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Research Paper

Telephone Consultation as a Substitute for Routine Out-patient Face-to-face Consultation for Children With Inflammatory Bowel Disease: Randomised Controlled Trial and Economic Evaluation

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ABSTRACT

Background: Evidence for the use of telephone consultation in childhood inflammatory bowel disease (IBD) is lacking. We aimed to assess the effectiveness and cost consequences of telephone consultation compared with the usual out-patient face-to-face consultation for young people with IBD.
Methods: We conducted a randomised-controlled trial in Manchester, UK, between July 12, 2010 and June 30, 2013. Young people (aged 8–16 years) with IBD were randomized to receive telephone consultation or face-to-face consultation for 24 months. The primary outcome measure was the paediatric IBD-specific IMPACT quality of life (QOL) score at 12 months. Secondary outcome measures included patient satisfaction with consultations, disease course, anthropometric measures, proportion of consultations attended, duration of consultations, and costs to the UK National Health Service (NHS). Analysis was by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT02319798.
Findings: Eighty six patients were randomised to receive either telephone consultation (n = 44) or face-to-face consultation (n = 42). Baseline characteristics of the two groups were well balanced. At 12 months, there was no evidence of difference in QOL scores (estimated treatment effect in favour of the telephone consultation group was 5.7 points, 95% CI −2.9 to 14.3; p = 0.19). Mean consultation times were 9.8 min (IQR 8 to 12.3) for telephone consultation, and 14.3 min (11.6 to 17.0) for face-to-face consultation with an estimated reduction (95% CI) of 4.3 (2.8 to 5.7) min in consultation times (p < 0.001). Telephone consultation had a mean cost of UK£35.41 per patient consultation compared with £51.12 for face-face consultation, difference £15.71 (95% CI 11.8–19.6; P < 0.001).
Interpretation: We found no suggestion of inferiority of telephone consultation compared with face-to-face consultation with regard to improvements in QOL scores, and telephone consultation reduced consultation time and NHS costs. Telephone consultation is a cost-effective alternative to face-to-face consultation for the routine outpatient follow-up of children and adolescents with IBD.
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1. Introduction

Crohn's disease and ulcerative colitis, collectively known as inflammatory bowel disease (IBD) are chronic relapsing disorders of the gastrointestinal tract. The incidence of childhood IBD has been increasing in the UK (Cosgrove et al., 1996; Gunesh et al., 2008) and is currently estimated to be 5.2 per 100,000 per year in people younger than 16 years old (Sawczenko et al., 2001). There is no medical cure for IBD and the natural history of the disorder is characterised by recurrent relapses alternating with periods of remission. In between periods of ill health, patients can be well for prolonged periods of time when their disease is in remission. At routine outpatient hospital reviews, patients are often well and do not usually require any intervention, highlighting the fact that regular fixed appointments do not necessarily coincide with disease relapses (Gethins et al., 2007).

In the UK, children with IBD are usually managed by paediatric gastroenterologists who are based in a few regional centres. Conventionally, patients are kept under routine face-to face outpatient follow-up.

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This means that many of them have to be taken out of school and, together with their families, have to travel long distances in order to attend out-patient clinics. For children who are doing well, such routine visits may be unnecessary.

Telephone consultations allow patients to have contact with healthcare professionals without the patient having to travel. For patients, the benefits of telephone consultations may include reduced travel time, reduced costs, and improved satisfaction (Car and Sheikh, 2003). In adults with various chronic diseases, telephone consultations were associated with reduced medical care utilisation without adversely affecting patient health (Wasson et al., 1992). Telephone consultations also cost-effectively increased asthma review rates, enhancing patient confidence with management, with no detriment to asthma morbidity (Pinnock et al., 2007). No study comparing telephone consultations with face-to-face consultations for children with IBD has been reported, but at least two uncontrolled studies have been reported in adults with IBD (Gethins et al., 2007; Miller et al., 2002). Miller et al. showed that a telephone clinic improved the overall quality of follow-up care for adults with IBD (Miller et al., 2002). In another study, Gethins et al. found that telephone clinics significantly reduced non-attendance rates and waiting times for urgent appointments (Gethins et al., 2007). Despite the potential advantages of telephone consultations, this approach has been given little attention in young people with IBD. We, therefore, aimed to provide evidence about the effectiveness and cost consequences of telephone consultations, compared to face-to-face consultations in childhood IBD.

2. Methods

2.1. Setting and Participants

We conducted a randomised-controlled trial at the Royal Manchester Children's Hospital, Manchester, UK, a regional Paediatric Gastroenterology referral centre. Children and adolescents with IBD from the North West of England are referred to this centre. Any patient who was aged between 8 and 16 years with a diagnosis of IBD was eligible for entry into the trial.

We identified eligible patients through the hospital's paediatric IBD database. Inclusion criteria were: diagnosis of IBD by established clinical, endoscopic, histological and radiological criteria; clinical remission defined as an abbreviated Paediatric Crohn's Disease Activity Index (aPCDAI) score of ≤10 (Shepanski et al., 2004) for patients with Crohn's disease or as a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of <10 (Turner et al., 2007) for those with ulcerative colitis and indeterminate colitis. Exclusion criteria were: active disease (aPCDAI >15 or PUCAI ≥15), and unwillingness to provide informed consent.

We sent a letter of invitation to participate in the study and a research information sheet outlining the nature of the study to eligible patients and their parents. Those who agreed to take part were interviewed by an investigator who provided full information about the trial and obtained parental and child's written informed consent. We obtained ethics approval from the North West of England research ethics committee.

2.2. Randomization and Masking

By means of a computer-generated randomisation scheme, participants were allocated to telephone consultation or face-to-face consultation. We used randomization with blocks of random sizes, and stratified by type of disease (i.e. Crohn's disease or ulcerative colitis/indeterminate colitis). The assignment schedule was held centrally and allocation was performed by staff of the hospital's pharmacy department independent from the trial team. Masking was not possible because of the nature of the two interventions.

2.3. Procedures

Patients in both groups were offered out-patient appointment dates and times. Those randomized to face-to-face consultation were asked to attend their routine appointments in hospital as usual. Those randomised to telephone consultation were told to expect a call from the gastroenterology doctor at the time of their appointment. The consulting doctor contacted the patient and parents via a telephone number (home or mobile) that the parents and patient had previously supplied as the number they would like to be contacted on. As much as possible, parents and patients were advised to be together at the time of the appointment in order to allow both of them to participate in the consultation as is usual in practice. Up to three attempts within 20 min were made to contact patients by phone. Patients who did not attend an appointment in either group were sent another appointment in accordance with our hospital's policy.

Apart from being randomised to telephone or face-to-face consultation, routine care was the same for patients in both groups. As it is in normal practice, if a participant experienced any symptoms that caused concern at any time during the study, the parent/child contacted the IBD nurse for advice and appropriate arrangements for assessment were made.

2.4. Outcomes

The primary outcome was quality of life (QOL) score at 12 months. QOL scores were assessed using the validated paediatric IBD IMPACT QOL questionnaire (Otley et al., 2002; Loonen et al., 2002; Ogden et al., 2011). Secondary outcome measures were patient and parent satisfaction with consultations (assessed with the Consultation Satisfaction Questionnaire {CSQ}) (Baker, 1990); the number of disease relapses (relapse defined by the aPCDAI or PUCAI); anthropometric measures (body mass index (BMI), height, and weight z-scores); number of hospital admissions; proportion of consultations attended; duration of consultations (measured with a watch); and costs to the UK National Health Service (NHS).

2.5. Statistical Analysis

Our sample size was based on the primary outcome measure and drew on previous studies (Shepanski et al., 2005; Afzal et al., 2004), where the minimum clinically important change in QOL scores was determined to be 10 points (total QOL scores range from 0 to 140 with higher scores representing better QOL). A power calculation indicated the need for 74 participants (37 participants per arm) to have at least 80% power at the 5% significance level to detect a 10 point difference in QOL scores at 12 months.

All data were analysed on an intention-to-treat (ITT) basis. For the primary and secondary quantitative/summary score outcomes (QOL score, anthropometric measures, CSQ scores and duration of consultations) analysis of covariance was used. For secondary count outcomes (number of disease relapses and number of hospital admissions for IBD), Poisson regression models were used. For the proportion of out-patient consultations attended throughout the duration of the study, a binomial logistic model was fitted. For all models, the baseline outcome in question, and disease type were included as covariates. The mean difference, the rate ratio, and the odds ratio on the treatment allocation factor were estimated as appropriate to evaluate the intervention effect. All tests were conducted at a significance level of 5%.

Missing baseline data were imputed as a 'missing' category for discrete covariates or using simple conditional mean imputation (White and Thompson, 2005) for continuous covariates. Sensitivity analyses for the primary outcome included multiple imputation under a pattern mixture model (Little, 1993) to explore informatively missing outcome data. This involved performing standard multiple imputation on the QOL data but modelling a conditional difference (delta) between these