

# Designing an integrated follow-up programme for people treated for cutaneous malignant melanoma: a practical application of the MRC framework for the design and evaluation of complex interventions to improve health

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**Background.** Complex health care interventions are difficult to design and evaluate, so the UK Medical Research Council (MRC) has developed a 'framework for the design and evaluation of complex health care intervention'. Researchers differ in applying the framework.

**Objective.** To describe and critically evaluate how the two initial phases of the MRC framework facilitate the design of an integrated follow-up programme for cutaneous melanoma to a standard suitable for testing in an exploratory randomized trial.

**Design of study.** Literature review, expert groups, semi-structured interviews and pilot exercise to develop an intervention.

**Setting.** A department of academic primary care. Two general practices.

**Methods.** Four techniques were used—iterative literature review, a steering group, semi-structured telephone interviews and an operationalization exercise. These techniques were used simultaneously and iteratively to complete the theoretical preclinical and phase I modelling of the MRC framework when developing an integrated follow-up programme for cutaneous melanoma.

**Results.** Components of an integrated follow-up programme for cutaneous malignant melanoma were identified, developed and refined into a practical intervention comprising GP training; structured protocol-driven appointments; a centralized recall system; a rapid access pathway and a patient information booklet. Several barriers that could have derailed the successful implementation of the intervention, including the different perspectives of stakeholders and resource needs in general practice were identified. The value of the principles of the initial two phases of the MRC framework in guiding the development of complex health care interventions was supported.

**Conclusions.** We recommend that the first two phases of the MRC framework be used iteratively and simultaneously when developing complex health care interventions.

**Keywords.** Aftercare, melanoma, primary health care, research methodology.

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## Introduction

Complex health care interventions are ‘made up from various interconnecting parts’.<sup>1</sup> They are difficult to develop, document and reproduce, and costly randomized controlled trials are required to demonstrate their effectiveness. The UK MRC has developed a ‘framework for design and evaluation of complex interventions to improve health’ advocating a phased approach (Figure 1).<sup>1</sup> In the first phase, knowledge is used to formulate theory which informs a potential intervention that is modelled in the next stage. In the third stage, an exploratory trial is used to practically refine the intervention before the fourth stage, a full-scale definitive randomized trial. The final stage is the implementation of proven interventions.

Several case studies describe using the framework, but interpret the content and purpose of phases differently.<sup>2–8</sup> It appears that carefully developing complex interventions is regarded as a good thing, with little agreement on the key tasks and processes.

A particularly important point is how the framework should be applied. The diagrammatic representation suggests a strictly linear approach, although accompanying text in the original paper clearly states that the phases are iterative, not linear.<sup>1</sup>

In the UK, routine follow-up of people who have had a cutaneous malignant melanoma is carried out at hospital clinics, but there is potential for an integrated system which shifts the focus into primary care. Such service redesign is complex and requires evaluation. We used the initial two phases of the MRC framework to guide the development of a programme of integrated melanoma follow-up suitable for testing in a randomized trial. The first preclinical phase is largely theoretical. The second phase comprising modelling where theory is tested and revised in the light of practical testing and discussion. This paper describes the tasks and processes undertaken to develop the intervention, how our approach fitted with the first two

phases of the framework, and the challenges and benefits of using it.

## Methods

The intervention idea arose from discussions with specialists, developed further after a broad literature review. Initially, we drafted potential models of follow-up (Figure 2), considered how they might work and sought evidence on what model might be most effective. Thus, the ‘theoretical’ (preclinical) and ‘modelling’ (phase I) stages of the framework occurred simultaneously over a period of approximately 18 months. They became increasingly structured through an iterative literature review, a steering group, semi-structured interviews and a 3-month operationalization exercise.

### *Iterative literature review*

The literature review was broad ranging. Appropriate literature was obtained by Medline search (key terms included, melanoma, primary care, cancer, aftercare), from personal archives and by studying the reference list from identified papers. Literature reviewed included melanoma follow-up guidelines and editorials, articles and original research on topics such as epidemiological studies, primary care cancer follow-up and integrated care, patient and professional perspectives on cancer follow-up and policy documents. Questions addressed by the ongoing review arose from gaps in theory and evidence identified as possible intervention models arose from steering group meetings and the ongoing research. The literature review became increasingly focussed as the intervention developed, informing specific aspects of the final design.

### *Steering group*

The steering group initially comprised three researchers, two interested GPs and three hospital specialists

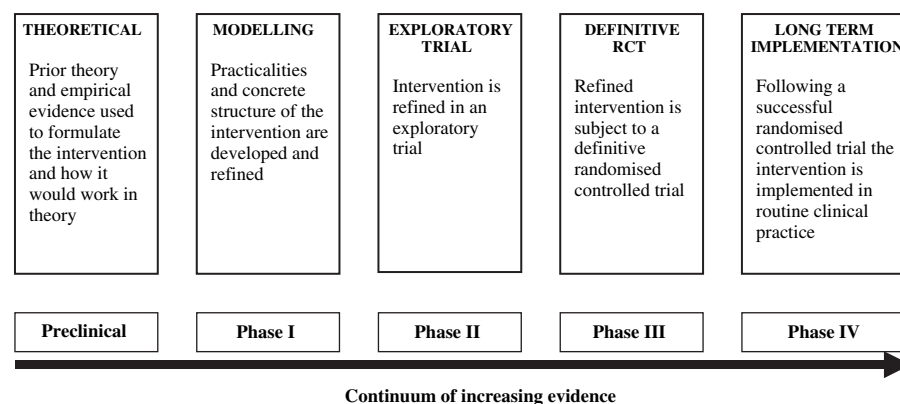


FIGURE 1 *The MRC framework for design and evaluation of complex interventions to improve health*<sup>1</sup>

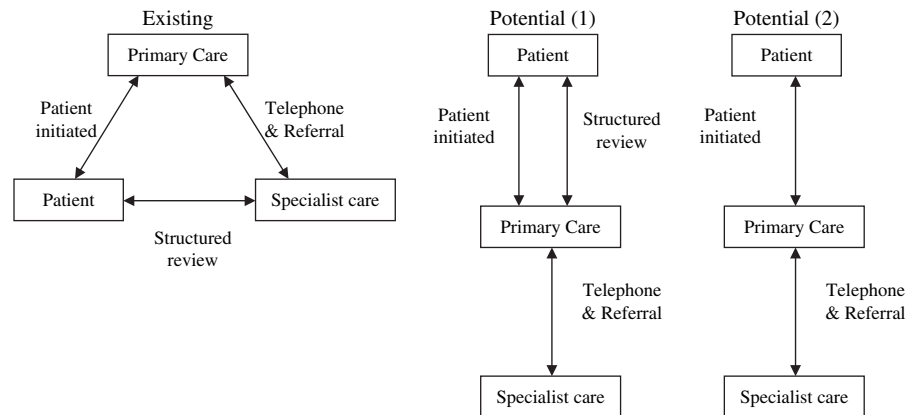


FIGURE 2 Existing and potential new models of structured melanoma follow-up

currently delivering melanoma follow-up at the local hospital. It aimed to identify likely components of an integrated melanoma follow-up programme from each discipline's perspectives.<sup>9</sup> Additional stakeholders were subsequently identified to join the group (Box 1). At the first full meeting, researchers outlined a potential model for the programme, which was discussed. At subsequent meetings, information from various sources, including literature review, interviews and the experience gained from the operationalization exercise were discussed and consensus reached about the detailed structure of each intervention component. The full group met formally three times over a 6-month period with informal contact in between.

#### *Semi-structured telephone interviews*

Nine patients (Table 1) were recruited as they attended the hospital clinic for melanoma follow-up, and 14 GPs were purposively sampled to reflect geographical variations in Grampian region. An interview schedule developed using knowledge gleaned during the developmental process sought the views of both parties on the feasibility, desirability, benefits, pitfalls and essential components of an integrated follow-up programme. The interviews were conducted by Peter Murchie. Interviews lasted between 12 and 56 minutes. Patients were telephoned at home in the evening and GPs at their surgery during the day. Interviews were recorded and transcribed verbatim. Transcripts were read in detail and common issues and practical points that would help refine the intervention noted. Special attention was paid to discordant views, paying attention to individual participant characteristics.

#### *Operationalization exercise*

Once the probable intervention had been designed in detail by the authors, one urban and one rural GP agreed to pilot it, to assess feasibility and to identify problems or deficiencies. Each GP invited all their eligible patients to participate. Six patients attended

Box 1 Composition of steering group

Three primary care researchers (all trained GPs, one currently part time, one currently undertaking regular sessional work)  
 Three people previously treated for cutaneous malignant melanoma  
 Patient involvement officer  
 GP with a special interest in dermatology  
 Two Macmillan GP advisors funded by cancer charity Macmillan (both principals in general practice)  
 Consultant plastic surgeon  
 Consultant oncologist  
 Consultant dermatologist  
 Health board manager (previously a GP)  
 Nursing services manager  
 Macmillan nurse

TABLE 1 Characteristics of patients participating in telephone interviews

	Sex	Age	Months since diagnosis	Location
Initial interviews				
Patient 1	Male	61	27	Suburban
Patient 2	Female	52	71	Rural
Patient 3	Male	51	18	Rural
Patient 4	Female	77	48	Rural
Patient 5	Female	?	12	Urban
Patient 6	Female	63	6	Suburban
Patient 7	Female	64	1	Urban
Patient 8	Male	?	?	Suburban
Patient 9	Female	37	37	Rural
Interviews following operationalization exercise				
Patient 1	Male	55	13	Rural
Patient 2	Male	38	33	Rural
Patient 3	Female	55	57	Urban
Patient 4	Male	71	18	Urban
Patient 5	Female	53	87	Urban
Patient 6	Male	?	?	Urban

a single GP melanoma follow-up appointment. After 4 weeks, the researcher conducted brief semi-structured interviews with all six participating patients (Table 1)

and both GPs. These interviews were not recorded but brief, structured, field notes were made during and immediately after each interview. Subsequent analysis focussed on the participants' practical experiences and views on how to optimize the intervention.

## Findings

### *Iterative literature review*

**Epidemiological background.** Melanoma can affect people of both sexes, and affects young people disproportionately.<sup>10</sup> Most people with melanoma survive for prolonged periods but recurrence is common, so long-term follow-up is recommended.<sup>11</sup> Detected early, recurrent melanoma can be treated by surgery, which improves survival.<sup>12</sup> The increased risk of a second primary also necessitates follow-up.<sup>13</sup>

**Melanoma follow-up.** Current guidelines do not specify where follow-up should take place.<sup>12,14,15</sup> Physical examination without invasive investigations is the cornerstone of follow-up.<sup>12,14,15</sup> Despite evidence that follow-up is important, key questions remain—which health care professionals should undertake it, which patients should be followed up and where?<sup>15–17</sup>

**Policy background.** Melanoma incidence and follow-up costs are increasing, prompting calls for new approaches.<sup>17</sup> The National Framework for Service Change in the National Health Service in Scotland highlights a need for sustainable services, meeting local needs and expectations, delivered in local communities rather than hospitals.<sup>18</sup> This suggested that integrated follow-up for melanoma would be welcomed by policy makers.

**Current follow-up systems.** The main purpose of follow-up is to detect recurrences early enough for successful treatment.<sup>12,14,15</sup> No trials comparing different follow-up systems were found. Several potential follow-up models exist, including one with primary care co-ordinating routine melanoma follow-up for most patients, and another relying on patients initiating follow-up (Figure 2).

**Problems with current systems.** Most UK melanoma follow-up is carried out in hospitals,<sup>17</sup> although most recurrences are detected by patients themselves between visits.<sup>19</sup> Travelling to hospital is burdensome for patients, especially in rural areas.<sup>17,20</sup> Problems with hospital follow-up include difficulty parking, transport and finance.<sup>17</sup> Despite this, patients value follow-up because of the examination received, reassurance obtained and the opportunity to ask questions.<sup>17</sup>

**Integrated care programmes.** Integrated care programmes are structured, multidisciplinary plans detailing essential steps in care of patients with specific conditions, co-ordinating activities and resources between primary and secondary care.<sup>21</sup> Evaluated for several diseases, they can be as effective as secondary care-based programmes, acceptable to patients and cost effective.<sup>21–25</sup> Benefits ascribed to them include reduced costs, improved patient outcomes and increased patient satisfaction.<sup>21</sup>

**Questions arising from the literature review.** The literature review suggested that an integrated melanoma follow-up programme was theoretically attractive, but several important questions remained. Do GPs have sufficient knowledge and skills to implement it? Do GPs have the potential, capacity and inclination to take on this work? Do patients want it and, if so, with what caveats? Furthermore, it was important to recognize the challenges of implementing any such programme. A rudimentary force-field analysis<sup>26</sup> identified several driving forces for change including patient convenience, cost effectiveness and unburdening specialist clinics. However, restraining forces included increased GP workload and specialist concerns about GP expertise. Clearly a subtle blend of change strategies would be required to implement any such programme.<sup>27</sup>

### *Steering group*

The steering group discussed and agreed that the purpose of follow-up was to detect recurrent disease and new primaries as early as possible. It was also agreed that follow-up should reassure patients and be an opportunity for patient education. The group identified protocol-driven review, GP education and rapid access to secondary care as key components of the integrated follow-up programme.

The group discussions produced a rich blend of perspectives from different disciplines. For example, the oncologist was keen on routine GP follow-up because of increasingly burdened outpatient clinics. Balancing this, the plastic surgeon was concerned about initial wound care and follow-up of people with thicker lesions. The dermatologist highlighted challenges in detecting new primaries, and the GP was concerned about specialists 'dumping' unwanted work onto them. One patient wanted an entirely physical review, while another highlighted the desirability of psychological support. Both patients suggested tailoring follow-up, for example, by making colour leaflets available on request.

A problem arising after steering group meetings was different perceptions of what had been agreed, for example confusion over inclusion criteria for the programme. Such issues were resolved subsequently in smaller face-to-face meetings.

At this stage, some key information was still missing, including the acceptability of the programme to people with melanoma and GPs, what GP training was needed to deliver the programme and how patients in GP follow-up might gain rapid access to specialists should the need arise (e.g. via a rapid access pathway).

#### *Patient interviews*

The nine patient interviews revealed broad support for GP follow-up although one patient strongly opposed it, blaming their GP for their initial diagnostic delay. Patients concurred markedly that the main purpose of follow-up was to provide reassurance. Most thought current follow-up achieved this but were concerned about large travelling distances and time implications, brief consultations and poor continuity. Both rural and urban participants perceived convenience to be a major benefit of GP follow-up, including reduced travelling and other costs. Several thought that access would be easier with a GP-led follow-up programme. Some viewed attending the GP as less threatening and thought they could see the same GP each time. All participants queried the experience and skills of GPs and said that training would be vital, but were vague about its content. Some were concerned about burdening GPs. Rapid access to specialist advice when necessary was viewed as crucial. More time, total skin examination, instruction in self-examination and more information were seen as desirable opportunities offered by GP follow-up.

The interviews confirmed that integrated follow-up was attractive to people who have had melanoma and highlighted the need for GP training and an explicit rapid access pathway to specialists.

#### *GP interviews*

In general, the 14 GPs interviewed were not greatly enthusiastic about the programme, although rural practitioners were keener. All GPs perceived improved convenience for patients and several mentioned better continuity. Generally, they perceived few advantages for themselves, though some cited more involvement in care, increased skills and knowledge and freeing up of specialists. Views on patient disadvantages contrasted starkly. Some GPs felt there were none, others were concerned about reduced reassurance. Two worried about patients being put at risk because of limited GP experience. Some were concerned about increased workload, particularly urban GPs although some rejected this citing small patient numbers. One GP viewed the programme as 'secondary care dumping work onto us' and one worried about medico-legal implications. The GPs concurred almost entirely on what was needed to make GP follow-up work—training, defined protocols, appropriate specialist support and resources. Four key themes emerged as to what was needed in the training

programme—basic information about recurrent melanoma; purpose of follow-up, what to look for and how to do it; how the system would work and an opportunity to discuss fears and concerns with specialists.

GPs indicated unwillingness to participate in an exploratory study without reimbursement. This provoked correspondence with the local GP subcommittee, with subsequent negotiation and agreement on appropriate reimbursement.

#### *Synthesizing all the evidence*

The synthesis process was lengthy and iterative. The information generated from the various sources was synthesized and a draft intervention outlined. This was revised repeatedly in light of subsequent discussion among the researchers and steering group members and after further evidence collection. Eventually the final proposed programme emerged in a form that we believed would function in real life. It comprised GP training, protocol-driven examinations by GPs, a centralized recall system, a rapid access pathway and a patient information booklet. Written documents were drafted, discussed and refined. Administrative requirements and systems were agreed and developed through a variety of meetings with local stakeholders, administrative and clinical staff. The final proposed system was tested in an operationalization exercise which enabled the programme to be optimized.

#### *Operationalization (prepiloting) exercise*

When interviewed after the operationalization exercise, both GPs generally approved of the protocol, suggesting minor amendments, such as provision of a laminated protocol card and extension of the initial appointment by 10 minutes to permit discussion of self-examination and complete total skin examination.

Of eight eligible patients, six agreed to take part (Table 1). All were generally satisfied with the follow-up appointment, with only one feeling that the GP was not as reassuring as a specialist. No changes were suggested regarding the way GPs conducted the appointments.

The operationalization exercise clarified the resources' requirements for practices to participate in the exploratory study, informing subsequent negotiations with the funding body (Cancer Research UK) for additional funds.

## Outcomes of the preclinical and modelling phase

#### *Final intervention*

Table 2 demonstrates how theory, evidence and expert opinion obtained from the various sources defined essential tasks and processes needed for an effective integrated melanoma follow-up programme.<sup>28</sup> The

components required to achieve these tasks and processes were designed and 'fine tuned' to produce a programme that we believe can succeed in practice. Figure 3 is a model of the intervention, now the subject of an exploratory trial.

#### *GP training*

A structured training afternoon (3 hours) was designed, consisting of four elements addressing each educational need identified during the GP interviews. This included discussion of the project and lectures from three specialists. The meeting was approved by the Educational Providers Accreditation Scheme (Scotland) of the Royal College of General Practitioners and supported by a written manual. A single GP from each intervention group practice attended.

#### *Structured protocol-driven examinations*

A flow chart was designed, clearly indicating appropriate steps and alternative actions to be taken during GP follow-up examinations (Figure 4).

#### *Centralized recall system*

For the exploratory trial, researchers will maintain a database and post reminders to patients and GPs when a follow-up examination is due.

#### *Rapid access pathway*

A referral form was designed for use by GPs when a problem is detected during follow-up. This will be faxed to a named secretary who will arrange a specialist review within 2 weeks of receipt.

#### *Patient information booklet*

In response to patients' identified need for more information about melanoma, a detailed booklet was written drawing upon existing sources.<sup>29</sup> Drafts were extensively reviewed by the steering group.

#### *Adequate resources*

GP reimbursement of £30 per review examination and expenses to attend training were agreed upon and secured.

TABLE 2 *Levels of definition of intervention*<sup>28</sup>

Level 1: theory and evidence	Level 2: essential tasks and processes	Level 3: people and context
<p>Target population and need for follow-up</p> <p>Patients treated for malignant melanoma are at high risk of relapse and require careful follow-up<sup>11</sup></p> <p>Guidelines exist detailing the follow-up of patients with cutaneous malignant melanoma<sup>12,14,15</sup></p> <p>Recurrent melanoma is manageable only by surgery, so rapid diagnosis and treatment is essential<sup>18</sup></p> <p>Detection of recurrence</p> <p>Most recurrences are detected by physical examination by doctors or self-examination by patients<sup>16,18</sup></p> <p>Investigations are not generally recommended for routine follow-up<sup>12,14,15</sup></p> <p>Role of patient education</p> <p>Patient education programmes providing information about the disease, treatment plan and each stage of the care journey are advocated by guidelines.<sup>9</sup> Patient education has been shown to have a positive effect on coping behaviour and affective disease states<sup>30</sup></p> <p>Integrated care and service provision</p> <p>Integrated care programmes co-ordinate the activities and resources of primary and secondary care in the management of patients with specific conditions. They are as effective as secondary care-based programmes, acceptable to patients and more cost effective than secondary care follow-up<sup>22–26</sup></p> <p>An integrated care programmes for breast cancer has been the subject of a successful trial<sup>23,24</sup></p>	<p>Identify patients with cutaneous malignant melanoma and form a register of melanoma patients</p> <p>Devise a system of structured recall</p> <p>Educational programme to primary care physicians on examination, integrated care pathways and educating patients</p> <p>Write manual for GPs</p> <p>Educate and empower patients to detect melanoma recurrence and act appropriately</p> <p>Patient educational package comprising information about disease, treatment, self-examination and care journey developed and incorporated into intervention</p> <p>Pathways established between primary and secondary care</p> <p>Development of pathways to ensure rapid treatment once recurrence detected</p>	<p>Patients previously treated for cutaneous malignant melanoma and undergoing follow-up</p> <p>General practices in Grampian region</p> <p>Primary or secondary care-based recall system</p> <p>Steering group to devise and implement training to GPs</p> <p>Intervention delivered by GPs in primary care settings. Recognition and reimbursement of resource costs</p> <p>Communication between primary and secondary care</p>

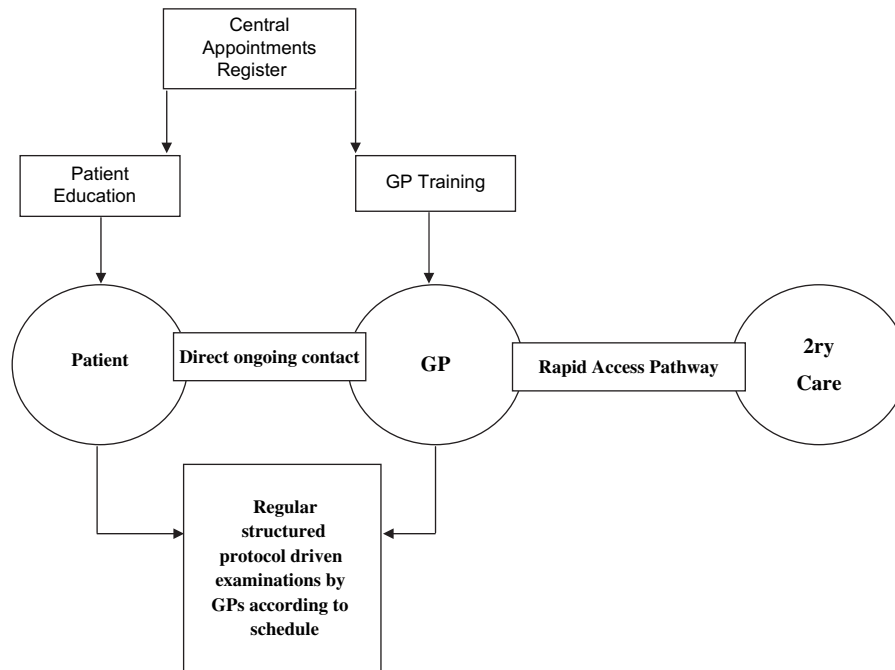


FIGURE 3 Model of intervention at conclusion of development

#### Design of phase II exploratory trial

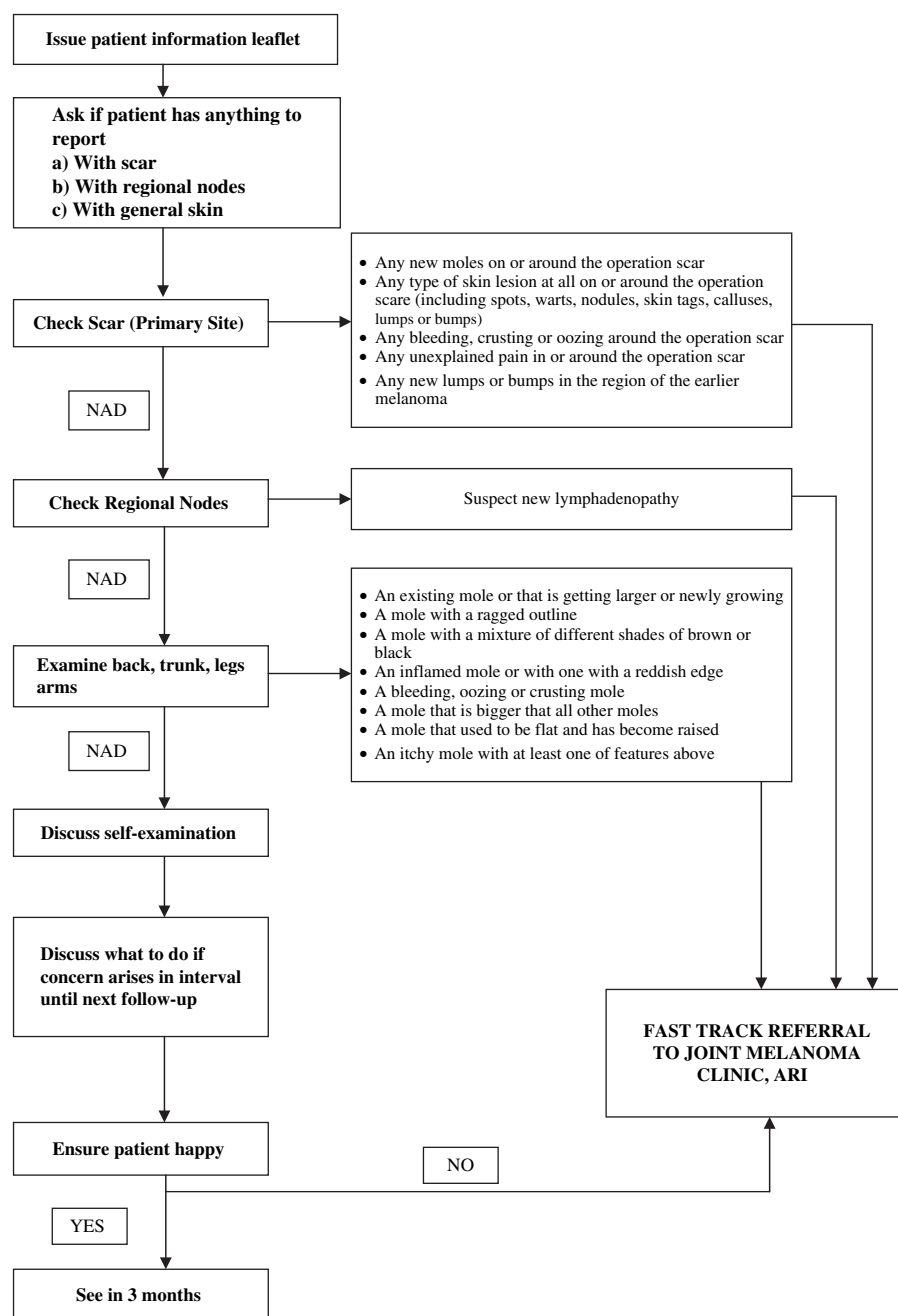
Information from the initial phases of the framework has informed the detailed design of a phase II exploratory trial to evaluate the above intervention. It became clear that the intervention was at general practice level (rather than patient or GP level) because of the training and infrastructure requirements, so randomization would also be at general practice level. Data from the melanoma clinic and operationalization exercise allowed us to estimate recruitment rates at 5 per 10 000 population and reassured us that retention should be high. Finally, patient, professional and expert perspectives on the key benefits and possible harms of the programme allowed us to ensure that appropriate outcome measures were employed (including processes of care, patient satisfaction, primary and secondary care resources use, quality of life and analysis of critical events).

Funding has been secured for a randomized phase II exploratory trial of the integrated follow-up programme for melanoma. Thirty-five practices in north-east Scotland have agreed to participate. Seventeen practices have been randomized to intervention and have sent a single GP to a training afternoon run by the researchers. Eighteen practices have been randomized to control. A total of 142 eligible patients have been recruited for the trial. Data collection at baseline and 1 year will patients at intervention practices have received the patient information booklet and are currently being followed up by a GP at their own practice via a central recall. These follow-up appointments are protocol driven (Figure 4). In the event that the GP or patient is concerned about a possible recurrence or

new lesion, a referral can be made to secondary care via the rapid access pathway, with patients seen by a specialist within 2 weeks. Patients in the control group continue to attend the hospital melanoma clinic for follow-up. Data will be collected at baseline and 1 year and will include patient questionnaires (comprising socio-economic questions, patient satisfaction survey, SF36 and hospital anxiety and depression scale) and case notes review for protocol compliance, general practice consultations and hospital appointments. A parallel qualitative study will provide more information to inform further intervention development if this is necessary. Further data will be collected on recruitment, retention and cluster effects to further inform a future phase III trial. The trial will run for 1 year with principal outcome measures of mortality, recurrence rates, patient satisfaction and costs.

#### Discussion

Key tasks in developing this intervention were collecting the theoretical and empirical evidence on likely benefits, disadvantages, incentives and barriers to primary care-based integrated melanoma follow-up, and using this evidence to produce a refined intervention for testing. Processes included early (and recurrent) paper modelling, literature review, expert groups, interviews with patients and GPs and an operationalization exercise. While we regard all the processes as within the 'theoretical' and 'modelling' phases of the MRC framework, we found that they occurred simultaneously, rather than as separate phases. The most

**FIRST APPOINTMENT (20 Minutes)**FIGURE 4 *Continued*

striking benefit arising from our approach was the identification of several factors that could have compromised the intervention, for example disagreements between key stakeholders and the need for reimbursement of GPs. Also important was identifying opportunities to refine the intervention.

Our approach had weaknesses. The number of questions we sought to answer from our literature reviews and limited resources meant relying predominantly on Medline and expert knowledge—more systematic reviewing may have yielded further evidence. Our

steering group relied on individuals participating, although previous studies have found that expert groups produce valid representations of the groupings from which experts are drawn.<sup>9</sup> The qualitative research we conducted with patients and GPs was limited to telephone interviews, perhaps lacking the depth of face-to-face interviews or focus groups. Additionally, the small number of participants in the operationalization exercise may have limited the generalizability of conclusions. Finally, although some parts of our intervention were based on evidence-based guidelines<sup>12,14,15,</sup>



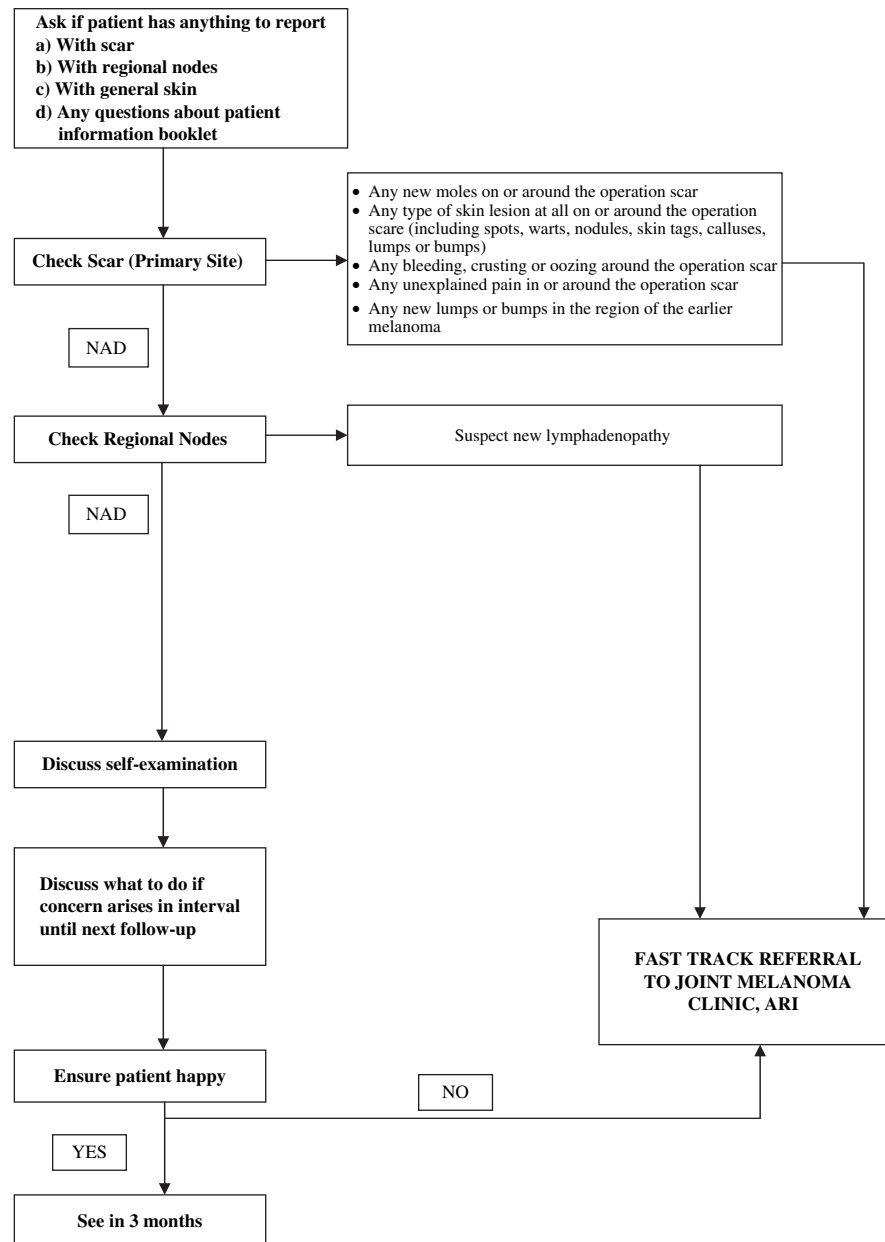
**SUBSEQUENT APPOINTMENTS (3,6,9 and 12 months) (10 minutes)**

FIGURE 4 Protocol flow charts used during GP follow-up appointments

much of it derived from theory, epidemiological evidence and expert opinion. Definitive evidence of effectiveness requires a randomized trial, but at least now we have an intervention worthy of further evaluation.

We have used the principles of the initial two phases of the MRC framework to develop a primary care-based integrated follow-up programme for melanoma now being evaluated in a randomized trial. We identified several important and unanticipated barriers that could derail the successful implementation of our intervention. Our experience emphasizes the value of conducting the initial two phases of the MRC framework simultaneously and iteratively when developing

complex health care interventions. We commend this approach to others.

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## Declaration

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Conflicts of interest: None declared.

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