

A randomised controlled trial, cost-effectiveness and process evaluation of the implementation of self-management for chronic gastrointestinal disorders in primary care, and linked projects on identification and risk assessment

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Scientific summary

Chronic gastrointestinal disorder self-management

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Background

Chronic gastrointestinal disorders are major burdens in primary care. Previous research has suggested that enhancing self-management (by improving patient information, training health professionals to provide support and improving access to care) can improve outcomes. However, it is not known if such models of care can be implemented at scale in routine NHS settings. It is also unclear whether or not it is possible to develop effective risk assessment procedures to identify patients who are likely to become chronically ill and could benefit from additional support.

Objectives (list of research questions)

What is the clinical effectiveness and cost-effectiveness of an intervention to enhance self-management support for patients with chronic conditions when translated from research settings into routine care? [Phase IV randomised controlled trial (RCT) and economic evaluation.]

What are the barriers and facilitators that affect the implementation of self-management support among patients, clinicians and organisations? (Process evaluation.)

Is it possible to develop methods to identify patients at risk of long-term problems with functional gastrointestinal disorders in primary care?

Methods

We conducted a pragmatic, two-arm, practice-level cluster Phase IV RCT evaluating outcomes and costs associated with an intervention to enhance self-management support.

We trained practitioners to assess patient self-management capabilities and involve patients in a choice of self-management options, including self-help guidebooks, community resources and a potential 'step up' to more intensive patient-focused hypnotherapy or cognitive-behavioural therapy.

We conducted a process evaluation using interviews and other methods to assess the barriers and facilitators that affect the implementation of the intervention at patient, clinical and organisational levels.

We conducted four studies around identification and risk assessment:

1. a database study was conducted to describe how clinicians in primary care record consultations with patients who experience functional lower gastrointestinal symptoms
2. a risk assessment study was conducted to validate a risk assessment tool for predicting symptom distress for irritable bowel syndrome (IBS)
3. a qualitative study was conducted to explore general practitioners' (GPs') views and experiences of defining, diagnosing and managing of functional lower gastrointestinal symptoms in primary care
4. a second database study was conducted to investigate patient profiles in IBS, inflammatory bowel disease and abdominal pain.

Results

Project 1

Forty-four practices were randomised and 5599 patients were recruited, representing 43% of the eligible population on the practice lists. A total of 4533 (81%) patients completed the 6-month follow-up and 4076 (73%) completed the 12-month follow-up.

No statistically significant differences were found between patients attending the trained practices and those attending control practices on any of the primary or secondary outcomes. All effect size estimates were below the prespecified threshold of clinically important difference. The intervention had little impact on either costs or quality of life within the time period of the trial and was unlikely to be cost-effective.

Although some aspects of the intervention were well received and there was significant uptake and attendance at initial training sessions, we found little evidence of demonstrable impact in terms of changed clinical practice or patient experience of care.

In the practices, self-management tools failed to be normalised in routine care. Practice nurses viewed themselves as being patient centred, yet psychosocial and behaviour change support was not generally incorporated. Nurses had concerns about the burden of providing enhanced self-management support in terms of both their own workloads and what they felt that their patients could accommodate.

Project 2

Our initial database analyses suggest that it is not yet possible to develop case definitions for primary care-based studies of patients with IBS using Read Codes.

Full assessment of the planned risk assessment tool was not possible because of the variable case definitions used in practices and as a result of wide discrepancies in the utilisation of Read Coding. The number of patients recruited to the risk assessment study was also much lower than anticipated. However, we were able to calculate sensitivity and specificity based on the sample recruited. The risk assessment tool appeared to be sensitive in predicting those with severe disease; however, it was not specific in predicting those without severe disease.

Variability in coding was found to be a function of practitioner preference and low utilisation was also related to lack of perceived clinical benefit. GPs reported that IBS was not a difficult condition to diagnose or manage, yet most described reluctance to add the Read Code for IBS to the record. Respondents acknowledged the link between IBS and psychological distress, but were reluctant to refer for psychological therapies and did not see the value of a risk assessment tool to predict chronicity.

Conclusion

The self-management intervention did not add value to existing care for any of the long-term conditions studied. The active components required for effective self-management support need further study. The results highlight the challenge of delivering improvements to quality of care for long-term conditions that are feasible to deliver in routine care at scale, yet demonstrably clinically effective and cost-effective. The active components required for effective self-management support need further study. The results highlight the challenge of delivering improvements to quality of care for long-term conditions. This may have implications for the piloting of interventions and linking implementation more clearly to local commissioning strategies.

Trial registration

This trial is registered as ISRCTN90940049.

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