ABSTRACT
Objectives: To develop and pilot a theory and evidence-based intervention to improve quality of life (QoL) in people with colorectal cancer.
Design: A complex intervention development study.
Setting: North East Scotland and Glasgow.
Participants: Semistructured interviews with people with colorectal cancer (n=28), cancer specialists (n=16) and primary care health professionals (n=14) and pilot testing with patients (n=12).
Interventions: A single, 1 h nurse home visit 6–12 weeks after diagnosis, and telephone follow-up 1 week later (with a view to ongoing follow-up in future).
Primary and secondary outcome measures: Qualitative assessment of intervention feasibility and acceptability.
Results: Modifiable predictors of QoL identified previously were symptoms (fatigue, pain, diarrhoea, shortness of breath, insomnia, anorexia/cachexia, poor psychological well-being, sexual problems) and impaired activities. To modify these symptoms and activities, an intervention based on Control Theory was developed to help participants identify personally important symptoms and activities; set appropriate goals; use action planning to progress towards goals; self-monitor progress and identify (and tackle) barriers limiting progress. Interview responses were generally favourable and included recommendations about timing and style of delivery that were incorporated into the intervention. The pilot study demonstrated the feasibility of intervention delivery.
Conclusions: Through multidisciplinary collaboration, a theory-based, acceptable and feasible intervention to improve QoL in colorectal cancer patients was developed, and can now be evaluated.

INTRODUCTION
Colorectal cancer is the third commonest cancer in men and second in women in the
Intervention to improve quality of life in people with colorectal cancer

UK. In the UK in 2009 over 41 000 people were diagnosed with colorectal cancer and in 2010 over 16 000 people died from it making it the second commonest cause of cancer deaths in the UK. However, more and more people are living for prolonged periods with colorectal cancer and 5-year survival rates in the UK have doubled over the past 40 years, from around 22% in the early 1970s to around 50% in the mid 2000s. Key advances have included the quality of surgery, MRI staging together with the selective use of preoperative pelvic radiotherapy in rectal cancer, and an increased use of more effective adjuvant chemotherapy.

Health-related quality of life (HRQoL) is impaired in people diagnosed with colorectal cancer. A large study (the PICT study) conducted in North East Scotland and Glasgow among people with colorectal cancer identified modifiable and unmodifiable factors associated with poorer quality of life. Unmodifiable factors included shorter time from diagnosis, female sex, more self-reported comorbidities and metastases at diagnosis. While these factors significantly predicted poorer quality of life, they explained little of its variability. More variability was explained by the presence of symptoms, especially fatigue, loss of appetite, dyspnoea, anxiety and depression. Some was explained by people’s perceptions that their cancer would have worse consequences and they had little control. In addition to direct effects, some of the impact of these factors was mediated through impairments in people’s ability to function in their normal role and social environment. These factors are potentially modifiable so there appeared to be potential to develop a targeted intervention designed to improve quality of life in people with colorectal cancer. This paper reports on the development and refinement of a theory and evidence-based intervention to improve quality of life in people with colorectal cancer.

DEVELOPING A COMPLEX INTERVENTION—METHODS AND RESULTS

Our approach was based on the key development activities outlined in the MRC framework for the development and evaluation of complex interventions. There were four non-sequential activities, which:

A. Identified the existing evidence on interventions to modify explanatory factors for HRQoL (symptoms and ability to function in a normal role and social environment).

B. Identified and developed theory to underpin the intervention by convening an expert group to discuss the evidence in the context of expert knowledge and wider theory.

C. Modelled processes and outcomes by reconvening the expert group to identify theory-based behaviour change techniques (BCTs), conceptualise the theoretical mechanisms of change in the intervention and identify process and outcome evaluation measures.

D. Assessed intervention feasibility and acceptability through interviews with patients who might receive the intervention and health professionals who would deliver it. It was then piloted with a small group of patients.

Further details of the activities undertaken are given below.

Existing evidence on modifying explanatory factors

A broad-based literature search was conducted to identify interventions targeted at fatigue, anorexia, dyspnoea, pain, diarrhoea, nausea and vomiting, insomnia, sexual problems, psychological well-being, social well-being and physical functioning among people with colorectal cancer. Where there were none, we expanded our search to encompass interventions developed for, and tested on people with any type of cancer. Electronic databases searched were: the Centre for Reviews & Dissemination HTA and DARE databases, Cochrane Database of Systematic Reviews, MEDLINE and EMBASE. No limits were imposed on types of studies or nature of interventions (design or components), thus the review encompassed any intervention or combination of interventions designed to reduce the impact of the physical, psychological or social factors we had identified as being important for HRQoL. Our assessment of whether an intervention would be an effective component of our intervention took account of the strength and consistency of evidence (systematic review of randomised trials carried the most weight), and focus (evaluations among colorectal cancer patients were weighted most highly). Using these criteria the literature review produced evidence as summarised in online supplementary appendix A.

We found that very few of the intervention studies focused solely on people with colorectal cancer; most research had been undertaken with people with breast cancer or in populations of people with different types and grades of cancer. This created challenges in identifying those interventions which could be extrapolated and adapted for use with our target population. However, the literature did provide an indication of the types of interventions successfully used to target specific symptoms and activities, and how they might best be delivered, for example by using nurse-led home visits.

There was good evidence from clinical trials demonstrating that: (1) diet and exercise interventions, including home-based walking and graded physical activity, could help with general symptoms but may be more effective when applied to specific symptoms, (eg, fatigue, diarrhoea and other bowel problems, nausea and vomiting, sleep disturbances, anorexia and cachexia) and to improve psychological and physical functioning; (2) self-management interventions (such as goal setting, graded activity and relaxation) could help with cancer-related pain and breathlessness; (3) nurse-led interventions, providing information and support especially in relation to symptoms, could help with fatigue,
Intervention to improve quality of life in people with colorectal cancer

breathlessness, nausea and vomiting, cancer-related pain and help reduce adverse psychological sequelae and (4) behavioural or counselling interventions could help with fatigue, cancer-related pain, bowel problems, nausea and vomiting, breathlessness and sexual and psychological functioning. Psychological methods such as group therapy, education, structured and unstructured counselling and Cognitive Behavioural Therapy offered most promise over the medium and long term. There was some suggestions that targeting those at risk of, or suffering, significant psychological distress may be most beneficial. On the other hand, there was little evidence of effective interventions that could improve social and sexual functioning.

We concluded that an intervention to improve HRQoL should target symptoms and activities, use primarily psychological methods, include information and self-management strategies and be nurse-led.

Identifying and developing theory

Theories which could underpin the intervention were identified by an expert group comprising three health psychologists, a medical sociologist, three general practitioners, a medical statistician and three health service researchers. This group first met over 2 days (14/15 July 2009).

It was agreed that our causal model would be based on the most widely accepted classification of health and health-related states—the WHO International Classification of Functioning Disability and Health (ICF). The ICF identifies three global domains that determine health state-impairment, activity limitations and participation restrictions. All three domains were apparent in the results of our original research and in the literature review, so it was decided that our intervention should tackle both symptoms (of impairment) and activities/participation. The underlying hypothesis guiding intervention development was that the quality of life of colorectal cancer patients could be improved if we could change patients’ behaviour to alleviate/better manage symptoms and facilitate engagement in activities that were personally important.

As the intervention focused on changing patients’ behaviour, a well-evidenced theory of behaviour change was selected to inform the intervention content; namely Control Theory. There is strong evidence that BCTs associated with this theory, especially goal setting and self-monitoring, are effective in changing behaviour. Control Theory also suggests that other BCTs, such as action planning and feedback might be effective in changing patient functioning.

Modelling processes and outcomes

The original expert group was reconvened for a second meeting (28/29 January 2010) and joined by additional secondary care cancer specialists (surgeon, oncologist and specialist nurse). The group conceptualised the intervention, identified the theoretical mechanisms of action and determined how process evaluation and outcome assessment could occur.

In order to change behaviours related to symptom management and activity participation, it was agreed that the intervention would need to:

- Identify symptoms and activities of importance to each individual participant;
- Set goals about these personally important symptoms and activities;
- Help participants plan progress towards these goals;
- Establish a method of monitoring participants’ progress towards these goals;
- Identify and plan to tackle barriers that prevent participants from spending time on important activities.

To address these needs, the Health Psychologists in the expert group identified appropriate evidence-based BCTs which were then incorporated into a pilot intervention by the whole expert group. It was decided during this development work that the intervention should be delivered in a one-off face-to-face session with a research nurse, with a follow-up telephone call 1 week later to discuss progress although it was recognised that there may be benefits from more follow-up.

Through multiple iterative rounds, the expert group designed an intervention with five stages that systematically addressed each of the needs identified (see below):

1. Identifying personally important symptoms/activities: Participants were asked open questions by the nurse delivering the intervention to identify symptoms and activities that they found problematic after their cancer diagnosis/treatment. ‘Prompt cards’ were used to facilitate the identification of personally important factors and discussions around particularly personal or sensitive issues (see online supplementary appendix B). The prompt cards were grouped into four themes: body (including physical symptoms), mood, activity and money—and each card was printed with an issue (identified from our previous research, the literature and discussions with patients and health professionals) which could be of concern to someone with colorectal cancer.

2. Setting goals: Participants asked to review the symptoms/activities identified, choose the one (or group of related symptoms/activities) they wanted to change or improve and identify how they wanted things to change (BCT: goal setting—outcome). If they identified an activity (eg, going on walks with friends), the nurse would ask them to identify what they believed was stopping them from performing that activity (eg, reduced fitness). If they identified a symptom (eg, nausea) these would refer to a set of symptom algorithms (see online supplementary appendix C) to identify something that could be done to help with that symptom (BCT: problem solving). Participants would then be asked if they had ever received information about the activity or symptom they identified. If not, a factsheet about the particular symptom/activity based on data from
multiple sources was provided. Each factsheet followed a similar format and included sections labelled (1) ‘things you can do to help yourself’, (2) ‘our research’ which described the results of our primary research, (3) ‘How (named symptom) might affect you’ and (4) ‘Getting help and more information’. The factsheet was used to focus the discussion on whether the suggestions for self-help (and additional sources of support) could be beneficial. A copy of the diarrhoea factsheet is provided in online supplementary appendix D).

3. Progressing towards goals: Nurses asked participants to make specific plans about how they could achieve their nominated goal. These plans were recorded on a specially designed ‘Goals and Action Plans’ sheet (see online supplementary appendix E) and included details about what the participant was going to do, where they would do it, when they would do it, and who or what they would need to do it (BCT: Action Planning). For example, if a participant identified shortness of breath on exercise as a symptom and going on walks with friends as the activity of most importance to them, an action plan might take the form ‘I will walk for 10 min a day (what), in the park (where) immediately after breakfast (when) after I have checked my wound dressings are secure (who or what needed). Participants would be encouraged to set goals that were practical and achievable but still challenging.

4. Monitoring progress towards goals: Once specific action plans were generated and recorded, participants were given ‘Self-Monitoring Sheets’ (see online supplementary appendix F) to record their progress (BCT: self-monitoring of behaviour). Participants were asked to record what they were monitoring (eg, number of minutes walked per day) and how often the monitored activity should occur (eg, every day). They would then be asked to record when they performed the activity (eg, Monday 1 March, 09:30), how they felt when they performed it (0=very bad to 10=very good), the details of what happened when they performed it and what preceded and followed the activity (eg, ‘I finished my breakfast and took the dog out to the park. I got a bit breathless but it wasn’t too bad. It took me 15 min to get there and back. When I got back I had a cup of tea and a sit down’). Participants would be encouraged to make their descriptions as detailed as possible to help them monitor progress and identify links between how they felt and the activities they carried out.

5. Barrier identification: At the end of the session with the nurse, participants were asked to rate how confident they felt about achieving their goal (from 1—not at all confident to 10—very confident). If they gave a rating of less than seven, nurses would ask participants about what was stopping them from feeling confident and what they thought might help (BCT: problem solving).

Follow-up would allow the nurse to review the goals, progress and barriers with the participant and provide encouragement.

Feasibility and acceptability

The feasibility of developing and delivering an intervention which could address the factors identified as being important for HRQoL and which could reduce restrictions to activity and participation, was an ongoing process throughout the project.

Qualitative interviews

Following the first Expert Group meeting, semistructured qualitative interviews about the proposed intervention were conducted with three stakeholder groups: (1) 28 patients with colorectal cancer were recruited from colorectal cancer clinics in NE Scotland and Glasgow. It was important that we received views from as wide a range of people with colorectal cancer as possible, so we attempted to be as inclusive as possible. Participants included 17 men and 13 women who had been diagnosed from 3 weeks to 5 years prior to interview. We recruited patients with all disease stages (from Dukes A to metastatic), experience of all treatment modalities (surgery, radiotherapy and chemotherapy) and from urban, rural, affluent and deprived areas. All interviews were carried out in September and October 2009; (2) 16 cancer care specialists from secondary care (oncologists, surgeons, stoma nurses, colorectal nurse specialists and dieticians), the third sector (Macmillan benefits advisors and Maggie’s Centre advisors) and social care and (3) 10 health professionals working in primary care (five general practitioners, four practice nurses and one district nurse).

Interviewees were presented with the factors that we had identified as being important for HRQoL and were asked questions under three key domains. First, we wanted to identify our target population. We asked questions around who should be offered the intervention, whether specific groups should be targeted, how they should be identified and how soon after diagnosis the intervention should be delivered. Second, we explored the desirability and feasibility of addressing these issues within the intervention. Third, we asked how best to deliver the intervention, which included questions about who should deliver the intervention and where and when it should be delivered. We sought responses (positive and negative) to the idea of the intervention and the perceived barriers and facilitators, and solutions to perceived problems. Responses fell into three main categories—feedback about the intervention components, about delivery style and about the timing and targeting of the intervention.

Acceptability of intervention components: The components of the intervention were well received by all three groups, although patients were cautious about anything labelled ‘psychological’ and professionals also commented on the possible ‘stigma’ related to this. Patients wanted reassurance that their experiences were as
expected, and some idea of what might lie ahead. Professionals emphasised that patients wanted information appropriate to the time of illness. Patients were open to sexual problems being mentioned. Professionals felt there was currently little provision for addressing female sexual problems. Financial and benefits information was important to patients, but primary healthcare professionals admitted to poor knowledge of where to access benefits or financial advice.

**Intervention delivery style**
Patients’ preferred approach was for their needs to be listened to and health professionals’ expertise used to devise ways to tackle these needs. An open conversational approach was thought likely to generate an individually meaningful dialogue, rather than merely completing questionnaires about how patients felt. Both patients and professionals were keen on a nurse-led service, patients believing nurses to be expert and approachable with more time available than some other health professionals. A proactive approach was needed to engage patients who might have difficulties articulating problems, and to broach sensitive topics such as sexual and financial problems. Good links between the intervention team, primary and secondary care, and other local and voluntary sector resources were emphasised as important.

**Intervention timing and targeting**
Both patients and professionals thought the intervention should start early after diagnosis (within 3 months of the colorectal cancer diagnosis), but continue through times of discharge from various aspects of hospital care (surgery, chemotherapy, follow-up). Patients rejected targeting only those with poorer quality of life because they thought that all may need some aspects of the intervention. Patients would value involvement of their partners, family and friends. Professionals cautioned against missing uncomplaining patients that may slip through the net.

**Patient and carer advisory group**
An advisory group, comprising people who had (currently or previously) received a diagnosis of colorectal cancer or who were carers of people with colorectal cancer, provided advice, guidance and feedback on the intervention components and the materials. The sample intervention materials were presented to this group and their thoughts and comments informed further minor amendments to the materials prior to piloting. The group emphasised the need for flexibility in the way in which the goal planning and self-management tools were introduced and that they may have to be adapted depending on the participants’ needs and preferences. The group identified irritability and sleep problems as being troublesome (particularly when receiving chemotherapy) and these were added to the set of prompt cards.

**Nurse training**
To maximise intervention fidelity, a script was written for the nurses who would be delivering the intervention to ensure consistent delivery of all intervention components. A nurse training pack was developed, which consisted of the results of our previous research, disease-specific information (eg, patient pathway, treatments and follow-up of colorectal cancer), all the intervention materials, vignettes and case studies and a DVD demonstrating the intervention being delivered to a (simulated) patient. Two days training was provided, which included meeting with a member of the Patient and Carer Advisory Group, and training in consultation skills with an expert in research and Medical Education. The nurses also had practical skills based sessions, where they attempted to conduct the intervention with simulated patients with the Medical Education expert in attendance, who gave constructive feedback.

**Pilot**
To further optimise the intervention it was piloted with 12 patients (6 in NE Scotland and 6 in Glasgow) to determine its feasibility and explore qualitatively the potential for benefit. In NE Scotland, participants were recruited from the colorectal oncology clinics, while in Glasgow participants were recruited via the colorectal specialist nurse. Participants were eligible for inclusion if they had a confirmed diagnosis of colorectal cancer in the 6–12 weeks prior to recruitment. This time frame was chosen to give participants the opportunity to recover from any short term after effects of their initial treatment(s). It was important that we received views from as wide a range of people with colorectal cancer as possible, however, we excluded people who were unable to give informed consent (eg, because of dementia), or who in the judgement of the clinical team it would not be appropriate to approach within the timescale of the study. Since this was a small, resource limited, pilot, we also excluded people who were unable speak or read English, as we did not have the resources to employ a translator or to produce information resources in languages other than English. All patients had been diagnosed with colon or rectal cancer. Written informed consent was obtained by the research team prior to the home visit by the research nurse. In each case, the patient was visited at home by a study nurse who delivered the intervention to them. Home visits were audio-recorded and the nurses completed contact sheets detailing what had been discussed and the goals and plan agreed. Six of the 12 participants set goals and completed action and monitoring plans. The nurses telephoned the participants 1 week after the home visit to determine the participant’s progress towards their stated goals. All of the participants who set goals achieved them.

Semistructured interviews were conducted with the two intervention nurses and all the participating patients 4–8 weeks after the home visit to explore their experiences and attitudes towards the intervention.

**Pilot post-intervention interviews**
Overall the intervention was well received. The home visits were particularly valued, as many patients still...
found travelling difficult. Some patients, however, felt ‘too well’ and not in need of help.

**Intervention materials**
The prompt cards were liked by both patients and nurses and were successful at identifying problems which could be used to develop goals. One patient said:

‘They [the cards] made me pick more cards than I would have spoken about’. Another said that they ‘put his thoughts into words’.

Some found goal setting and follow-up monitoring and feedback helpful:

‘Very worthwhile. What she did got me going, especially as she would be phoning to find out I had done it’.

Patients usually met or exceeded their goals by follow-up. Factsheets were found useful and kept for reference. On the other hand, some patients had forgotten the content of the nurse consultation by the time of interview (4–8 weeks later).

**Suggestions for improvement**
The nurses would have valued more training, especially more contact with colorectal cancer patients. More training on the use of materials may have helped prevent some deviations identified from the intervention protocol. A run-in phase would have been useful as the nurses felt that they only became confident delivering the intervention after the first couple of visits. The nurses would have liked access to patients’ medical records before their visit.

Some patients felt they did not need the intervention and others reported benefit and wanted it to continue. A suggested solution was for a first short assessment visit, with ongoing follow-up for those who might benefit. Overall, the resources were found to be clear and well constructed.

**Final intervention**
The final intervention took the form of a single, 1 hour nurse home visit 6–12 weeks after diagnosis, and telephone follow-up 1 week later (with a view to ongoing follow-up in future). Intervention materials can be found in the online appendices.

**DISCUSSION**

**Strengths and limitations of our approach and research**
The authors have developed a feasible community-based intervention for people with colorectal cancer using the MRC Framework. In doing so, the authors applied an iterative approach to intervention development that they have used successfully before.\(^\text{15, 16}\) Strengths of this approach include basis in evidence, theoretical underpinning and appreciation of context. The MRC Framework advocates an approach that is, however, time consuming and costly in terms of research resources. Although our literature review included papers only up to the end of 2008, recently published research confirms our findings.\(^\text{17, 18}\) The currently reported successful pilot does not guarantee wider relevance of the intervention given the limited geographical and demographic range evaluated; to do so would require yet more resources. The practicalities of availability, engagement and commitment meant that the interests of stakeholders were not represented equally during the development process. This could lead to the risk of over or under-representation of particular viewpoints in equal measures. We have only evaluated acceptability and feasibility; evidence of effectiveness will require a randomised trial. So, is this development process worthwhile? The approach we have used (ie, the MRC Framework approach) followed recognition that complex interventions too often proved ineffective in expensive randomised trials and that, whatever the outcome of their evaluation, little could be concluded about how or why they had (or had not) worked.\(^\text{9}\) Our systematic approach ensures that the intervention has the best possible chance to be effective and is therefore worth evaluating. Our description of the mechanism of action should allow an informative evaluation of effects on processes and outcomes to be conducted.

**Relationship to other research**
Most programmes of follow-up for colorectal cancer concentrate on detection of disease progression or recurrence.\(^3, 4\) Some interventions have been based in specialist care for specific symptoms and have shown benefits, for example, to depression.\(^19\) Others have focused on survival care plans at the transition between primarily hospital-based care back to primary care and on increasing the amount of follow-up conducted in primary care.\(^20, 21\) These have shown promise but need evaluation. There is interest in whether increased continuity of care might improve patients’ quality of life, but a Cochrane review found that evidence remains weak.\(^22\) Our intervention is focused on an important global patient outcome (quality of life) rather than a feature of care. We worked backwards from the desired outcome to generate the most appropriate intervention. In doing so, we attempt to build on previous interventions targeting individual symptoms that are important to global quality of life.

**Meaning and implications of our experience**
The first implication of our experience is that a community-delivered intervention has a realistic chance of improving HRQoL in patients with colorectal cancer. The intervention could be based from primary or secondary care, although primary care has the advantage of ensuring all patients are included not just those on active treatment or follow-up. Community delivery ensures ease of access for patients with activity restrictions, who may be those most likely to benefit. To date,
23 Evaluation of effectiveness is, then, desirable. The second implication is for future evaluation. The intervention we developed aims to improve quality of life by reducing the symptoms (including anxiety and depression) and participation restrictions identified in our previous research. Thus, the outcome measures used in our original study should track this interventions mechanism of action.7

Regarding the development process, we garnered experience in how best to develop an intervention with a high level of complexity and low level of existing evidence. First, considerable care and thought was expended in the formation and conduct of the multidisciplinary group tasked with devising this intervention. The task of combining the elements into a coherent, co-ordinated and holistic intervention to be delivered in the community was facilitated by giving time to open discussion across disciplines and by referring to the theoretical expertise of health psychologists, sociologists and health service researchers while tempering these with the practical experience and insights of patients and clinicians. This permitted several barriers to be identified and rectified both at the level of theory selection (eg, by selecting theory that explained and guided behaviour change rather than theory that simply explained behaviour but did not guide change) and optimisation in practice (eg, the use of prompt cards to identify important symptoms and activities). Second, the apparent success of our developmental process, we believe, depended on the identification of potential intervention components already evaluated in randomised trials and on the identification of theoretically based specific BCTs. Third, the development of the intervention was iterative, with much discussion, questioning and refinement of individual components before they were brought together as a single coherent intervention, with further detailed consideration of how all the elements fitted together in the light of the views of potential recipients and deliverers, with a further level of refinement possible in light of the piloting exercise. Broadly, we followed four phases but all fed forward and backward into one another to produce an intervention with the potential to affect real improvements in the quality of life of people with colorectal cancer.

**CONCLUSIONS**

We have conceptualised the components of an intervention to improve quality of life in people with colorectal cancer, by tackling factors which impair HRQoL, increasing activities and enabling participation. Patients and professionals are positive about our intervention and helped to improve it. Our pilot study suggests that this intervention is feasible. It has the potential to improve quality of life but this now needs formal evaluation.

**Author affiliations**

1Division of Applied Health Sciences, Academic Primary Care, University of Aberdeen, Aberdeen, UK
2Division of Applied Health Sciences, Aberdeen Health Psychology Group, University of Aberdeen, Aberdeen, UK
3General Practice & Primary Care, University of Glasgow, Glasgow, UK
4Cancer Care Research Centre, School of Nursing, Midwifery and Health, University of Stirling, Stirling, UK
5Division of Applied Health Sciences, University of Aberdeen, Aberdeen, UK
6Aberdeen Royal Infirmary, Aberdeen, UK
7Hull York Medical School, University of Hull, UK
8Institute of Health and Society, Newcastle University, Newcastle Upon Tyne, UK
9Institute of Health and Wellbeing, College of Social Science, University of Glasgow, Glasgow, UK

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Intervention to improve quality of life in people with colorectal cancer


