5.2 per 100,000 to 19.1 per 100,000 person-years (5).

The cornerstone for management of CD remains a gluten-free diet (GFD) (6), to prevent complications such as an increased risk of bone fractures and malignancy (7,8). Adherence to a GFD however can be challenging, with a reduction in patient wellbeing and psychological distress being noted (9), with reported adherence between 42% and 91% in the literature (10). It is therefore essential that newly diagnosed individuals are seen by dietitians, so hidden sources of gluten can be identified, as well as to ensure healthy gluten-free substitute grains are provided to ensure adequate fiber and nutrient content are met (6). This is also the preferred method for patients, who want to be seen by a dietitian with a doctor available (11).

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Initial appointment			Follow-up appointment		
Data collected	**Topics covered**	**Information Provided**	**Data collected**	**Topics covered**	**Information Provided**
Weight	What is CD?	Diet Sheet	Weight	Adherence?	Supplementation
Height	Diagnosis	Starter Cards	Height	Ongoing Symptoms?	Membership
BMI	GFD	Membership cards	BMI	Getting prescriptions?	
Serology	Prescriptions	Prescription lists	Dietary History	Healthy Eating	
Evaluation form	Cross Contamination	Letter About Increased Baggage Allowance	Serology	Weight Reduction	
				Bloods if available	
				DEXA Scan results	

Figure 1. Topics covered in one-to-one and group clinics. BMI, body mass index; CD, celiac disease; DEXA, dual energy x-ray absorptiometry; GFD, gluten-free diet.

Currently, celiac dietetic advice is provided by one-to-one appointments. However, dietetic group clinics have been proposed as a new method to manage these patients (12). Potential benefits of this approach include the ability for peer support, with peer support having been shown to improve outcomes in patients with both diabetes and hypertension (13–15). The effectiveness of group clinics has also been demonstrated in the field of gastroenterology, in particular group clinics for the low fermentable oligosaccharides, disaccharides, monosaccharides, and polyol diet in patients with irritable bowel syndrome (16). The rise in diagnosis of CD has also resulted in an increased demand in healthcare services and led to a strain on existing resources. There appears to be a wide variation in the provision of dietetic services for CD in the United Kingdom, with many centres failing to deliver the required provision as suggested by UK national guidelines (17). Group clinics may provide an opportunity to standardize dietetic care in CD, both in the United Kingdom and globally.

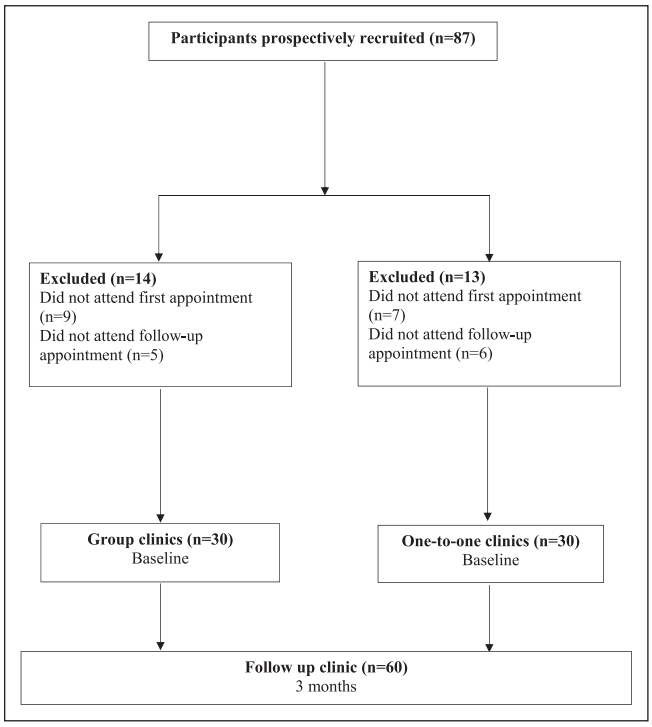

Figure 2. Flow chart for participants during trial.

Although there are several potential benefits of group clinics, little is known on its efficacy for patients with newly diagnosed CD in comparison with traditional one-to-one appointments. As a result of this, this study aimed to assess the outcomes of the novel set up of group clinics in comparison with traditional one-to-one clinics for the first time in CD.

METHODS

Study design and patients

Participants were prospectively recruited and allocated over an 18-month period through referrals from primary and secondary care to the dietetic service at Sheffield Teaching Hospitals, United Kingdom. Participants were recruited for group clinics initially. After this, participants were recruited for one-to-one clinics. The study ceased once 30 participants had been recruited for both group and one-to-one clinics. Participants were not given a choice in allocation to intervention.

Patients older than 18 years with newly diagnosed celiac disease were recruited, as defined as a either a positive immunoglobulin A (IgA)-tissue transglutaminase (TTG) or IgA-endomysial antibody (EMA) in conjunction with biopsy-proven CD (Marsh 3a or above). Patients with multiple diagnoses (e.g., Crohn's disease,

Table 1. Baseline demographics

Demographic	One-to-one clinics (n = 30)	Group clinics (n = 30)	*P* value
Gender			0.70[a]
Female, n (%)	22 (73.3)	17 (56.7)	
Male, n (%)	8 (26.7)	13 (43.3)	
Age (yr), mean ± SD	45.7 ± 17.2	50.7 ± 14.8	0.24[b]
Weight (kg), mean ± SD	70.8 ± 14.6	77.9 ± 19.4	0.12[b]
BMI (kg/m^2), mean ± SD	24.4 ± 3.9	26.5 ± 4.2	0.05[b]
Time seen from initial diagnosis (wk), mean ± SD	10.7 ± 11.0	11.3 ± 10.3	0.84[b]
Follow-up duration (wk), mean ± SD	16.1 ± 14.5	12.6 ± 2.2	0.19

BMI, body mass index.
[a]χ^2 test.
[b]Independent *t* test.

Table 2. Comparison of biochemical markers, adherence scores and questionnaire data between one-to-one clinics and group clinics at baseline and follow-up

	Baseline			Follow-up			Baseline vs follow-up	
	One-to-one clinics (n = 30)	Group clinics (n = 30)	*P* value	One-to-one clinics (n = 30)	Group clinics (n = 30)	*P* value	One-to-one clinics (n = 30), *P* value	Group clinics (n = 30), *P* value
Biochemical markers								
EMA								
Positive, n (%)	30 (100.0)	27 (90.0)	N/A[a]	12 (40.0)	8 (28.6)[b]	0.67[c]		
Negative, n (%)	0 (0.0)	3 (0.0)		18 (60.0)	20 (71.4)[b]			
TTG (U/mL), mean ± SD	71.0 ± 43.5	63.4 ± 45.2	0.51[d]	22.1 ± 36.9	13.2 ± 15.7[e]	0.25[d]	<0.01[a]	<0.01[a]
Hemoglobin (g/dL), mean ± SD	135.4 ± 13.1	142.1 ± 13.7	0.06[d]	134.1 ± 23.7	133.2 ± 35.2[b]	0.92[d]	0.73[a]	0.45[a]
Ferritin (μg/L), mean ± SD	64.1 ± 65.3	99.4 ± 140.3	0.22[d]	70.1 ± 82.1	126.8 ± 172.5[f]	0.11[d]	0.44[a]	0.21[a]
B12 (ng/L), mean ± SD	363.7 ± 163.3	326.3 ± 122.5	0.32[d]	452.6 ± 339.1	392.8 ± 186.6[f]	0.41[d]	0.19[a]	0.08[a]
Folate (μg/L), mean ± SD	9.9 ± 6.6	8.2 ± 3.9	0.21[d]	11.2 ± 4.9	11.6 ± 4.8[f]	0.72[d]	0.31[a]	<0.01[a]
Vitamin D (nmol/L), mean ± SD	62.9 ± 30.3[f]	52.6 ± 27.9[e]	0.20[d]	74.4 ± 23.2	75.3 ± 28.9[f]	0.90[d]	<0.01[a]	<0.01[a]
Adjusted calcium (mmol/L), mean ± SD	2.3 ± 0.1	2.3 ± 0.1[f]	0.53[d]	2.4 ± 0.1[f]	2.3 ± 0.1[e]	0.38[d]	0.03	0.26[a]
Adherence questionnaire								
Biagi adherence score, mean ± SD				3.1 ± 0.4	3.1 ± 0.7	0.66[d]		
Questionnaire data								
SF-36 physical summary, mean ± SD[g]	45.8 ± 9.6	47.3 ± 9.3	0.54[d]	47.3 ± 8.9	45.8 ± 9.2	0.52[d]	0.19[a]	0.35[a]
SF-36 mental summary, mean ± SD[g]	46.5 ± 9.8	44.6 ± 10.9	0.47[d]	46.4 ± 9.5	44.8 ± 11.8	0.57[d]	0.91[a]	0.84[a]
HADS anxiety, mean ± SD[h]	6.1 ± 4.0	7.6 ± 4.8	0.18[d]	5.3 ± 3.1	7.6 ± 4.9	0.04[d]	0.17[a]	0.94[a]
HADS depression, mean ± SD[h]	4.2 ± 3.4	4.8 ± 3.8	0.52[d]	3.8 ± 3.4	4.8 ± 4.1	0.32[d]	0.47[a]	1.00[a]

EMA, endomysial antibody; HADS, Hospital Anxiety and Depression; SF-36, Short-Form 36; TTG, tissue transglutaminase.
[a]Paired *t*-test.
[b]Missing values n = 28.
[c]χ^2 test.
[d]Independent-samples *t* test.
[e]Missing values n = 27.
[f]Missing values n = 29.
[g]SF-36 is based on norm-based scoring i.e., average population is noted to have a score of 50 with an SD of 10, with a lower score indicating poorer health.
[h]An HADS score of more than 11 implies a definite cause of anxiety or depression, a cutoff of 8–10 a probable case and 7 or less not being the case.

ulcerative colitis, and diabetes mellitus), communication barriers, and who had specifically requested an individual clinic were excluded.

The median group size was 6 participants (minimum 4, maximum 9; total 5 groups). The same topics were covered in group clinics vs one-to-one appointments and included education on a GFD, prescriptions, traveling, and information on Coeliac UK (Figure 1). Both sessions relied on discussion with the dietitians with PowerPoint presentations.

All patients had nutritional assessments at baseline (first appointment) and bloods performed in line with British Society of Gastroenterology guidelines. Baseline demographics, celiac serology (IgA-EMA and IgA-TTG), hemoglobin, adjusted calcium, vitamin D, vitamin B12, folate, and ferritin levels were recorded. Validated questionnaires were completed at baseline, which were the Short-Form 36 (SF-36) survey (18) and Hospital Anxiety and Depression Score (HADS) (19).

After this, all patients were re-evaluated at a 3-month follow-up appointment. At this point, adherence was assessed using a validated questionnaire (Biagi score), as well as celiac serology (IgA-EMA, IgA-TTG), hemoglobin, adjusted calcium, vitamin D, vitamin B12, folate, and ferritin levels being recorded. SF-36 survey and HADS were once again completed. Figure 2 outlines the study flow.

Celiac serology

Enzyme-linked immunosorbent assay kits (Aesku Diagnostics, Wendelsheim, Germany) were used to assay TTG antibodies. A TTG titer of >7 U/mL was regarded as positive as per manufacturer's guidance. IgA-EMA was detected by immunofluorescence on oesophageal sections (Binding Site, Birmingham, United Kingdom). Total IgA was measured using Behring BN2 nephelometer (Haywards Heath, West Sussex, United Kingdom).

Dietary adherence questionnaire

A validated questionnaire was used devised by Biagi et al. (20), which is made of 5 levels (0–4). Scores of 0 or 1 were defined as not following a strict GFD; score of 2 was defined as following a GFD but with important errors that require correction. Patients with a score of 3 or 4 were defined as following a strict GFD.

Ethical considerations

The study protocol was approved by the Yorkshire and Humber Research Ethics committee and registered with the local research and development department of Sheffield Teaching Hospital NHS Foundation Trust (REC reference 14/YH/1216). Written consent was obtained from all patients.

Statistical analysis

All data were analyzed using SPSS version 24 (International Business Machines, Armonk, NY). Data were summarized using descriptive statistics, including counts and percentages for categorical data and mean ± SD for continuous data. Paired *t* tests were used to compare continuous data within groups, with the independent *t* test to compare continuous data between groups. Comparison between categorical data between both groups was performed using χ^2 testing. Statistical significance was considered when $P < 0.05$.

RESULTS

A total of 87 patients with newly diagnosed CD were prospectively recruited and allocated for a dietetic consultation between December 2014 and August 2016. Of these, 16 patients (18.4%) failed to attend their first appointment, with 11 patients (12.6%) failing to attend their follow-up appointment. Of the remaining 60 patients (n = 39 female, mean age 48.2 ± 16.1 years), 30 patients were seen in group clinics and 30 had one-to-one appointments (Figure 2).

The demographics of all patients are outlined in Table 1. There was no difference in baseline age ($P = 0.24$), weight ($P = 0.12$), body mass index ($P = 0.05$), time seen from initial diagnosis ($P = 0.84$), or follow-up duration ($P = 0.19$) between group clinic patients and one-to-one appointment patients.

Table 2 shows the outcomes of patients after being seen in the both one-to-one and group clinics. The mean duration of follow-up in group clinics was 12.6 ± 2.2 weeks. A statistically significant reduction in TTG was noted after group clinics (63.4 ± 43.4 U/mL vs 13.2 ± 15.7 U/mL, $P < 0.01$), as well as an increase in folate levels (8.2 ± 3.9 μg/L vs 11.6 ± 4.8 μg/L, $P < 0.01$) and vitamin D levels (52.6 ± 27.9 nmol/L vs 75.3 ± 28.9 nmol/L, $P < 0.01$). No differences in hemoglobin, ferritin, B12, adjusted calcium, SF-36, and HADS were noted after being seen in a group clinic.

The mean duration of follow-up in one-to-one clinics was 16.1 ± 14.5 weeks. A statistically significant reduction in TTG was noted after one-to-one clinics (71.0 ± 43.5 U/mL vs 22.1 ± 36.9 U/mL, $P < 0.01$), as well as an increase in vitamin D levels (62.9 ± 30.3 nmol/L vs 74.4 ± 23.2 nmol/L, $P < 0.01$) and adjusted calcium levels (2.3 ± 0.1 mmol/L vs 2.4 ± 0.1 mmol/L, $P < 0.01$). No differences in hemoglobin, ferritin, B12, folate, SF-36, and HADS were noted after being seen in a group clinic.

There was no significant difference in baseline and follow-up biochemical parameters, between one-to-one and group clinics, as seen in Table 2. At follow-up, there was no statistically significant difference between mean GFD adherence scores (3.1 ± 0.4 vs 3.1 ± 0.7, $P = 0.66$) between one-to-one and group clinics. The HADS Anxiety score was higher in the group clinics vs one-to-one clinics at follow-up (7.6 ± 4.9 vs 5.3 ± 3.1, $P = 0.04$). No other differences in baseline and follow-up SF-36 and HADS scores were noted between one-to-one and group clinics.

The potential time savings of a group clinic were calculated, as seen in Table 3. Time savings were based on the length of the group clinic being estimated at 90 minutes, in comparison with 60 minutes for a one-to-one appointment, with an average of 6 patients per group clinic. As can be seen from Table 3, the estimated time savings for group clinics was 28 hours (54% reduction).

DISCUSSION

Our findings support that dietetic led intervention is effective for the management of newly diagnosed CD. This is the first study to demonstrate that group clinics are as effective as one-to-one clinics in the delivery of CD dietetic advice in patients with newly diagnosed CD. Both dietetic interventions led to similar adherence at follow-up, with improvement in noninvasive serological markers, with no difference between groups. Although serological markers and questionnaires were used to assess adherence in addition to the dietary review, it is known that serology may not accurately predict mucosal recovery (21), as well as patients being seen at relatively short-term follow-up. Nonetheless, the Biagi score is a validated score to assess adherence in CD (20), with

Table 3. Time comparison of group vs one-to-one clinics (n = 30 per group)

	Actual time spent for group clinics	Estimated equivalent time for one-to-one clinic
Patient education (hr)	7.5	30.0
Resource development (hr)	14.0	14.0
Postclinic documentation (hr)	2.0	7.5
Total hours	23.5	51.5

a mean score of greater than 3 being seen in both group and one-to-one clinics in this study, suggesting strict adherence for patients in both groups. This highlights that group clinics are likely to result in strict GFD adherence for patients with CD.

Nutritional adequacy can be a concern on the implementation of a GFD (22), with this study noting no difference between groups with regards to B12, folate, ferritin, and adjusted calcium. Quality-related measures of life were also not different between groups, other than noting that individuals having one-to-one clinics had a statistically significantly lower HADS anxiety scores than group therapy at follow-up. However, this is unlikely to be of clinical significance as the mean HADS scores in both one-to-one and group clinics were below 8, which is the threshold for probable anxiety or depression (19). It is also important to note that there were no changes seen in other quality of life parameters. There were significant improvements in folate and vitamin D levels after patients received group therapy, as well as reductions in TTG levels. This highlights that group therapy may beneficially improve these parameters. It must be noted that these findings for group clinics were seen at a mean follow-up 12.6 ± 2.2 weeks. It is therefore unclear whether these parameters would be maintained at a longer follow-up period, with further research required to assess long term biochemical parameters in individuals with CD receiving advice via group clinics.

The overall findings of this study are in line with similar methods used for other dietetic clinics, such as the low fermentable oligosaccharides, disaccharides, monosaccharides, and polyols approach, where group clinics have been shown to be as effective as one-to-one advice (16). This has also been seen in type 2 diabetes, which has demonstrated group based self-management education to be as effective as routine management (15). In addition to group clinics showing equally efficacy to traditional individual appointments, there is also likely to be the added benefit of peer-to-peer support provided by group clinics, which is not available in individual appointments. Also, face-to-face social networks have been shown to be associated with higher quality-of-life scores in patients with CD, which group clinics provide (23). It also appears that group clinics are a cost-effective intervention, with a 54% reduction in the number of dietetic hours required to deliver this service.

The strength of this study includes it methodology. Patients with a diagnosis of confirmed CD through serological and histological markers were only included, with patients with multiple diagnoses excluded. This ensured that the changes seen after dietetic advice were a result of CD management, rather than a result of other coexistent pathology, such as diabetes mellitus. Also, the dietary advice given to patients was uniform, preventing bias.

A potential limitation of the study was that this study was performed in a tertiary center. As this study was performed in one specialized unit in the United Kingdom, it may not be applicable to other centers, which may differ in dietary expertise. However, the information given in clinics was standardized, with the aim of generalizability of care for these patients and to reduce geographical variation, which is currently occurring, as seen from the survey from Coeliac UK on the provision of dietetic services (17). However, further studies assessing group therapies in CD in the United Kingdom and globally, with collaboration between different centres, may help standardization of care further. Also, patient and public involvement may help facilitate this.

This first study assessing group clinics in newly diagnosed CD demonstrates that this is a cost-saving intervention, with an estimated 54% reduction in dietetic resources, with no detriment to patient education and GFD adherence. Group clinics also provide the added benefits of peer support, and are likely to be beneficial globally, with further studies required to assess this.

CONFLICTS OF INTEREST

Guarantor of the article: David Surendran Sanders, MBChB, MRCP, MD, FACG, FRCP.

Specific author contributions: N.T. collected the data for the study. A.R., N.T., M.K., F.B., and D.S.S. drafted the manuscript. All authors approved the final manuscript.

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Potential competing interests: D.S.S. receives an educational grant from Schaer (a gluten-free food manufacturer). Dr. Schaer did not have any input in drafting of this manuscript. The remaining authors disclose no conflicts of interest.

Ethical approval: REC reference 14/YH/1216.

Study Highlights

WHAT IS KNOWN

- ✓ Internationally, dietetic advice (GFD) for patients with CD is delivered by dietitians on a one-to-one basis.
- ✓ Group clinics have been demonstrated to be effective in other medical conditions but have yet to be assessed in CD.

WHAT IS NEW HERE

- ✓ Group clinics have been shown to be as effective as individual appointments in CD.
- ✓ Peer support is an added benefit of group clinics.
- ✓ Group clinics are more efficient than one-to-one appointments, with a 54% reduction in dietetic resources.

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