TITLE

The Role Of Virtual Dietetic Interventions In Patients With Coeliac Disease

SHORT STUDY TITLE

Virtual Dietetic Interventions in Patients with Coeliac

IRAS Number:	**340526**
Sponsor Name and Address:	**Sheffield Teaching Hospitals NHS Trust,** 8 Beech Hill Road, Sheffield, S10 2SB
Sponsor's Reference:	**STH22680**
Directorate:	**Gastroenterology**

Contents

1 KEY STUDY CONTACTS

Chief Investigator	Professor David S. Sanders david.sanders1@nhs.net
Study Co-Ordinator	Nick Trott nick.trott@nhs.net
Data Custodian	Professor David S. Sanders
Key Protocol Contributors	Professor David S. Sanders Nick Trott Dr Arka Dhali
Sponsor	Sheffield Teaching Hospitals, NHS Foundation Trust, Trust Headquarters, 8 Beech Hill Road, Sheffield, S10 2SB sth.researchadministration@nhs.net
Sponsor Representative	Ms Jemima Clarke
Sponsor Contact	sth.researchadministration@nhs.net

2 STUDY SUMMARY

Study Title	The role of virtual dietetic interventions in patients with coeliac disease
Internal Ref./ Short Title	Coeliac disease dietetic webinars
Study Design	Prospective cohort study
Study Participants	Adult patients (≥18 years old) with coeliac disease referred for dietetic implementation of a gluten-free diet
Follow Up Duration	6 months
Research Aims	1. To develop a "first appointment" on-demand dietetic webinar (ODW) for patients with newly diagnosed coeliac disease. 2. To assess the effectiveness and patients' acceptability of online dietary advice. 3. To compare the ODW to the current standard of care face-to-face or telephone appointments.

2.1 RESEARCH QUESTION

Is a 'first-appointment' pre-recorded, on demand webinar equivalent to traditional one-to-one dietetic consultations in relation to standard clinical outcomes in coeliac disease

2.2 ABSTRACT

1. Both the incidence and prevalence of coeliac disease is increasing - however only approximately 36% of patients are diagnosed in the UK.
2. Increased diagnosis in the coming years will likely lead to difficulties with service provision.
3. Research has highlighted a lack of specialised dietetic services in England who are central in managing this condition effectively.
4. We have previously shown that 'in-person' group sessions can help to effectively manage this caseload and free up 50% of dietetic time.
5. On demand '1st-appointment' webinars are another novel delivery modality for this patient cohort that are yet to be studied.
6. Potential additional benefits of on demand webinars are:
    a. They can be rolled out nationally with educational delivery from specialist centres.
    b. Patients can consolidate their knowledge by re-watching the webinars at their convenience.
    c. It would likely offer an additional time saving in relation to dietitian resources that could be redirected to more complex cases - including the increase of refractory or non-responsive disease.

3 STUDY SPONSOR

Sheffield Teaching Hospitals NHS Foundation Trust. Responsible for sponsor duties in accordance with the UK Policy Framework for Health and Social Care Research will be the Data Controller.

4 BACKGROUND

Coeliac Disease (CD) affects 1% (approximately 530,000) of all adults in the UK, currently only 36% of sufferers are diagnosed. This condition affects multiple organ systems, increasing the prevalence of vitamin and mineral deficiencies, other autoimmune disorders, osteoporosis and gastrointestinal malignancies. The cornerstone for treatment is the Gluten Free Diet (GFD) which is delivered by Dietitians across the UK. Approximately 12,000 newly diagnosed patients with CD are diagnosed annually. The diet can be difficult to follow without appropriate dietetic support, even a small quantity of gluten (<1 gram) inadvertently ingested can cause symptoms and inflammation[1].

Best practice indicates that patients should have one to one consultations with a dietitian at their first appointment and given a broad educational overview of the GFD. However, NHS dietetic services in the UK are underfunded and as a result patients are either often not seen (~40%) or given a minimum of 6 weeks to wait after their diagnosis has been confirmed by a doctor [2].

Discussions with patient representatives have indicated they have a strong preference for immediate access to dietetic education and support post-diagnosis. This would help reduce the possibility of them accessing contradictory or inappropriate dietary information. In particular the patient group supported the premise of an interactive dietetic service rather than a didactic seminar. Patients highlighted a desire to have more than a generic first consultation [2].

For this reason, the use of a dietetic-led, pre-recorded, On-Demand Webinar (ODW) has the potential to offer an immediate first-patient consultation which could improve patient equity of access, standardise dietetic care and have significant cost-savings to the NHS and patients.

5 RATIONALE

Approximately 12,000 patients with CD are diagnosed annually in the UK and the only current treatment is a strict lifelong Gluten Free Diet (GFD) delivered by dietitians. The GFD is difficult to follow without dietetic support; small quantities of gluten can cause inflammation. NHS Dietetic services in the UK are underfunded and national surveys indicate approximately 40% of patients with CD in the UK may receive no dietetic input.

National guidelines dictate all patients with CD should receive an overview of the GFD from a dietitian at their initial appointment. Through the use of a dietetic-led ODW covering the GFD there is an opportunity to deliver the first appointment using digital technology. ODWs are increasingly applied in healthcare settings negating the need for hospital appointments,

reducing time and financial costs to patients. The viability and patient acceptability of a ODW in CD has not been investigated.

6 RESEARCH AIMS

6.1 Objectives

I. To develop a 'first appointment' ODW for patients with newly diagnosed CD.
II. To assess the effectiveness and patients' acceptability of online dietary advice.
III. To compare the ODW to the current standard of care face-to-face or telephone appointments.

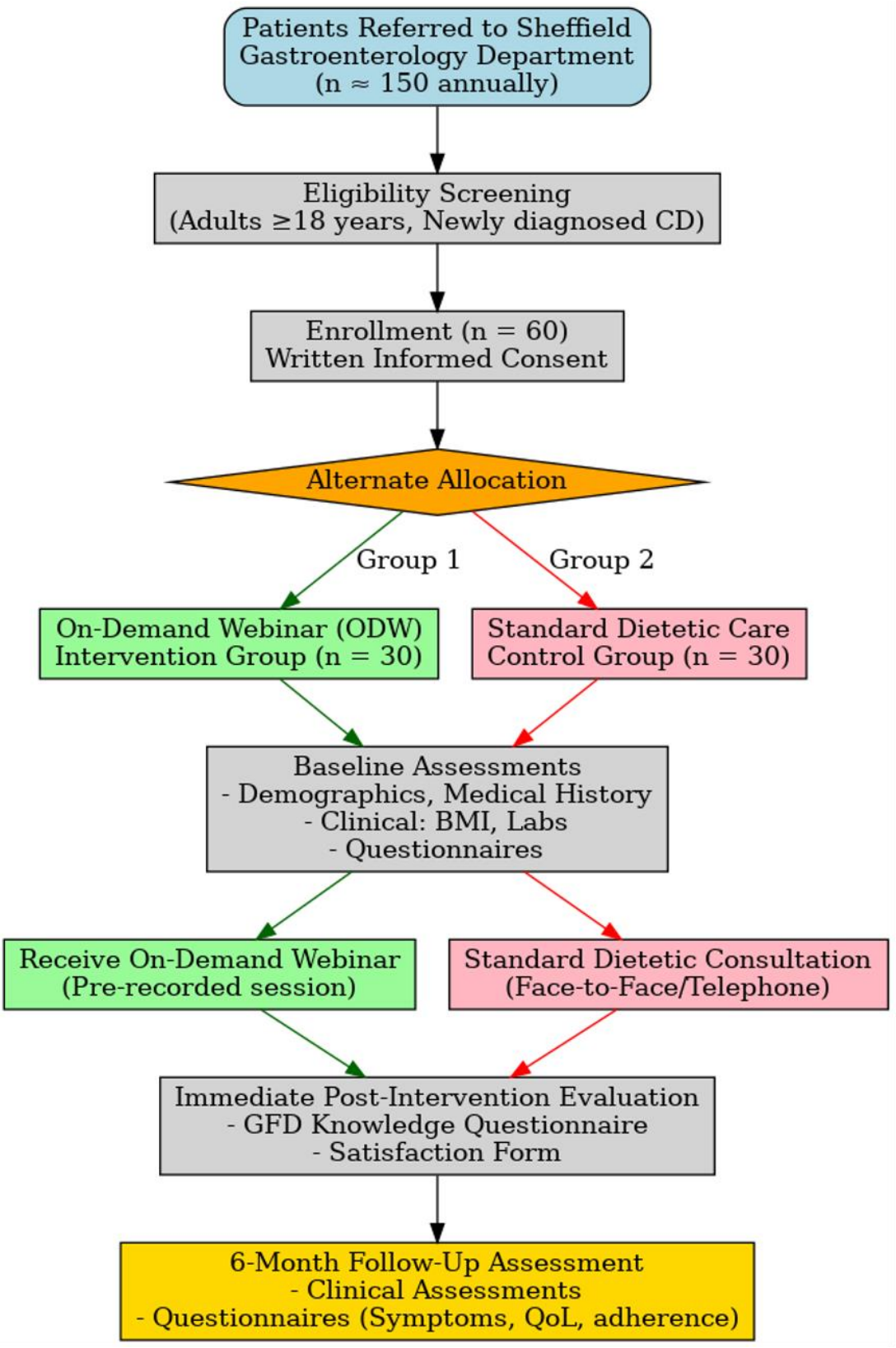
6.2 Outcomes

IV. Change in patient knowledge of the GFD pre- and post-intervention, assessed using a structured questionnaire based on previously validated tools.
V. Adherence to the GFD at follow-up, assessed using the Biagi adherence score and standardised dietetic evaluation.
VI. Clinical outcomes, including coeliac serology and haematinic markers (B12, folate, ferritin, vitamin D).
VII. Patient-reported acceptability and satisfaction, assessed using a purpose-designed questionnaire based on existing validated frameworks.
VIII. Quality of life outcomes, assessed using the EQ-5D questionnaire
IX. Comparison of these outcomes between patients receiving the ODW and those receiving standard care.

7 STUDY DESIGN AND METHODS OF DATA COLLECTION AND DATA ANALYSIS

This is a single-centre prospective study. Adults newly diagnosed with coeliac disease are screened and invited to participate following informed consent. Sixty patients are alternately allocated into two equal groups: one receiving a dietitian-led, pre-recorded ODW, and the other receiving standard of care (via face-to-face or telephone) consultation. Both groups undergo identical baseline assessments, including clinical measures, medical history, and validated questionnaires. Following their respective interventions, participants complete a knowledge questionnaire and satisfaction form. At six months, outcomes including clinical outcomes, symptom burden, quality of life, and adherence to the gluten-free diet are (re)assessed, allowing comparison of the ODW's effectiveness and acceptability against standard care. This pragmatic design reflects both clinical realities and patient preferences, aiming to inform scalable, digitally delivered first-line dietary support for coeliac disease.

The flow diagram below illustrates the study design:



The following data will be collected:

Type of Data	Purpose	When Completed	Completed by
Basic patient demographics	To collect key characteristics (age, sex, height, weight, BMI)	Pre-intervention and follow-up (for anthropometrics)	Patients / PI
Medical history	To identify relevant comorbidities and clinical background	Pre-intervention	PI
Histological, laboratory data collected as part of standard clinical care	To confirm coeliac diagnosis and assess response to the GFD	Pre-intervention and follow-up	PI
Standardised dietetic evaluation of GFD adherence	To assess dietary intake, understanding of gluten sources, risk of cross-contamination, nutrition adequacy, and confidence with the GFD	At follow-up	PI

Questionnaires	Purpose	When Completed	Completed by
Coeliac Disease and Gluten-Free Diet Quiz	To assess patient knowledge about Coeliac disease and the GFD Pre-post Intervention and follow-up.	Pre-intervention, post-intervention, and at follow-up	Patients
Overall Symptoms Questionnaire	To evaluate symptom burden	Pre-intervention and at follow-up	Patients
EQ-5D Quality of Life Questionnaire	To assess overall health status and quality of life	Pre-intervention and at follow-up	Patients
Biagi Gluten-Free Diet Adherence Score	To evaluate adherence to the gluten-free diet.	At follow-up	Patients
Acceptability Evaluation Satisfaction Form	To evaluate satisfaction and acceptability of the dietetic education provided (both ODW and standard care)	Post-intervention	Patients

8 STUDY SETTING

The gastroenterology directorate at STH is a large, clinically and research active directorate with a very significant outpatient and inpatient activity. STH is one of only a handful of centres nationwide that offers tertiary level care for endoscopy and is one of only 2 centres in the UK, and one of 21 centres globally to be recognised as a World Endoscopy Organisation Centre of Excellence. The Sheffield Centre has the largest number of patients with coeliac disease in the UK (more than 2500) who have been diagnosed and managed over 20 years. Referrals come from across the UK and as a result the unit is now the designated NHS England National Centre for Refractory Coeliac Disease. Research governance support is provided by the STH Clinical Research & Innovation Office.

9 SAMPLE AND RECRUITMENT

9.1 Eligibility Criteria

9.1.1 Inclusion criteria

Patients aged 18 years and over with serology- or biopsy-proven coeliac disease.

9.1.2 Exclusion criteria

Patients under the age of 18 years.

Patients unable to provide written informed consent.

Patients who are unable to understand or speak English.

Patients unable to access digital resources.

Poly-diagnosis that requires additional nutritional intervention (i.e. Diabetes or Inflammatory Bowel Disease).

9.2 Sample size

Research by Sim and Lewis (2012) recommends a sample size of at least 30 participants per group in order to estimate the pooled standard deviation of the outcome, with a reasonable degree of precision. In our previous real-world study (2015–2016) investigating the efficiency of group clinics for coeliac disease, we recruited 60 patients over an 18-month period. This was out of a possible 100 and equates to a 60% recruitment rate over that period. Dietary intervention studies tend to have higher uptake and patient participation than pharmacological studies. Since that trial, our centre has experienced a year-on-year increase in referrals for newly diagnosed coeliac patients—averaging 150 patients referred per annum. It was therefore felt that 60 participants would provide sufficient data to meet the study's aims and objectives.

9.3 Recruitment, sample identification and consent

Eligible patients aged 18 years and over with serology- or biopsy-proven coeliac disease referred from primary or secondary care for implementation of GFD will be offered the chance to participate in the study. If in agreement, informed written consent will be obtained from the patient. All participants will be informed they can withdraw consent and their involvement in the trial at any point and their data will not be used in any part of the analysis. The participants will be alternately allocated to either the webinar or a one-to-one appointment so that 30 participants are consecutively allocated into either group 1 or group 2.

Quality Control:

The study will be monitored as per STH clinical research and innovation office guidelines

Timescales:

Recruitment, data analysis, publication and disseminating of the results is estimated at 24 months. These timescales are based on our previous work (see reference 4).

10 ETHICAL AND REGULATORY CONSIDERATIONS

10.1 Research Ethics Committee (REC) and other Regulatory review & reports

A favourable opinion will be sought from a REC for the study protocol. Amendments to the protocol will be submitted via the IRAS portal, through the usual process.

10.2 Patient & Public Involvement

From previous PPI events we have held, patients felt it was beneficial to see a dietitian on diagnosis rather than wait a long time for a referral. Their advice was based on the fact that they found it difficult to know what information to trust from current internet sources. We plan to involve patient representatives in shaping how study findings are shared, including through Sheffield-based Coeliac UK groups and wider national engagement. We'll also engage with peer-to-peer communities via podcasts and social media platforms—both the PI and the Sheffield Gastroenterology team have active online presences, with a combined following of over 5,000, offering a direct route to reach patients and the wider coeliac community.

10.3 Protocol compliance

We will work closely with the STH Clinical Research & Innovation Office to ensure our research meets appropriate research governance standards

10.4 Data protection and patient confidentiality

This research project will follow the standard governance procedures that apply to all STH research projects (including Information Governance, Clinical Director approval, the Clinical Research and Innovation Office approval process).

The case report forms, source data and Investigator Site File will be stored in a designated room that is secured by a locked door. Electronic data will be stored on STH PCs only, which are encrypted, networked and password protected.

The data will be stored for 10 years.

10.5 Data Custodian

Professor David Sanders (Consultant Gastroenterologist)

Email: David.sanders1@nhs.net

Work phone: 01142713412

Academic Unit of Gastroenterology, Glossop Rd, Broomhall, Sheffield S10 2JF

10.6 End of Trial definition and access to the final study dataset

The declaration of end of trial will be submitted once the data analysis has been completed and publications have been drafted.

Requests for access to the data will come primarily from within the Gastroenterology and surgical teams of doctors and clinicians, including partners from the University of Sheffield. In some cases, the data may be used by medical trainees such as Specialist Registrars/Research Fellows and BMedSci students who undertake research projects as part of their training at the Academic Unit of Gastroenterology at STH. Additionally, there may be some requests for access to data from other staff in other directorates of Sheffield Teaching Hospitals. Finally, some data may on occasion be requested from external researchers - this may be as part of collaborative research activity between STH and other NHS organisations, academia or industry with researchers based worldwide. In all cases, data will be de-identified before any data are sent to researchers and before any research is carried out. All patient information will be managed in accordance with the Data Protection Act 2018, and local approval will be obtained from the STH Information Governance Officer/Caldicott Guardian, and R&D Department.

11 DISSEMINATION POLICY

Results of the study will be collated as scientific papers for submission to peer reviewed journals. Data will also be submitted for presentation at local, national and international patient and scientific meetings. Equally the results will be shared with patient charity groups including Coeliac UK (national patient charity, who have endorsed the webinar).

12 STUDY MANAGEMENT, MAINTENANCE, AND FINANCE

The research project would be subject to standard policies and procedures laid down by STH. The webinar is funded from the research account of Professor David Sanders.

Intellectual Property: None.

Taking the project forward: Should it be successful, this study has the potential to change current clinical practice. Findings could inform the adoption of on-demand webinars as a standard first-line dietetic intervention for newly diagnosed coeliac patients (particularly in settings with limited dietetic capacity) with the model offering potential for wider national implementation to improve equity of access and reduce waiting times for specialist dietary input.

To support uptake, results will be disseminated at both national and international meetings and conferences, including our biannual National Gastroenterology Dietetics Symposium held in Sheffield, which is attended by over 300 dietitians and made available on demand across the UK and internationally. We also plan to present at the International Coeliac Disease Symposium (ICDS) to support global awareness of the approach. In addition, we aim to publish the findings in an open-access format, making them freely accessible to dietitians - particularly important given the lack of institutional access to academic literature within the dietetic profession.

Should there be significant uptake of this delivery model, future research could explore health-related and food-related quality of life in patients with coeliac disease, using the webinar as a platform for data collection. National adoption would offer a valuable opportunity to examine these aspects in a larger population through a well-powered study.

13 EXPERTISE OF THE STUDY TEAM:

Sheffield Gastroenterology Department have been the recipients of 11 Clinical Service Awards (10 national and 1 international) and 9 Clinical Research Awards (6 National & 3 International) in the last decade. The department has published many papers in high impact journals. In relation to this particular study we have already published in the area successfully (Ref 4) and are now looking to build on this previous publication and extend the data collection and research to on demand webinars as a novel delivery modality for gluten-free patient education.

14 STATISTICAL OPINION:

All data will be analysed using SPSS version 29 (International Business Machines, Armonk, NY). Data will be summarised using descriptive statistics, including counts and percentages for categorical data and mean ± SD for continuous data. Paired *t*-tests will 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 will be performed using C2 testing. Statistical significance will be considered when $P < 0.05$.

15 REFERENCES

1. Caio, G. *et al.* Celiac disease: a comprehensive current review. *BMC Med.* **17**, 142 (2019).
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in England. *Frontline Gastroenterol.* **12**, 380–384 (2021).

3. Sim, J. & Lewis, M. The size of a pilot study for a clinical trial should be calculated in relation to considerations of precision and efficiency. *J. Clin. Epidemiol.* **65**, 301–308 (2012).

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5 Biagi, F., Andrealli, A., Bianchi, P. I., Marchese, A., Klersy, C. and Corazza, G. R. (2009) 'A gluten-free diet score to evaluate dietary compliance in patients with coeliac disease', *British Journal of Nutrition*, vol. 102, no. 6, pp. 882–887

16. APPENDICES

16.1 Appendix 1 - Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made