



<b>Title</b>	<b>LIFELAX - Diet and LIFEstyle versus LAXatives in the Management of Chronic Constipation in Older People: Randomized Controlled Trial</b>
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<b>Reference</b>	Volume 14.52. ISSN 1366-5278. <a href="http://www.hta.ac.uk/project/1310.asp">www.hta.ac.uk/project/1310.asp</a>

## Aim

To investigate the clinical and cost effectiveness of laxatives versus dietary and lifestyle advice, and standardized versus personalized dietary and lifestyle advice.

## Conclusions and results

The trial planned to recruit and retain 1425 patients from 57 practices, but only 154 patients were recruited from 19 practices. Baseline patient characteristics suggest that they experienced few symptoms of constipation, and constipation had no major impact on their quality of life. Most patients were satisfied with their laxatives, and levels of anxiety and depression were low. Daily diaries (maintained for 6 months) were an acceptable method of outcome data collection. Due to low recruitment rates, firm conclusions could not be drawn about the effectiveness of the interventions. For the economic evaluation, all of the trial arms experienced a reduction in utility. Data on related healthcare costs show a cost saving of 13.34 pounds sterling for those in the personalized arm, compared to the control arm, and a smaller cost saving for the standardized arm. No statistical evidence suggested that either the personalized intervention arm or the standardized intervention arm was associated with significant changes in utility at 3 months compared to the control arm. Cost minimization indicated that the personalized arm appeared to be the preferred course, producing the greatest cost savings. The qualitative process evaluation highlighted several factors that contributed to the conduct and progress of the trial, which may be relevant to others conducting research on a similar topic or population.

## Recommendations

See Executive Summary link [www.hta.ac.uk/project/1310.asp](http://www.hta.ac.uk/project/1310.asp).

## Methods

We used a prospective, pragmatic, 3-armed cluster (at the GP level) randomized trial with an economic evaluation and integrated process evaluation. Fifty-seven general

practices were allocated to 1 of 3 arms: prescription of laxatives; standardized, nonpersonalized dietary and lifestyle advice; personalized dietary and lifestyle advice, with reinforcement. Patients were aged 55 years or over with chronic constipation, living in private households. The primary outcome was the constipation-specific PAC-SYM/PAC-QOL. Secondary outcomes comprised: EQ-5D, reported number of bowel movements per week; the presence/absence of other Rome II criteria for constipation; adverse effects of treatment; and relapse rates. These data were collected through diaries, postal questionnaires, and telephone interviews. The qualitative process evaluation comprised semistructured interviews with purposive samples of: members of the project management and steering group; general practitioners, practice managers and nurses working to recruit and deliver patients to the trial and conduct the interventions; and (3) patients participating in the trial. We used a combination of qualitative research techniques, following Glaser and Strauss' model of constant.

## Further research/reviews required

The process evaluation identified several issues regarding the development and implementation of RCTs. The problem of the trial's topic, setting, and training packages might have been identified had a prior feasibility study been conducted. However, numerous system-wide problems, eg, the changing RM&G guidelines and research briefs that did not match General Medical Service's contracts, also taxed the capacity of the trial to be successful.