Interventions for improving psychosocial care and support in routine oncology practice

Emma Joanne Ingleson

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The candidate confirms that the work submitted is her own, except where work which has formed part of jointly authored publications has been included. The contribution of the candidate and the other authors to this work has been explicitly indicated below. The candidate confirms that appropriate credit has been given within the thesis where reference has been made to the work of others.

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Emma Ingleson (candidate) conducted data extraction and analysis in conjunction with L.C. Bingham. The candidate authored all sections with guidance on content from P. Wright and G. Velikova, and editorial support from all co-authors. P. Wright was the Principal Investigator on the original cross-sectional study from which the data was obtained. P.J. Selby was the lead of the Psychosocial Oncology and Clinical Practice Research Group at the time the original study was conducted. G. Velikova was the lead at the time of the analysis presented in the paper and its publication. K.M. Roberts was involved in the original study as an independent advisor.

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Abstract

A cancer diagnosis may have a significant impact on an individual and those around them. This is not always recognised in routine oncology practice, and information provision for patients on psychosocial difficulties may be delivered in an ad-hoc manner. Unresolved social difficulties may undermine patients' abilities to deal with the larger stressors of the disease and its treatment, increasing the burden on patients and services. The overall aim of the work presented in this thesis was to explore implementation of a programme of social difficulties assessment, which utilised the Social Difficulties Inventory (SDI-21) and included staff training and provision of information to patients. Pilot randomised controlled trials (RCTs) were conducted to explore the role of two components of this programme in managing social difficulties. The first was a study-specific information resource, which was developed, evaluated, and its impact on processes of care, patient behaviours and well-being assessed through the pilot RCT. Secondly, an assessment method, incorporating training for nurses in utilising the SDI-21, was evaluated in the second RCT. Both RCTs were used to calculate estimates of effect sizes to inform future trials of these interventions. The information resource was not widely used. Qualitative data suggested various reasons for this, including that patients are faced with an often overwhelming amount of information. Difficulties in implementing the assessment process were experienced in the second RCT, confounded by issues with recruitment. Qualitative data provided depth of understanding around implementation issues and highlighted key considerations for future trials. Small effect sizes were observed for both interventions. Development of a full RCT cannot be recommended based on the findings presented here, and alternative trial designs (e.g. quasi-experimental, service improvement models) should be considered.

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Abbreviations

ACST	Advanced Communication Skills Training
AHP	Allied Health Professionals
ALLINEX	Allograft Information Exchange Study
CPQ	Close Persons Questionnaire (included as appendix 5)
CNS	Clinical Nurse Specialist
DART	Distress Assessment and Response Tool
DTPL	Distress Thermometer and Problems Checklist
eHNA	Electronic delivery of holistic needs assessment
EORTC	European Organization for Research and Treatment of Cancer
EORTC – QLQ-C30	EORTC Quality of Life Questionnaire Core 30 (included as appendix 3)
ePOCS	Electronic patient-reported outcomes from cancer survivors study
FACT-G	Functional Assessment for Cancer Therapy – General (included as appendix 2)
HADs	Hospital Anxiety and Depression Scale (included as appendix 4)
HCA/ HNA	Holistic Common Assessment/ Holistic Needs Assessment
HCPs	Healthcare Professionals
HRQoL	Health-related quality of life
HSCT	Allogenic Haemopoeitic Stem-Cell Transplant
ICSS	Information, Care and Support Services
IMD	Indices of multiple deprivation
IPOS	International Psychosocial Oncology Society
MDT	Multi-disciplinary team
MRC	Medical Research Council
NCAT	National Cancer Action Team

NCSI	National Cancer Survivorship Initiative
NHS	National Health Service
NICE	National Institute for Health and Clinical Excellence
NPCRDC	National Primary Care Research and Development Centre
NPT	Normalisation Process Theory
NTP	Nurse Training Package
POG	Patient Reported Outcomes Group
PPM	Patient Pathway Management System
PROMS	Patient Reported Outcome Measures
RAG	Research Advisory Group
RCT	Randomised Controlled Trial
SD-16	Global Social Distress Scale
SDI-21	Social Difficulties Inventory (included as appendix 1b)
SMOG	Simple Measure of Gobbledegook
SSIP	Support Services Information Pack (included as)
WISE	Whole-system Information Self-management Engagement
YCN	Yorkshire Cancer Network

List of Appendices

Additional material – The Support Services Information Pack for Patients (SSIP)

Enclosed in pocket on inside of back cover.

Chapter 1: Introduction

1.1 Overview of this thesis

This thesis describes a programme of work aimed at exploring two potential interventions for dealing with social difficulties in a routine oncology setting; 1) an information booklet, and 2) an assessment of social difficulties, utilising the Social Difficulties Inventory (SDI-21-appendices 1a and b). The Medical Research Council's (MRC) framework for the evaluation of complex interventions[1] was used as the methodological structure. Greenhalgh et al's models of diffusion (MoD) framework for understanding diffusions of innovations in service organisations was selected as the main theoretical foundation [2]. Table 1.1 demonstrates the first three phases (*pre-clinical* to *phase II*) of the MRC Framework and how each chapter presented within this thesis relates to the framework and each of the other chapters. The work included in this thesis does not extend to the latter phases of the MRC framework (*phase III, definitive RCT and phase IV, long-term implementation*).

The ***current chapter (1)*** outlines the background to the work and, in line with the MRC framework *pre-clinical/ theory phase*, the justification of the need for the intervention. ***Chapter 2*** further contributes to this phase by describing the possible relevant theories and why the MoD framework was selected as the theoretical basis for the work. ***Chapter 2*** also includes table 2.1 which provides further detail on the thesis structure in relation to the MRC framework and related theories. ***Chapters 3 and 4*** also contribute to the *pre-clinical/ theory phase* by presenting secondary analysis of existing data. These analyses provide further evidence for the need for the intervention by demonstrating levels of unmet need in terms of lack of discussion of social difficulties and unresolved social difficulties reported by patients.

As ***chapters 3 and 4*** provided evidence for unmet need in terms of social difficulties, ***chapters 5 and 6*** begin to fulfil *phase I (modelling)* of the MRC framework by describing the development of the first of two interventions (an information intervention) and a pilot study conducted to assess the utility of this in addressing these unmet needs for patients. Continuing to provide evidence for this phase, ***chapter 7*** describes the development of the second of the two interventions, a training package to enable nurses to assess patients for the presence and severity of social difficulties during routine clinic appointments. ***Chapter 8*** describes the randomised

controlled pilot conducted to assess the acceptability, feasibility and potential impact of the nursing assessment intervention.

Chapter 9 begins to *fulfil phase II, the exploratory trial phase*, by presenting an evaluation of a pilot of an electronic holistic needs assessment (eHNA) in an oncology outpatient clinic. ***Chapter 10*** reviews and discusses the findings of the work presented here and considers implications for future research and clinical practice.

Table 1.1: Phases of MRC Framework[1] and fulfilment by chapters in this thesis

<table>
<tr><td rowspan="2">MRC Framework Phase</td><td>Theory</td><td>Modelling</td><td>Exploratory trial</td></tr>
<tr><td>Pre-clinical</td><td>Phase I</td><td>Phase II</td></tr>
<tr><td></td><td>Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues</td><td>Identify the components of the intervention, and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other</td><td>Describe the constant and variable components of a replicable intervention AND a feasible protocol for comparing the intervention to an appropriate alternative</td></tr>
<tr><td></td><td colspan="3">Continuum of increasing evidence ➔</td></tr>
<tr><td rowspan="4">Chapter Aims (Methods)</td><td>Chapter 1: Introduction
Explore current research
(literature search)</td><td rowspan="2">Chapter 5: Development and evaluation of an information intervention
Chapter 6: Pilot study; simple information versus standard care
Assess role of information provision
(Randomised pilot study)</td><td rowspan="4">Chapter 9: Staff and patient responses to a pilot of an electronic Holistic Needs Assessment (eHNA); a service evaluation
Evaluate the impact of assessment within the social domain in real oncology practice
(evaluation of the pilot of the eHNA)</td></tr>
<tr><td>Chapter 2: Theory, hypothesis and thesis structure
Establish theories around use of interventions and acceptance of innovations
(literature search, comparison of theories)</td></tr>
<tr><td>Chapter 3: Current practice; frequency of discussion of social difficulties
Establish current practice
(secondary analysis of existing data)</td><td rowspan="2">Chapter 7: Development and evaluation of a Nurse Training Package (NTP) to facilitate delivery of an assessment for social difficulties
Chapter 8: Feasibility, acceptability and impact of an assessment of social difficulties in routine practice
Assess role of formal programme
(randomised pilot study)</td></tr>
<tr><td>Chapter 4: Levels of unmet need for social difficulties, and potential impact of routine assessment
Assess potential effect of an assessment programme
(secondary analysis of existing data)</td></tr>
</table>

1.2 Advances in oncology and the changing burden of cancer

Oncology is one of the most rapidly advancing areas of medicine[3]. Between 1979 and 2008 UK incidence of all cancers rose by 26% [4]. This may be attributed to a number of factors, including an aging population[5]. Other causes maybe increases in risky behaviours (e.g. sun-bed use, excessive alcohol consumption, obesity), as well as increased surveillance and improvements in early detection and diagnosis [4, 6]. Considerable progress has been made in the last century both in understanding causes, and the availability and effectiveness of detection methods and treatments [3, 6, 7]. These factors have led to an increase in early diagnosis and survival; the latter has improved dramatically, doubling in the last 40 years[6].

Living as a disease-free survivor or with cancer as a long-term condition has potential consequences for the patient, their families and caregivers [7-9]. The threat of disease progression and possible side effects of treatments may be a significant burden [10]. This is particularly the case as treatments advance and their length and complexity increase, with some regimens lasting for years. In order to cope with this impact the patient will have to make adjustments, both practically and psychologically[7]. The changing needs of oncology patients have been recognised and reflected in developments in psycho-oncology as a field[11], and also in UK Government Policies and Guidelines [12-14], as well as in other countries (Australia, the USA and Canada[15]). The International Psychosocial Oncology Society developed the International Standard of Quality Cancer Care;

1. Quality cancer care today must integrate the psychosocial domain into routine practice
2. Distress should be measured as the 6th Vital Sign after temperature, blood pressure, pulse, respiration and pain) [16].

1.3 Changing patient role and self-management

Advancements in medicine have led to many diseases being defined as chronic rather than acute. This now includes many cancers, although the characteristics that define cancer as a chronic disease are poorly defined [17]. In response to this changing situation, the Department of Health (DoH) acknowledged a requirement to move away from the “reactive, unplanned and episodic” response to these conditions in the

publication on 'Supporting People with Long Term Conditions' (2005), with the goal to achieve systematic and patient-centred care [18]. This ties in with a shift in patient role from that of passive recipient of care, to increasing involvement in the decision making around their care and treatment. This has been shown to increase patient satisfaction, and has the potential to improve coping and psychological outcomes [19, 20], but still requires supportive infrastructure to help patients gain the confidence and skills to self-manage[21]. The Expert Patient Programme (piloted from 2002 to 2004) is one of the main initiatives within the UK, working towards the goal of 'systematic, patient-centred' approach recommended by the DoH [18, 22].

1.4 Self-management

The theory of self-management goes further, considering not only the individual in isolation but in the context of living with chronic disease. This concept was described by Clark et al (1991) as "…day to day tasks an individual must undertake to control or reduce the impact of disease on physical health status…" [23]. A more detailed definition is "…the individual's ability to manage the symptoms, treatment, physical and psychosocial consequences and life style changes inherent in living with a chronic condition…[self-management] encompasses the ability to monitor ones' condition and to effect the cognitive, behavioural and emotional responses necessary to maintain a satisfactory quality of life [24]". This acknowledges that self-management is more than about the practical issues and the physical management of a condition, but also takes into account psychosocial issues that must be managed. Although well-explored in other diseases (e.g. diabetes), it is an emerging concept within cancer care, as certain types of cancer are becoming chronic illnesses, due to improvements in awareness and treatment [18].

Self-management has not only the potential to reduce the burden of chronic illness on the National Health Service (NHS), but may also have a beneficial impact on well-being in the short term, and specifically where psychosocial well-being is addressed an improvement in mood has also been noticed [24]. It is one of the key concepts within the NHS Improvement Plan, towards the goal of a patient-centred care system, which includes the Expert Patient Programme [18]. Expert Patients are those who are well informed about their disease, how it affects them, what the treatments are and who is involved in its management. They are intended to overcome the barriers still found

despite initiatives to re-structure the NHS to become more flexible, diverse and patient centred [10]. However, despite these policy initiatives a need for further research has been recognised, particularly in order to define 'self-management' and provide further evidence for the suggested positive outcomes of self-management. The UK's Cancer Experiences Research Collaborative was awarded funding by the National Cancer Research Institute in order to progress towards these aims [25]. Work by Foster and Fenlon has used data from two UK wide consultations [26, 27] to develop a framework for supporting patients in self-management[21].

It has been suggested that self-management may be able to fill the gaps between available service provision and the patient's needs [24], and therefore provides one of the key concepts underpinning the hypotheses. Provision of information may help to facilitating self-management of certain difficulties.

1.5 Social impact of cancer

For the 338,623 people in the UK receiving a diagnosis of cancer annually [28], the disease and subsequent treatment will have a significant impact on their lives. As well as the physical changes that occur, the effects are likely to be felt in all areas of life [9, 29], and the impact is commonly felt right through the family and existing social network, particularly for caregivers [30-32].

An initial list of 32 specific social problems was generated during the development of the SDI-21 (appendices 1a and 1b), through interviews and focus groups involving 96 patients, living with a range of diagnoses (table 1.2) [9]. These social problems may be experienced in isolation, or may cause or compound other difficulties. Some difficulties may have been present prior to the patient's diagnosis, and may have increased in their severity as a result. These may be practical issues, e.g. a physical inability to work caused by disease or treatment may impact on a person's financial situation if this leads to a significant reduction in their income. Other interactions may be more subtle or psychological in nature; for example, issues around body image may have an impact on or cause difficulties in relationships.

Table 1.2: List of social problems (adapted from Wright et al, 2002[9])

Category	Items
In the home	Maintaining your independence Difficulty in carrying out domestic chores Difficulty in maintaining personal care Difficulty in looking after those who depend on you Difficulty in getting support for those who care for you
Health and welfare services	Difficulty with support services Difficulties with aids and adaptations Difficulties with location of care
Financial issues	Difficulties with benefits and grants Financial difficulties Difficulties with financial services (e.g. mortgages, pensions)
Employment	Difficulties with work Difficulties with education
Legal issues	Difficulties with legal matters Difficulties with wills and funerals Difficulties in sorting out family affairs
Relationships	Difficulties in communicating with those closest to you Difficulties in communicating with others Difficulties with relationships with those closest to you Difficulties with relationships with others Difficulties with new relationships
Sexuality and body image	Difficulties with sexual matters Difficulties with fertility Difficulties with appearance and body image Experiencing stigma due to illness
Recreation	Difficulties in participating in social activities Difficulties in carrying out leisure pursuits Difficulties with holidays and travel
Individual social problems	Difficulties with isolation Difficulties with housing Difficulties in getting around Experiencing discrimination due to illness

Although the presence and severity of these difficulties may alter throughout the disease trajectory, they are often present in one form or another throughout and into survivorship [9, 33, 34]. A cancer survivor is defined by Macmillan Cancer Support as "someone living with or beyond cancer", including those who have completed initial treatment and has no evidence of active disease, those who are living with progressive disease but are not considered to be in the terminal phase of illness, or anyone who has had cancer in the past[35].

1.6 The role of information

Provision of information may be sufficient to empower patients to act for themselves to find resolutions to social difficulties, either by legitimising discussion of these topics,

or by enabling them to access services on their own initiative [36]. It is well documented that ensuring patients are well informed may increase their ability to cope, subsequently leading to improved well-being [20]. Conversely, inaccurate information may be harmful [37], and one review suggested that the timing of delivery of an intervention is key to achieving a beneficial effect[38]. In comparison to other interventions, information is relatively inexpensive and simple[34], and it has the potential to prevent progression of multiple smaller difficulties into a larger psychological issue, which may be more resource and cost-effective[39] (see figure 1.2). Accessible, timely and accurate information has the potential to reduce the need for complex interventions[36].

1.7 Definition of psychosocial and social difficulties

The question has been raised of how to distinguish between psychosocial and social difficulties. Psychosocial difficulties can be described as "…involving both psychological and social aspects…" or "…relating social conditions to mental health…"[40]. It can be challenging to separate the psychological and social elements of these psychosocial difficulties, and any intervention provided to deal with them may be psychological, social or even physical. The common aspect of difficulties that are social in comparison to psychological is that they are external, concrete difficulties as defined by Dr Penny Wright throughout the research that has preceded these studies[9]. For the purposes of this research the following definition of social difficulties will be used:

> *"A social difficulty is any disruption to a person's ability to conduct the activities that constitute their day-to-day life."*

The following example attempts to illustrate these definitions. A patient may report difficulties with domestic chores. The root of the problem may be physical, e.g. fatigue. A physical intervention would be advice or an information resource on dealing with fatigue, e.g. pacing oneself or sitting down to complete tasks where possible (ironing, peeling vegetables). The psychological element may be that the patient finds it difficult to accept that they cannot do these simple tasks, and may have to relinquish this role to someone else within the family. It may be that other family members are also finding this difficult, leading to strained relationships. Therefore the psychological intervention would be to encourage the patient to allow others to help, provide

reassurance that this period of fatigue will pass and they will eventually be able to resume their normal role (if this is the case), or refer them and/ or their family for help with adjustment issues. The social aspect to this problem may be that the patient may not have the financial resource to pay for extra help around the house. In this case the social intervention would be to provide the patient with information on benefits or other financial aid.

This example includes a physical cause, brought on by treatment for the disease. It is important to be aware in the context of this work that what constitutes a social difficulty is not defined by its cause, but rather its impact on the patient's day to day life. Causes of social difficulties will be varied and not necessarily a direct consequence of the disease or treatment. For some patients social difficulties will be long standing issues that are exacerbated or highlighted as a result of the disease.

1.8 Burden of social difficulties

Failure to recognise and deal with social difficulties may lead to consequences for patients and healthcare professionals. Living with unresolved social difficulties may undermine patients' ability to manage the larger stressors of the disease and treatment. This may lead to more complex psychological difficulties requiring more specialist input. This would result in significant increase in burden for patients, their family and social networks and HCPs and service providers[39] (Figure 1.2).

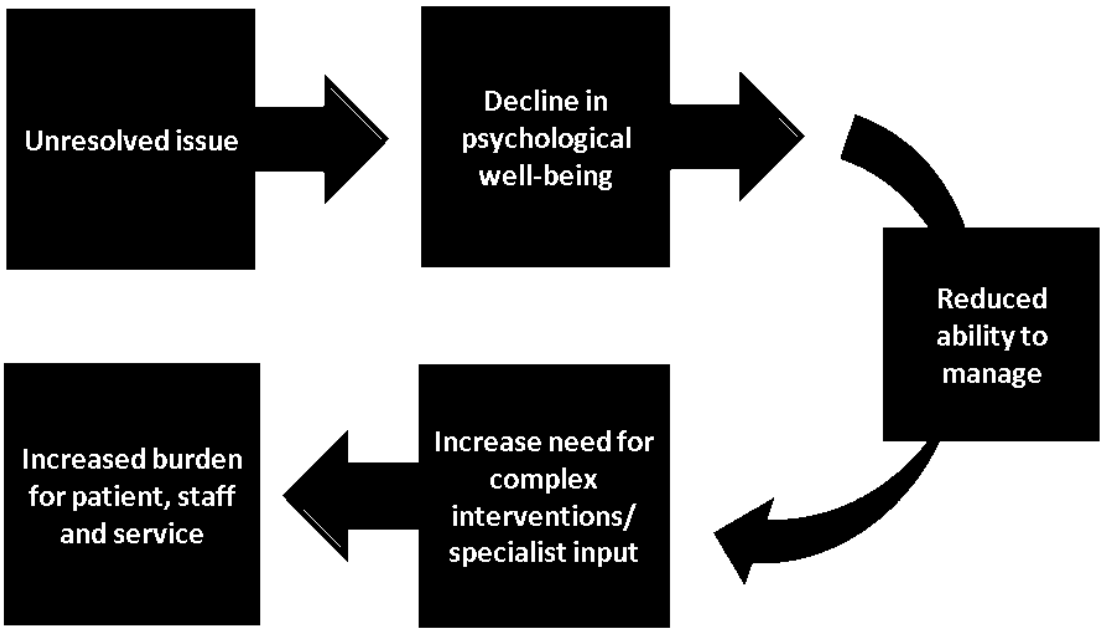


Figure 1.1: Potential consequences of unresolved social difficulties

1.9 Challenges to detection and recognition in policy and practice

Despite an increasing awareness of the impact of these issues[39] and the need to deal with them [33, 41, 42], social difficulties remain largely unrecognised in routine practice[36, 41, 43, 44]. Identification of social difficulties is largely informal [45]. There is little existing evidence on the frequency with which social difficulties are raised during standard outpatient consultations[46]. Explorations of psychosocial content of clinical consultations have tended to consider 'emotional issues' rather than social difficulties as a specific subset of psychosocial matters [47-49]. Data from recent studies suggests social functioning is discussed in 41 to 46% of consultations [46, 50].

Discussion of such issues may be dependent on patients instigating discussions where clear physical implications of disease or treatment are not immediately obvious to HCPs. Practice varies between patient groups and localities. Patients cared for by a team including a dedicated Clinical Nurse Specialist (CNS) may be considered more likely to have their social difficulties and other unmet needs addressed, although this has been shown to be reliant on one to one discussion with the patient and their carer, which may not be possible in busy clinic settings [51]. There are a number of barriers to the identification and discussion of these issues, including; attitudes, practical issues and lack of skills and competencies. These are described in Table 1.3.

Table 1.3: Barriers to detection of social difficulties

Barrier	**Impact**
Attitudes	Attitudes to psychosocial care will impact the provision of this strand of care on two levels; Individual Organisational [33, 40] Both patients and Healthcare Professionals (HCPs) may avoid difficult topics, e.g. sexual difficulties [52] Patients may have pre-conceived ideas about what is appropriate for discussion with the doctor[52] Busy staff may have genuine concerns regarding any perceived increase in workload and consultation time [36, 50] as a result of implementing an extra assessment It must be considered that caring for cancer patients, particularly providing psychosocial care can be stressful for HCPs and may lead to burnout [52, 53]
Practical	Information provision to staff and patients for such difficulties and supportive services is ad-hoc[52] There is a lack of standardised guidelines for identifying affected patients [42, 54] Time is often reported as a key obstacle[55] A lack of an appropriate screening tool may also be an obstacle [56]
Lack of skills	Attitudes to psychosocial care at any level may result in a lack of motivation to train HCPs in dealing with these issues[52] A lack of skills and knowledge in identifying and dealing with social problems is therefore a significant obstacle[52]

As well as the potential burden for patients, it must also be considered that caring for cancer patients, particularly providing psychosocial care, can be stressful for HCPs and may lead to burnout [52, 53, 57, 58]. Practical and logistical barriers also impede resolution of social difficulties. Information provision to staff and patients for social

difficulties and appropriate supportive services is ad-hoc, and there has historically been a lack of standardised guidelines for identifying affected patients [42, 54].

A lack of time is perhaps the most often-reported key obstacle to providing this care [55]. This may increase healthcare professional's unwillingness to raise complex issues that may not easily be dealt with in their limited time. A lack of an appropriate and standardised assessment method may also provide one of the greatest obstacles, which has been identified in the work preceding this project and will be discussed further[54].

Assessment tools are often recommended as a way to facilitate staff, particularly nurses, in providing holistic care and dealing with psychosocial issues. For nurses, the challenges to providing such care may be more complex and organisationally deep-rooted than a lack of a standardised assessment tool. Nursing as a profession has undergone many changes since NHS reform which has had wide-reaching implications[59]. Changes made to maximise the efficiency and cost-effectiveness of the NHS have been made (e.g. changes to 'skill mix'), but for non-specialist nurses this has led to workload intensification and more obvious role delineation. This in turn has created task-orientated day to day schedules for many front-line staff, leaving minimal room in their workload for provision of psychosocial care [59, 60]. Findings from chapters 8 and 9 demonstrate how high workloads and lack of flexibility within roles can inhibit the provision of psychosocial care by nurses.

The Holistic Common Assessment initiative is an example of how standardised assessments are implemented with the aim of facilitating psychosocial care. In 1995, the DoH published The Policy Framework for Commissioning Cancer Services[61], the aim of which was to address inequalities and improve outcomes in cancer care nationally. This outlined the importance of providing psychosocial support as one of its general principles governing the provision of cancer care. As part of the resulting service guidance programme, the National institute for Health and Clinical Excellence (NICE) published guidance in 2004 on Improving Supportive and Palliative Care Needs for Adults with Cancer, which stated *"6.18: Teams should ensure that social care needs of each patient are identified as part of initial routine assessment and, are then assessed on an on-going basis"* [12].

As a result of this guidance, the DoH commissioned the National Cancer Action Team to produce the Holistic Common Assessment (HCA) of Supportive and Palliative Care Needs for Adults with Cancer[62]. The goal of the guidance is to enable service providers to "adopt a unified approach to the assessment and recording of patients' needs". It recommends that all patients who have received a diagnosis of cancer should receive the assessment, and identifies key points throughout the disease trajectory where it should be completed.

The HCA sets out five domains for assessment:

1. Background information and assessment preferences
2. Physical needs
3. Social and occupational needs
4. Psychological well-being
5. Spiritual well-being

Again, although the HCA pilots are were attempting to fill this gap, this is not yet fully established as standard practice. Negative attitudes at an organisational level may result in a lack of motivation to train HCPs to deal with social difficulties, providing a significant obstacle. This may be compounded by trying to implement this additional care in busy clinic settings.

In 2007, the Cancer Reform Strategy was published by the DoH, and stated that care providers were required to provide evidence of implementation of the HCA guidance [63]. An implementation steering group was set up within the local NHS Trust, which, in collaboration with the POG, aimed to identify potential instruments to fulfil the five domains.

1.10 Current practice: guidance for the provision of supportive care

1.10.1 National and local guidance

Following the publication of the Calman-Hine Framework for Commissioning Cancer Services in 1995[61], NICE produced guidance on Improving Supportive and Palliative Care for Adults with Cancer[12]. This introduces the concept of a Key Worker, the aim of which is to improve access to information and support for patients. Locally the Yorkshire Cancer Network (YCN) reviewed work with patients and patient groups from May 2007 to define the role of the key worker and set out policy recommendations

and competencies for the role. The YCN Policy documents define the Key Worker as "the main contact person for the patients and carers for a specific part of the patient's pathway of care. The person will be determined based on the complexity of the patient's needs."[64] The policy documents outline performance criteria competencies but do not identify who specifically should undertake the role, and suggests that each multi-disciplinary team (MDT) should make this decision for their patient population [64-66].

As well as introducing the concept of the Key Worker, the Supportive and Palliative Care guidance stated a series of key recommendations, one of which is:

> *"Assessment and discussion of patients' needs for physical, psychological, social, spiritual and financial support should be undertaken at key points (such as at diagnosis; at commencement, during, and at the end of treatment; at relapse; and when death is approaching). Cancer Networks should ensure that a unified approach to assessing and recording patients' needs is adopted, and that professionals carry out assessments in partnership with patients and carers."[12]*

The Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer[62] guidance offers a framework for how a holistic assessment should be conducted, including:

- Who should be assessed
- When the assessment should take place
- Who should undertake the assessment
- Advice on preparing for the assessment
- Content of assessment (the five domains; background, physical, social and occupational, psychosocial and spiritual well-being)
- Recording, storing and sharing the information gathered during the assessment
- Action to take as a result of the assessment

As with the Key Worker guidance, the YCN has developed local guidance based on the national policy documents relating to the delivery of the Holistic Needs Assessment (HNA) [66].

1.10.2 Delivery of supportive care

At the time of conducting the pilot studies described in this thesis, the Key Worker and the person with the responsibility for conducting the HNA was typically the CNS. A selection of records on the Patient Pathway Management (PPM) System was reviewed to see if a HNA had been conducted. Overall, 38% of patients audited had received a HNA, which is a relatively low figure. This may not account for cases in which the assessment may have been conducted but not recorded explicitly in CNS episodes within PPM. These findings are similar to those from the National Cancer Patient Experience Survey; only 24% of patients surveyed were certain that they had been offered a written assessment and care plan[67].

1.11 Potential interventions

This chapter provides evidence of the social impact of cancer, and the burden that unresolved social difficulties may place on patients and those in their social networks. Identifying the patients living with such difficulties is an essential first step in providing support, but despite national guidance on providing psychosocial care, there is currently no standardised way of assessing patients to identify those that are experiencing social difficulties[54].

While it is clear that information can have an empowering impact on patients and may assist them in dealing with some issues independently, the provision of this information in terms of quality and timeliness is ad-hoc. Evidence suggests that following detailed assessment of social difficulties, approximately 43% of patients required further intervention suggesting unmet need even in those well into the cancer-care pathway in a large cancer centre (further exploration of this data is presented in chapter 3) [36, 54].

Information may have a role as a stand-alone intervention (which is explored in chapter 6). However, a multi-faceted intervention that assesses the presence and severity of specific social difficulties in patients, and provides the appropriate level of intervention could be more effective. For example, low level intervention such as information provision directly to patients would address the less complex, patient-manageable problems by signposting them to solutions, and would leave the issues

that require higher levels of intervention to be identified by the SDI-21 and dealt with by trained staff[17, 60].

Existing good practice could be supported and improved by developing ways to address the barriers to detection of social difficulties. Possible approaches may include:

- Provision of information to patients on practical solutions to social difficulties
- Screening patients for social difficulties using validated questionnaires
- Training staff to be aware of and enquire about social difficulties
- Training staff in how to deal with social difficulties, e.g. how to access appropriate information and referral pathways

A formal assessment programme would provide the most comprehensive method of detecting social difficulties, but would require training for staff in the use of an appropriate assessment tool, referral pathways and interventions. Simply increasing the level of detection of problems in patients is not sufficient to result in better management; training and management guidelines are necessary for an effective intervention. This is demonstrated in the whole-system information self-management engagement model (WISE) proposed by the National Primary Care Research and Development Centre (figure 1.3)[68].

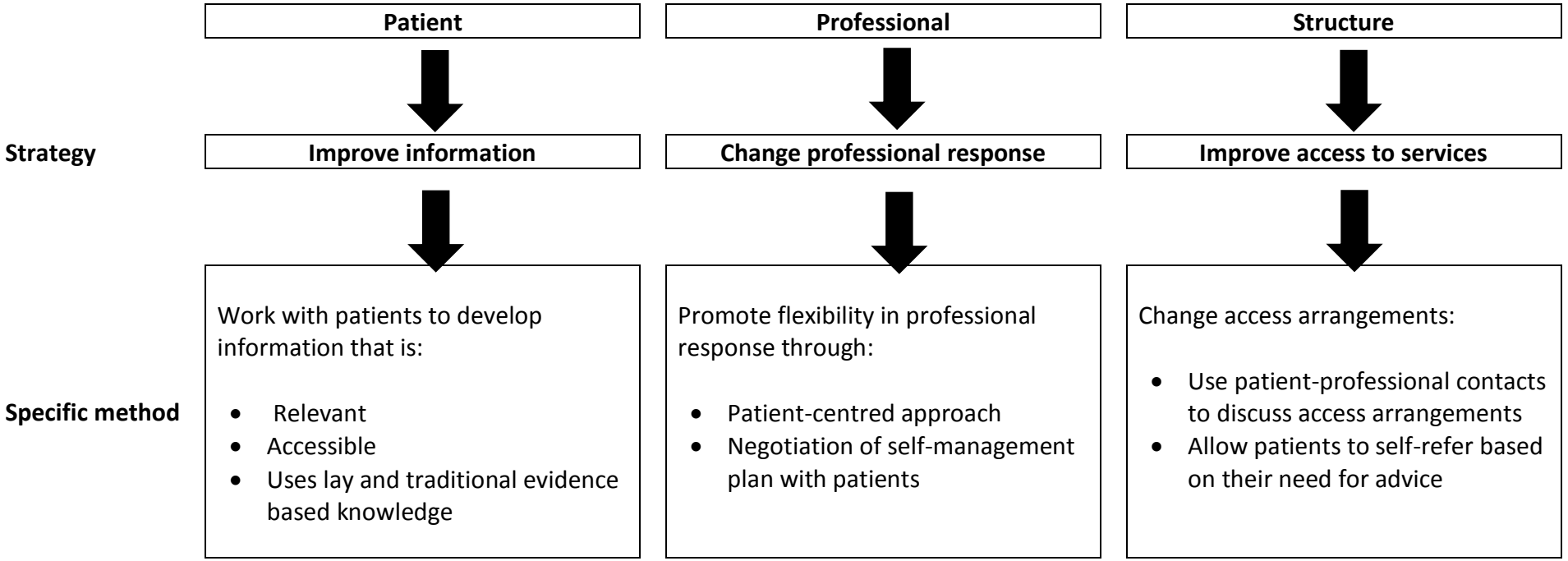


Figure 1.2: Example of an intervention based on a whole systems model (taken from Kennedy, Rogers and Bower, 2007) [68]

1.12 Scope of this thesis

The aim of the work presented in this thesis is to explore implementation of a programme of social difficulties assessment, including staff training and provision of information to patients, into routine practice. This thesis does not include further testing of the SDI-21, but rather its use as a component of a complex intervention and the acceptability and feasibility of introducing such an intervention into routine clinical practice.

The work that has preceded this thesis identified the need for an assessment and support programme for patients with social difficulties, comprised of four key elements (Figure 1.4). These are; 1) a tool for assessment, 2) guidance on interpreting results from this assessment, 3) knowledge of current practice, and finally 4) an intervention comprised of formal assessment and patient information. Fulfilment of this proposed design would cover all the suggested approaches for tackling some of the practical barriers (Table 1.1) to the detection and management of social difficulties. The barriers relating to organisational structure, attitudes and time/ workloads for staff are more challenging, and may only be dealt with in part by the proposed programme.

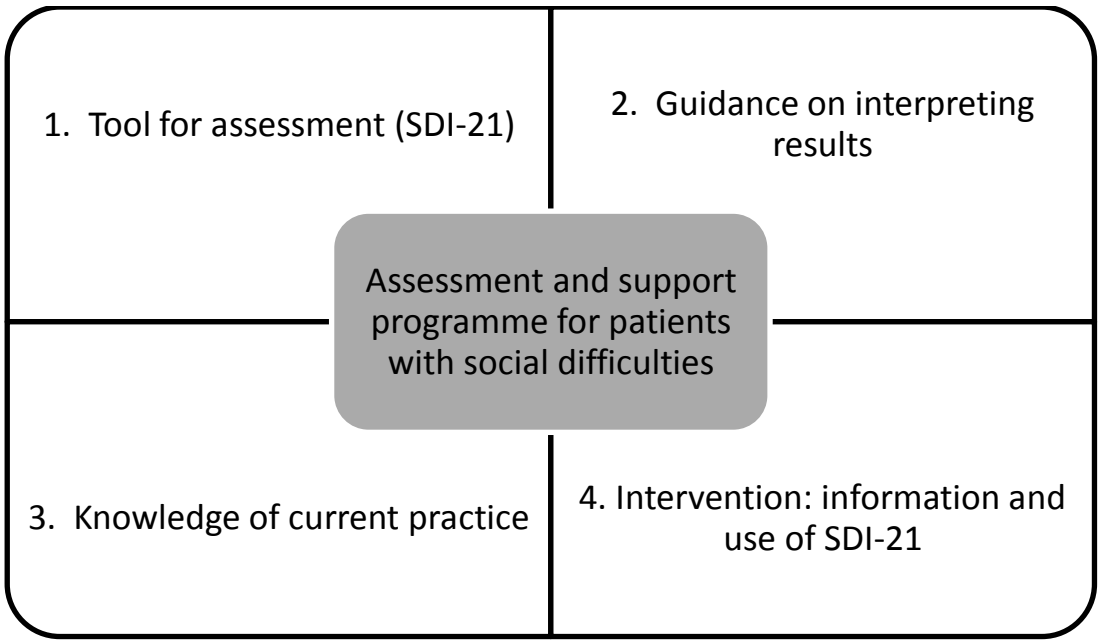


Figure 1.3: Proposed elements of an assessment and support programme for patients with social difficulties

Elements 1 to 2 have been fulfilled by the development and validation of the SDI-21 (preceding this thesis)[9, 44, 45, 54, 56, 69-71], and provides the foundation for the work outlined here, which aims to fulfil elements 3 and 4;

Element 3: Knowledge of current practice

In order to create an assessment programme that will be feasible and acceptable to existing oncology practice, research was undertaken to gain a full understanding of what already constituted this practice. In-depth interviews were carried out with patients, nurses and doctors, which were then analysed using detailed framework analysis[72]. This research demonstrated that although all the team (in this context including patients) worked collaboratively, nurses took a lead in certain areas of management, including many of the issues that were considered social difficulties. The findings also highlighted who had responsibility for assessing social difficulties, what kind of support is wanted and available, and how this should be managed in clinic. This was used to produce guidance for staff and information for patients [60, 71].

Further analyses planned within this thesis will add to this evidence base. This includes an exploration of the potential extra workload that may be generated following detailed assessment of social difficulties[36], as well as evidence of how frequently social difficulties are raised during standard clinical consultations (see chapters 3 and 4).

Element 4: Intervention: information and use of the SDI-21

The work presented in this thesis aims to work towards achieving the goal of a comprehensive assessment and support programme for dealing with social difficulties. Two interventions have been developed; 1) an information intervention (chapter 5) and 2) an assessment of social difficulties using the SDI-21 administered by staff who have received appropriate training (chapter 7). Two pilot studies have been designed to test the two interventions (chapters 6 and 8).

1.13 Summary

Social difficulties are a very real consequence of living with cancer. They may impact patients and their families throughout the disease trajectory and often beyond. Leaving such issues unresolved may result in a decline in psychological well-being and increase burden on patients and resources. Despite recognition of the consequences

of this and many government strategies developed to deal with them, current practice still demonstrates a lack of mechanisms to identify and deal with these issues. There are a number of approaches that may address these gaps in practice that can be explored. These include the role of staff training, information provision to patients, and the implementation of a formal assessment programme.

The literature suggests that although services are available, and problems remain unresolved in patients, it appears that the link between the patients experiencing the problems and their access to potential solutions is not being made. There are two possible deficits in current practice that could be causing this, which I aim to address in this thesis. The first is a lack of specific, relevant social support services information to guide the patients to the correct solutions. The second is a lack of standardised, routine method for identifying patients with these difficulties, and staff knowledge of how to deal with them once they are recognised. These will be addressed by the assessment of two interventions; an information pack and a programme of routine social difficulties assessment, to include staff training.

The successful implementation of new interventions within a well-established organisation is a complex process. It involves more than simply communicating knowledge to those involved. The next chapter explores the mechanisms that will influence the implementation and success of these interventions.

Chapter 2: Theory, hypotheses and thesis structure

2.1 Theory overview

Chapter one provided the background of research and practice in the provision of psychosocial care, specifically relating to social difficulties. Two potential gaps in current practice were identified; a lack of support services information and a lack of a standardised method to assess the presence and severity of social difficulties. The pilot studies presented in this thesis aim to explore how the use of two interventions may bridge these gaps in provision of social support for patients. The goal of this chapter is to outline the underlying theories and mechanisms which are relevant to the interventions and may influence their implementation in practice.

The interventions are; an information resource, designed specifically for use in this research, and an assessment of social difficulties using the SDI-21, by nurses who have received study-specific training in the delivery of and interpretation of results from the SDI-21 assessment. Although research into health care improvements suggests that simple interventions are not as effective as multifaceted approaches[68], previous research (presented in chapter 4) suggests that information may have a role in dealing with a range of social difficulties[36], so this will be explored first. In order for these interventions to have an impact on patient's social difficulties, their potential to be utilised within existing practice needs to be maximised. The introduction of new interventions into a well-established organisation is a complex process. Successful adoption by potential users involves more than simply communicating knowledge to those involved.

To achieve a whole-systems approach in developing interventions, recommended in the WISE model proposed by the National Primary Care Research and Development Centre [68], the structure of the organisation (the NHS), and the people within it (service providers and patients) must be considered as separate but inter-related elements.

The nature of the interventions must also be considered, and the underlying theory should take into account the relationship between the three elements (figure 2.1). For the information intervention, the characteristics of the resource and the nature of its delivery must be carefully considered in order to maximise the likelihood that patients

will use it. Factors that influence patient's use of information must be taken into account, including the characteristics of the information resource as well as the timing and method of delivery. The assessment, using the SDI-21 and including training of nurses, is a more complex intervention; the SDI-21 and training represents an intervention in terms of both nursing practice and patient experience. The method of training and the practicalities of introducing a change in current practice must be carefully considered.

The elements to consider are (figure 2.1);

1. The intervention
    a. Information resource
    b. Assessment with SDI-21
2. The individuals
    a. Patients
    b. Staff
3. The structure and nature of the organisation (existing practice in individual clinics)

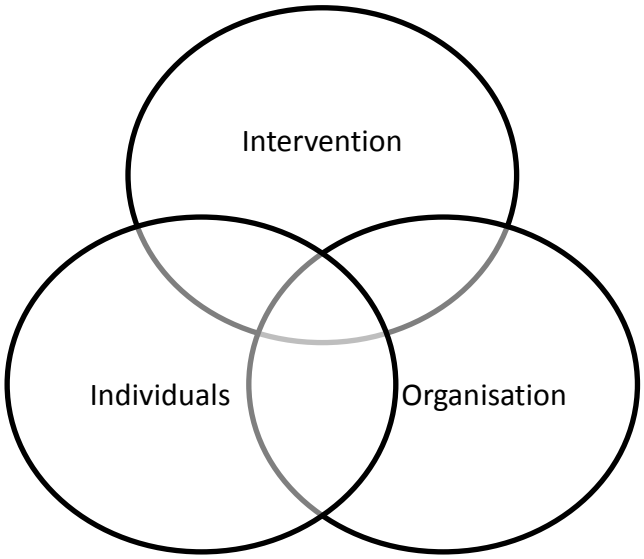


Figure 2.1: Elements and their relationships to consider in the selection of underlying theory

There exists a vast array of theories and models that apply to one or more of these elements, e.g. implementation theories and models, behavioural theories, theories around use of information, and learning theories that will be utilised in the development of the training intervention. Whilst not exhaustive, this chapter outlines some of the key theories and assesses their applicability in this context.

2.1.1 Implementation theories

2.1.1.1 Models of diffusion

The **Models of Diffusion** (MoD) framework was developed in 2004, based on Diffusion of Innovations (DoI) theory[73]. It considers the relevant elements (innovation, individuals [adopters], the organisation) and the relationship between them[2]. DoI theory is an established and well-studied theoretical framework, exploring the processes by which a new idea or 'innovation' becomes adopted or rejected. Everett M. Rogers first proposed the theory in 1962, and although its origins are in rural sociology, it has continued to evolve and be employed in a variety of sectors, including health services [2, 73]. As technologies within healthcare have advanced, the DoI theory has become a popular framework for those innovators seeking to establish the processes by which their ideas or tools may be adopted or rejected. It is a useful theoretical framework within a complex system such as the NHS, with staff and patients potential 'adopters'. Recognising the potential of the DoI in the healthcare setting, in 2004 the DoH commissioned Greenhalgh et al[2] to conduct an extensive systematic review (as part of the NHS's modernisation agenda). This resulted in the development of the MoD framework, which provides a robust evidence-based model for considering diffusion of innovations in healthcare[2], expanding upon Rogers' (1995)[73] original work to include health-service specific considerations of the DoI model.

Figure 2.2 shows Greenhalgh et al's conceptual model[2], in which they identified 13 research areas that provided evidence relevant to DoI theory within health services organisations. These include early diffusion research traditions, including rural and medical sociology, communication studies and marketing, as well as development studies, health promotion and evidence-based medicine[2].

The review produced robust findings on the attributes of innovations, the characteristics and behaviour of adopters and the nature and extent of influences on adoption decisions[2], in line with Rogers' original theory[73]. It also identified potential limitations and assumptions;

- Considering only the innovation and the adopter as the only relevant 'units of analyses'.

- Assuming that the innovation is better than what was previously available.
- The successful adoption of an innovation is more worthy of study than situations where the innovation was rejected.
- That adoption behaviours reflect fixed personality traits.
- That findings of diffusion research are always transferable to new settings[2].

Evidence-based medicine was a research area identified as a development from the original conceptual models. Innovations within this context were defined as health technologies or practices supported by research evidence. Innovation in this area was until recently considered as a linear, technical process at the individual level, and therefore typically described as changes in behaviour of healthcare professionals in line with guidelines. It has been recognised that implementation of clinical guidelines requires change to the system and therefore change on an individual as well as at an organisational level. It is also acknowledged that evidence for some innovations in this context may be ambiguous and requires reframing in line with local priorities[2].

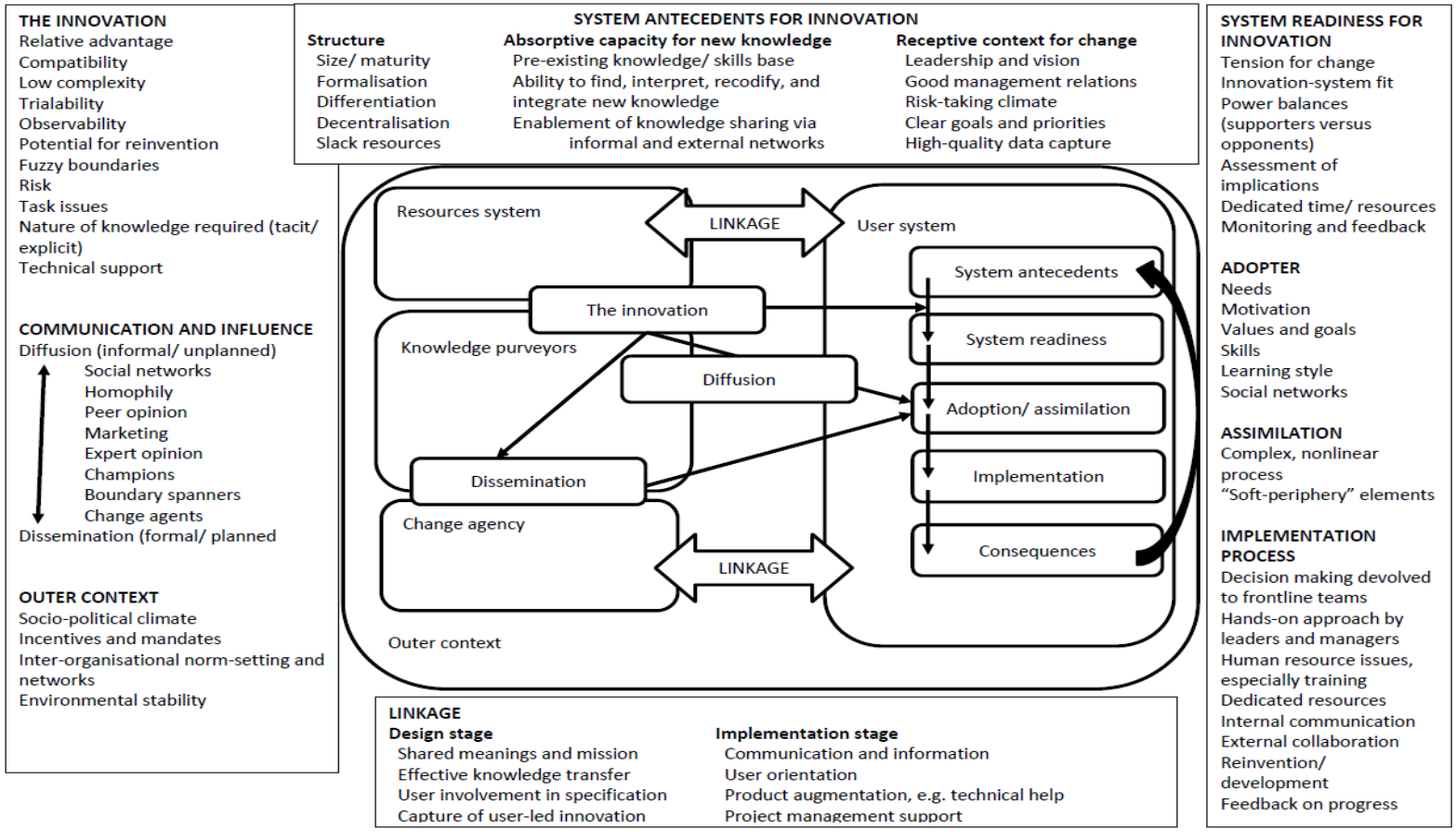


Figure 2.2: Conceptual model for considering the determinants of diffusion, dissemination, and implementation of innovations in health service delivery and organisation, based on a systematic review of empirical research studies (taken from Greenhalgh et al, 2004) [2]

The *innovation* is typically something new and unfamiliar. As with any new practice or technology, a level of uncertainty is inevitable; this presents a potential barrier to adoption. This uncertainty may be eased by provision of or gathering of information; described by Rogers as an "…uncertainty reduction process…"[73]. In the context of this research and the interventions involved, an information resource will not be an unfamiliar intervention to patients, and awareness of the need to address psychosocial problems is increasing. However, routine screening for social difficulties is not yet carried out formally within standard practice.

The two interventions being tested within this thesis can be considered as two separate innovations. The first is the information intervention. This is a stand-alone intervention, with no additional elements, and involves patients only. Although the specific information resource will be new to them, the concept of obtaining an information resource should not be novel. For the assessment intervention, as there are a number of separate but inter-related elements, most of which are new and unfamiliar to both the staff and patients, which must all be considered within the organisational context into which they are being introduced.

These are;

1. The SDI-21 assessment tool.
2. The technology on which the SDI-21 is delivered.
3. The training required to enable use of the SDI-21.

The assessment intervention can be considered as a technology cluster, involving both hardware and software. The hardware is the physical aspect; in this instance the touch-screen technology on which the SDI-21 is administered. The software is the knowledge base for the innovation; the SDI-21 itself and training on its delivery and interpretation of results. Rogers[73] sets out attributes of an innovation, which are considered one of five variables that may affect the success, or the rate of adoption. Greenhalgh et al's review[2] found evidence to support these original key attributes of innovations (*relative advantage*, *compatibility*, *complexity*, *trialability* and *observability* and *reinvention*). These can be considered as the 'standard attributes' of the innovation, and although necessary to consider, are often not sufficient to explain the adoption or rejection of innovations within an organisation, but should be taken into account when the interventions are being developed:

Relative advantage refers to the extent to which the innovation or new technology is perceived as offering an improvement over existing practice. For example, if the new practice offers a way to save time or effort for the potential adopter in comparison to the existing practice. In the context of this research, the interventions will be perceived as having *'relative advantage'* if the staff and patients can foresee that they will assist in dealing with social difficulties. In the case of the information intervention, this will be if it can be seen to have the potential to increase patients' access to information and support services, and enable them to self-manage any difficulties more effectively.

For the assessment intervention, this will be if the staff perceive that the formalised assessment will assist them in identifying and dealing with outstanding social difficulties in comparison with existing practice, in a more standardised and routine way than is currently possible. It is important to note that this refers to *perceived advantage*; actual advantages that are witnessed once the innovation is in use are discussed as *'observability'*.

Relative advantage is considered to be one of the strongest predictors of the success or rate of adoption, and represents a balance between the potential benefits of adopting an innovation against the costs of implementation. Costs are not restricted to financial costs and other benefits within the cost/ benefit balance may include a decrease in undesirable tasks or situations, and saving of time and/ or effort. In the context of this research, specifically the assessment intervention, the potential costs to the staff may include the time they will have to spend training, and the potential disruption to their everyday practice. The potential benefit is a standardised way to assist patients in dealing with their social difficulties, which should lead to an improvement in their well-being. This may also lead to increased job satisfaction for the staff [58, 74]. There is little cost or burden to the patients of receiving the information resource.

These factors have implications when designing the interventions, particularly in the approach to the training of nurses. The training package should inform the staff of the potential benefits and advantage, whilst minimising the cost of participation, including time spent participating in the training. Staff will also differ in their responses to the

intervention and training; some will perceive the opportunity to learn new skills as a benefit rather than a cost.

Compatibility

The *compatibility* of the innovation refers to how well it fits with current values and needs of the potential adopters. This may be in terms of values and cultural beliefs, previous ideas and existing methods, and needs of the adopters. An innovation that is *compatible* with existing values, previous ideas and needs will be more likely to be adopted.

The technology of the interventions proposed here should not be entirely *incompatible* with existing cultural values and beliefs. Information resources are widely available in a variety of media, and computers are widely used. Although the touch-screen technology may be new to staff and patients, it should not be *incompatible* with existing values. However, the content of the information and the questions on the SDI-21 may go against patients or staff beliefs on what should be discussed within a clinical setting, e.g. finances or sex and relationships[52]. For both interventions the patients have the freedom to choose whether to read the information resource relating to these issues, and there is also the option to skip over the relevant questions.

An innovation that is *compatible* with previous ideas and methods will be adopted more quickly. Conversely, if an innovation is too close to original methods then the issue is raised of how innovative it really is, and therefore how useful and how much it provides *relative advantage.* This may not be an issue if a highly-*compatible* innovation is tested as a component part in a step-wise introduction of a technology cluster (i.e. the information intervention), and this may help introduce less *compatible* innovations (the assessment intervention).

'*Innovation negativism*' is related to *compatibility*, and occurs when a negative experience with a previous innovation impacts the individual's attitude to future changes. Provision of information is a low-risk intervention and therefore patients are unlikely to have negative experiences relating to this. However, it may be possible that patients feel overwhelmed with information, and this may impact their acceptance and use of the intervention. It is possible that staff may demonstrate '*innovation negativism*', towards new practices in general, rather than the physical technologies.

This may manifest as cynicism from staff towards initiatives driven by the DoH, which has been suggested as a potential barrier to change within the NHS[75].

Compatibility with need refers to whether the potential adopters feel there is a need for the proposed innovation. If there is no perceived need, the rate of adoption may be reduced, or adoption completely prevented. In some cases, potential adopters might not realise they need the innovation until they can *observe* the benefits. When needs are identified and met adoption usually occurs more quickly. The perceived need for these interventions may vary between patients and staff, who will vary in their views and satisfaction in provision of this care. *Compatibility* is associated with the success of adoption (measured by Rogers as the rate of adoption[73]), but not to the same extent as *relative advantage*. The two concepts may be difficult to separate in practice.

Complexity

The *complexity* of an innovation refers to how difficult is it to understand and use. The more *complex* an innovation is perceived to be, the slower the adoption process is likely to be. The information intervention should not be *complex* for literate patients who have no visual impairment (provision of information in other formats is not possible within the remit of the pilots presented in this thesis). The assessment intervention does involve more *complexity*. The staff will need to be trained to use both the technology, i.e. the touchscreen technology, and the SDI-21. They will need to know how to assist the patients in completing the questionnaire, as well as accessing and interpreting results. The level of *complexity* can be reduced via the training and with continued support.

Trialability

Innovations that can be experimented with have a greater likelihood of adoption than those that cannot. This allows the potential adopters to become familiar with the innovations with minimal *risk*. As these interventions are being tested as part of a research study they are *trialable*.

Observability

Observability relates to the extent to which the outcomes of an innovation can be seen by potential adopters. If benefits are easily *observed* and can be communicated between adopters, the innovation is more likely to be adopted. Within the context of

this research, this may be difficult; the impact of the interventions is being tested, and any impact of their implementation won't be known until the pilot study has been completed. What is known, and what should be communicated to staff particularly is the perceived need; research has shown that there are gaps in service provision and that these need to be addressed [42, 52, 55].

Reinvention

Reinvention refers to the potential for the adopters of an innovation to adapt and refine any or all aspects of the innovation to fit their *needs* more effectively. If *reinvention* is permitted, the innovation is more likely to be adopted.

Greenhalgh et al[2] proposed the following additional attributes of the innovation;

Fuzzy boundaries

Complex innovations in organisations may be considered as having a 'hard core' and a 'soft periphery'. The hard core refers to the fixed components of the innovation. The soft periphery is the organisational structure and system required for the implementation of the innovation. The adaptability of the soft periphery is considered a positive attribute of the innovation[2], linking with Rogers' concept of *reinvention* and with '*innovation-system fit*' [73].

Risk

An innovation that is considered '*risky*' to the potential adopter (i.e. to carry a high degree of uncertainty of outcome or impact) is less likely to be adopted. The *risks* and benefits of a given innovation may differ for different areas within an organisation[2]. For example, senior managers within the NHS may perceive the benefits associated with implementing government policies, whereas the nurses on the 'front line' who are dealing with significant changes to their day-to-day practice may see only the *risks.*

Task issues

An innovation will be adopted more easily if it is relevant to the potential adopter's day-to-day tasks and can assist them in improving their performance. Limited evidence also suggested that innovations that increase task relevance are feasible, easy to use, and workable are more easily adopted[2].

Knowledge required to use it

If the knowledge necessary to use the innovation can be easily communicated it will be more easily adopted[2]. For example, if the instructions required to access the online system can be easily communicated to the nurses from the researcher, it will increase the likelihood of adoption.

Augmentation/ support

If a technological innovation is provided along with customisation, training and technical support it will be more likely to be implemented[2]. In the context of the assessment intervention, its likelihood of adoption is increased by the provision of training and on-going support.

Adoption by individuals

There is little evidence within Greenhalgh et al's review[2] to support Rogers' adopter categories (innovators, early adopters, early majority, late majority and laggards[73]). These categories do not take into account the adopter's complex and varied response to a complex innovation; they are not just passive recipients of an innovation. Rather than labelling each individual in the network as one of the five categories, Greenhalgh et al identify the key individuals (opinion leaders, champions and boundary spanners, described below)[2].

The **MoD** framework proposes seven aspects of adopters and the adoption process, based on Rogers' original work[73] and the evidence from the review[2]. These are:

1. *General Psychological Antecedents* – traits associated with likelihood of trying innovations (e.g. motivation, values)
2. *Context-Specific Psychological Antecedents* – e.g. a motivated adopter for who the innovation meets a specific need
3. *Meaning* – this may differ between adopters and those proposing the innovation (*change agents*); it may be possible for it to be re-framed through discussion.

4. *The Adoption-Decision* – this matches closely with Rogers' types of innovation decisions[73]. The decision may be contingent (depending on a decision made by someone else), collective (the individual has a certain amount of choice but must ultimately comply), or authoritative (individual is told whether or not to adopt the innovation)[2].

The remaining three aspects are based upon the Concerns Based Adoption Model (CBAM)[76, 77];

5. Concerns in pre-adoption stage
6. Concerns during early use
7. Concerns in established users

Adoption is a process, with different concerns being prominent at different stages[2], which was the justification for the inclusion of the CBAM in preference to Rogers' original adoption stages (*awareness*, *persuasion*, *decision*, *implementation* and *confirmation*)[73].

Assimilation by the system

Innovation research has traditionally dealt with non-complex, product-based innovations, e.g. mobile phones and electric cars, measuring the unit of adoption as the individual, and in situations where diffusion occurs by reproduction of the use of the innovation[73]. This is a simplistic approach when considering complex interventions within a service organisation. The term assimilation is proposed by Greenhalgh et al as being more appropriate than adoption at this level. The unit of assimilation in the service organisation context is not the individual but the department or team in which the innovation is to be introduced, and individual adoption is only one component of successful assimilation. Assimilation is not usually a linear process (moving from few individuals utilising an innovation to many), but rather a 'messy' or 'organic' process, where individuals and the organisation may fluctuate between initiation, development and implementation [2].

Diffusion and dissemination

Greenhalgh et al suggest that the influences upon the innovation can be described as lying on a spectrum between pure diffusion (unplanned, informal and decentralised) and active (formal, planned and occurring through vertical hierarchies- Figure 2.3)[2].

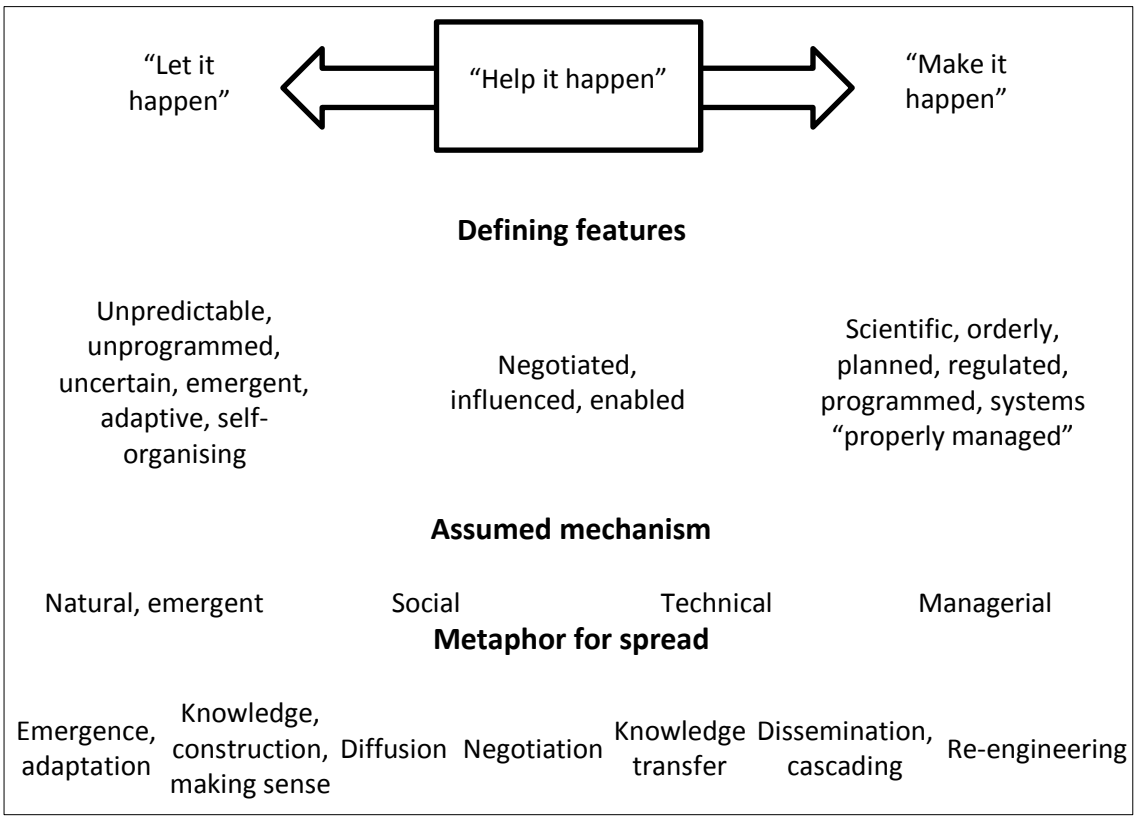


Figure 2.3: Different conceptual and theoretical bases for the spread of innovation in service organisations (taken from Greenhalgh et al, 2004)[2]

Using a combination of Rogers' original theory and evidence from their review, Greenhalgh et al[2] identified seven components of diffusion and dissemination as part of their model:

Network structure

The quality and structure of social networks influence the likelihood of individual adoption. Networks may be considered horizontal or vertical; the former being informal and between peers, the latter a more hierarchical network from senior to junior individuals. Horizontal networks tend to support construction and reframing of meaning and encourage peer to peer influence. Vertical networks are more useful in passing on authority decisions and mandatory changes. Understanding the nature of the networks into which the innovation is introduced is key[78].

Homophily

When individuals are closer in terms of educational and cultural backgrounds and socioeconomic status, adoption is more likely, i.e. the use of the innovation is more likely to diffuse between a group of individuals who are similar in such terms [2, 73].

Opinion leaders

Opinion leaders may be described as experts in the specific field or context. They are individuals who may exert influence over other potential adopters, either through status and authority, or they may be *peer opinion leaders*, who can exert influence via representativeness and credibility. Attracting support from opinion leaders is important to the success of an innovation [2, 73]. Failure to identify the *opinion leaders* and engage them with the project will limit the success of an innovation[2].

Champions

Champions will be key individuals who are engaged with the innovation, but may not necessarily be in a position to influence other potential adopters[73]. Greenhalgh et al found little evidence provided on how to identify these individuals and engage them[2].

Boundary spanners

These are individuals who provide a link between organisations[2], e.g. the lead clinician with responsibility for implementing government guidelines may be considered the *boundary spanner* between their specific NHS trust and the DoH.

Formal dissemination programmes

An example of a *formal dissemination programme* in the health services context may be a quality improvement initiative, e.g. the Patient Safety First Campaign in the UK[79]. When an innovation is introduced via such a programme, Greenhalgh et al recommend the following actions to increase the likelihood of adoption;

- Account for needs and perspectives of individuals, particularly in balancing costs and benefits.
- Consider the features of individuals/ groups of individuals and tailor strategies appropriately.
- Identify and utilise appropriate communication channels.
- Include evaluation and monitoring of defined goals.[2]

System antecedents for innovation

The success of an innovation will be influenced by the structural and non-structural features of an organisation. *Structural determinants of innovativeness* refer to the size and structure of an organisation. Innovations will be more successful in an organisation that is large, well-established and mature, well differentiated (i.e. divided

into semi-autonomous departments), and has access to resources to support innovations, with a decentralised decision-making structures. In the context of health services, the creation of semi-autonomous MDTs is independently associated with successful implementation[2].

Non-structural determinants include capacity to absorb new information, and receptivity to change. Organisations that have an ability to utilise new information and link it with existing knowledge base and skills would be considered as having an absorptive capacity for change. For example, application of research evidence is a vital use of knowledge in healthcare, and health service providers need to be constantly updating their knowledge of new developments, what is no longer considered good practice, and modify their practice accordingly. Organisations receptive to change "will demonstrate strong leadership, a clear strategic vision, and encourage an experimental climate"[2].

System readiness for innovation

An organisation that is *ready for innovation* may demonstrate the following qualities that suggest it is open to innovations. These include;

- *Tension for change* refers to the need for a new system or innovation; if the new practice/ technology offers an improvement on the current method it is more likely to be adopted[2]; Rogers describes this as *relative advantage[73]*.
- *Innovation-system fit*; this describes how well the innovation sits within the existing context and with existing values, norms and goals. This is a combination of Rogers' *compatibility* attribute[73] and the *fuzzy boundaries* described by Greenhalgh et al [2].
- *Assessment of implications*; if all of the possible outcomes and implications of an innovation can be anticipated, its chances of adoption are increased[2].

Other important characteristics are the availability of support, dedicated time and resources, and a capacity to evaluate the innovation[2].

The *outer context* – inter-organisational networks and collaboration will also influence adoption by a system. This may include informal networks, the wider environment and political directives. The decision of comparable organisations to adopt an innovation may influence the decision, positively or negatively[2].

Implementation and routinisation

Implementation may be defined as "…the early usage activities that often follow the adoption decision…"[2]. Progressing from the consideration of an innovation as an option, to the decision to adopt it is rarely a linear process. Elements associated with successful implementation and routinisation of innovations are;

1. Organisational structure (needs to be adaptive and flexible, and support devolved decision making).
2. Leadership and management (need to support innovation and have leaders actively involved and consulted).
3. Human resource issues (motivated and capable staff provided with high quality training).
4. Funding.
5. Intra-organisational communication.
6. Inter-organisational networks.
7. Feedback (accurate and timely evaluations and feedback).
8. Adaptation/ reinvention (adaptable to a local context) [2].

The Greenhalgh model[2] is derived from robust evidence from a relevant context, and considers all of the identified key elements and the relationship between them. Employing this model will produce replicable methods for any future randomised controlled trial (RCT), and therefore provides an ideal, testable underpinning theoretical framework. There are a number of other theories/ models that may also apply to one or more of the elements, and these should also be considered. Figure 2.4 extends figure 2.1 to include alternative theories and how they relate to the three elements of individuals, the organisation and the intervention. These are discussed in more detail below.

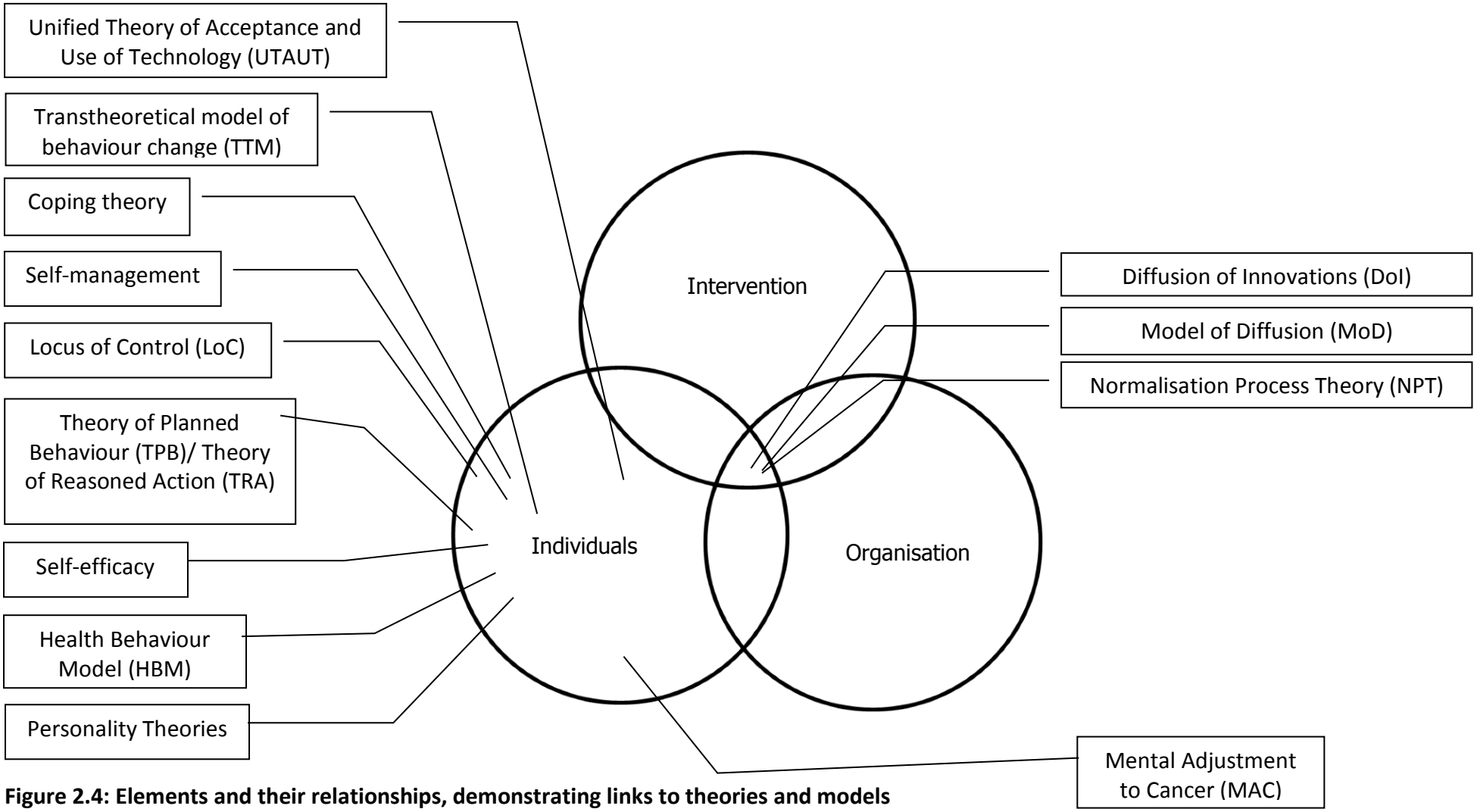


Figure 2.4: Elements and their relationships, demonstrating links to theories and models

2.1.1.2 Normalisation process theory (NPT)

NPT was proposed by Professor Carl May in order to aid understanding of how interventions become normal practice, or how they are "operationalised in healthcare and other institutional settings…" (see http://www.normalizationprocess.org/ [80]). This links most closely with the Rogers' confirmation stage of the innovation-decision process[73], and the implementation and routinisation of Greenhalgh et al's model[2]. Rather than focusing on innovators or champions, it focuses on the conditions of use and how everyday users respond to the innovation. Previous research has been in the context of chronic disease[80].

NPT focuses on three core problems:

1. Implementation…the social organisation of bringing a practice or practices into action
2. Embedding…the processes through which a practice or practices become (or do not become), routinely incorporated in everyday work of individuals and groups
3. Integration…the processes by which a practice or practices are reproduced and sustained among the social matrices of an organisation of institution"[81]

NPT theory proposes that four factors govern how interventions are implemented, with each factor suggesting a proposition that can be applied to the assessment and evaluation of an intervention [80];

Interactional workability refers to how work is enacted by the people doing it. A complex intervention will affect co-operative interaction over work (congruence), and the normal pattern of outcomes of this work (disposal). Therefore; "*…a complex intervention is disposed to normalisation if it confers an interactional advantage in flexibly accomplishing congruence and disposal of work…"*[80].

Relational integration refers to how work is understood within the networks of people around it. A complex intervention will affect not only the knowledge required by its users (accountability), but also the ways that they understand the actions of people around them (confidence). Therefore; "*…a complex intervention is disposed to normalisation if it equals or improves accountability and confidence within networks…"*[80].

Skill-set workability refers to the place of work in a division of labour. A complex intervention will affect the ways that work is defined and distributed (allocation), and the ways in which it is undertaken and evaluated (performance). Therefore; "*…a complex intervention is disposed to normalisation if it is calibrated to an agreed skill-set at a recognisable location in the division of labour…"[80].*

Contextual integration refers to the organisational sponsorship and control of work. A complex intervention will affect the mechanisms that link work to existing structures and procedures (execution), and for allocating and organising resources for them (realisation). Therefore; "*a complex intervention is disposed to normalisation if it confers an advantage on an organisation in flexibly executing and realising work."[80]*

The NPT offers propositions that may form the basis of testable hypotheses about observable activities with measurable outcomes. It is collective and not individual action that is the focus of evaluating complex interventions and assessing their probable outcomes (in the NPT) [82]. It focuses more on relationships and processes than individual characteristics of individuals, organisation or innovation [80-83].

2.1.1.3 Unified theory of acceptance and use of technology (UTAUT)[84]

The UTAUT model brings together key constructs from eight theories/ models that are regularly used within information technology acceptance research [84]. The diffusion of innovations model[73] is included in this, along with the theory of reasoned action (TRA)[85], the technology acceptance model (TAM)[86, 87], the motivational model (MM)[88], the theory of planned behaviour (TPB)[89], a model combining theory of planned behaviour and technology acceptance model (C-TPB/ TAM)[90], and social cognitive theory (SCT)[91] and the model of PC Utilisation (MPCU)[92].

The UTAUT model has been developed in order to unify a number of theories, and is intended to provide a tool to assist managers to understand what motivates individuals to accept a technology, therefore assessing its likelihood of success. The model (figure 2.6) identifies four direct determinants of acceptance and usage; performance expectancy, effort expectancy, social influence and facilitating conditions. Four moderators were also identified; gender, age, experience and voluntariness of use [84].

The UTAUT model focuses mainly on the individuals and their responses to an innovation or technology. Although it considers some aspects of the environment in which the individual is working, e.g. facilitating conditions and social influence, it does not consider in any great detail the organisation. It also does not consider the intervention.

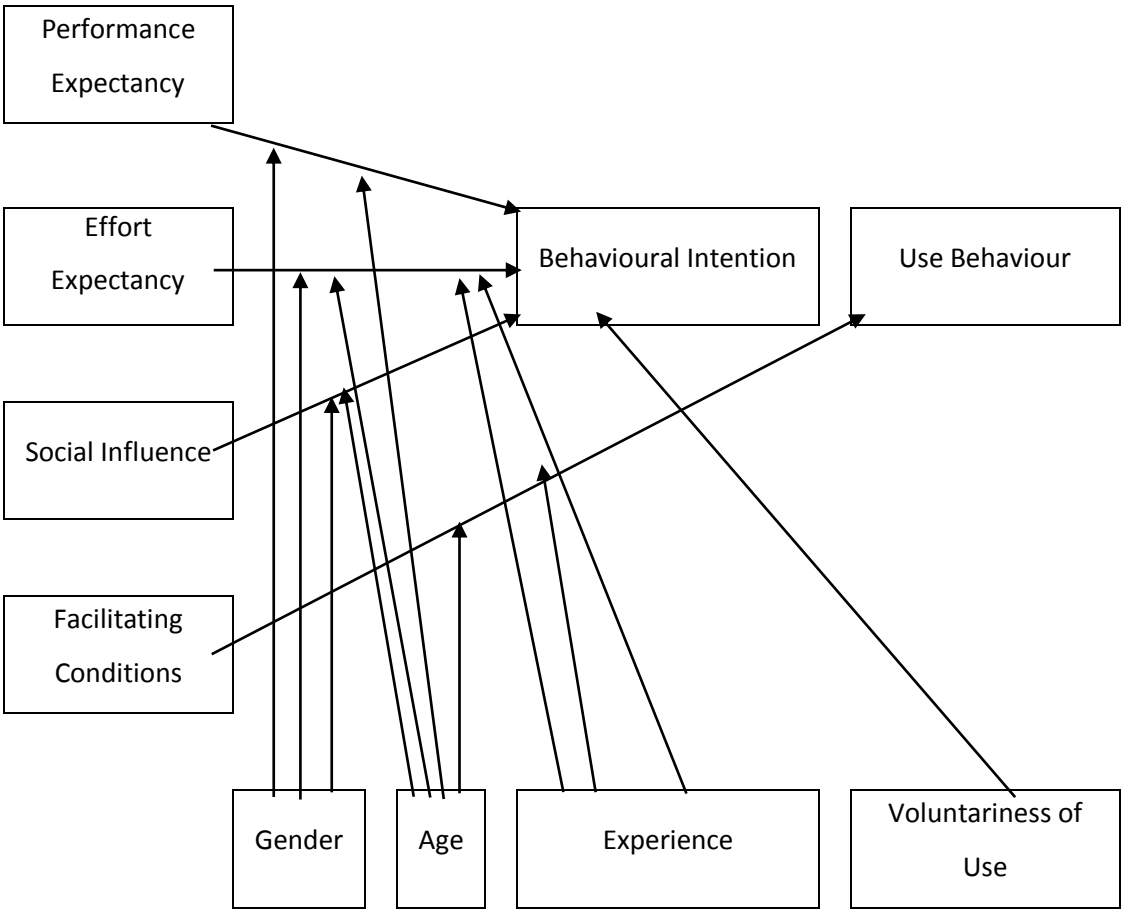


Figure 2.5: UTAUT Model (adapted from Venkatesh et al, 2003[84])

2.1.2 Psychological and behavioural theories

There are a large number of stand-alone theories that relate to individuals, their health behaviours, attitudes and perceptions of control; Michie et al (2005) identified 33 psychological theories alone that relate to behaviours in individuals[93].

2.1.2.1 Transtheoretical model of behaviour change[94]

This is often described as the 'readiness to change' model [95], and deals with the acceptance of changes in behaviour or practice from the individual's point of view. It is one of the most widely employed and researched theories in healthcare, and is commonly used to try and understand health behaviours in patients. It can also be

applied to clinical staff in terms of their 'readiness to change' in context of accepting changes to practice, e.g. new guidelines and it has been shown to be reliable in improving clinician's practice [95, 96].

There are 14 components of the model, divided into three categories; stages of change (pre-contemplation, contemplation, preparation, action and maintenance), dependent variables (decisional balance and self-efficacy/ temptation) and independent variables (10 processes of change)[97]. The transitions between the stages of change involve alterations to emotional processes, and require the individual to have positive beliefs about their ability to undertake change and develop new skills. Transition to the maintenance stage (maintaining a particular behaviour for more than 6 months) requires social support, reward systems and potentially a change to the individual's environment[98]. Considering the concept of change as a process stresses the importance of understanding individuals' readiness when applying innovations.

In terms of this research, the transtheoretical model emphasises the need to consider the interventions as a change in practice to which individuals will vary in their responses to, but will all undergo some process of alteration that may or may not result in the successful implementation of the suggested intervention. Applied to the information intervention, this refers to the patient's response to being provided with a new source of information. This theory is perhaps more applicable to the assessment intervention, which will involve a greater change to the practice of the service providers than simple delivery of information.

It could be therefore be used to assess individual staff member's readiness to change in terms of the introduction of the SDI-21 assessment, and use this information to tailor the delivery of the intervention appropriately (known as stage-targeted intervention). It could also predict and describe their subsequent journey through the phases of behaviour change[98], or be applied in the same manner to the patients' response to a new information intervention. This would involve development of a method to allocate staff and patients to a readiness to change category and a measure with which to define the processes of change [99].

For the service providers, these measures would have to be taken before the training resources and methods could be planned. As there are only a small number of staff members to be involved, this could potentially lead to development of a tailored

training package for each staff member. This could perhaps be feasible but may involve interviews with staff members to assess their readiness to change. As the bulk of research on methods for allocating to a stage of change is with patients and their health behaviours, this would be a novel approach and therefore may not be possible to validate how staff or patients had been allocated. Other studies suggest that methods to allocate people to stages may be flawed and research has mainly been in patients relating to health behaviours [100], mainly in the field of physical activity and related interventions [99].

The transtheoretical theory has the potential to shape the training intervention, depending on the 'readiness to change' of the staff. This would involve work to develop accurate measures for the stage and process of change. This would not be applicable to the patients and the information intervention.

2.1.2.2 Health belief model[85]

This is similar to the transtheoretical model in that it deals with an individual's 'readiness' to take a particular health action (Figure 2.5). The health belief model argues that there are four perceptions that influence an individual's readiness to take a health action; susceptibility to disease, severity of disease, benefits of health action, and barriers to performing the action. Like the theory of planned behaviour and the theory of reasoned action it also accepts that these are influenced by demographic and psychological characteristics.

This model tends to focus on individuals, and not on characteristics of an intervention or the environment/ organisation. It could be measured to assess a patient's likelihood of taking action in terms of any social difficulties they are experiencing. Valid scales are available but only within specific health-behaviour domains, e.g. breast self-examination[101].

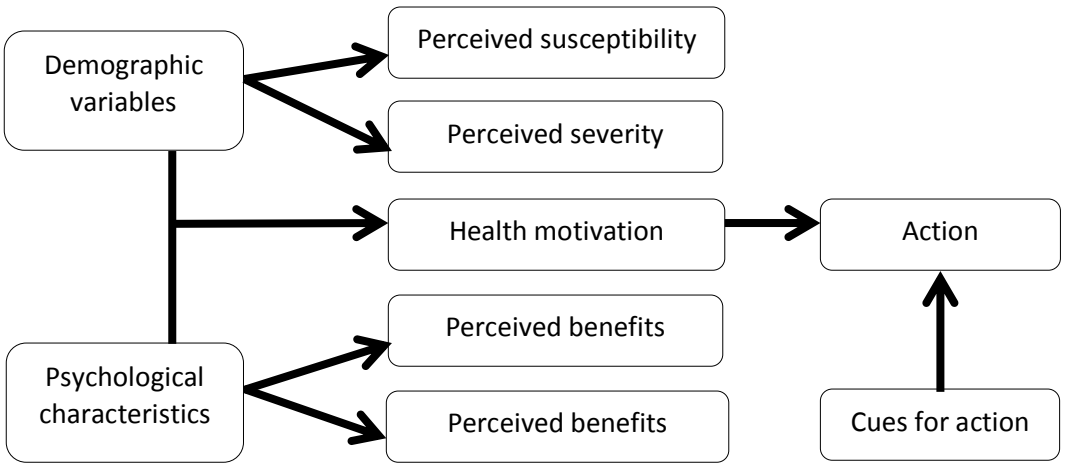


Figure 2.5: The Health Belief Model [85]

2.1.2.3 Health locus of control/ multi-dimensional health locus of control

The original health locus of control was developed to measure an individual's perception of whether their state of health is attributed to themselves, those around them (particularly 'powerful others', i.e. doctors), or fate or chance. The multi-dimensional locus of control was created to expand the original instrument to include three dimensions of locus of control; internal, powerful others and chance HLC [102]. People who believe they have control over what happens to them are described as having an internal locus of control. Those who believe it is due to chance or others, as having an external locus of control[85]. For example, those with a more internal locus of control may be more likely to feel that management of their social difficulties is down to them, and be more likely to take action to deal with them.

This theory focuses only on the patient and their perceived locus of control. It is important to consider this as a facet of personality that may influence the patient's decision to access social support. It may be interesting to ask patients to complete the HLC and compare this to the use of the information intervention. Scales are available, with various forms comprising up to 36 items [102, 103]. However, evidence of their validity is limited [103].

2.1.2.4 Self-efficacy[104]

Closely linked to the concept of locus of control is that of self-efficacy, first proposed by Bandura in 1977. Like the locus of control, this suggests that an individual's behavioural response is influenced by their level of perceived self-efficacy. That is, whether or not someone participates in a particular health behaviour (positive or

negative), depends on their perception of how much control they have over the behaviour [104]. Therefore, similarly to the locus of control theory, those participants who feel they have more control over their behaviour (to access social support) may be more likely to do so. Bandura also argued that one's sense of self-efficacy could be increased or developed through experiencing success and verbal support from others. This means it has a bi-directional effect; a sense of self-efficacy can result in increased behavioural effort. If this effort results in a satisfactory outcome, a further increased sense of self-efficacy may be experienced. Support from others may add to an increase in the likelihood of an increased sense of self efficacy leading to further behaviours and more success [104].

Within the context of this research, this may include the discussion with the researcher about any positive outcomes that have resulted through increased awareness created by the information pack or by simply taking part in the study. This is potentially one of the mechanisms by which the expected increase in access to social support services will occur. Measuring levels of self-efficacy may predict whether patients are likely to act upon the information intervention they are provided with. There are a number of self-efficacy scales that have been developed within specific health domains. Cancer-specific self-efficacy measures exist that could be used to measure levels of self-efficacy should it be decided to test this theory [105]. This focuses on the patient in the main and their likelihood to use the information intervention. Again, it does not consider all three elements (intervention, individuals –staff and patients, and the organisation) or the relationship between them.

2.1.2.5 Theory of planned behaviour/ theory of reasoned action[85]

These theories are based upon Bandura's theory of self-efficacy[104], but differ from it in that they do not incorporate the 'positive feedback' element. Both theories suggest that an individual's behavioural intentions are driven by attitudes and subjective norms, as well as perceived control, which is included in the theories of planned behaviour model (see Figure 2.7). As this demonstrates, external variables such as demographics and personality characteristics are seen to feed into outcome beliefs, normative beliefs and perceived likelihood of occurrences. Each of these items is considered in conjunction with an objective evaluation of outcomes, the motivation to comply and the individual's sense of control, respectively. These in turn result in

attitudes towards behaviours, overall subjective norm and overall sense of perceived control, leading to behavioural intention and actual behaviour. Perceived control is acknowledged as the one item that can influence behaviour in isolation[85].

These theories have been well used to predict health-relevant behaviours, e.g. smoking cessation, condom use[85]. Again, this is an important demonstration of how key external and internal factors can work together to affect an individual's behaviours, and therefore what factors will be involved in a person's choice to access social support. It must be remembered, however, that these theories are only used to predict the intention to behave, not the actual behaviour, and there is no firm association demonstrated between the two. One large meta-analysis suggested that intention controlled only 28% of actual behaviour [94]. This could apply to both patients and staff. It would be necessary to assess personality traits and assess attitudes and beliefs prior to providing the intervention. This would be unlikely to be feasible for patients prior to their information intervention.

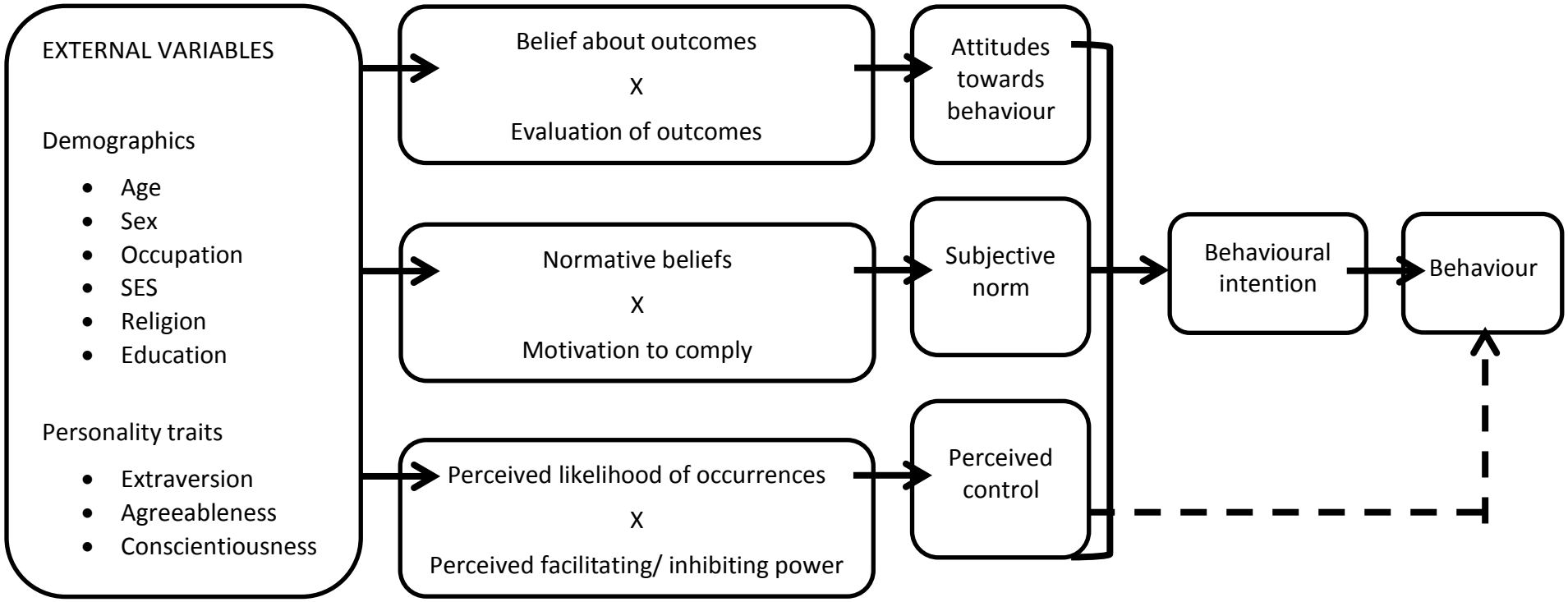


Figure 2.7: Model of the Theories of Planned Behaviour and Reasoned Action (taken from Marks et al, 2006) [85]

2.1.2.6 Coping theory

There is a wealth of published research on coping theory and impact of personality traits. Many applications of these theories and associated measures have been made in healthcare, particularly within oncology. The processes involved in how individuals perceive and cope with stress has gained much interest and been the subject of much research since the 1980s[106], when Lazarus and Folkman made a conceptual analysis in their publication "Stress, Appraisal and Coping"[107]. There are also studies suggesting a link between coping style and disease outcome [108, 109]. Lazarus and Folkman identified two main types of coping; problem-focussed and emotion-focussed. Problem-focussed coping involves the individual doing something in order to alter the source of the stress, and is likely to be employed in a situation where it is felt some constructive activity may be undertaken to achieve this. Conversely, emotion-focussed coping predominates when the stress is considered as something to be endured rather than something that can be altered[106]. Similarly, Miller (1987) proposed two main psychological coping styles; monitoring and blunting. Monitoring, in parallel to problem-focussed coping, relates to managing the stressor by 'attending to' it. These patients are more likely to be more knowledgeable about their disease, more concerned about their cancer risk, and more demanding regarding their psychosocial management. Those patients identified as having a 'blunting' coping style are more likely to avoid any information regarding their disease. Further work by Miller (1995) demonstrated that patients report a better outcome when the information they are given is tailored to their coping style [110, 111]. Lazarus and Folkman (1984) and Miller's (1987) theories are frequently referred to in health information-related literature, as seeking information is considered as a coping mechanism[112].

Carver et al (1989) acknowledged the wealth of research available on this topic, particularly the number of instruments that had been developed with the intention of assessing coping strategies. As part of their 'Theoretically Based Approach' to the subject, they identified potential faults with the existing scales, and developed a new tool for this purpose[106]. The resulting questionnaire includes 13 distinct scales, representing 13 types of responses to stress, as follows; active coping, planning, suppression of competing activities, restraint coping, seeking social support for

instrumental or emotional reasons, focussing on and venting of emotions, behavioural disengagement, mental disengagement, positive interpretation and growth, denial, acceptance, and turning to religion. Whether the different styles and specific activities employed by an individual in coping are inherent, and brought with them to a stressful situation, linked to characteristics of their personality, or whether their coping style will adapt and change dependent on the stressor is a source of debate[106].

The latter theory links with the variable of the stressor itself; some stressors are considered more changeable than others. Although the existence of malignancy and the treatment may be out of the patient's control to an extent, the resultant difficulties that may ensue may be viewed as more controllable. Therefore, although the likelihood of a patient accessing their own support is liable to be affected by their personal characteristics and coping styles, those who receive the information pack may perceive their social difficulties as more 'controllable' and therefore may be more likely to take a problem-solving approach regardless of their personal coping characteristics. The theories of coping relate to this research by identifying what individual characteristics and motivations may impact the access to social support.

Assessment of coping style could be used to predict use of the information intervention for patients. The Mental Adjustment to Cancer Scale (MAC), outlined below, would be the most appropriate measure.

2.1.2.7 Mental adjustment to cancer

Coping styles within the specific context of cancer patients have been explored and identified, culminating in the development of the MAC scale[113]. Based on Lazarus and Folkman's theories[107] five categories of cancer-specific coping-style were identified;

1. *Fighting Spirit* is characterised by full acceptance of the diagnosis, direct use of the word cancer, determination to fight the illness, active information seeking and an optimistic attitude, and perhaps viewing the disease as a 'challenge'.
2. *Helplessness/ Hopelessness* is described as being overwhelmed by the diagnosis, having everyday life disrupted by fears of cancer and death, and a pessimistic attitude.

3. *Anxious Preoccupation* is persistent anxiety and may include symptoms of depression; someone with this response may seek information but will interpret the findings negatively. Persistent worry that minor aches and pains or symptoms denote a recurrence.
4. *Fatalism/ Stoic Acceptance* are evident in someone who demonstrates acceptance of the diagnosis but is not proactive in seeking information or taking other action to reduce the risk; they are likely to 'leave it all to the doctor'.
5. *Avoidance/ Denial* - someone exhibiting an avoidance coping style will not accept the diagnosis or will minimise the seriousness, they are unlikely to use the word 'cancer' [113, 114].

The key difference between Folkman and Lazarus' theory and mental adjustment theory is that the latter includes emotional responses to an event whereas the former propose that emotional reactions are the result of a specific coping strategy [115]. The MAC scale has been developed and validated [114, 116] and continues to be used to explore how the mental adjustment characteristics relate to outcomes [115, 117]. The Mini-MAC (MMAC) has also been developed for use in a general cancer population[118].

2.1.2.8 Personality theories

Personality can affect an individual's health behaviours [24], but there is also some debate as to whether there is a relationship between certain personality traits and health outcomes [109]. Personality testing is not an exact science, and the argument as to how many dimensions of personality exist are varied and on-going [85]. Three of the most influential theories are those of Eysenck, Cattel and McCrae and Costa [85]. Eysenck proposed only 2 types; extraversion and neuroticism, and then added psychoticism [119]. Cattel identified sixteen separate types [85], whilst McCrae and Costa identified the 'big five' dimensions, based on the work of Norman (1963) [120]; extraversion/ introversion, agreeableness/ antagonism, conscientiousness, neuroticism/ emotional stability, and openness to experience [121]. There are also Type A and B personality types. Type A personalities are described as highly competitive, lacking patience, and achievement orientated – or 'choleric'. Type B

personalities tend to be more laid back, even tempered, lethargic, slower than type A, and more philosophical [85].

The variety of personality types are important to consider, and means that there are certain types of individuals who will be more or less active in accessing information, regardless of whether or not they have been provided with the information pack. Again, a measurement of personality type could be used to predict use of information. A major concern in measuring a number of stand-alone theoretical variables is the potential increased burden on patients and staff. Although a number of these variables would be interesting and useful to measure, the additional questioning and measurements that would be required may increase burden.

Having considered a wide range of both stand-alone theories and conceptual models, the diffusion of innovations model provides a well-established and testable theoretical underpinning to the research set out in this thesis. It considers all of the required elements (intervention, individuals and organisation/ structure), the relationships between them, and has evidence of being tested within health care services. It provides a number of generalisations relating to each dimension that can be tested without additional outcome measurement to the patients or staff, i.e. additional questionnaires. (These generalisations are dealt with within each relevant chapter.)

2.1.2.9 Theories on use of information

Although the DoI provides a good general theoretical foundation, this thesis is testing two specific interventions, which have their own knowledge base and theories within healthcare research, which are not covered by DoI. These relate to patients' behaviours relating specifically to information, and education theories that will be used to inform the development of training for staff in the use of the SDI-21 and the assessment intervention. These are outlined below.

The bulk of the information literature is around Health Information Seeking Behaviour (HISB), particularly around the use of the internet and other modern media [122]. In a review from 2007, Lambert and Loiselle [112] demonstrated that the majority of literature around HISB did not identify a standard model or theoretical framework. They did outline two theories and four models that were typically used as a basis for understanding HISB. Coping theories, specifically those of Lazarus and Folkman

(1984)[107] and Miller (1987)[111], are employed frequently. These theories aid understanding of HISB by viewing information seeking as a coping mechanism and as a response to stressors, but neither attempt to describe the processes involved in HISB[112]. The four models identified by Lambert and Loiselle [112]aim to identify stages through which individuals will progress to seek information. These are depicted below. The first model is an information-seeking model proposed by Lenz (1984)[123], which identifies 7 stages of the information search process;

1. A stimulus
2. Goal setting
3. A decision regarding whether to seek information actively
4. Search behaviour
5. Information acquisition and codification
6. A decision regarding the adequacy of the information found
7. Outcome[123]

Freimuth, Stein and Kean (1989)[124] proposed the health information acquisition model (figure 13).

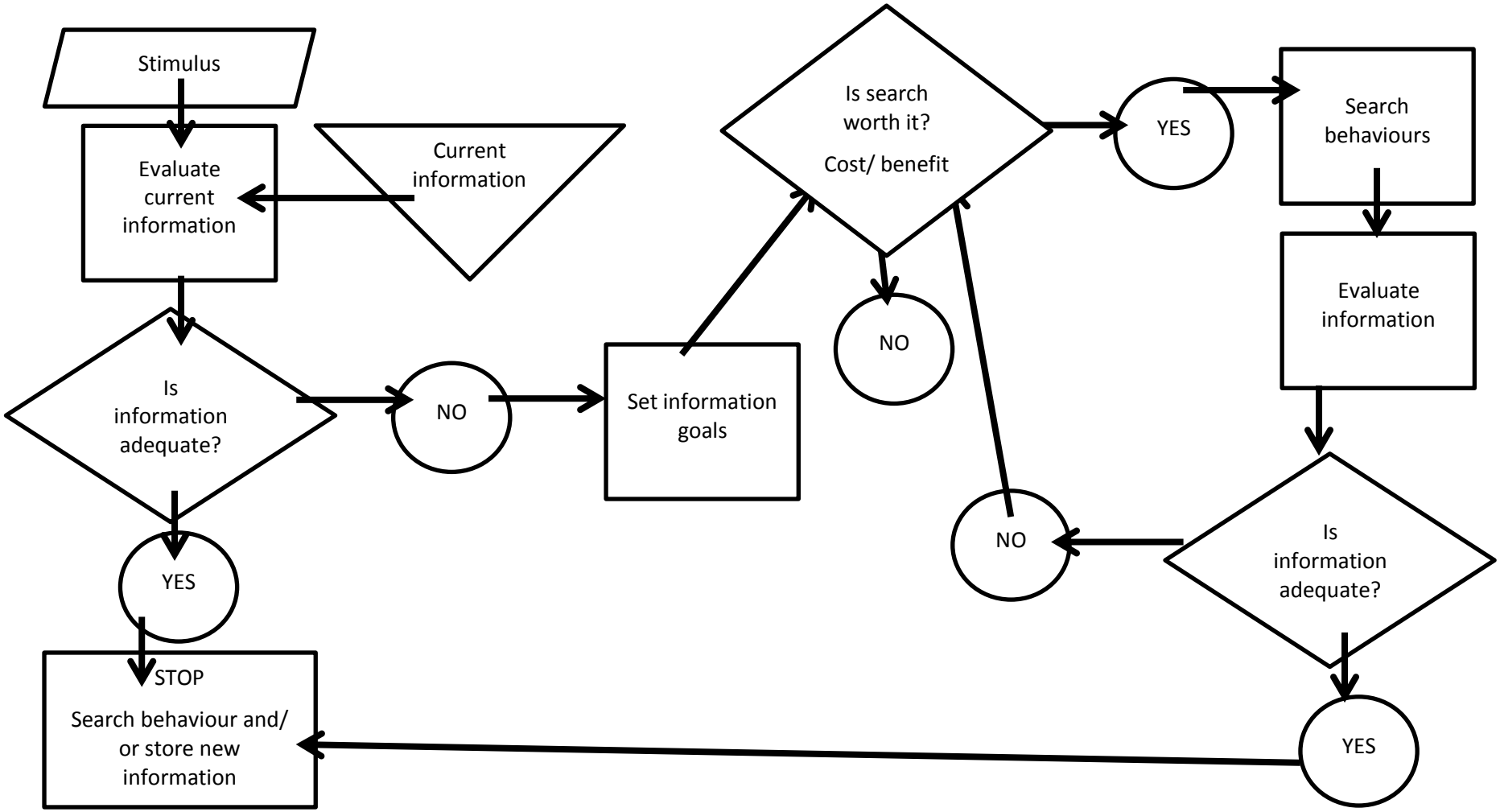


Figure 2.8: Health Information Acquisition Model (HIAM, taken from Freimuth, Stein and Kean [1989])[124]

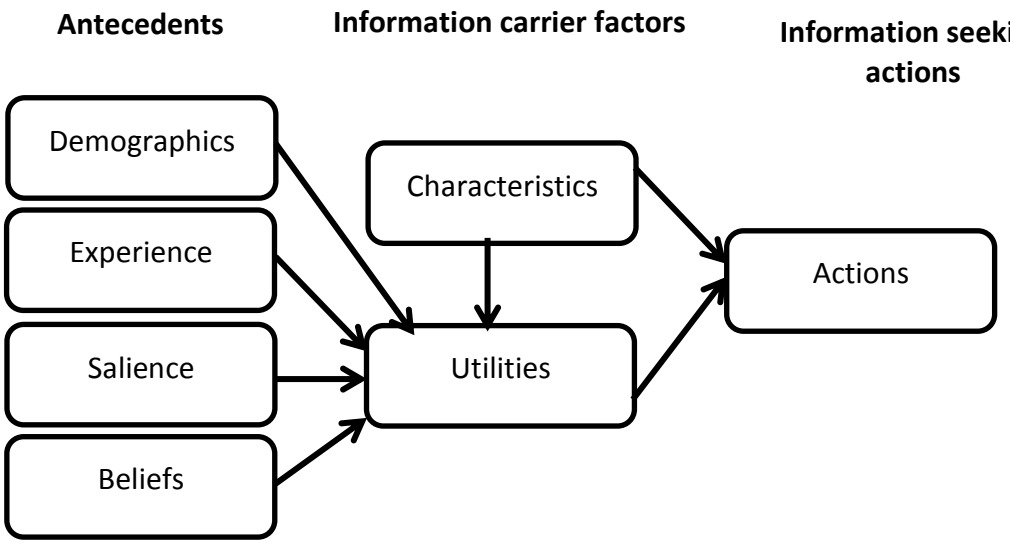


Figure 2.9: The Comprehensive Model of Information Seeking (CMIS) [125]

Although informative, the design of the information intervention pilot (chapter 7) is such that the patients in the study are not actively seeking information, but they are open to the possibility that it may or may not be provided depending on their randomisation. Therefore it was necessary to consider patients as passive recipients of information, rather than what drives patients to actively seek information. Of all the models outlined, it is only Longo's model (figure 2.10) that considers responses to passive receipt of information [112, 126]. This model conceptualises what may influence information seeking depending on the context and personal attributes, and outlines possible phases that patients may go through, depending on whether they have actively sought or have been passive recipients of information.

Although developed within breast cancer patient populations, this provides a model that can be tested within the first pilot to see if the variables, phases and outcomes are applicable within the specific population. This model is also derived from patient experience, in line with patient-centred model of care[126] making it the most appropriate to test within the information intervention pilot (chapter 6). As with other models, this is designed mainly in relation to information about disease and treatment. How it is applicable in response to supportive care information will be tested within the pilot (chapter 7).

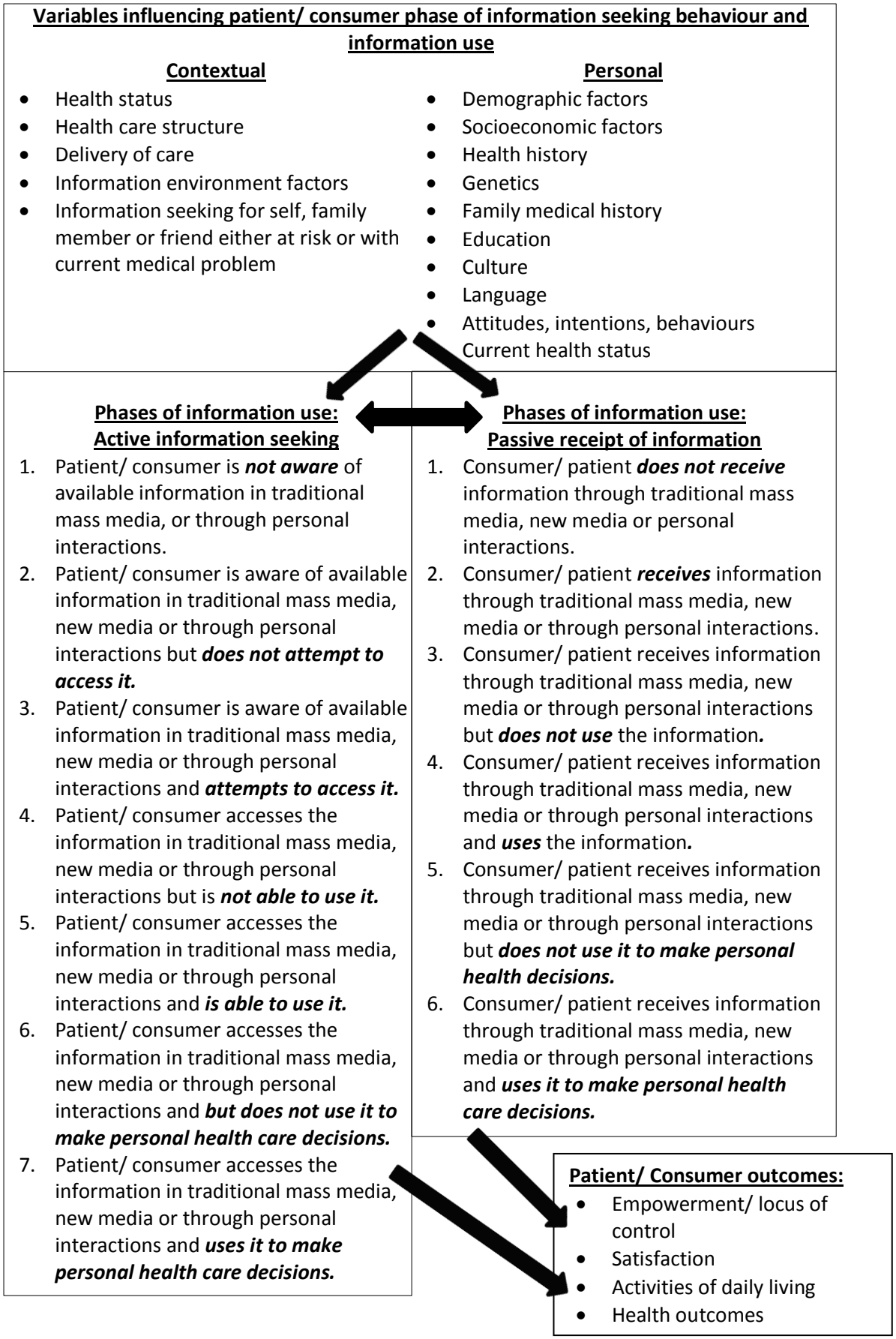


Figure 2.10: Expanded conceptual model of health information seeking behaviours and the use of information for health care decisions (adapted from Longo, 2005[126])

2.1.2.10 Learning and educational theories

There are a vast number of general learning theories and models[127] available for consideration; it is not feasible to consider all possible models and processes within the remit of this thesis. What is required for the assessment intervention pilot study (chapter 8) is a theoretical basis that will inform the practical development of the training that will provide the staff with the skills necessary to conduct a formal assessment of social difficulties.

In considering the practical issues around how to deliver the training, The Learning Pyramid provides evidence for which delivery methods will be most effective in the retention of knowledge and practical skills. In line with this model, where passive learning activities result in the lowest levels of retention, problem-based learning is widely used within healthcare education, and there is a wide literature base supporting this method [128].

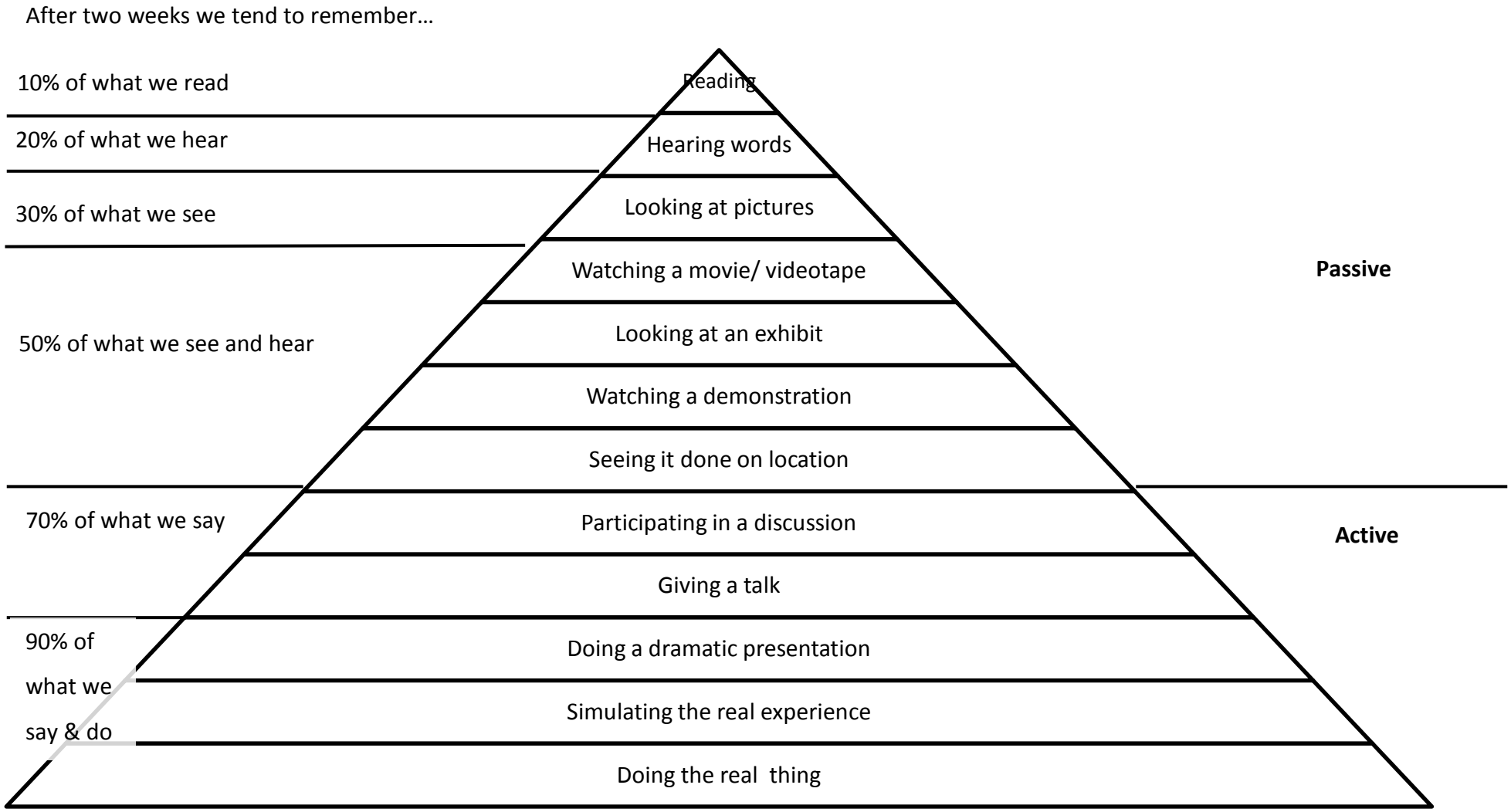


Figure 2.11: Adaptation of 'The Learning Pyramid'(taken from Dale, 1969) [129]

Timescales between delivery of training and utilising the new skills are also an important consideration. Figure 2.12 demonstrates a general overview of how long new skills or knowledge are retained for.

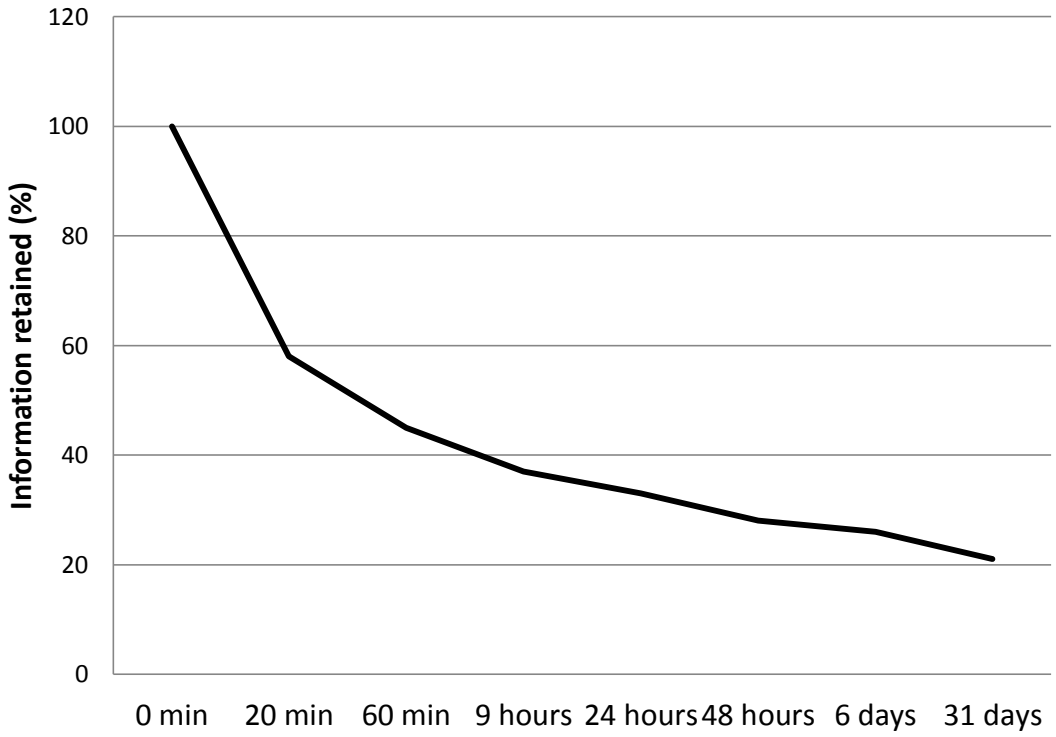


Figure 2.12: Retention of knowledge (taken from Wood, 2004[130])

Generally, active learning methods, particularly practising by doing, are the most effective techniques in terms of retention. It is important to complete the training as close to the start of patient recruitment as possible, in order to minimise the impact of time on the retention of knowledge. Lecturing and demonstration should be kept to a minimum and active learning techniques will be employed where possible[130].

2.1.3 Summary

Greenhalgh's MOD framework provided a sound theoretical basis for the work presented in this thesis, and was particularly valuable in this context for a number of reasons. The framework is based on a significant amount of research evidence, primarily in healthcare research that addresses innovations in service delivery. It provides a whole-systems approach by considering all elements included in the testing of the interventions (intervention, individuals, and organisation – figure 2.1) and the relationships between them. It defines innovations as a "…novel set of behaviours, routines and ways of working"[2] rather than limiting the innovation definition to one

specific tool or technology as in other theoretical models (e.g. the UTAUT model [84]), therefore encompassing the complexity of interventions such as the SDI-21 assessment. Although the model considers a range of factors, Greenhalgh et al acknowledge that there may be gaps in the model, and that further testing is required[2]. Within this context it was used to inform the development of the interventions (i.e. *attributes of innovations* were considered), as well as being tested for its applicability within this context and with the proposed interventions. The interview schedules (appendices 7, 8, 9, 10a, 10b and 11) were developed with elements from the MoD in mind to ensure all areas for consideration were explored. Theories relating more closely to the specific interventions were also included to inform the development of the interventions.

This chapter has reviewed theories relevant to this work and identified which models apply most closely to the intended research. The hypotheses and framework for the application of these models is outlined in section 2.2.

2.2 Hypothesis, methods framework and thesis structure

The aim of this section is to outline the hypotheses and provide an overview of the methods framework and the structure of the thesis. The underlying theory is the MoD framework, which is described in chapter 2.1. Table 2.1 outlines the structure of this thesis, which phases of the framework will be fulfilled in each chapter, and which theories will be utilised or tested in each section.

Hypothesis

The main hypothesis is that successful diffusion of a technology cluster (comprised of social difficulties assessment using the SDI-21, including staff training and provision of information to patients), if developed in line with suggested innovation attributes from the MoD model, and with consideration to the other dimensions outlined, will have the following effects:

- Increase patient awareness of and access to services
- Help patients to resolve their social difficulties
- Increase detection of social difficulties by patients and staff
- Increase communication between staff and patients about social difficulties
- Increase staff awareness of services and interventions made
- Improve patient well-being, when compared with standard care.

Methods overview

A randomised pilot study design was chosen to begin to test the hypothesis outlined above, and separate studies were conducted for each intervention component. A pilot study is conducted as a small replica of an intended larger study. The overall aim is to ensure that the components of the study will work, and mainly focusses on the processes such as recruitment. A pilot study will duplicate many of the characteristics of the main study, including the primary outcome measure. Although pilot studies often run as an 'internal pilot', (run as an initial phase to a larger study and data from the pilot included), this is not the case here; in this context the pilot studies are external pilots. In comparison, feasibility studies are conducted in order to see if the research can practicably be conducted, and considers practical issues such as the willingness of participants to take part[131].

Due to the number of separate components within the technology cluster the intervention is considered a complex intervention [132]. Therefore the Medical Research Council's (MRCs) framework for evaluating complex interventions was selected as an appropriate model, specifically developed within a health services perspective[133]. The framework presents a useful phased approach to testing such interventions, but is not prescriptive, and is widely utilised and cited in healthcare research[134]. The work outlined in this thesis was based upon the original MRC Framework[135], an updated version of which was produced in 2008[1]. The most recent guidance identifies and attempts to address the key limitations of the original model, which relate to its linearity and perceived lack of flexibility. The new guidelines also provide more information on how to consider whether a randomised controlled trial (RCT) is the most appropriate method of evaluation. Figure 2.18 demonstrates the key phases of the original framework and how the work planned in this thesis fits within it [135], including where the relevant theoretical models will apply and be tested.

Table 2.1: Structure of this thesis

Chapter(s)	Relevant MRC framework stage	Relevant theories
1. Introduction **2. Theory, hypothesis and thesis structure** **3. Current practice; frequency of discussion of social difficulties** Chapter 3 aims to fulfil the theory/ pre-clinical phase of the MRC Framework, which requires (in addition to the description above) the justification of a need for an intervention. This will be achieved by using existing data sources to explore current practice for discussion of social difficulties in routine oncology consultations, providing a baseline on which to make later comparisons of intervention effects. Establishing standard practice in this way will help to build a picture of the social system into which the interventions are being introduced, which will help understand how compatible they are with current practice. **4. Levels of unmet need for social difficulties, and potential impact of routine assessment** Chapter 4 contributes to this phase by describing an evaluation of the potential effect of implementing an assessment programme, based on the SDI-21, also done using existing data from a previous study. This will establish the potential increase in workload and referrals that may be expected when a formal assessment method is employed, providing evidence for the likely *compatibility* and possible perceived *relative advantage* (or disadvantage) of the innovation. The aim of this is to start to address perceived increase in workload, a barrier to provision of care for social difficulties.	*Pre-clinical/ Theory* "Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues."[1, 135]	Models of diffusion framework[2]; • establishing current practice to enable later assessment of *compatibility* • *relative advantage* of the innovation • potential consequences of the innovation

Chapter(s)	Relevant MRC framework stage	Relevant theories
5. Development and evaluation of an information intervention Chapter 5 describes the development of an appropriate information resource, based on findings from previous studies. **6. Pilot study; simple information provision versus standard care** Chapter 6 reports on the randomised pilot study used to compare the provision of this information against current standard care. Although evidence suggests that simple interventions are not as effective as multifaceted approaches[68], previous research (presented in chapter 4) suggests that information alone may be sufficient to deal with a range of social difficulties[36], so the role of information as a stand-alone intervention will be explored first. **7. Development and evaluation of a Nurse Training Package (NTP) to facilitate delivery of an assessment for social difficulties** **8. Feasibility, acceptability and impact of an assessment of social difficulties in routine practice** Chapters 7 and 8 describe the development of a nurse training resources and protocol to equip staff with necessary knowledge and skills to conduct SDI-21 assessments, and the subsequent randomised pilot study, conducted to compare the formal assessment of social difficulties against current standard care.	*Phase I/ Modelling* "Identify the components of the intervention, and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other."[1, 135]	Models of diffusion framework[2], specifically; • utilising knowledge of attributes to assist in development of intervention • *relative advantage* • confirming attributes of innovation • recognising innovation decisions Longo's expanded model of health-information seeking behaviour [126] Theories on teaching techniques and retention of information[127-130]

Chapter(s)	Relevant MRC framework stage	Relevant theories
9. Staff and patient responses to a pilot of an electronic Holistic Needs Assessment (eHNA); a service evaluation Chapter 9 fulfils in part the Exploratory Trial (Phase II) stage of exploration recommended by the MRC Framework. The MRC recommends exploratory trial, followed by a definitive RCT and a long-term implementation plan. An evaluation of the HNA pilot within the clinic at a Teaching Hospitals NHS Trust will act as a brief exploratory trial.	*Phase II/ Exploratory trial* "Describe the constant variable components of a replicable intervention AND a feasible protocol for comparing the intervention to an appropriate alternative."	Models of diffusion framework[2]
Not covered by this thesis	*Phase III/ Definitive RCT* "Compare a fully defined intervention to an appropriate alternative using a protocol that is theoretically defensible, reproducible and adequately controlled, in a study with appropriate statistical power."	N/A

Chapter(s)	Relevant MRC framework stage	Relevant theories
Not covered by this thesis	*Phase IV/ Long term implementation* "Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term."	N/A
10. Discussion and Conclusions Chapter 10 summarises the key findings and discusses them comparing with existing research and looks at future directions. The future plans for this research are viewed according to the MRC Framework, with consideration of either a definitive parallel-group RCT or using quasi-experimental designs (such as Continuous Quality Improvements), which may be more suitable for health services research projects.	Overall framework	All

2.3 Summary

This thesis presents a body of work aimed at;

- Establishing what gaps may be present in the provision of psychosocial care, specifically social difficulties
- Identifying possible interventions that may bridge these gaps
- Identify and evaluate the mechanisms by which these interventions may be adopted by patients and staff to achieve the outcomes predicted in the hypotheses outlined above

This will be carried out in line with the MRC Framework[135] for evaluating complex interventions, and starts to fulfil the exploratory trial phase of this framework by also conducting a service evaluation of a mandatory programme of assessment.

Chapter 3: Current practice; frequency of discussion of social difficulties

3.1 Overview

The previous chapters have provided an introduction to social difficulties within oncology (chapter 1) and the theories that may influence the adoption of the proposed interventions (chapter 2). As outlined in chapter 2, how *compatible* an innovation is to existing practice has an influence on how successful its adoption will be. An innovation is considered *compatible* if it fits with existing beliefs, needs and/ or methods. If an innovation is too far removed from existing practices, it will not be easily adopted. Conversely, an innovation that is too compatible with existing methods will not offer any *relative advantage* (i.e. would offer no improvement on existing practice), and is also at risk of being rejected[73].

The goal of this chapter is to describe existing standard practice, focussing on the content of clinical consultations between doctors and patients. This will increase understanding of what sort of issues are raised within the doctor-patient consultation. This can be used to inform the development of the proposed interventions to maximise their *compatibility*.

The opportunity was taken to examine standard practice from the doctor-patient perspective by undertaking secondary analysis of baseline audio-recordings and an outcome measure from two previous RCTs conducted by the POG group (original findings published in 2004 and 2011 respectively [50, 136]). This should provide insight into what constitutes and influences standard discussion during the outpatient consultations.

3.2 Background

Published research prior to the first of the two RCTs had shown that collecting individual health-related quality of life (HRQoL) data could be useful in informing clinicians, and helped communication between patients and their doctors [50]. It had been recognised that the traditional processes of history-taking in the standard consultation were not conducive to the repeated, routine collection of data on physical and functional problems over time. The medical consultations experienced by most oncology patients have a standard structure. The initial consultation with a new patient will differ from subsequent review appointments, and usually occurs between

diagnosis and the start of a new treatment regimen. This appointment will be used to evaluate family, personal and social history, including working life, living conditions, support networks and recreational activities[137]. At subsequent on-treatment review appointments medical issues still form the bulk of the discussion, even when patients require support for non-clinical difficulties[46]. These consultations are an important opportunity to pick up on patients' unmet needs, and both patients and clinicians report that they would like to discuss emotional and social issues. The literature suggests that in the main this does not happen in reality[46].

The original RCTs described in section 3.3 were conducted in response to a need for further research into the impact of collecting HRQoL data on patient well-being, specifically the need to explore the impact of repeated measures, and employing touch-screen technologies for delivery [50]. The initial RCT examined the impact of regular collection and use of routine HRQoL data in routine oncology practice, comparing standard care (arm 1) with HRQoL assessment with results fed back to the oncologist (arm 2), and HRQoL assessment without any feedback of results to the clinician (arm 3)[50]. An unexpected result from this study suggested an improvement in patient well-being for those who had HRQoL measured but not fed back to the clinician, so a subsequent two-arm RCT was conducted to confirm whether this was the case[138].

The overall aim of the original studies was to explore the impact of obtaining HRQoL data (and in some cases feeding this back to clinicians) on the content of consultations and patient well-being. The aim of the secondary analysis described in section 3.4 was to utilise the data from these original studies to explore how frequently specific issues were discussed in consultations. Outcome data was also used to explore any relationship between issues being raised and patient functioning in these areas.

3.3 Original studies

Original studies - methods

In both of the original RCTs, patients attending routine outpatient clinics were invited to participate. Eligible patients were those who could speak English, had recently commenced chemotherapy, and were expected to attend a minimum of four on-treatment review appointments. Approval was sought from local research ethics

committees and patients provided written informed consent prior to participation. Socio-demographic and clinical details were obtained for patients, and clinicians provided demographic and professional data. Postcodes were collected to allow later calculation of Indices of Multiple Deprivation (IMD) scores and allow patients to be categorised according to levels of social deprivation. During these studies, audio-recordings were made of participants' consultations with their doctors. These recordings were taken over four time points, including one baseline and three post-intervention. Figure 3.1 demonstrates the study design and patient pathway throughout the studies.

Both studies measured process of care outcomes and patient outcomes. Process of care outcomes were the content of doctor-patient consultations and changes to patient management, accessed via audio-recordings of on-study consultations subjected to content analysis. Patient outcome was well-being, measured by the Functional Assessment for Cancer Therapy – General (FACT-G, appendix 2). In this context it was used as an outcome measure, to assess patient's well-being. It is a 28-item questionnaire, comprised of four subscales; physical wellbeing, social and family wellbeing, emotional wellbeing and functional wellbeing. Responses are given to a series of statements on a five-point Likert scale, ranging from 0 (not at all) to 4 (very much). The social and family well-being subscale covers items relating to work, sleep and general enjoyment of life. The FACT-G does not include any item relating to financial issues[139].

The initial three-arm RCT was carried out at St James's University Hospital. Patients were recruited from outpatient clinics and chemotherapy pre-assessment for all non-haematological disease groups. At the time of the original studies these clinics were located in a dedicated suite at St James's. Although the location has now moved to Bexley Wing, the role of the nurse within the outpatient clinic remains mainly unchanged. Patients book in on arrival with a clerk, and the clinic nurses have responsibility for weighing patients, taking their blood pressure and sending them for other tests, e.g. blood tests and x-rays where required. Contact between the nurses and patients is typically brief and informal, and occurs whilst the patients are getting weighed or during brief discussions in the waiting room. Occasionally nurses will

perform procedures, such as flushing chemotherapy lines, which may provide an opportunity for longer contact and potential discussion with patients.

Patients were approached by the research team whilst waiting for their consultation with the doctor. Once they had consented to participate, they had that day's consultation with the doctor audio-recorded, and were then provided with a paper version of the FACT-G (appendix 2). This was provided post-consultation, to be completed at home and posted back to the research team. Patients were then randomised to one of three arms; 1) intervention, 2) attention-control and 3) control arm (figure 3.1), in a ratio of 2:1:1 respectively. Participants were seen for a further 3 on-study visits, all of which were audio-recorded, regardless of intervention arm. Those in arms 1 and 2 completed the European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core C30 (EORTC QLQ-C30 – version 3.0, appendix 3) and the Hospital Anxiety and Depression Scale (HADs – appendix 4) prior to each of these visits. The EORTC QLQ-C30 and the HADs were provided as the interventions in both studies, and were delivered on a touchscreen computer. The EORTC QLQ-C30 is a 30-item questionnaire, including five functional scales (physical, emotional, cognitive, social and role), three symptom scales (fatigue, pain and nausea/ vomiting), a global HRQoL scale, and six single items on typical symptoms[140]. The HADs is a 14-item instrument used to identify patients with anxiety and depression. Scores range from 0-21 on each scale (anxiety and depression) with higher scores indicating more distress, providing valid measures of severity[141].

Those in arm 1 had their EORTC QLQ-C30 and HADs responses fed back to their clinician, who had been trained to interpret the results. Patients in arm 2 had completed the intervention questionnaires but the results were not fed back to the clinician. Those in arm 3 received no intervention and standard care. All patients (regardless of intervention arm) completed the FACT-G on paper at the following time-points; after baseline, after three further on-study visits, and at four and six months post-study (figure 3.1).

The subsequent two-arm RCT was carried out at the St James's University Hospital and in two regional cancer units; Bradford Royal Infirmary and Huddersfield Royal Infirmary. Although the cancer units were smaller, the roles and processes were much the same as at St James's. Patients were again approached in clinic, and participants

had that day's consultation audio-recorded, and provided with the FACT-G after the baseline visit to complete at home. Participants were then randomised to one of two arms; intervention or control (figure 3.1). Those in the control arm received standard care, but were asked to repeat the FACT-G at the final visit. Patients in the intervention arm completed the FACT-G, along with the EORTC QLQ-C30 and HADs, but responses from the intervention questionnaires were not fed back to the clinician. In both studies, all groups had all four consultations (baseline plus three further visits) audio-recorded.

Original studies - analysis

Content analysis was carried out on recorded outpatient consultations from both studies, for participants who had a set of four complete recordings. The content analysis framework covered symptoms and functions derived from the EORTC QLQ, as well as other symptoms, medical decisions and non-medical interventions[142].

The team conducting the analysis was made up of four Research Assistants, including the author (EJI), and were supervised by the Principal Investigator (GV). The research team undertaking the analysis were blinded to the identity of the patients and their study arm allocation. When a conversation occurred regarding symptoms, side effects or functioning took place, the basic details of the conversation, whether the issue was mentioned or discussed, and who raised the issue (doctor, patient or relative) was recorded. Where conversations regarding functions were recorded, direct quotes from the audio tape were noted, in order to clarify what had been considered relevant to a particular function. A minimum of two researchers analysed each consultation individually. They then met to discuss their analyses and come to a consensus. Analyses of 20 consultations were repeated to gauge for coding drift over time. Kappa (κ) analysis was used to demonstrate levels of agreement between coders, which were good (three arm κ-coefficients 0.48-1.00, median 0.86, two arm 0.5-1.00, median 0.83) [50].

In the original analysis, when an issue was recorded as being raised, this was then categorised as 'mentioned' or 'discussed'. Where an issue was raised at less than two separate time-points, and there was no significant exchange between the doctor and patient, this was considered as 'mentioned'. If the issue was raised at three or more

separate time-points, and/ or there was a significant exchange, this was considered as ‘discussed’.

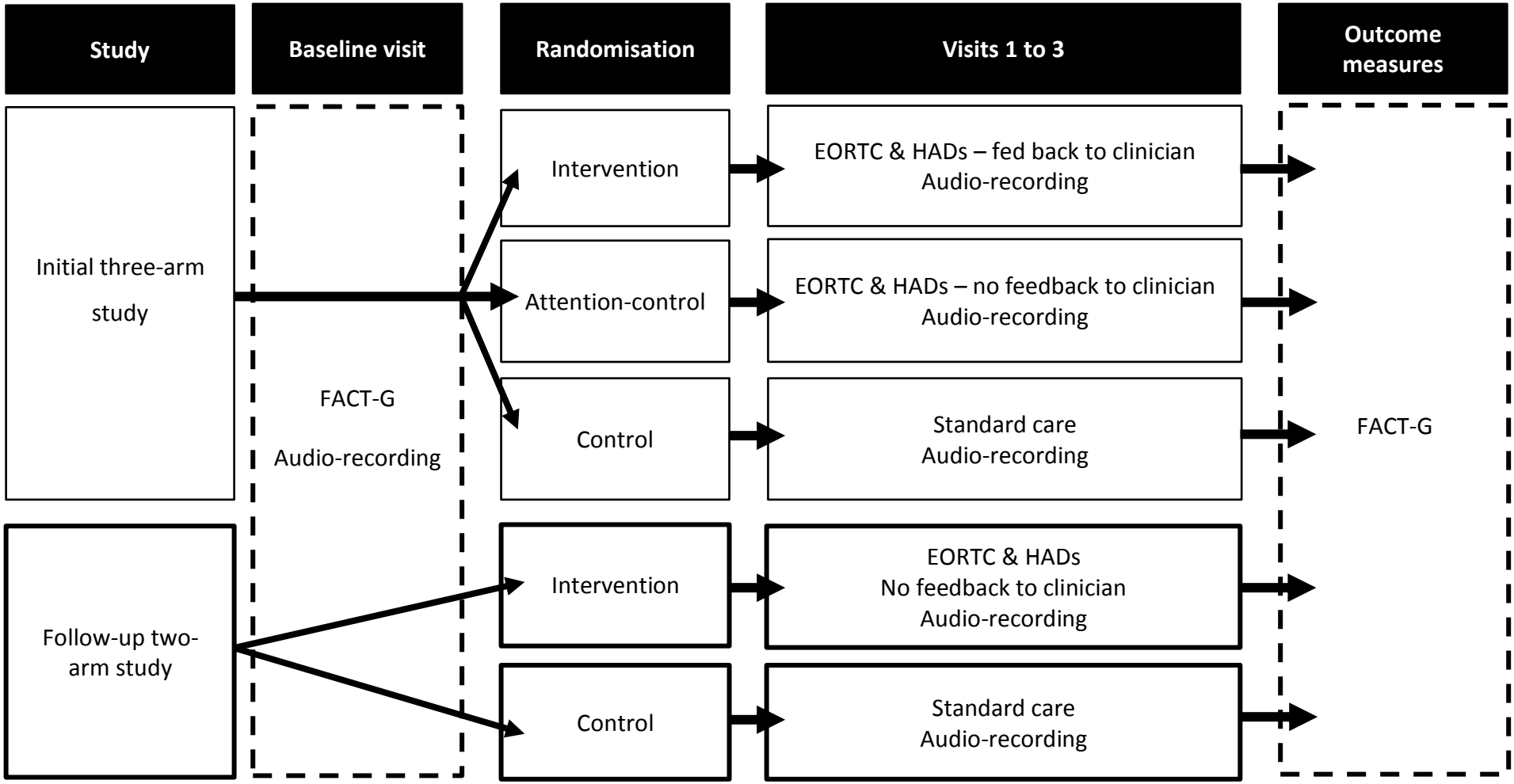


Figure 3.1: Original study designs and methods for the three-arm and subsequent two-arm RCTs [50]

3.4 Current analysis

3.4.1 Aims

The overall goal of the current analyses was to utilise data from the previous studies to establish what constitutes standard practice in terms of discussion of social functioning, role functioning, and financial concerns within routine clinical consultations. These areas were selected as the three most pertinent areas of concern for which relevant items were available on the FACT-G, which related most closely to subscales within the SDI-21 (but without duplicating earlier analyses [46, 50, 136, 138]), and for which pre-intervention baseline consultation data had been recorded, therefore reflecting standard practice. SPSS Statistics software (version 19) was used to conduct analysis.

3.4.2 Objectives

I. Describe the baseline FACT-G subscale scores
II. Describe the frequency of discussion of social functioning, role functioning and financial concerns
III. Explore associations between discussion of functions and socio-demographic and clinical factors
IV. Explore any association between FACT-G subscale scores and the frequency of discussion of functions

3.4.3 Methods

3.4.3.1 Content analysis

The text of the items from the EORTC QLQ-C30 was used to define the coding of functions during the original content analysis, and which items and scales from the FACT-G corresponded to them for the purposes of the statistical analysis described here. Social functioning as described by the EORTC QLQ-C30 includes the impact on family life and social activities. Corresponding items within the social and family well-being subscale of the FACT-G cover; meeting the needs of the family, closeness to friends, emotional support, family's acceptance of illness and satisfaction with communication, and how close the patient feels to their partner or source of main support. EORTC QLQ-C30 role functioning includes issues relating to work and other

daily activities, as well as hobbies or leisure activities. Corresponding items within the FACT-G functional well-being subscale refers to the ability to work, whether work is fulfilling, and whether the patient enjoys life in general and the things they usually do for fun. Financial concerns relates to any financial worries, e.g. additional expenses, loss of income. There are no corresponding financial items available on the FACT-G and therefore it was not possible to explore a relationship between reporting of difficulties and the frequency of discussion of financial concerns.

Table 3.1 demonstrates how subscales of the FACT-G were matched to areas of functioning reported in the consultation as derived from the EORTC QLQ-C30. Items from the relevant subscales of the EORTC QLQ-C30 were listed, and statements from the FACT-G that could be closely related were matched to them. As a result the role functioning and social functioning subscales of the EORTC QLQ-C30 were matched to the functional well-being subscale of the FACT-G respectively. Although not all items within the functional well-being scale match directly to items in the QLQ-C30, using the subscale score rather than individual item scores provides more robust scores for analysis. Although one item* from the physical wellbeing scale of the FACT-G could be matched to the social functioning subscale of the QLQ-C30, this was not used as a single item. Although the social and family well-being subscale has an optional item relating to sexual difficulties, this was not included in this analysis.

Table 3.1: Matching FACT-G items and subscales to functioning subscales from EORTC QLQ-C30

EORTC QLQ-C30 Items	FACT-G Items
Role functioning	***Functional well-being***
6: "Were you limited in doing either your work or other daily activities?"	*22: "I am able to work (include work at home)*
7: "Were you limited in pursuing your hobbies or other leisure time activities?"	*23: "My work (including work at home) is fulfilling"*
	24: "I am able to enjoy life"
	25: "I am enjoying the things I usually do for fun"
Social functioning	***Physical well-being***
26: "Has your physical condition or medical treatment interfered with your family life?"	**3: "Because of my physical condition, I have trouble meeting the needs of my family."*
27: "Has your physical condition or medical treatment interfered with your social activities?"	***Social and family well-being***
	9: "I feel close to my friends"
	10: "I get emotional support from my family"
	11: "I get support from my friends"
	12: "My family has accepted my illness"
	13: "I am satisfied with my family communication about my illness"
	14: "I feel close to my partner (or the person who is my main support"
Financial concerns	
28: "Has your physical condition or medical treatment caused you financial difficulties?"	*No matching subscale/ items*

Examples of what conversations were coded as each function/ concern were extracted from the original coding data. Case studies were compiled by identifying patients who had reported poor functioning in the selected areas and reviewing the coding and audio-recordings of their baseline consultations.

3.4.3.2 Statistical analysis

Data from both the three and two-arm RCTs were pooled to create a full dataset on which to conduct the secondary analysis outlined here. Sociodemographic and clinical data for all participants was summarised by study and overall. Counts were taken of how many consultations in which functions were raised. Coding of whether functions

were mentioned or discussed was simplified to raised and not raised for the purposes of the secondary analysis described here. Counts were taken of how many consultations had each of the three functions raised.

Univariate (Pearson's Chi-Squared [χ^2] analysis) was used to explore associations between discussion of functions and available sociodemographic and clinical variables (study, centre, geographical location [Leeds/ non-Leeds], gender, age group, marital status, occupation, degree or equivalent qualification, grouping by Indices of Multiple Deprivation [IMD] score, diagnosis and extent of disease).

Mean scores were calculated for the subscales of the FACT-G. Higher scores denote better functioning in both subscales. In line with guidance, missing scores were to be substituted with the mean of the completed items when more than 50% of the items were completed [143]. No records had to be excluded for this reason. Subscale scores range from 0 to 24 (social and family well-being) and 0 to 28 (functional well-being). Mean subscale scores were summarised by study. Frequencies of total subscale scores were calculated and histograms were created.

Independent-samples t-test was used to compare the mean subscale scores and patients who had the functions raised in their consultations and those who did not. Multivariate logistic regression was performed to assess the impact of variables identified by univariate analysis at a significance level of ≤0.1. Omnibus tests of model coefficients were used to indicate the model's performance and Hosmer and Lemeshow goodness of fit tests were used to assess the fit of the model[144].

3.4.4 Results

3.4.4.1 Sociodemographic and clinical data

Table 3.2 demonstrates the sociodemographic and clinical characteristics of participants who were included in the secondary analysis described here, summarised by study and overall. The patient populations were similar in all characteristics except for extent of disease, with a higher percentage of patients with metastatic disease in the three-arm study. The majority of patients included in this analysis were female (73% - this may be related to the diagnostic groups; gynaecological and breast patients accounted for 56% of participants). Most patients were married (58%), and either retired or unable to work due to illness (35% and 28% respectively). The majority did

not have a degree or equivalent professional qualification (66%). Sixty-seven per cent of all patients had a diagnosis of metastatic disease.

Table 3.2: Sociodemographic and clinical characteristics of participants

	Two-arm (n=346)		Three-arm (n=207)		Combined (n=553)	
	n	**%**	**n**	**%**	**n**	**%**
Gender & Age						
Male (combined median age [range] = 60 [19 to 87])	109	32	43	21	152	27
Female (combined median age [range] = 58 [23 to 92])	237	68	164	79	401	73
Marital status						
Married	190	56	133	64	323	58
Cohabiting	25	7	16	8	41	7
Separated or divorced	24	7	16	8	40	7
Widowed	39	11	19	9	58	11
Single	25	7	15	7	40	7
Missing	43	12	8	4	51	10
Occupational status						
Employed	48	14	45	22	93	17
Unable to work due to illness	89	26	65	31	154	28
Retired	129	37	62	30	191	35
Homemaker/ other	32	9	26	13	58	10
Missing	48	14	9	4	57	10
Degree or professional qualification equivalent						
Yes	78	22	55	27	133	24
No	227	66	141	68	368	66
Missing	41	12	11	5	52	10
Levels of social deprivation						
Bottom 20% - least affluent areas	79	23	30	14	109	19.8
20 to 40%	73	21	37	18	110	19.8
Middle 20%	64	18	45	22	109	19.8
60 to 80%	61	18	49	24	110	19.8
Top 20% - Most affluent areas	69	20	40	20	109	19.8
Missing	0	0	6	2	6	1
Diagnosis						
Gynaecological	125	36	80	39	205	37
Germ cell/ Renal/ Bladder/ Sarcoma	78	23	59	29	137	25
Breast	72	21	42	21	114	21
Melanoma/ Colorectal/ GI/ Other	23	7	19	9	42	7
Lung	48	13	4	2	52	10
Extent of disease						
Primary local or disease free	100	29	29	14	129	23
Local recurrence	39	11	11	4	50	10
Metastatic	207	60	167	81	374	67

3.4.4.2 Baseline FACT-G scores for social and family well-being and functional well-being subscales

The FACT-G has no item relating to financial difficulties; therefore no outcome data was available on patients' functioning relating to this area. Scores were available for 502 respondents both subscales. Table 3.3 describes the scores. Participants demonstrated a higher mean score in the social and family subscale than in the functional subscale, suggesting overall better functioning in social and family well-being. These scores were compared with published data a previous US study, and normative data collected from the general United States (US) adult population [145] (table 3.3). This comparison demonstrates higher scores from the US populations than seen in the two and three arm studies.

Table 3.3: FACT-G scores by subscales and between studies

	SFWB		**FWB**	
	Mean (range 0 to 24)	**SD**	**Mean (range 0 to 28)**	**SD**
Two-arm study scores	16.81	4.06	9.72	5.62
	n=300		*n=302*	
Three-arm study scores	16.48	4.39	9.71	5.73
	n=202		*n=200*	
Combined study scores	16.67	4.19	9.72	5.66
	n=502		*n=502*	
US cancer patient scores[145]	*22.3*	*4.8*	*18.8*	*6.4*
	n=308			
General US adult population[145]	*19.1*	*6.8*	*18.5*	*6.8*
	n=1,075			

Figure 3.2 demonstrates the distribution of total social and family well-being scores. The scores are heavily skewed to the right, with higher scores denoting better functioning. Figure 3.3 shows the distribution of total functional well-being scores. Fifteen respondents scored the lowest possible score on the functional well-being subscale (0 – denoting worst possible functioning), compared with only one respondent scoring 0 on the social and family well-being subscale.

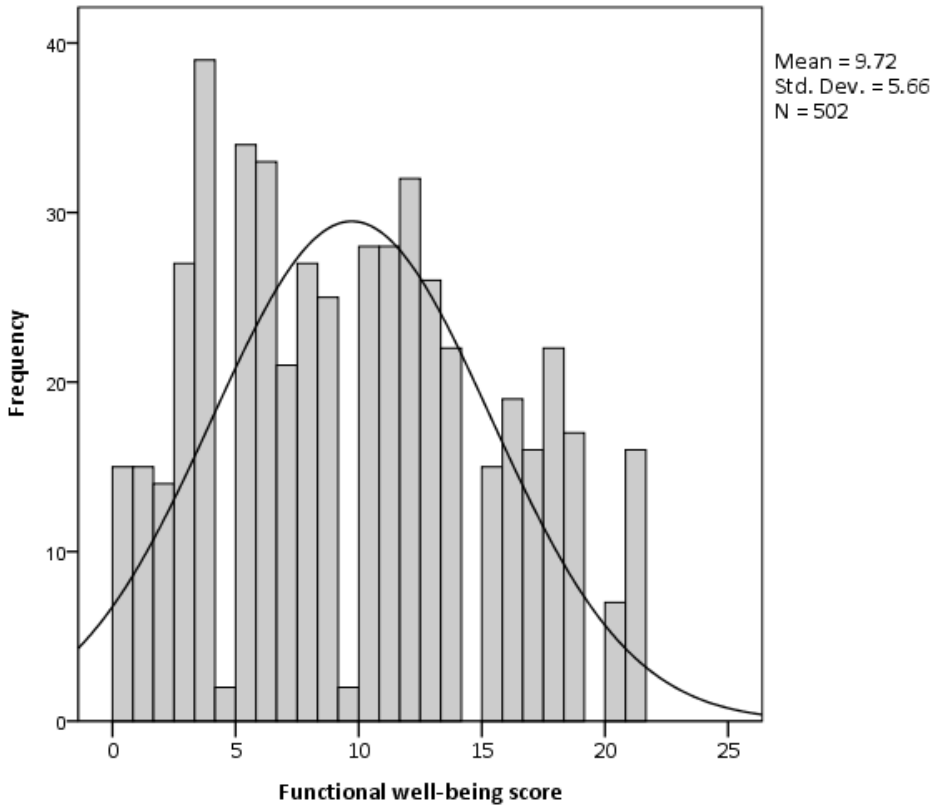


Figure 3.2: Distribution of total social and family well-being scores

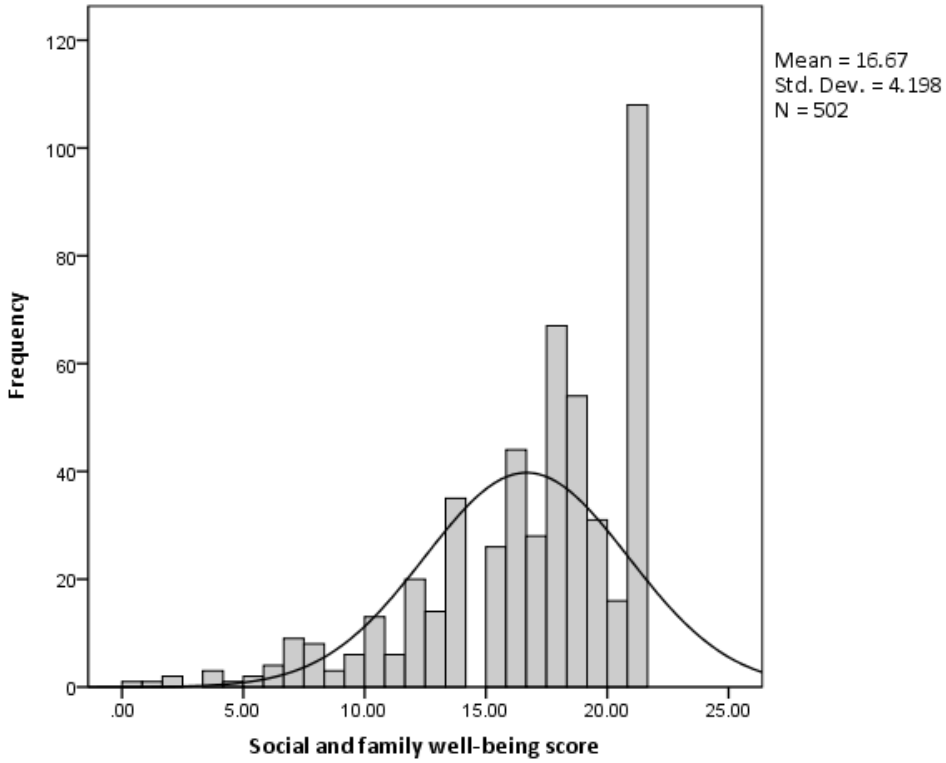


Figure 3.3: Distribution of total functional scores

Independent samples T-tests showed no significant difference in mean social and family well-being subscale scores between patients who had social functioning raised in their consultation (M = 16.6, SD = 4.31) and those who did not (M = 16.7, SD = 4.14; t (500) = -.09, p = .93, two-tailed). The results from the logistic regression (table 3.5) also support the finding that there was no significant link between scores on the social and family well-being subscale and whether social function was raised during the consultation.

There was also no significant association found between mean functional well-being subscale scores and whether patients had role function raised in their consultation (M = 10.2, SD = 5.67) and those who did not (M = 9.6, SD = 5.6; t (500) = 1.04, p = .29, two-tailed). The results from the logistic regression (table 3.7) also provide evidence that there is no significant link between scores on the functional well-being subscale and whether role function is raised during the consultation.

3.4.4.3 Social Function

Social functioning involves impact on family life and social activities. This may range from a patient simply mentioning that they have children, to the wider impact, as shown in example SF1 (figure 3.4). This is a quote from a patient's husband, who was expressing the impact of caring responsibilities on his work, as well as the impact on the family's ability to go abroad on holiday. Social function may also relate to the level of support that patients feel they have from those closest to them (SF2), or lack of support (SF3).

SF1	Husband:	*"…I've been on sick for the last nine weeks, but I'm going back to work on Monday, so what I'm going to have to do, she'll be alright during the day, I'm working locally…then I will take a lieu day/ annual leave day on the Friday. Because there's no way I can go abroad again this year, not with the state she's in. That's totally out."*
SF2	Patient:	*"I've got a good support team of five children…they're all grown up."*
	Doctor:	*"Do they help you out?"*
	Patient:	*"Oh yes."*
SF3:	Sister:	*"She's depressed...her husband's not here he's away from her, he's working away."*
SF4:	Patient:	*"I am so not used to sitting still…I'm getting bored* (during treatment)*…usually I'm never at home, I'm always at the golf course or the gym…"*
SF5:	Doctor:	*"We thought you were going to go home last week…what happened?"*
	Patient:	*"Social."*
	Doctor:	*"Oh right."*
	Son:	*"We had a slight problem with that, he doesn't want any help and I do want help…so now it's sorted out and he's getting some help."*
	Patient:	*"I'm not happy…I've coped on my own for 15 years…"*
SF6:	Patient:	*"…diarrhoea is a real problem…unless I take heavy doses of medication…some days it's been all day…it's so unexpected…if you're out, its…it's stopped me going out…"*

Figure 3.4: Examples of social function (SF) discussion within consultations

Social function was the most frequently raised of all the three functions/ concerns studied. The frequency of social function being raised was higher in the three-arm study than the two-arm (figure 3.5).

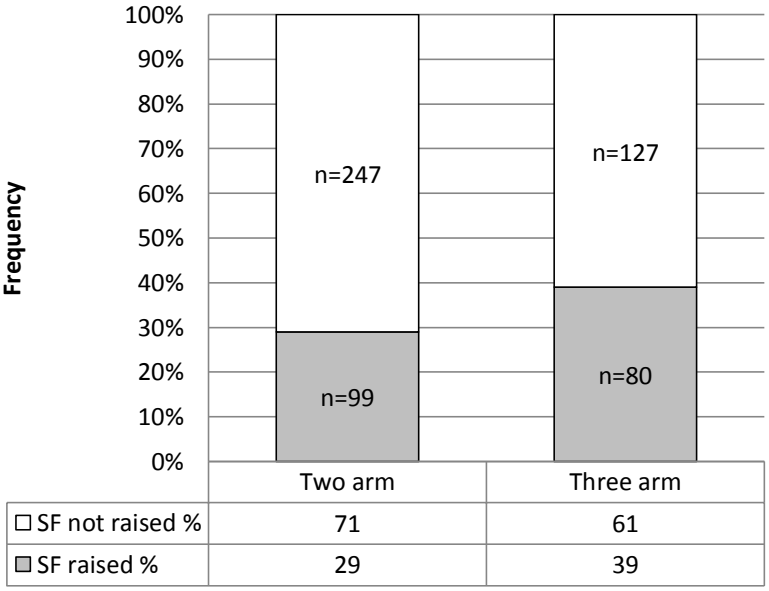


Figure 3.5: Frequency of social functioning (SF) being raised in consultations by study

Of the three study locations, Bradford had the highest frequency (40% versus 34% and 31% in Huddersfield and Leeds respectively). The frequency of raising social function was similar between gender (33% of males and 32% of females), and between age groups (34% and 32% of those ages 18 to 59 years and those aged 60 and over respectively). In terms of marital status, the frequency of social function being raised was highest in those who were separated/ divorced (43%), and also slightly higher in those who were employed or homemakers/ others (39% and 38% respectively). Those with a degree or equivalent professional qualification also had a slightly higher frequency than those who did not (figure 3.6).

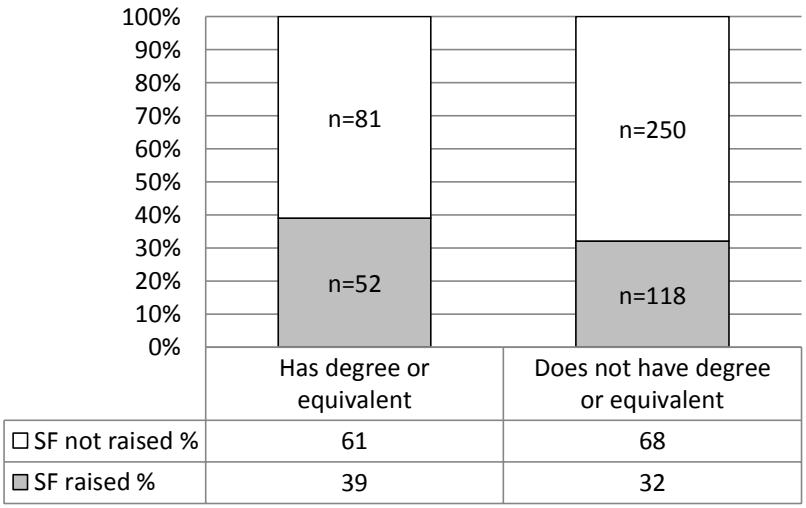
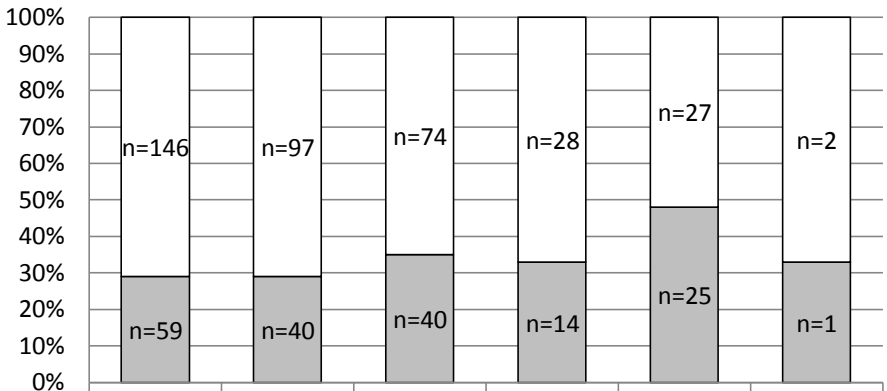


Figure 3.6: Frequency of social function (SF) being raised by whether the patient had a degree or equivalent professional qualification

Frequency of discussion of social function was highest in people who lived within the classification of the 41% to 60% most socially deprived areas (38%). In terms of diagnosis, lung patients experienced the highest frequency of social function being raised (figure 3.7). There was no notable difference between categories determined by extent of disease (33% of those who were disease free or with primary local diagnoses, compared with 30% with local recurrence and 32% of those with metastatic disease).



	Gynaecological	Germ cell/ sarcoma/ renal/ bladder	Breast	Melanoma / GI/ Colorectal / Other	Lung	Unknown primary
☐ SF not raised %	71	71	65	67	52	67
▩ SF raised %	29	29	35	33	48	33

Figure 3.7: Frequency of social function (SF) being raised, by diagnostic group

Univariate analyses

Table 3.4 shows Chi-squared results for each variable against whether social function was raised or not. This demonstrated no significant association between centre (Leeds, Huddersfield, and Bradford), geographical location (Leeds, non-Leeds), gender, age group, marital status, occupation, IMD group, diagnosis and extent of disease.

A significant association (≤0.1) was seen between whether social function was raised and the study, with participants in the three-arm study demonstrating a higher frequency (39% versus 29% - figure 3.5). An association was also noted between raising social function and whether the patient had a degree or equivalent professional qualification; those who had such a qualification had social function raised in 39% of their consultations, compared with 32% of those who did not (figure 3.6). The patient's diagnosis also showed a positive trend, with lung patients having the highest frequency (raised in 48% of consultations – figure 3.6).

Table 3.4: Results of Chi-Square Test for independence between study, sociodemographic and clinical variables and whether SF was raised in the consultation

	χ2 (df, n)	**Value**	**p**	**phi**
Study	*χ2 (1, n=553)*	*5.95*	***0.02***	*-0.10*
Centre	χ2 (1, n=553)	1.59	0.5	0.05
Leeds/ non-Leeds	χ2 (1, n=553)	1.13	0.29	-0.05
Gender	χ2 (1, n=553)	0.26	0.87	0.007
Age group	χ2 (1, n=553)	0.67	0.41	0.04
Marital status	χ2 (1, n=502)	8.6	0.13	0.13
Occupation	χ2 (1, n=496)	2.5	0.48	0.07
Degree/ equivalent qualification	*χ2 (1, n=501)*	*8.15*	***0.02***	*0.12*
IMD Group	χ2 (1, n=547)	4.8	0.31	0.09
Diagnosis	*χ2 (1, n=550)*	*8.1*	***0.09***	*0.12*
Extent of disease	χ2 (1, n=553)	0.18	0.91	0.02

Multivariate Logistic Regression Analysis

Direct multivariate regression was performed to assess the impact of those variables shown to have a significant association with whether social function was raised following χ2 analysis (table 3.4), i.e. study, whether the patient held a degree or equivalent professional qualification, and diagnosis, along with the social and functional well-being score from the FACT-G. All variables were categorical data, except the social and functional well-being scale, which was continuous. The model explained between 2.9% (Cox and Snell R squared) and 4% (Nagelkerke R squared) of variance in whether social function was raised, and classified 65.8% of cases correctly. Table 3.4 shows that three of the variables made a unique significant contribution, which were; being a participant in the three-arm study, and having a diagnosis of gynaecological or lung disease. A lung diagnosis was the strongest predictor of having social function raised, with an odds ratio of 2.75.

Table 3.5: Logistic regression predicting likelihood of being raised in discussion

	B	S.E.	Wald	df	Sig.	Exp (B)	95% C.I. for EXP(B)	
							Lower	Upper
Study (three-arm)	*.421*	*.203*	*4.291*	*1*	***.038***	*1.523*	*1.023*	*2.267*
Degree (yes)	.346	.219	2.507	1	.113	1.414	.921	2.171
Gynaecological			*10.199*	*4*	***.037***			
Germ cell, renal, bladder, sarcoma	-.047	.262	.032	1	.857	.954	.571	1.595
Breast	.277	.265	1.100	1	.294	1.320	.786	2.217
Melanoma/ GI/ colorectal/ other	.174	.383	.205	1	.651	1.189	.561	2.522
Lung	*1.010*	*.342*	*8.696*	*1*	***.003***	*2.745*	*1.403*	*5.372*
Social and functional well-being	.002	.023	.007	1	.935	1.002	.957	1.049
Constant	-1.127	.446	6.399	1	.011	.324		

Social function is the most frequently raised, compared with role function and financial concerns. The examples presented demonstrate the wide range of issues that are included within social function, e.g. holidays, family support (or lack of support). Univariate analysis showed that frequency of social function being raised was significantly higher in consultations drawn from the three-arm study, and also patients with a lung diagnosis (table 3.4). This was supported within the multivariate logistic regression, which also showed a gynaecological diagnosis as having a uniquely significant contribution to the model (table 3.5).

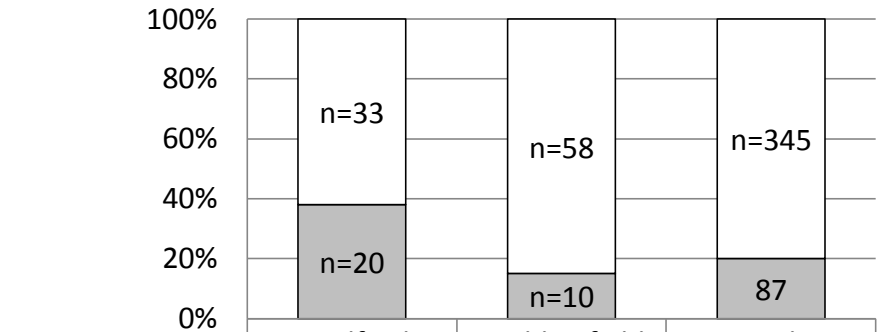
3.4.4.4 Role Function

Role function involves the impact on the patient's role, which may be within their working life and/or the home setting, i.e. the jobs they typically have responsibility for around the house. Example RF1 in figure 3.8 is from a patient who was experiencing hearing difficulties due to one of the chemotherapy agents used in their treatment regimen. As the patient worked as an actor and singer their hearing was a key element in fulfilling their role. In response to these difficulties the patient's doctor reduced the dose of the specific agent causing the tinnitus (bleomycin).

RF1:	Patient:	*"…I've had quite a bit of tinnitus…sounds like someone's put some electronic equipment in my ear…"*
	Doctor:	*"What sort of work do you do?"*
	Patient:	*"I'm an actor and singer."*
	Doctor:	*"So your hearing is fairly important to you?"*
	Patient	*"Yes."*
RF2:	Patient	*"I just do a little bit when I feel like it (housework)…"…"I do a voluntary job and it's at the cancer shop in X, I've been there 18 years…"*
	Doctor:	*"Are you still working now?"*
	Patient:	*"…just a…morning…so I'm able to go in, so they're very pleased…"*
RF3:	Patient:	*"…the next couple of days is* [sic] *a bit tiring (after chemo), I've got an open fire and I've got to go down to the cellar for my coal and just getting a bit of coal can be a task."*
RF4:	Patient:	*"…yesterday I was off work, so I decided I'd get down on my hands and knees and sweep round the skirting boards, but as soon as I bent down it* (prosthetic limb) *was sticking into me…"*
RF5:	Patient:	*"…starting to do little things…I did pick up the Hoover….it pulled too much so I couldn't do it."*
RF6:	Patient:	*"…I haven't stopped doing me* [sic] *errands…"*

Figure 3.8: Examples of role function discussion within consultations

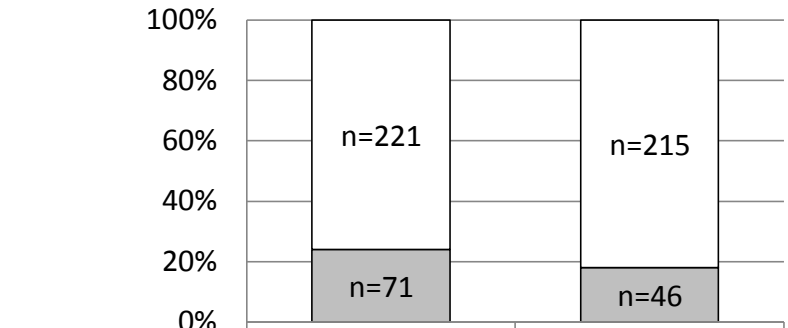
Role functioning was raised in 21% of consultations overall. There was no notable difference in frequency of discussion of role between studies (raised in 20% of consultations in two-arm study compared with 23% of those in the three-arm study). Bradford demonstrated the highest frequency of role function being raised of the three centres (figure 3.9).



	Bradford	Huddersfield	Leeds
☐ RF not raised %	62	85	80
▩ RF raised %	38	15	20

Figure 3.9: Frequency of raising role function (RF) by centre

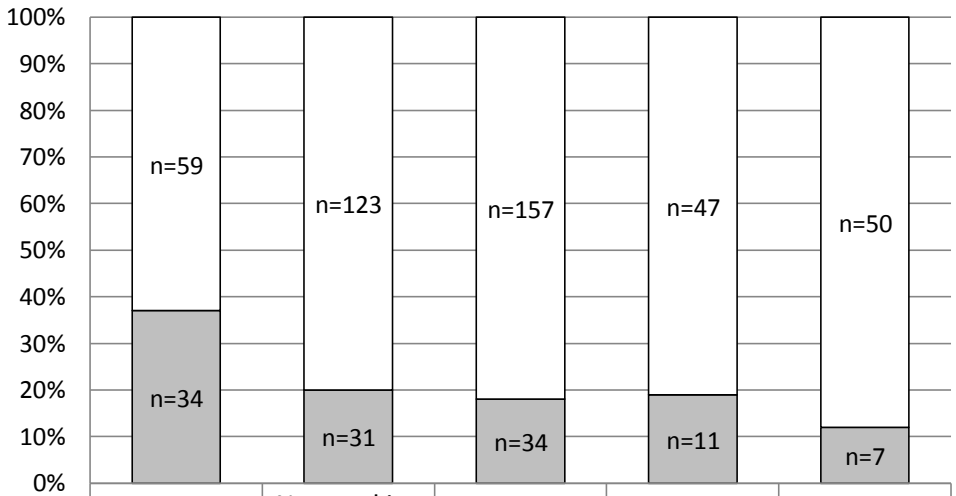
There was no notable difference in frequency of role being raised by gender (24% of males and 20% of females). The younger age group demonstrated a higher frequency of 24% of consultations, compared with 18% of the older patients (figure 3.10). It was also slightly higher in those who were separated/ divorced (33% compared with 19 to 25% in other groups).



	18 to 59 years	60 years plus
☐ RF not raised %	76	82
▩ RF raised %	24	18

Figure 3.10: Frequency of raising role function (RF) by age group

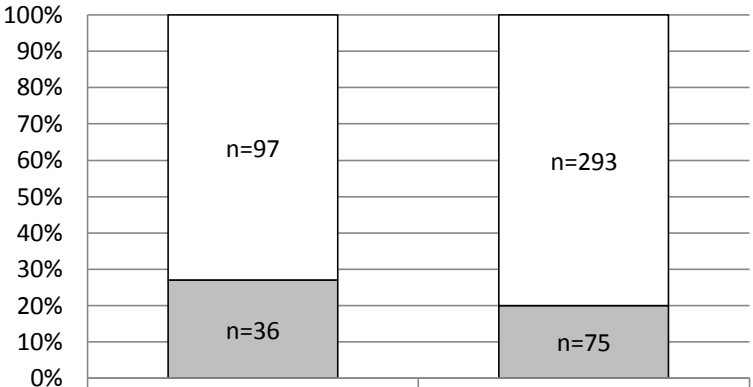
Frequency of role function discussion was much higher in those who were employed compared with other groups (figure 3.11), which was expected.



	Employed	Not working due to illness	Retired	Homemaker / other	Missing
☐ RF not raised %	63	80	82	81	88
▩ RF raised %	37	20	18	19	12

Figure 3.11: Frequency of raising role function (RF) by employment status

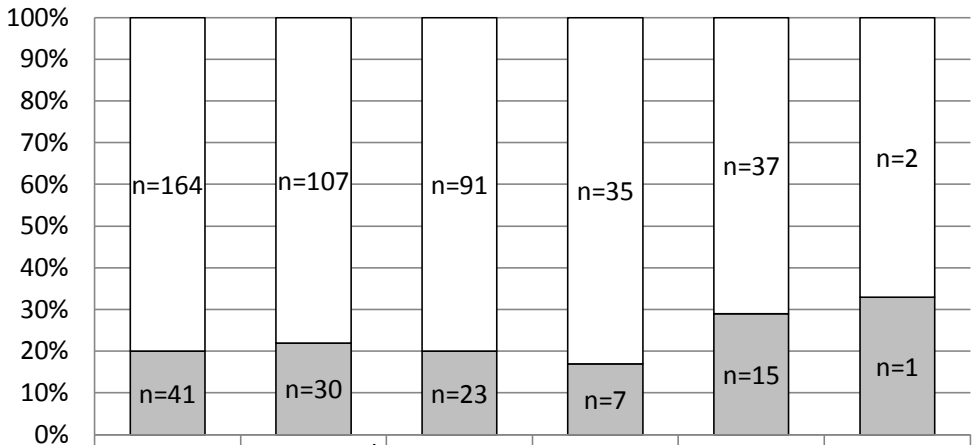
It was also higher in those who had obtained a degree or equivalent professional qualifications than those who did not (27% and 20% respectively, figure 3.10). Twenty-six per-cent of those in the 21% to 60% most socially deprived groups had role function raised, versus 15% to 20% in other groups. Fifteen per-cent was the lowest frequency of the IMD groups and occurred in the lowest 20%.



	Has degree or equivalent	Does not have degree or equivalent
☐ RF not raised %	73	80
▒ RF raised %	27	20

Figure 3.12: Frequency of raising role function (RF) by whether the patient has a degree or equivalent professional qualification

Of the diagnostic groups, those with lung disease demonstrated the highest frequency compared to the other diagnostic groups (figure 3.13).



	Gynaecological	Germ cell/ sarcoma/ renal/ bladder	Breast	Melanoma / GI/ Colorectal / Other	Lung	Unknown primary
☐ RF not raised %	80	78	80	83	71	67
▒ RF raised %	20	22	20	17	29	33

3.13: Frequency of role function (RF) being raised by diagnosis

Those categorised as disease free or with primary local disease had higher frequency of role function being raised than those with local recurrent or metastatic disease (26% versus 18% and 20% respectively).

Univariate analyses

Table 3.6 shows Chi-squared results for each variable against whether role function was raised or not. This demonstrated no significant association between study, geographical location (Leeds, non-Leeds), gender, marital status, levels of social deprivation, diagnosis and extent of disease.

A significant association was seen between whether role function was raised and the centre (p=0.005), with Bradford patients showing the highest frequency (38% versus 15% and 20% in Huddersfield and Leeds respectively; (figure 3.7). Frequency of discussion of role was also significantly associated with the age group of the participant, with role being raised less frequently in the older patient group (p=0.05). Patients in the younger age group (18 to 59 years) had role function raised in 24% of their consultations, versus 18% of those of 60 years and over (figure 3.8).

The patient's occupation also demonstrated a signification association with whether role was raised, with those who reported being employed (full or part-time) having the highest frequency (37% - figure 3.9, p=0.003). Whether the patient held a degree or equivalent professional qualification also had a significant relationship to whether role was raised or not. Those patients who held a degree or equivalent professional qualification had role function raised in 27% of their consultations, versus 20% of those who did not (figure 3.10, p=0.06).

Table 3.6: Results of Chi-Square Test for independence between study, sociodemographic and clinical variables and whether role function (RF) was raised in the consultation

	χ2	Value	p	phi
Study	χ2 (1, n=553)	0.82	0.37	-0.04
Centre	*χ2 (1, n=553)*	*10.7*	***0.005***	*0.14*
Leeds/ non-Leeds	χ2 (1, n=553)	1.23	0.27	-0.05
Gender	χ2 (1, n=553)	1.28	0.26	0.05
Age group	*χ2 (1, n=553)*	*3.69*	***0.05***	*0.08*
Marital status	χ2 (1, n=502)	6.32	0.28	0.11
Occupation	*χ2 (1, n=496)*	*13.9*	***0.003***	*0.17*
Degree/ equivalent qualification	*χ2 (1, n=501)*	*5.8*	***0.06***	*0.10*
Level of social deprivation	χ2 (1, n=547)	6.5	0.16	0.11
Diagnosis	χ2 (1, n=550)	2.6	0.62	0.07
Extent of disease	χ2 (1, n=553)	2.8	0.25	0.07

Multivariate Logistic Regression Analysis

The impact of those variables demonstrated to be significant during univariate analysis was assessed using direct logistic regression, along with the functional well-being subscale score from the FACT-G. All of the variables were categorical, except for functional subscale score, which was continuous.

The regression model explained between 2.2% (Cox and Snell R squared) and 3.4% (Nagelkerke R squared) of variance in whether role was raised, and classified 77.9% of cases correctly. None of the variables included in the model made a uniquely significant contribution (table 3.7).

Table 3.7: Logistic regression predicting likelihood of role function being raised in discussion

	B	S.E.	Wald	df	Sig.	Exp(B)	95% C.I.for EXP(B)	
							Lower	Upper
Degree (yes)	.282	.245	1.327	1	.249	1.325	.821	2.141
FWB	.015	.020	.545	1	.460	1.015	.976	1.055
Leeds	-.388	.258	2.271	1	.132	.678	.409	1.124
Age group – 60 and over	-.286	.246	1.355	1	.244	.751	.464	1.216
Working/ studying/ homemaker	.429	.252	2.904	1	.088	1.536	.938	2.517
Constant	-1.218	.326	13.925	1	.000	.296		

Role function was raised in 21% of consultations overall. The examples show that it includes roles both in the home and in employment, as well as voluntary work.

Although univariate analysis suggested significant associations between centre, age group, occupation and whether the patient had a degree or professional equivalent qualification (table 3.6), none of these made a uniquely significant contribution to the multivariate logistic regression analysis (table 3.7).

3.4.4.5 Financial Concerns

Financial concerns relate to issues around day to day finances or financial services, e.g., insurance or pensions. Example FC6 in figure 3.14 is a quote from a consultation where the patient had left a form to be completed by the doctor, which relates to the patient's pension; the patient mentions how they have to do "...all the 'pushing around'…" The patient in example FC1 is referring to difficulties obtaining health insurance, which is a common issue for patients following a diagnosis[36].

Financial concerns were infrequently discussed, and were only raised in 3% of consultations overall (table 3.9). Due to the low frequency of consultations in which it was raised it was not possible to conduct any meaningful analysis to explore any associations between sociodemographic and clinical variables. As there is no financial item on the FACT-G questionnaire it was also not possible to compare patient-reported financial difficulties and the frequency of discussion in the consultation.

FC1:	Patient:	*"Hopefully, I'm going abroad on holiday…it's just the insurance…they won't insure me for that with having this…"*
FC2:	Patient	*"Is* (CNS) *about, because…we tried to get something towards the fare because it costs us £25 a week to come in, but we couldn't get anything, but there is a…service from Airedale… "*
FC3:	Patient:	*"I'm going down to half pay next month."*
FC4:	Patient:	*I just give you this, it's another of those forms to say that I've been in St James's, and I can claim so much a night from PPP, which you've done before…I might as well claim it because I can give it back to the hospital if I want to."*
FC5:	Patient:	*"There was a lady in the chemo room the other day…we were talking about wigs…which I've got, she's ordered me two to have a look at which one I want, and…the lady opposite me…she got one and it was £35 but I've had to put £53 to…why is it different…?"*
FC6:	Doctor:	*"Thanks for writing to me. I've got a letter on my desk which I have to say I haven't given my full attention to, but I see there's a form attached and I'll fill all of that in."*
	Patient:	*"The problem with this – it's for my pension – is that I'm having* [sic] *to do all the 'pushing around' of the forms…"*

Figure 3.14: Examples of discussions of financial concerns within consultations

Table 3.8: Frequency of financial concerns being raised in consultation by study and sociodemographic and clinical characteristics

		FC raised		FC not raised		Total
		n	%	n	%	n
Study	Two arm	11	3	335	97	346
	Three arm	8	4	199	96	207
Centre	Bradford	3	6	50	94	53
	Huddersfield	1	1	67	99	68
	Leeds	15	4	417	97	432
Geographical Location	Leeds	15	4	417	97	432
	Non-Leeds	4	3	117	97	121
Gender	Male	6	4	146	96	152
	Female	13	3	388	97	401
Age group	≤59	10	4	282	97	292
	≥60	9	4	252	97	261
Marital status	Cohabiting	2	5	39	95	41
	Married	8	3	315	98	323
	Separated/ Divorced	3	8	37	93	40
	Single	1	3	39	98	40
	Widowed	3	5	55	95	58
	Missing	2	4	49	96	51
Occupational status	Employed	4	4	89	96	93
	Not working due to illness	5	3	149	97	154
	Retired	8	4	183	96	191
	Homemaker/ other	0	0	58	100	58
	Missing	2	4	55	96	57
Degree/ Professional Qualification	Yes	4	3	129	97	133
	No	13	4	355	96	368
	Missing	2	4	50	96	52
Level of social deprivation	0% to 20%	2	2	107	98	109
	21% to 40%	6	6	104	95	110
	41% to 60%	3	3	106	97	109
	61% to 80%	4	4	106	96	110
	81% to 100%	3	3	106	97	109
	Missing	1	20	5	83	6
Diagnosis	Gynaecological	5	3	200	98	205
	Germ cell, sarcoma, renal, bladder	6	5	131	96	137
	Breast	3	3	111	97	114
	Melanoma, GI, colorectal, other	2	5	40	95	42
	Lung	2	4	50	96	52
	Unknown primary	1	50	2	67	3
Extent of disease	Disease free/ primary local	3	2	126	98	129
	Local recurrence	1	2	49	98	50
	Metastatic	15	4	359	96	374

3.4.4.6 Summary of key findings

Financial concerns are not frequently raised in standard clinical consultations (raised in only 3% of the sample analysed). Social and role functions are more frequently discussed; 32% and 21% of sample analysed respectively. Participants report better functioning in the social and family well-being subscale than in functional well-being, with scores heavily skewed to the high scores, which denotes better functioning (figures 3.2 and 3.3). Univariate analysis suggested a potential relationship between whether social function was raised and the following variables; the study the patient participated in, whether they held a degree or equivalent professional qualification, and their diagnosis (table 3.4). The study and diagnosis of lung or gynaecological disease were also shown to have a uniquely significant contribution to the multivariate logistic regression analysis, therefore supporting the univariate findings (table 3.5).

Univariate analysis suggested associations between whether role function was raised and centre, age group, occupation, and whether the patient held a degree or equivalent professional qualification (table 3.6). However, these variables were not found to have a uniquely significant contribution to the subsequent multivariate logistic regression (table 3.7).

Independent samples t-tests showed no significant differences in distribution of social and family well-being or functional subscale scores between groups who had social function or role function was raised or not respectively. This was supported by the logistic regression, which showed no contribution from subscale scores to the models (tables 3.5 and 3.7).

3.4.4.7 Case studies

In order to illustrate the findings presented here, two patients were selected and more detail on their individual situation extracted from their records and described below.

Case Study 1: 36 year-old male sarcoma patient

This patient's original diagnosis was synovial sarcoma of the calf, which was resected in 2003. He then returned to work as a painter and decorator. In November 2004 he was diagnosed with pulmonary metastases, for which he was receiving chemotherapy at the time of the study. His baseline consultation for the purposes of the study took place following his second cycle of chemotherapy. The focus of this consultation was

to review results from a recent scan and discuss whether chemotherapy was worth continuing. He went on to complete six cycles and had a brief period of stable disease before progression and referral for palliative care in September 2005.

His score on the baseline FACT-G functional well-being subscale was 1/ 28 (combined study population mean was 15.64), suggesting very poor function. His key difficulties were breathlessness and pain caused by the disease, which meant that he could no longer work in his previous role as a painter and decorator. Role was not raised in this particular consultation. Social function was recorded as being raised during the consultation, but on reviewing the audio this was just him mentioning that he had a 9 year old daughter. His FACT-G social and family well-being subscale score was 9/ 24, which is close to the average for the combined study population mean of 9.72.

Case Study 2: 59 year-old female breast patient

This patient had extensive metastatic breast disease. She had previously run her own business, but was no longer able to work due to her disease. She had significant mobility issues caused by both disease and long-standing back problems, and was incontinent. Role functioning was raised in her consultations, as herself and the doctor discussed how active she used to be and ran her own business, but was no longer able to work, and struggled to do jobs around the house as she could not stand for very long. Her score on the functional well-being subscale was 1/28, compared with the combined study population mean of 9.72, reflecting her mobility problems and her inability to work due to illness.

She lived with her husband, who was her main carer, but he also had mobility issues due to a problem with his shoulder and back; this was coded as social functioning. This caused a particular difficulty as she required the use of a commode but her husband's physical problems meant he found it very difficult to get her on and off it. The doctor offered her a catheter, but the patient was not keen on this idea as it would limit her mobility further, and she wanted to keep as mobile as possible for as long as possible. She received great support from her husband and family, and her social and family well-being score reflects this at 17/ 24.

3.5 Discussion

Patients reported better functioning in the social and family well-being subscale (mean =16.67), when compared with the functional well-being functional well-being subscale (mean=9.72). Only 1 person scored 0 (i.e. lowest possible functioning) on the social and family well-being subscale, compared to 15 scoring 0 on the functional well-being score.

The social and family subscale covers items relating to the emotional support and closeness experienced by the patient from their family and friends. The functional subscale includes ability to work and the fulfilment provided by work; as 28% of patients were unable to work due to illness, this may have influenced the lower scores on this subscale. The functional subscale also includes items relating to general enjoyment of life and things the patient 'usually (do) for fun', and contentment with quality of life. As the data was taken from patients on active treatment, it is likely that the side effects of treatment were having an impact on these areas of life, and therefore the responses to these items. This suggests that even when patients are experiencing impact on their functional well-being due to active treatment and symptoms of disease, their social and family well-being may not be impacted to the same extent. Indeed, there is an emerging body of research on the positive impact of the cancer experience for both patients and carers, in terms of developing resilience and re-evaluating their lives and relationships [15, 16]. This shared experience of benefit-finding in a significantly traumatic life event may indeed strengthen some relationships [15].

These scores compare less favourably with published US cancer patient scores (social and family subscale mean =22.3, functional well-being mean =18.8) and normative data from a sample of the US general adult population, (social and family subscale mean =19.1, functional well-being mean =18.5; table 3.2) [13]. This sample included a variety of patients, and there was no clear data on whether patients from other study data were on active treatment; this is the likely cause of the low functional well-being scores in the sample presented here [13].

Social functioning and role functioning were raised more frequently than financial concerns, which were raised in only 3% of all consultations. On univariate analysis, significant associations were found between frequency of discussion of social function

and the study in which the patient had participated in, whether they had a degree or equivalent professional qualification, and their diagnosis. The logistic regression carried out supported the significance of the study from which the data was taken (the three arm study had a higher frequency) and demonstrated a trend in that those with a gynaecological or lung diagnosis had social functioning raised more frequently. Whether role function was raised appeared to be influenced by centre, occupation and whether the patient had a degree or equivalent professional qualification on univariate analysis, with occupation being shown as the only factor to have a uniquely significant contribution to the logistic regression model.

As this is baseline data for participants, the difference in randomisation allocations between the two studies cannot account for the difference. However, clinicians involved in the three-arm study will have seen responses from patients in the intervention arm as the study progressed. This could have caused them to become sensitised to the issues dealt with on the questionnaires, and potentially increased the likelihood of these areas being discussed [2]. Other differences between the two studies that may influence discussion may be; the time of the study, and different centres and therefore different clinicians. The influence of the centre was studied as an individual factor and not found to be significant in terms of discussion of social function, but did appear to have an influence on whether role was raised. The timing of the studies, i.e. the year in which they were conducted could be significant in terms of the progress of delivery of communication skills training. The NICE Supportive and Palliative Care Guidance published in 2004[17], recommended the provision of Advances Communication Skills Training (ACST) for all HCPs working within oncology and palliative care. It would be expected that the advent of this training occurred prior to either of the RCTs presented here, that this could influence the frequency of issues such as those considered here. However, the findings from this analysis suggest that the first of the two RCTs from 2004 had the highest frequency of discussion. This does not fit with the suggestion that increased delivery of ACST would influence the frequency of discussion. There is also some debate on the effectiveness of ACST on patient experience [18].

Whether the patient held a degree or equivalent professional qualification was shown to have an influence on whether both social and role functioning were raised.

Previous studies have shown that patients with higher levels of education are more likely to be more active participants in the clinical consultation [19]. This increased engagement in the consultation by the more highly education patient may account for the higher frequency of discussion of social and role functioning.

The patient's diagnosis also influenced whether social function was raised, specifically those with a diagnosis of lung or gynaecological disease. The influence of a gynaecological diagnosis, as a female-only disease, may be related to gender; women have been reported as being more likely to express negative feelings and concerns within consultations [19]. Amongst lung patients in this sample this is not likely to be the case as the genders of patients were fairly balanced (n=29 versus 23 females). Patients with a diagnosis of lung cancer have been found to be more active participants in consultations in other studies, but this was in comparison with patients from non-oncology settings [19].

On examining actual quotes from the consultations analysed, it appears that social and role issues may be closely linked to physical functioning. For example, as a result of a general question regarding mobility, a patient started to discuss how they were still able to play golf (social function), another started to talk about how they were still managing to do the shopping (role function). This suggests that social and role functioning may be more likely to arise as a result of an originally medical line of conversation. This could potentially make it easier for the patient to mention these issues.

Due to such low frequency of discussion of financial concern, it was not possible to conduct any meaningful analysis to explore associations between sociodemographic and clinical data and whether financial concerns were raised. Financial concerns may not be so easy to raise as part of the general medical discussion, and may generally be considered more sensitive and potentially embarrassing. Findings in other literature suggest that patients do not feel the clinical consultation is an appropriate place to raise financial issues [20]. In comparison to social and role function, finances are a very specific topic, whereas social and role function include a number of issues that can be classified as relating to that function. The higher frequency of social and role functioning may also be explained, as even a brief mention of issues relating to these functions were coded. For example, "I haven't stopped doing me errands…" (Quote

RF6), is a simple statement from a patient but has been coded as a role function being raised. This may be a limitation caused by the simplification of the coding from discriminating between 'mentioned' and 'discussed' in the original analysis to 'raised' and 'not raised' in this analysis.

As there is no financial item or subscale on the FACT-G questionnaire it was also not possible to compare any patient-reported level of difficulty in this area and whether financial concerns were raised. However, patients do raise financial issues, albeit infrequently. As the earlier examples show, this is often when there is some practical response that may be required from the doctor, e.g. completion of forms to provide medical information, or advice about the cost of wigs. Evidence from audio-recordings shows that completion of forms and providing advice on holiday insurance is standard practice for doctors.

This analysis suggests that there is no significant association between scores reported on the FACT-G questionnaire and whether the related issues are discussed. This suggests that even when patients are experiencing poor functioning in some areas, this does not guarantee that the concerns will be raised in the consultation with the doctor. The potential barriers to discussion of psychosocial issues within this context are well reported and outlined in table 1.1 in chapter 1[21]. For example, staff and clinicians may have defined views on what issues are appropriate for discussion and resolution within the medical consultation. Doctors report time and busy workloads as a common reason for reluctance to begin a dialogue on potentially emotive issues [21]. Other analyses from these studies have demonstrated that patient and clinician preferences for what they would like to discuss during the consultation does not account for low frequencies of discussion [2].

There are a number of factors that will influence what issues are raised in the consultation. This may be individually influential and/ or may have an interaction with other variables [19]. The aim of this analysis is not to explore the barriers exhaustively, but rather to identify the key barriers and tailor the proposed interventions to overcome these effectively in a way that is both compatible with existing practice and offers *relative advantage* on current standard care.

The sociodemographic and clinical profiles of the patients in these studies may not be representative of the general population attending the Leeds Cancer Centre and other

units within the region. This should be considered when interpreting the results of the analysis.

It should also be considered that at the time of these recordings the patients would be undergoing active chemotherapy regimens, having had a minimum of two cycles. This means that the format of their consultation is likely to focus on their clinical status and side effects. The case study presented in section 3.4.4.7 highlights two of these issues; 1) how simple statements have been coded as social function, and 2) how the focus of the consultation is on the symptoms and side effects of disease and treatment.

These results show that participants were functioning better in the area that was also seen to be more likely to be discussed in the consultation. This analysis does not go far enough to provide evidence of a causal effect. It was also important to explore the impact of the study from which the data was sourced. The different studies introduced a number of variables, including the hospital site, disease groups (different diseases are treated at different sites), doctors, patients, and the timing, as there were a number of years between the studies. Timing would be particularly important if the second study came after the advent of increased formal communication skills training. However, no effect was noted.

One of the aims of this section of analyses was to identify if there was an association between scores on the FACT-G and the impact of this on the likelihood of the related issues being discussed in the consultation. The EORTC QLQ-C30 was provided as an intervention in both of the studies from which the data had been sourced. To use EORTC QLQ-C30 scores may therefore have introduced bias, as the patients' may have had increased awareness. It would also only have allowed analysis of a sub-set of data. This required 'matching' FACT-G scores to consultation data derived from an EORTC QLQ template. This was achieved by matching items from each instrument to identify which subscales on the FACT-G most closely matched the functions captured by the EORTC QLQ-C30. Previous work has shown that physical, emotional and functional scores could be equated between the two items, but that the social subscale scores could not be matched as accurately [22]. Although this is a potential limitation its impact is likely to be minimal as the analysis did not involve matching scores from the two questionnaires directly.

A possible limitation of these findings is that the findings relate to data collected a number of years ago. More data from consultations will be collected throughout the course of this work and will allow a comparison and further exploration of the impact of time and whether increased awareness of the need for holistic care and communication skills will impact the clinical consultation.

Another issue was how to distinguish between role and social functioning issues, as there was often overlap. For example, the activity of shopping would often be coded as role functioning, if in the context of the weekly food shop for the family. On the other hand if someone was going shopping with friends this would be considered social. This was an issue that was often faced during the consultation analysis.

3.6 Conclusions

These findings support a wealth of existing evidence that for patients on active treatment, the format of the clinical consultation remains, in the main, medical. However, social difficulties are discussed, although some issues such as financial concerns may be raised infrequently. This suggests that interventions whose aim is to increase this discussion and subsequent detection of social difficulties, such as those I propose to develop and test within this thesis will not be entirely incompatible with existing practice. These issues are raised, just not frequently or as routine practice. The compatibility of the interventions and the effects they may have are vital to the adoption and therefore impact of the innovation. This is important in considering the development of interventions, specifically the staff and settings involved at the point of delivery to the patient. Delivery by oncologists within the setting of such appointments may be incompatible, considering the barriers such as time that already exist. The alternative setting would be delivery by nurses outside of the typical clinical consultation. The feasibility of this delivery will be explored in future chapters.

Another key issue is *relative advantage*. This analysis shows that even when patients are experiencing difficulties with some functions, this does not guarantee that the concerns will be raised with the doctor. Therefore interventions that will help to make these discussions more frequent and part of routine practice will offer an advantage to existing standard care. The next chapter will explore the issue of *relative advantage* further, by establishing the level of unmet need in a sample of patients.

Chapter 4: Levels of unmet need for social difficulties, and potential impact of routine assessment

4.1 Overview

The previous chapter explored the content of doctor-patient consultations for two reasons; to inform the development of interventions to ensure that they are compatible with standard practice, and also for later comparison with post-intervention consultations. This highlighted that while medical issues form the bulk of the clinical consultation, some social difficulties are raised in this setting, albeit with varying frequencies. Therefore interventions that aim in part to increase the frequency with which these issues are discussed in this setting are not entirely incompatible with current practice. In terms of DoI theory, this *compatibility* is important to the success of adoption of the proposed interventions[73].

Concerns may exist that introducing interventions to increase detection of problems, (particularly a detailed assessment of patients' social difficulties) will increase the time staff spend on advising patients and bureaucracy related to interventions required. For example, this could generate extra referrals, increasing workload both for those identifying the problems and the service to which the referral is made. It is important to estimate this potential increase in workload; if this is seen to be unmanageable it may negatively influence the adoption of the interventions. Oncology staff already report higher rates of burnout than colleagues in other specialties, making this an important consideration [58, 146]. This would result in an intervention being viewed as incompatible with current practice in an already stretched service, which would negatively affect its adoption.

However, an observable improvement in patient care and wellbeing as a result of the interventions may lead to improved relationships between doctors and their patients, and a subsequent increase in patient satisfaction with care. This could have the knock-on effect of increased job satisfaction for oncology staff, which has a protective effect on their mental health [58, 74]. These factors would provide evidence of the *relative advantage* of implementing the interventions when compared with current standard practice.

The goals of this chapter are; 1) to assess the level of unmet need in terms of social difficulties, and try and quantify what proportion of a group of patients may have

difficulties that have not yet been dealt with; 2) to assess the potential increase in workload created by a detailed assessment of social difficulties. This information is vital to the concept of *relative advantage* in terms of diffusion of innovations. If evidence can be provided of the unmet need of patients, whilst offering a method to deal with this that is compatible with existing practice, this will result in an intervention that is both compatible and an improvement on existing care (*relative advantage*), two key components of a successful adoption of an innovation[73].

A cross-sectional study was conducted to establish the clinical meaning and utility of the SDI-21 (reported elsewhere)[54]. The opportunity was taken to undertake secondary analysis on existing data from this study to establish the level of unmet need, and also to identify any potential increase in interventions and workload that may result from detailed assessment of social difficulties.

4.2 Original study methods

The original cross-sectional interview study was conducted to examine the clinical meaning and utility of the SDI-21. Patients were recruited from a regional Cancer Centre, specifically from outpatient or day units in haematology, medical and clinical oncology, and chest medicine. Sociodemographic and clinical data was collected for both participants and non-participants.

Participants were asked to complete four questionnaires on a touchscreen computer. These were; the Social Difficulties Inventory (SDI-21 – appendix 1b)[147], the Hospital Anxiety and Depression Scale (HADs – appendix 4)[141], the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30 – appendix 3)[140] and the Close Persons Questionnaire (CPQ – appendix 5)[148]. Patients were also asked to consider each of the SDI-21 items and state if they felt they would have benefited from help with that area.

Following completion of the touch-screen assessment, patients were asked to participate in an interview with Dr Penny Wright (PW), who is a researcher with a medical social work background. The interview was conducted within a week of completing the touchscreen. To ensure unbiased comparisons between the patients' responses, PW was blinded to the patients' touchscreen data. The interviews were audio-recorded, semi-structured, and lasted for around one hour.

The interview began by asking the patients for an overview of their individual disease and treatment regime. They were then asked in more detail about each of the subscales and single items of the SDI-21, which were derived from factor analysis undertaken in a previous psychometric study of the SDI-21[43] (figure 4.1). Patients were asked about any difficulties they had experienced within these subscales or items over the previous month, whether a resolution had been reached, and if so, how this was achieved or what issues were outstanding. Further questioning was dependent upon the responses provided by the patient. Where an outstanding need had been identified, this was discussed further. At the close of the interview and with agreement from the patient, PW provided interventions for these difficulties, either in the form of information, or a referral to the appropriate supportive service. This section of the conversation was not recorded, but PW made hand-written reports that included details of and motivations for interventions.

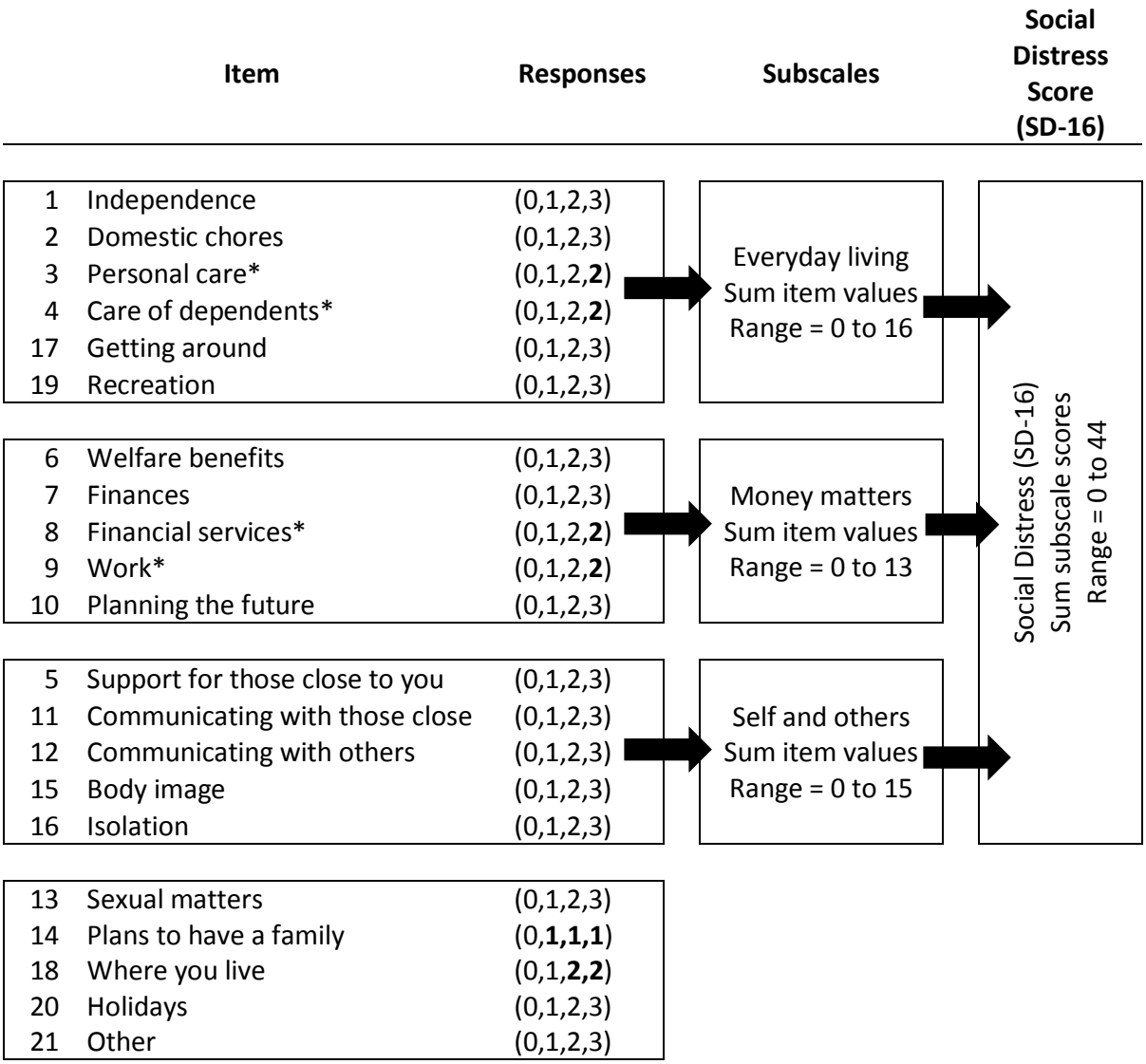


Figure 4.1: Scoring method for SDI-21

4.2.1 Original study analysis

Pearson's Chi-Squared [χ^2] analysis and t-tests were used to explore differences between participants and non-participants. Post-interview interventions were classified as provision of information or referral to support services. In order to validate the cut-off score and inform early development of guidance on use of the SDI-21 for the original study, counts of the post-interview interventions were taken.

4.2.2 Current analysis

4.2.2.1 Aims

The aims of the secondary analysis reported here were to assess the level of unmet need in terms of social difficulties, and identify any potential increase in required interventions that may occur as a result of detailed assessment of social difficulties.

4.2.2.2 Objectives

I. Describe the proportion of participants for which further intervention was required.
II. Explore any associations between the sociodemographic and clinical profiles of those who required any intervention and those who did not.
III. Describe the nature of the interventions made, categorised as;
    a. information provision,
    b. referral to another service,
    c. both information provision and referral to another service.
IV. Describe and categorise the topics on which information was provided, and describe frequencies for each
V. Describe the services to which referrals were made
VI. Describe the rates of referral to each service
VII. Describe the motivations for provision of the interventions

4.2.2.3 Methods

Descriptive analyses of the socio-demographic and clinical data, and the number and nature of interventions were carried out as part of the original study[54]but were repeated and checked as part of this secondary analysis. At the time of the original study and the secondary analysis reported here, only historical local audit data from 2006 were available for comparison. These data reported on referrals from a dedicated radiotherapy unit to local support services. Referrals from outpatient clinics to the on-site social work team were 3.2%, and the referral rate from the cancer centre to psychosocial services (clinical and health psychiatry and liaison psychiatry) was 1.5%[54].

Univariate (Pearson's Chi-Squared [χ^2] analysis) was used to explore associations between available sociodemographic and clinical data and whether an intervention was required.

Counts were taken of the number of participants receiving one or more interventions, the nature of the intervention(s), the service to which patients were referred and the topic of information provided. The reasons for providing interventions were categorised according to the most common themes. These categories included; welfare benefits or finance, communication difficulties, body image, sexual difficulties, requirement for disabled parking (Blue Badge) and isolation. Combinations of reasons were recorded where appropriate. Where the participant required general support for an unspecific issue, this was categorised as 'uncertainty and adjustment' or 'general coping'. These categories relate to matters around adjusting to the impact of the diagnosis and treatment. Counts were taken of the categories of reasons for interventions.

4.3 Results

4.3.1 Sociodemographic and clinical data

There were 183 participants who completed the original study in full, and who were therefore included in this analysis. Socio-demographic and clinical profiles of the participants are shown in table 4.1. The sociodemographic and clinical profiles of these patients were compared to those included in the analysis presented in chapter 3. Although there were similar patterns between the two groups in the majority of variables, there were many more females in the sample analysed in chapter three, which is related to the high number of patients recruited from gynaecological clinics.

Table 4.1: Socio-demographic and clinical details of participants			
		n	**%**
Gender	Male (median age 60 years, range 18 to 88)	98	54
	Female (median age 54 years, range 23 to 87)	85	46
Marital status	Single	18	10
	Married or cohabiting	136	74
	Separated or divorced	16	9
	Widowed	13	7
Who do you live with	Immediate family	157	86
	Friends	1	1
	Alone	23	13
	Other/ missing	2	1
Accommodation	Owner-occupier	143	78
	Renting privately	10	5
	Renting from council	23	13
	Other	7	4
Occupational status	Full time employment (inc homemaker)	81	44
	Unemployed	19	10
	Student	2	1
	Retired	74	40
	Other	7	4
Working hours	Working same hours	29	16
	Working less hours	18	10
	Not working	132	72
	Working more hours	4	2
Degree/ equivalent professional qualification	Yes	55	30
	No	128	70
Ethnic origin	White	173	95
	Black Caribbean/ African	3	2
	Not disclosed	7	4
Diagnosis	Head and neck (including neurological)	7	4
	Lung	24	13
	Genitourinary	14	8
	Germ cell	12	7
	Haematological	21	11
	Gastro-intestinal	37	20
	Breast	27	15
	Gynaecological	24	13
	Sarcoma	7	4
	Melanoma	10	5
Extent of disease	Disease free	60	33
	Primary local	34	18
	Local recurrent	5	3
	Metastatic	61	33
	Other	23	13

4.3.2 Frequency of requirement for interventions

Interventions provided to patients were classified as information provision, referral to another service, or both. Of all participants included in this secondary analysis (n=183), 59% required no additional intervention for any outstanding need (n=108). Information on why no further help was required was only available for 18 participants. In all 18 of these cases, the individual cited the support already in place, which included a Macmillan Nurse (n=5), Social Work (n=3), their GP (n=2) or a legal adviser (n=1). Seven patients described a support network made up of a combination of services and/ or personal sources of support, including family members and a psychiatrist. One example of this is a patient who was attending the hospice one day per week, but who also had a designated Macmillan Nurse, support from district nurses as well as their CNS.

Additional interventions were provided post-interview to the remaining 41% of patients (n=75). Of these, 42 patients were provided with information, 28 were referred to another service (three of whom ultimately declined the service), and 5 patients were given information and referred on to another service.

4.3.3 Associations between sociodemographic and clinical variables and requirement for intervention

Table 4.2 shows Chi-squared results for each variable against whether an intervention was required. This demonstrated no significant association between any of the sociodemographic variables apart from who the patient lived with and whether an intervention was required. It was not possible to include ethnicity in the Chi-squared analysis, due to small numbers of participants in the non-white or not disclosed group.

The patient's diagnosis also had no significant association with requirement for an intervention. A significant association (≤0.1) was seen between whether an intervention was required and who the patient lived with the extent of disease (table 4.2). Participants with metastatic disease accounted for 44% of the patients receiving an intervention, compared with 19% from the disease free group and 23% from those with a primary local diagnosis or locally recurrent disease. For the remaining 15% the extent of disease data was unavailable.

Table 4.2: Results of Chi-squared tests for independence between sociodemographic and clinical variables and whether an intervention was required

		Value	p	phi
Gender	χ2 (1, n=183)	0.12	0.726	-0.10
Age group	χ2 (1, n=183)	0.03	0.875	0.05
Marital status	χ2 (1, n=183)	5.15	0.161	-0.05
Who you live with	*χ2 (1, n=182)*	*2.81*	***0.094***	*0.007*
Accommodation	χ2 (1, n=183)	0.89	0.343	0.04
Occupation	χ2 (1, n=183)	0.001	0.972	0.13
Working hours	χ2 (1, n=183)	3.851	0.146	0.07
Degree/ equivalent qualification	χ2 (1, n=183)	0.031	0.859	0.12
Diagnosis	χ2 (6, n=183)	3.088	0.798	0.130
Extent of disease	*χ2 (1, n=183)*	*12.621*	***0.006***	*0.02*

4.3.4 Information

Including the five patients who received both interventions, 47 patients were provided with 67 'items' of information in total (accounting for 26% of all participants). Figure 4.3 shows the topics on which information was provided. Percentages shown are of the total number of items (n=67). Holidays were the most common topic on which information was provided (27% of all items). Most of the information provided on holidays was regarding holiday insurance (14/18 items). Support centres or groups, and welfare benefits and finance each accounted for 13% of all information items provided. Information on welfare benefits and finance was general advice on entitlement and accessing the most appropriate service. Eleven per cent of all information items provided were on Social Work, which consisted of contact details to allow self-referral, and general advice on what the service may be able to assist with. 'Other' areas of information included careers service, complementary therapy, how to contact the CNS, and advice regarding having a water meter installed.

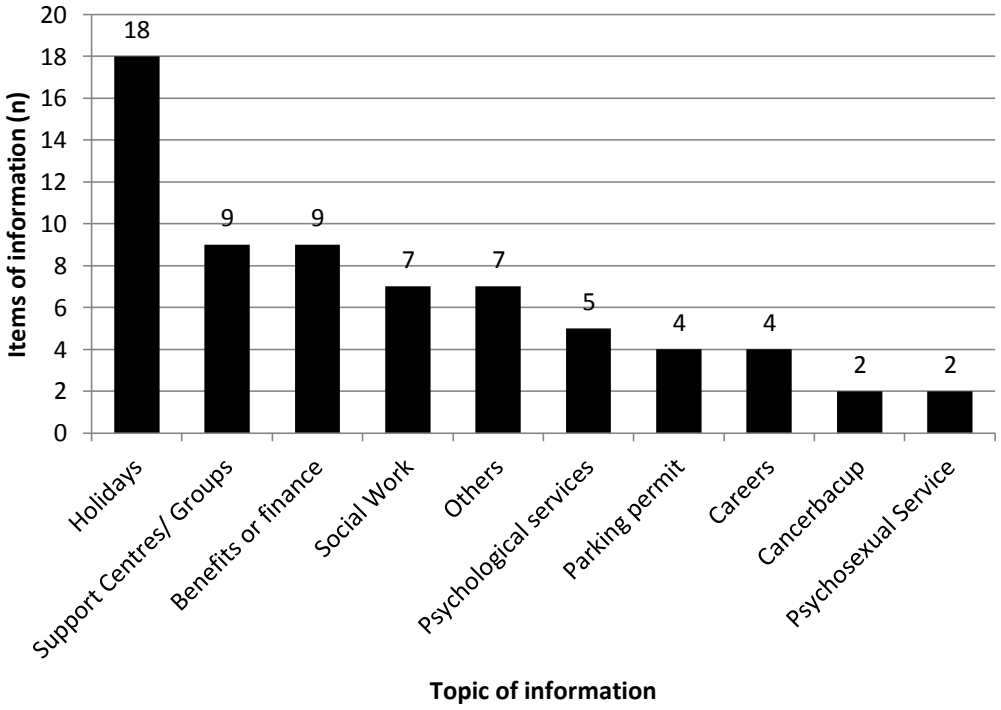


Figure 4.2: Topics on which information was provided

4.3.5 Referrals

Including the five patients that received both interventions, a total of 36 referrals were made for 33 patients; three participants were referred to two services. The overall referral rate was 18%, which included cases where both interventions were provided. Figure 4.4 shows the frequency of referrals to support services. The majority of referrals were to social work (61%, n=30). Three patients were referred to social work in combination with a referral to another service (dietician, Look Good Feel Better and psychological services).

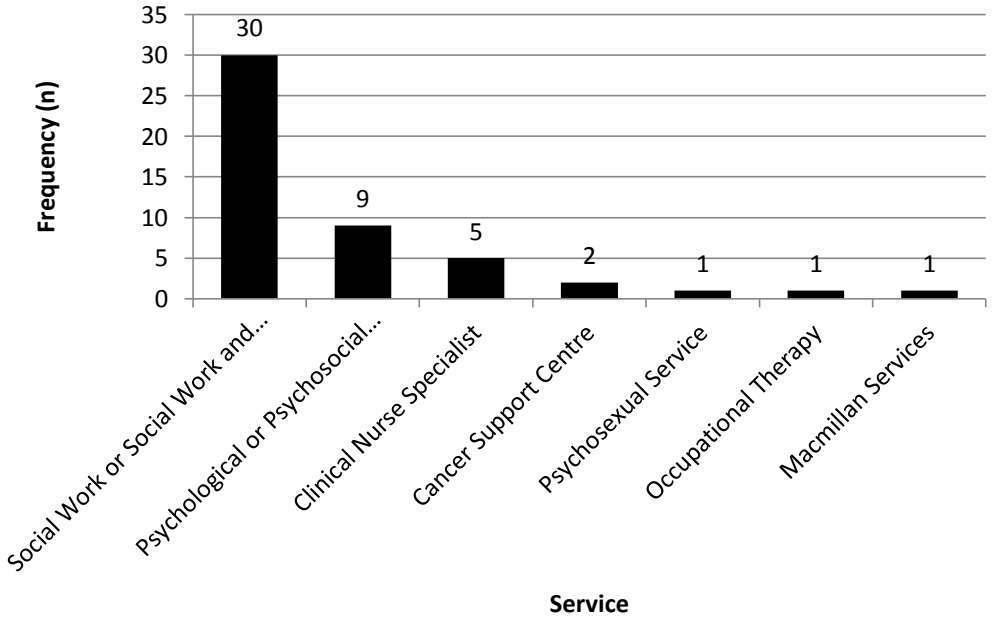


Figure 4.3: Frequency of referrals to support services

Table 4.3 shows the services to which patients were referred, and the reasons for referral. Forty-nine reasons were cited for the 36 referrals made. The most common reason for referral was to discuss welfare benefits and/ or finances (42%). The majority of referrals for welfare benefits or financial issues were to a social worker, with others to a Macmillan nurse and a Clinical Nurse Specialist (CNS). Other referrals to the CNS were made for a combination of communication difficulties, body image, and uncertainty and adjustment (n=1) and sexual difficulties (n=1). Uncertainty and adjustment issues were cited as the reason for referral in 14% (n=7) of all referrals; in 6 of these cases this was listed as one of a combination of reasons.

Table 4.3: Reasons for referral by service

	Service						
	Social Work Or Social Work and Other	**Psychological or Psychosocial Services**	**Clinical Nurse Specialist**	**Cancer Support Centre**	**Psychosexual Service**	**Occupational Therapy**	**Macmillan Services**
Welfare benefits or finance	16		1	2			1
Coping/ adjustment	2	4	1				
Parking Permit	5						
Body Image	3	1	1				
Unknown	1	2				1	
Communication difficulties	1	1	1				
Isolation	1	1					
Sexual difficulties			1		1		
Planning the future	1						
Total	30	9	5	2	1	1	1

4.4 Summary of key findings

Over half (59%) of the 183 participants did not require any intervention over and above the support they were already receiving as standard care. Only 3% of all patients required both information and a referral to a supportive service. There was a significant association between the extent of a patient's disease and their requirement for an intervention, with those with metastatic disease accounting for the majority of patients who received an intervention.

The bulk of information provided was on holiday-related issues, specifically holiday insurance (27% of all information items provided). The majority of referrals were made to Social Work, either as a stand-alone referral or in combination with another service (n=3). The main reason for referral was relating to welfare or finance (42% of all reasons for referral).

4.5 Discussion

In total, 40% of patients attending routine outpatient appointments required an intervention for social difficulties following completion of the SDI-21 and an interview with a social work researcher (PW). Around half of these people required information only. Referrals to social work accounted for over half of the overall referral rate, and most were for welfare benefits information. Other referrals for finances were made to cancer support centres, Macmillan Nurses and a CNS.

Uncertainty and adjustment issues were defined as non-specific concerns that could not be identified as relating to a specific item on the SDI-21, i.e. general worry regarding or coming to terms with diagnosis. Half of these were to social work, three to psychological services and one to a CNS. Applications for the disabled badge parking scheme accounted for 10% of referrals. Social work was also involved in three of five referrals made for body image issues. The majority of information provided was in the context of 'signposting' patients in the direction of the appropriate service, e.g. providing a list of contact details for specialist insurance companies. Other information commonly provided in this way was on contacting support groups/centres and welfare benefits. Only 14% of information provided was noted as being on more miscellaneous subjects that may not be readily linked to an existing service.

The findings and recommendations made in key guidance documents [11-13] and previous analysis in this thesis (chapter 3) are mirrored in this analysis, suggesting that identification of social difficulties in routine care may still be limited, with 41% of patients still living with unresolved issues at the time of participation. In around half of these cases, increased accessibility of information may have avoided the problems with which patients presented. The findings regarding reasons for referral also demonstrate this. For example, provision of a leaflet on welfare benefits and disabled parking could potentially reduce referrals. This has implications for staff training. Whether identification of social difficulties happens through formal channels or through informal discussion in the waiting room, it is important that the staff know how to advise patients once an issue is raised. Consideration of these factors in implementing an assessment would help to optimise use of staff and patient resources and minimise the impact on workload and services, increasing its compatibility and therefore likelihood of adoption. It is important to note that many of the issues raised were relatively minor and could be solved with minimal input from staff.

This analysis demonstrated that there were no significant associations between sociodemographic characteristics or diagnosis, and whether an intervention was required. A significant relationship was seen between the extent of disease and whether an intervention was required, with patients with metastatic disease making up the greatest percentage of the intervention group. This is likely to be related to the progression of the disease and reflects this increasing burden on the patient. As the symptoms and impact on functioning experienced by the patient also progress, their needs may become increasingly complex. This burden is felt not only by the patient, but on caregivers and health professionals responsible for their care [14].

During this study, difficulties were assessed in a rigorous way by discussion with an experienced researcher, trained in medical social work. The discussion may have identified more problems than can be expected in routine clinical practice. Although the work within this thesis aims to determine the best application of the SDI-21 in this setting, it is unrealistic to expect that each patient would go through such a detailed process. This report demonstrates a referral rate to social work of 11%, which is higher than that reported locally (a local cancer unit—3.2%), perhaps reflecting the experience and background of the researcher and the rigorous data collection in a

research project. Similarly, a 13% increase in referrals to psychosocial services (clinical and health psychology and liaison psychiatry) is also demonstrated, up from 1.5% in the local historical data (a local Cancer Centre) to 20% in this analysis.

This suggests large increases in workload. However, providing effective information on services may potentially have reduced these figures by ensuring information was accessible to patient, to enable self-referral where appropriate, e.g. accessing support groups for body image issues or information on disabled parking permits. Coping and adjustment issues are more likely to be complex needs, requiring intervention over and above information provision, and therefore, these have not been included in this estimated reduction. The researcher's knowledge of patient eligibility and available resources resulted in referral where there was no specific difficulty, but the patient was unaware of an entitlement to welfare benefits. This again highlights the importance of good signposting and accessibility of information.

Throughout this analysis, an assumption has been made that referral to another service would be the most time consuming of the interventions. Specific timescales may depend on a variety of factors, e.g. the knowledge base of the referrer, the service to which the referral is being made (i.e. their processes and availability) and the lines of communication between the two. Information provision should be the least time consuming, but is dependent on the nature of the problem and the type and availability of information. Studies to assess the impact of information provision to patients on referral rates, communication on these issues during clinician contact, process of care and patient outcome measures are described in chapter 6 of this thesis. The availability and processes of information provision are subject to variability between sites and health care service providers.

4.6 Conclusions

In conclusion, in-depth assessment of social difficulties appears to increase referrals, but increased availability and accessibility of relevant, high-quality information for patients could reduce the need for interventions. The information required could be made available as leaflets or other resources that patients can access in the waiting room. Implementation of the SDI-21 by trained staff has the potential to increase the frequency with which social problems are identified and dealt with, fulfilling the requirements of the Cancer Reform Strategy[63].

These findings suggest the identification of social difficulties in routine practice is limited. This reflects findings in key guidance documents [12, 63], and the evidence provided in chapter 3. In 56% of cases, increased accessibility of information may have avoided the difficulties. This has implications for staff training, as they need to know how to advise patients. These factors should be considered to optimise staff and patient resources.

Detailed assessment of social difficulties appears to have increased referrals, but improved availability of information may have reduced these rates. The potential impact of information as a lone intervention has been explored in the pilot study described in chapter 6. Further data on the impact of an assessment programme on workload and referral rates has been obtained during the pilot study described in chapter 8.

In terms of diffusion of innovation theory and the models of diffusion framework, the evidence in this chapter suggests that patients are experiencing unresolved social difficulties, highlighting that any intervention that can improve this will offer *relative advantage* to the current situation. If this can be achieved by providing interventions that are compatible with existing practice and do not increase workload to an unmanageable level, then the adoption of these interventions is more likely.

Results of these analyses were presented as a poster at the 2007 International Psychosocial Oncology Society (IPOS) Conference in London [149], and published as a Short Communication in Supportive Care in Cancer in 2009 [36].

Chapter 5: Development and evaluation of an information intervention

5.1 Overview

The preceding chapter (chapter 4) demonstrated that despite availability of a huge range of available information, there is still unmet need for patients in terms of information and referrals to help them deal with social difficulties. Chapter four also provides evidence for areas of difficulty typically experienced by patients, adding to previous work by Dr Penny Wright (PW) which informed the development of the SDI-21 questionnaire[9]. This current chapter outlines the process by which an information intervention was developed and evaluated (5.3 and 5.4). Chapter six describes the subsequent pilot study in which the impact of the information intervention (i.e. its role in fulfilling patients' unmet need) is assessed.

5.2 Background

As demonstrated, information has the potential to help patients' deal with a number of difficulties[36], whilst being relatively inexpensive and simple to deliver[34]. These are positive attributes for an intervention, which should increase its acceptability to those within the NHS, an organisation which is experiencing an increasingly pressured and complex financial situation[78]. There is a vast array of information available on diagnosis, treatment and support services for oncology patients. This is provided on a local and national level by a number of sources, such as Macmillan Cancer Support, local hospital Trusts and other charities, and is available via a variety of media. The internet has particularly increased the availability of information and support for cancer patients[150].

In relation to diffusion of innovations theory[73], an information leaflet is not a new technology or concept to patients. This may raise the question of how valuable the testing of a new information booklet is, as the theory proposes innovations too compatible with existing practice are not taken up because they offer no real *relative advantage*. Despite this, there are two key reasons why a new information resource was tested and developed. Firstly, evidence from the literature and the findings in chapter three demonstrated that, despite an abundance of information, there was still be a need for information to assist with social difficulties. The *relative advantage* offered by this specifically-designed resource is that its content will be developed using

evidence of patients' specific requirements for such information. Secondly, the work presented in this thesis has been developed in line with the MRC Framework, and as such the information will be tested as an individual component of a complex assessment and support programme.

The primary objective of the work presented in this chapter was to develop and evaluate an information booklet for patients. The resulting information resource was then tested in a pilot randomised controlled trial (RCT) to assess its impact on processes of care and patient well-being in comparison to standard practice, and provide estimates of the effect size of this intervention in a future randomised controlled trial (chapter six).

5.3 Development of an information intervention

A project-specific information resource was developed for the purposes of the pilot RCT (chapter six). The aim of the intervention was to increase patients' awareness of and access to services that could assist with difficulties reported in the literature and in the findings from chapter four. The information needed to cover the specific difficulties reported by patients in previous analysis (chapters three and four), providing information on local and national services. The volume and diversity of existing information resources was too high and came from a number of sources. Selecting one resource from all those available would have been difficult. Keeping abreast of changes and updates may also prove a problem if an existing information source was used. Control of updates and changes was necessary to ensure that all patients received the same information. The resource also had to be geographically relevant to the population that it serves, and replicable for the second pilot study (chapter seven).

The information was provided in a simple written format in order to investigate the role of the information itself. To deliver this in a novel way, e.g. via a website, would be introducing additional variables relating to behaviours around the use of technology. Therefore the resource format was kept as simple as possible to ensure that the content of the information itself that was being tested, rather than the method of delivery.

Various existing sources were drawn upon to inform the content and presentation of the booklet.

An initial version of the booklet was then evaluated (section 5.4), before being tested as an intervention in a pilot randomised controlled trial (chapter 6). Section 5.3.2 explains the methods that were used to access the sources, the findings from which are outlined in section 5.3.3. Section 5.3.4 describes the resulting information booklet, the evaluation of which is explained in section 5.4.

5.3.1 Aims

The aim of this section of work was to develop an initial version of the information intervention, the goals of which were;

- to 'signpost' patients to support services,
- to increase awareness of what support is available,
- describe what issues services may be able to assist with,
- inform patients of the best way to access these services.

5.3.2 Methods

Local guidance from the Information for Oncology Patients Group (INfOP) was obtained and for advice on the development of acceptable patient information[151], specifically the INfOP 'Checklist for producing patient information' (appendix 6).

The following sources were identified that would contribute to the content and presentation of the information intervention;

- Research Advisory Group (RAG),
- findings from previous analysis (chapter 4),
- exploring existing literature (chapter 1),
- Information, Care and Support Services (ICSS) located at the local cancer centre,
- Allied Health Professionals (AHPs), also located within the local cancer centre.

Accessing this range of sources fulfilled guidance in terms of;

- consulting key stakeholders, both in content and reviewing of drafts

- maintaining relevance, consistency and ensuring the information provided within the booklet was up to date [151].

Accessing these sources facilitated the generation of; a list of issues/ areas of concern, identification of key services, and considerations for the design and writing of the booklet. Table 5.1 summarises how each source was accessed, and whether the source contributed to content, presentation or provided general advice on producing a booklet.

Table 5.1: Summary of sources, how they were accessed and contribution to the information booklet

Source	Method	Contribution to:		
		Content	Presentation	General
RAG	Emails and meetings	√	√	√
Previous analysis	Secondary analysis	√		
Literature	Review of existing literature	√	√	
ICSS	Meetings and tours with staff	√		
AHPs	Meetings with staff	√		

5.3.2.1 Research Advisory Group (RAG)

The Patient Reported Outcomes Group set up a Research Advisory Group in 2007 (then known as the User Partnership Group). The Research Advisory Group continues to provide patient and carer viewpoints on all aspects of the research process on all projects. Members of the advisory group were approached via email and at routine meetings and asked for their thoughts on what factors are important in information provision, and about their own experience of information provision as patients and/or carers. Three members provided feedback.

5.3.2.2 Findings from previous analysis (chapter 4)

Secondary analysis was undertaken to demonstrate levels of unmet need in terms of information requirements (chapter 4). This analysis was used to generate lists of topics for which patients required information, services to which patients were referred, and the reasons behind the referrals.

5.3.2.3 Literature review

A broad literature search was undertaken to inform the introduction and background to this thesis (chapter 1). These original references were reviewed again to identify publications that would contribute to the content and/ or presentation and format of the proposed intervention. Key papers were identified that looked at the impact of psychosocial information and/ or patients' preferences for receiving such information. These papers were reviewed in detail, and their contribution to content and/ or presentation summarised. A 'snowballing' technique was then used, which involves scouring the references and citations to identify other sources to inform the development of the information booklet[2]. The references found during this process were also reviewed for contribution to content and/ or presentation.

5.3.2.4 Information Care and Support Services (ICSS)

In order to establish what patient information is currently available at the Local Cancer Centre, in terms of sources, format and ease of access, meetings and tours of the ICSS were arranged with the Macmillan Information and Support Manager (SS), the Macmillan Information Co-ordinator (PM), and the Trust Radiotherapy Patient Information Officer (RL). As a result of these meetings I also obtained additional information from a radiotherapy open evening and had a number of leads from SS, PM and RL that were followed up using internet searches.

5.3.2.5 AHPs

This encompasses the Rehabilitation Team (physiotherapists, occupational therapy dieticians and speech and language therapists), Oncology Social Work and Macmillan Social Work. The requirement for such input had been raised in previous findings (chapter 4), and so the team were approached to ask for their input into the booklet.

5.3.3 Content

The ***Research Advisory Group (RAG)*** members highlighted the following issues relating to the content of the information booklet. They noted that creating a generic/ standardised information pack removes the need (in the first instance) for identifying specific needs for each individual. They also felt that too much information would be overwhelming and practically not possible. The resource should not be too weighty

but should be thorough enough for people to be able to use it as a way to access the right services.

Findings from previous analysis (chapter 4) showed that patients required information on (ranked in order of frequency); 1) Holidays, 2) Support centres/ groups, 3) Welfare benefits or finance, 4) Social work, 5) Others (includes complementary therapy, contacting the Clinical Nurse Specialist [CNS], and advice about having a water meter installed), 6) Psychological services, 7) Parking permit, 8) Careers, 9) Cancerbackup[1], 10)Psychosexual service. Table 4.3 from chapter 4 demonstrates the services to which patients were referred and the reasons they were referred. This allowed me to generate a list of common services to which people were referred or provided with information on, and a list of topics/ difficulties commonly experienced (figure 5.1), forming the foundation for the content that could be added to as the other information sources were explored.

Services
Support centres
Social work
Careers services
Complementary therapy
CNS
Psychological/ psychosexual services
Cancerbackup (now Macmillan)
Occupational Therapy

Topics/ areas of difficulty
Holidays
Welfare benefits/ finance
Water meter
Parking permit
Coping/ adjustment
Body image
Communication difficulties
Isolation
Sexual difficulties
Planning for the future

Figure 5.1: List of services and areas of difficulty generated from data from chapter 4

The original references found during the original ***literature review*** used in chapter 1 (n=43) were reviewed again to identify those that would inform the content (i.e. contained evidence for patients' expressed information requirements or key specific information resources), or presentation of the booklet. Table 5.2 outlines which of these were discarded and the reasons. Four key papers were identified that looked at information relating specifically to psychosocial/ social problems in oncology patients. These were; Cox et al (2006)[20], Mossman, Boudioni and Slevin (1999)[34], Stanton (2006)[8], and Wright et al (2002)[9].

Table 5.2: References discarded

[1] Macmillan Cancer Support and Cancerbackup merged in April 2008

Reason	Reference	n
General psycho-social oncology information	[11, 44, 52]	3
Theory	[73, 126]	2
Self-management/ expert patients	[10, 22-25, 68]	6
Guidance	[12, 15, 18, 61-63]	6
Patients' views on what should be researched	[26, 27, 41]	3
Non-information needs/ interventions	[29, 33, 39]	3
Side effects of treatment/ treatment decisions	[7, 19, 38]	3
Impact on carers/ children/ clinicians	[30, 31, 53, 57, 58]	5
Development of instruments/ technology	[43, 45, 50, 54, 56, 69, 71, 152]	8
Total		**39**

Table 5.3 demonstrates the original four key references and other publications found via snowballing/ incidental finding whilst searching, and the findings from these on content. References excluded during this process are not listed. A list of all topics was generated using the papers (n=88). Twenty-four medical and non-medical categories were identified (table 5.3). Medical issues will not be included in the information resource.

Table 5.3: Information categories for consideration in the information booklet (generated from sources listed in table 5.3)

Medical (n)*	Non-Medical (n)*
Cause of cancer (1)	Body image (3)
Clinical trials (1)	Complementary and alternative medicines (CAMs – 3)
Diagnosis (4)	Communication, impact on friends and family (4)
Fertility (1)	Coping/ adjustment issues (3)
Genetic risk (2)	Emotional issues (2)
Prognosis (4)	Everyday issues/ general functioning (3)
Rehabilitation (1)	Finance/ work (6)
Tests (2)	Legal issues/ planning the future (3)
Treatment choice/ side effects (17)	Social/ isolation (4)
Diet and lifestyle (6)	Relationships and sexual issues (7)
End of life/ euthanasia (2)	Self-care (3)
	Support groups and services (7)

*n refers to the number of times items relating to this category were mentioned throughout all papers

ICSS consists of a Macmillan Centre (MC), three information lounges and one information 'kiosk' in the new dedicated cancer wing. The services provide a library of information resources, including publications from Macmillan Cancer Relief, along with

information on local and national support groups. Apart from the kiosk, all the rooms are staffed by full-time members of staff and supported by a team of information volunteers who try to ensure a comfortable, supportive environment with as much privacy as possible. The MC also offers a variety of support services for patients and their families including complementary therapies, counselling, support groups and self-help courses. The service provides information for patients, relatives and carers in a variety of formats which include written, audio-visual and electronic. There is information available on all the issues raised by the SDI-21. Internet access is available, with staff and volunteers on hand to help people use it.

Before the opening of the dedicated cancer wing there was only the MC available at the hospital site, apart from some leaflet provision in outpatients and outreach visits to wards to increase awareness of the unit and the services available. The information lounge that now resides in the radiotherapy department within the dedicated cancer wing was originally at a local cancer unit before its closure in 2008. Despite the increased availability of information services an increased uptake had not been noticed at the time of this research. There are various possible reasons for this, as suggested by volunteers and staff, and include lack of effective sign-posting, the clinical feel to the information lounges due to the layout of the rooms and the fact that they are part of the clinical setting. The layout of the information lounges is not conducive to private discussion away from the clinical setting.

AHPs

From the Rehabilitation Team a list of all services that were available within the hospital was compiled, along with appropriate referral pathways (e.g. can patients self-refer), and contact details. Details were obtained of what sort of difficulties each service could potentially assist with. Internet searches were conducted for details of the relevant Professional bodies and noted the websites (e.g. Chartered Society of Physiotherapists). Details on each service were written in conjunction with the services themselves. The final list of topics that were included in the booklet is described in section 5.1.6.

5.3.4 Presentation

Research Advisory Group (RAG) members thought the availability of 'take away' information was incredibly important; people may not always have time to sit and chat

with an information officer, particularly if they have already been at the hospital for a considerable time. This is often the case in busier clinics and particularly when patients are paying for parking. RAG members felt an information pack might allow some patients to bypass the need to visit an information lounge in the first instance, and allow them to get home and consider the information, then make further arrangements if necessary in their own time. They thought that some patients may also feel uncomfortable using an information lounge, and some patients may feel like they are being watched, so it would be advantageous to have something they could take away with them.

Literature searches

A number of important considerations regarding the presentation of the information booklet were raised through exploring the literature, including readability (in the context of the reading age of the target population), use of colour and pictures, contact details, and using patient need as a starting point for the content[34].

In a trial of different information booklets, the version favoured by patients was the one with a level of reading age closest to that of the sample. The Simple Measure of Gobbledygook (SMOG) can be used to assess the reading age of text. The SMOG formula (see Figure 5.2) is a tool used to measure the "years of education needed to understand a piece of writing". The SMOG website provides a free SMOG calculator to make determining the score easier[153]. This has been applied to the text within the SSIP. The exact figure for the UK national reading age stands somewhere between 9 and 11 years, but there is some variation between sources and no definitive evidence [154]. The score for the first version of the SSIP is 13.74, giving a reading age of approximately 14 to 16. As this is higher than the suggested national average, the readability will be carefully considered during further evaluation stage.

$$1.0430 \sqrt{number\ of\ polysyllables \times \left(\frac{30}{number\ of\ sentences}\right)} + 3.1291$$

Figure 5.2: SMOG Readability Equation (taken from McLaughlin, 2008)[153]

Minimising the reading age can be achieved by writing in a brief[155], note-form style [156]. No definitive guidance has been found on the use of illustrations, pictures, or the use of colour. One paper highlights how pictures can sometimes be perceived as

trivialising a serious issue[156]. Including the contact details of a named individual are useful to include, as would a question and answer sheet [155]. Patient-driven information is preferred, and Mossman et al (1999), recommend that anyone designing information should "…start with needs defined by patients…"[34].

5.3.5 General

Research Advisory Group (RAG) members thought the timing of the delivery of information would be very important. They thought that immediately after diagnosis would not be appropriate, as people are still coming to terms with the diagnosis and maybe dealing with treatment decisions. Timing it correctly would add to the value of the resource. When discussing timing, one of the RAG members used the analogy of a snow globe, likening the time just after diagnosis to the period just after a snow globe has been shaken – everything is disrupted and information on psychosocial issues would be best provided when the snow has settled.

Another RAG member suggested that it might be best to leave the decision on when such information is provided to the HCPs responsible for the patient's care. The patients recognised that individuals will have different requirements depending on their diagnosis, personality and individual situations, and that this should be accounted for. One patient had also been a carer and reported how their information requirements differed greatly when faced with a relative's diagnosis compared with their own. When a relative was diagnosed they reported being hungry for information and tried to seek out as much as possible. When diagnosed personally however, they reported that they did not wish to actively seek information.

5.3.6 Result: The Support Services Information Pack for Patients (SSIP)

The title of the information resource was 'Support Services Information Pack for Patients", which was abbreviated to 'SSIP' (included as additional material).

5.3.6.1 Content and organisation

Seven areas of concern were selected in which to organise the information pack. These are:

1. Money matters
2. Holidays/ travelling

3. Getting around/ transport
4. Working life/ career
5. Coping/ needing someone to talk to
6. Relationships/ family issues, and
7. Other practical issues

These were compiled using a list of the areas for which information was required, and the reasons patients had been referred (from the previous analysis described in chapter 4 [36]). The SSIP was organised so that users can search by areas of concern rather than by services, using symbols and a key[34]. The role of the SSIP is to alert patients to resources; as such it was considered more useful to allow them to search by problems rather than simply providing a catalogue of services. It was acknowledged that patients may have a specific service in mind that they would like to access, therefore the SSIP is also organised alphabetically and a contents page is included.

The SSIP begins with introductory pages, outlining the purpose of the booklet, and how to find things within it. Following this is a description of each of the seven areas of difficulty and what these areas cover. This section also shows which symbols refer to which area of difficulty. The next pages are made up of a grid, which lists services alphabetically and cross references these to the areas of difficulty that that specific service can help with. Details of each service are then provided, with a brief description and relevant contact details. Where possible local offices are included as well as national phone lines. Where relevant website addresses are given. There are then two pages for patients to make their own notes, and a page of acknowledgements.

5.3.6.2 Design and format

The SSIP was an A5 size booklet, which would allow it to be filed in the 'Blue Book', an A5 ring-binder containing treatment-specific and other information. Patients undergoing chemotherapy or radiotherapy received these folders on commencement of treatment. Some patients referred to them constantly and carried them at all times, but others barely used them. The design of the SSIP ensured that it could be filed into the blue book or used alone as desired. Pages were included for patients to make notes, in order that they could jot down questions or pertinent information. For the

purposes of this study the SSIP was published only in written English, and was not made available in any other language or format, e.g. braille, large font or audio. This would restrict certain patients from participating, but alternatives could be considered for future trials if required.

5.3.6.3 Style and readability

The information within the SSIP was presented and written according to the Information for Oncology Patients Group (INfOP) guidelines[151]. Information for in-house production for oncology patients under the care of the local Hospitals NHS Trust is subject to policies set out by the Trust and by Information for Oncology Patients Group (INfOP). INfOP is a group of lay people and health professionals who have set out guidance on production of leaflets and aim to "…provide quality control for all patient information produced…" The guidance set out in these documents was considered when creating the information pack.

The language was kept as straight-forward as possible, and written in a relaxed and conversational manner. The reader was referred to as 'you'. Short sentences were used as much as possible, and long ones punctuated effectively. The full meaning of any acronym was included on its first use. Where possible bullet points were used in preference to long paragraphs[151]

The acceptability of the symbols used was carefully considered. This was be a point for consideration on further evaluation of the SSIP in 5.4, and will be amended as appropriate if it is felt they are unacceptable or unclear. The INfOP guidance[151] includes a 'Checklist for Producing Patient Information'. This has been used as a guide in the development of the first version of the SSIP and has been used as a guide to assessment during the evaluation process.

5.4 Evaluation of the SSIP

The development of the information resource was an iterative process of amendments and reviews, which continued until the final version was completed by consensus between the research team steering group, service providers, ICSS and members from the RAG (figure 5.3).

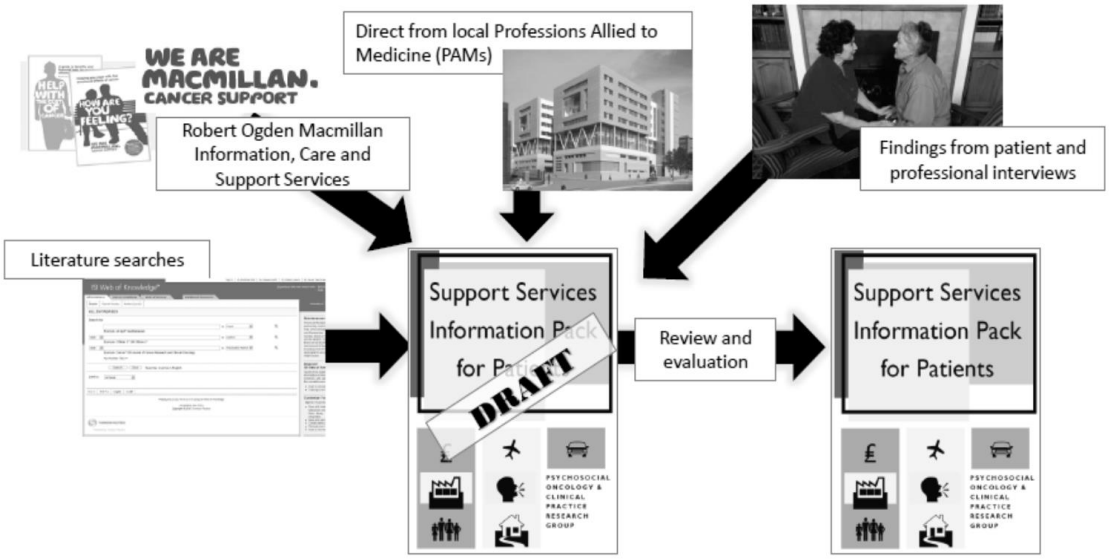


Figure 5.3: Development and evaluation of an information resource

5.4.1 Aims

To assess patient and service provider opinion on all aspects of the information resource, including:

a. format,
b. layout,
c. content,
d. ease of use,
e. readability,
f. suitability of language.

5.4.2 Methods

Members of the RAG were contacted via post and provided with a copy of the information resource, and asked to provide their feedback. Members of the in-house teams that had contributed or were included in the information resource were also sent copies of the resource and feedback requested.

5.4.3 Feedback and changes

There were five respondents to the information pack, four members of the RAG and one internal contributor. Various comments and suggestions were made and key issues are outlined below.

Use of symbols

The use of symbols was very well received. Macmillan employs the use of symbols in their directories and they are found to be useful. Overall they were felt to aid the use of the pack and facilitated its use as a quick reference guide. Only one respondent thought the symbols wouldn't work and shouldn't be used. Respondents were asked to comment on the acceptability of the symbols themselves but no concerns were raised. Therefore the symbols will be used in the intervention version of the SSIP, and any concerns or comments raised about them by participants during the pilot RCT will be noted.

Design (colours, format, length)

Generally the design of the pack was again very well received. Only one respondent felt the pack was too descriptive and long. One respondent reported that although "I get bored easily when reading", found the pack about the right length and layout to maintain interest. The language and tone were felt to be appropriate and understandable. One respondent felt the colour scheme was too dull and that introducing the symbols on the front cover may make grab the reader's attention. As a result the symbols have been introduced on the front page. The colour scheme has not been changed, but again will continue to be reviewed during stage two.

Content – suggested deletions

Only one respondent felt that parts of the booklet should be removed, based on their view that the use of symbols wouldn't work. As the symbols were generally accepted and are remaining in the pack the related sections will also remain. The same respondent also felt that there was too much detail regarding the rehabilitation services. However, the aim of the pack is to inform patients of services they may not have heard of before, therefore some description is key to empowering patients to decide whether the service may help. It was also suggested that names of staff in departments should be removed and only generic contact details included, preventing the pack becoming out-dated should staff change. This advice will be followed as good practice and the specific staff names removed.

Content – suggested amendments/ additions

One respondent suggested there should be more specific detail about how to access support groups. Where a service can provide access to or details on support groups

this has been outlined and it was felt that no more specific information was required. Some respondents requested direct contact details for services such Clinical Psycho-Oncology, but in these cases self-referral by patients is not appropriate (as advised by the service). Instead, users of the pack are asked to discuss the service with their clinical team. Direct contact details for Clinical Psycho-oncology have therefore not been included.

General comments

The majority of respondents felt the SSIP was useful and acceptable. The use of symbols as a way of signposting readers to useful services was also thought useful. Respondents felt the purpose of the pack was clear, and that the inclusion of telephone contact details was useful for non-internet users.

5.5 Conclusion

The structured procedure described here followed available guidance[151] and is in line with other reported methods of resource development[157, 158]. The resulting Support Services Information Pack for Patients (SSIP – included as additional material) would now be tested against standard care in a randomised pilot study (chapter 6).

Chapter 6: Pilot study - simple information provision versus standard care in managing social difficulties

6.1 Overview

Previous chapters have described how information may still be lacking for some patients, yet have an important role in assisting patients in dealing with social difficulties (chapter 4). The preceding chapter (chapter 5) described the development of an information intervention (the Support Services Information Pack – SSIP, included as additional information), which was designed to fulfil this unmet requirement. The current chapter describes the pilot study in which the role of a SSIP in helping patients deal with social difficulties was explored in comparison with standard care.

6.2 Aims

The primary aim of this pilot study was to investigate the impacts of the SSIP on processes of care, patient behaviours and well-being

Secondary aims were;

- to inform adequately powered future studies on the most appropriate outcome and process measures and estimate effect sizes and confidence intervals, and
- to further evaluate the SSIP.

6.3 Hypothesis

It was expected that the information intervention (SSIP) would motivate patients to raise issues it covers more frequently, or make contact directly with services listed. The result of this would be increased access to services and a potential subsequent impact on levels of social and psychological distress.

6.4 Methods

6.4.1 Study design

This pilot study followed a randomised parallel group design, intervention versus standard care, using process of care and PROMs. Randomisation was selected as it would allow the best estimate of the potential effect size of the intervention by comparing the two arms (figure 6.1), which could be used to inform future studies.

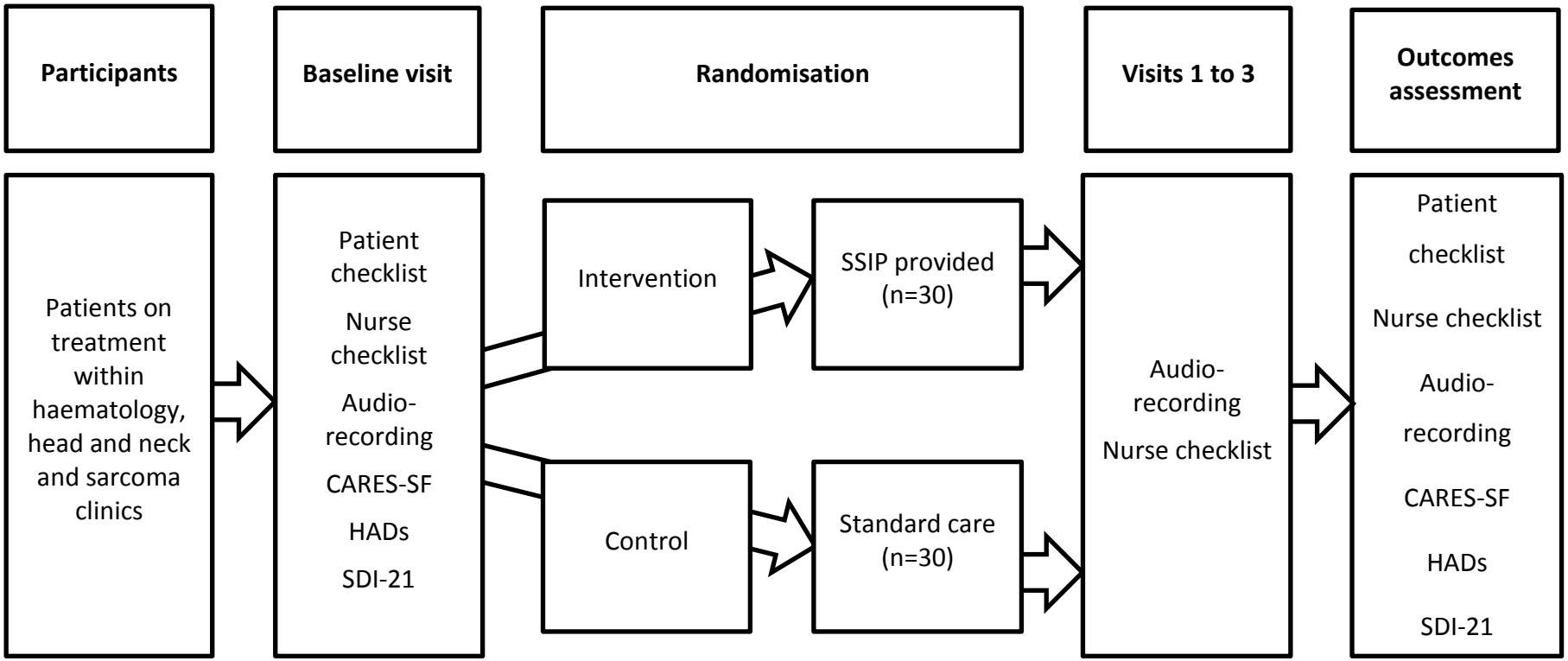


Figure 6.1: Study design

Key

CARES-SF: Cancer Rehabilitation Evaluation Scale (Short Form) [Appendix 6]
HADs: Hospital Anxiety and Depression Scale [Appendix 4]
SDI-21: Social Difficulties Inventory (21 item) [Appendix 1]
SSIP: Support Services Information Pack [included as additional material]

6.4.2 Setting

This pilot study was conducted at a large regional cancer centre, which provides radiotherapy and other specialist treatments. Patients may also be served by local cancer centres and only attend the cancer centre to receive specialist treatments not provided at local cancer units. Participants were accessed and recruited from outpatient clinics serving patients with a diagnosis of head and neck, sarcoma or haematological cancer (table 6.1).

6.4.3 Participants

Although social difficulties can be experienced by any cancer patient (or anyone from the 'general' population), previous studies have suggested that they may be more common in younger cancer patients and those on active treatment [44]. In order to detect any change in social distress as a result of the SSIP, the sample needed to contain sufficient patients likely to be experiencing social distress. To represent a population who are likely to experience a wide range of social difficulties, patients were recruited from haematology, head and neck and sarcoma clinics, who were over the age of 18 years, and on active treatment (chemotherapy, radiotherapy or chemo radiotherapy).

Eligible participants were those who had received at least one of a minimum of four cycles of chemotherapy, or who had commenced radiotherapy with the intention for treatment to continue for a minimum of four weeks, and would be attending the hospital for a minimum of four consecutive appointments over a 3 to 6 month period.

Other eligibility criteria were;

- ability to read and understand English,
- have the capacity to give informed consent and complete the questionnaires, and
- non-participation in other psychosocial studies or clinical trials with a significant psychosocial element.

Patients within the head and neck group included those who were living with limited or no speech following surgery. These patients were not immediately considered ineligible for this reason alone, despite the audio-recording of consultations. Each

patient's situation was considered on an individual basis and alternative methods of data collection employed where necessary, e.g. asking the patient to write responses during the recorded consultation and then taking photocopies of these responses to allow complete analysis.

Patients were randomised to study arm (intervention or control) following consent. Randomisation was stratified by age, gender and disease site (table 6.1). Randomisation was achieved using the telephone service provided by the Clinical Trials Research Unit at the University of Leeds.

Table 6.1: Stratification criteria

	Male			**Female**			**Total**
	Head & neck	Sarcoma	Haemat-ology	Head & neck	Sarcoma	Haemat-ology	
≤ 50 years	5	5	5	5	5	5	**30**
>51 years	5	5	5	5	5	5	**30**
Total	**10**	**10**	**10**	**10**	**10**	**10**	**60**

6.4.4 Sample size

As this was a pilot study there was no formal sample size calculation. Following the guidance recommended by Lancaster, Dodd and Williamson for pilot studies, the primary aim was to determine initial data to allow a sample size calculation for future trials[159]. The study design was also required to provide evidence with which to decide the most appropriate measure to use as the primary outcome measure and to determine initial data for this. Thirty patients per arm (60 in total) were required to allow estimate of effect sizes. Allowing for a 20% drop-out rate, a minimum of 38 patients per arm was the target for recruitment, which ended when complete data was collected for a minimum of thirty patients per arm. The sample was open to be increased, subject to the need for refinement of the intervention, but this was not required. Consultants and nurses associated with the relevant clinics were also considered participants as they would be asked to participate in interviews, provide details of their contact with patients (nurses) and have consultations recorded (consultants).

6.4.5 Intervention

The intervention was the provision of the SSIP (included as additional material), which was created and evaluated as described in chapter 5. Patients randomised to the intervention group received the SSIP. This was provided as soon as possible after all baseline measures were collected, either in person or by post (figure 6.1). Patients requesting the SSIP were informed that, if they were not randomised to the intervention group, they would be provided with a copy at the end of the study.

6.4.6 Procedure

The protocol for this study was approved by the Leeds (Central) Ethics Committee (ref 09/H1313/4). Authorisation to access patient data specifically for the purposes of this project was obtained, following a successful application by Professor Galina Velikova to the National Information Governance Board (NIGB). This authorisation provided support under section 251 of the NHS Act 2006 to allow research staff working on this and other research projects within the programme of research to process patient identifiable data without consent.

Consultants and nurses associated with the selected clinics were approached and provided with information sheets, and asked to consent to participate in recordings of consultations, exit interviews, and provide details of contact with patients (nurses). If they were happy to participate they were asked to complete a consent form. For consultants the consent form also provided consent for the patients within their care to be approached for the purposes of the research project.

Prior to patient recruitment commencing, posters and leaflets were displayed and made available in outpatient and day unit clinics. These alerted patients that research staff would be in clinic, and explained the research activity that was under way.

Eligible patients were identified using the electronic patient records system, Patient Pathway Manager (PPM). Lists of potential patients were checked with an appropriate member of clinical staff to ensure that there was no reason why potential participants should not be approached regarding the research (e.g. if they were very ill or anxious, or had recently received bad news). Although inclusivity was vital, it would have been unethical to add burden to a patient who was already in distress and who could potentially be approached at a different, more appropriate time, without breaching

their eligibility in terms of treatment regime. In concordance with NIGB recommendations, members of the research staff were introduced to potential patients by the clinic staff. This allowed the patients the opportunity to decline to be approached by the researcher.

When a patient consented to being approached, the details of the study were fully explained and the patient provided with an information sheet. Patients were given as much time as necessary to decide if they wanted to participate. It was explained to them that their eligibility may be at risk if their time to decide out-ran the period of their treatment and/ or attendance at the hospital as required for the data collection procedures. For patients who wished for time to consider, verbal consent to approach again at their next visit or contact by telephone was obtained.

Patients who consented to be approached but declined to participate were asked to complete a 'Declined to Participate' Consent Form, which permitted an anonymised record of the patient's basic socio-demographic and medical information to be kept. This was used to explore differences between participants and non-participants at the end of the study. For patients who did not wish to sign this form, a record of the number of patients on whom it was not possible to access any basic demographic information was kept. Patients who did not wish to be considered for any of the psychosocial research activity could request that this be noted on their PPM record so that their wishes could be respected and they would not be approached for any studies. For the period of the study a secure record was kept on PPM of the names of patients who declined to participate or withdrew from the study, again so that their wishes could be respected and they would not be approached again.

Patients who decided to participate were asked to read and sign a consent form, initialling each statement of consent. They were then asked to complete the baseline measures, and have their subsequent clinical consultation recorded. Nurses were asked to complete the nurse checklist (appendix 13), for each study participant at the end of their baseline clinic visit. Clinical and socio-demographic data was collected from PPM, including postcode, age, gender, ethnicity, diagnosis, extent of disease, site of metastases (if applicable) and current treatment. Postcode data was used to calculate Indices of Multiple Deprivation (IMD) scores and ranks, which demonstrate a relative measure of deprivation.

All patients, regardless of randomisation group, were monitored for three further, consecutive visits with nurse checklists and audio-recordings of consultations completed at each one. After the last of these three visits, patients were asked to complete outcome measures. Patients were asked to participate in the final stage of the study, the semi-structured exit interview, with the aim of conducting this within two weeks of the last on-study clinic visit. Alternative methods of data collection were employed for patients with limited or no speech who wished to participate.

6.4.7 Process of care measures

6.4.7.1 Patient checklists

A study-specific patient checklist was developed, the aim of which was to assess patient awareness of and use of support services. Two versions were generated; one for baseline and end of study (appendices 14 and 15), and were developed in conjunction with the SSIP using the same sources of information. The aim of these checklists was to identify if the SSIP has alerted any patients within the intervention group to specific services, and by what other means the standard care group may become aware of services during the period of their treatment.

At baseline (appendix 14) patients were asked if they had used any of the following services within the last 3 months, with a simple tick-box to respond yes or no; 1) healthcare-related, e.g. occupational therapy, physiotherapy, 2) Government or local council, e.g. Blue Badge Parking scheme, Department for Work and Pensions, 3) Charity/ voluntary, e.g. Macmillan Centres, support groups, 4) Other hospital-based, e.g. Social Work, Clinical Psycho-Oncology Service, Information, Care and Support Services, 5) Websites, e.g. Cancerbackup/ Macmillan, Cancerhelp. They were also asked to include any other services or resources they may have accessed that were not on the list. The number of services listed in detail was kept to a minimum to reduce the risk of patients being 'primed' to services before they started the study.

The end-of-study patient checklist (appendix 15) listed the same services, but asked the patient in more detail about their use of these services and reasons why they had accessed or not accessed them, with the following questions about each one;

- Have you used any of these services in since you took part in this study? (Tick if yes, leave blank for no)

- If yes, how did you find out about the service?
- If no, why have you not accessed the service? (E.g. didn't need it, never heard of it)
- Do you think you would use the service in future? (Tick if yes, leave blank for no)

The content and acceptability of the checklists was evaluated on the first five patients with a view to making amendments if necessary, but no concerns were raised and so no changes were made.

6.4.7.2 Nurse checklists (appendix 13)

To monitor the role of nurses in dealing with social difficulties, a study-specific nurse checklist was designed. Nurses were asked a series of questions about different areas of the patients' life that may be affected, based on the subscales of the Holistic Common Assessment Guidance[62]; 1) Managing at home and in the community (ability to prepare food and feed independently, getting around the home/ key transfers, other personal care and housekeeping), 2) Work and finance (work issues, day to day finances, planning for the future), 3) family and close relationships (patient's close relationships, including children, sexual relationships), 4) social and recreational (social interactions, recreation and leisure).

For each of these areas nurses were asked to record if the issue was discussed with the patient, and if it was, who raised the issue, whether the nurse took any action following the discussion, and if yes, what the action was. Although audio-recording is the best way of logging conversations between patients and clinicians, the goal of this measure was to record the informal contact that typically happens in waiting rooms whilst the patient is undergoing weighing and blood pressure monitoring prior to their outpatient appointment. Audio-recording in this situation would be very difficult. The content and acceptability of the checklist was evaluated by asking nurses to review it before commencing the study, but no concerns were raised and no amendments were made.

6.4.7.3 Audio-recordings of clinical consultations

Audio-recordings of consultations were used to record the discussion between patients and oncologists during the outpatient review appointments. This method

involved taking a digital audio- recording of the whole consultation. This allowed detailed analysis of the frequency of discussion of social difficulties and support services, who initiated any such discussion, what information was provided and what actions were taken following such discussions. Audio-recording allowed careful analysis of all these factors without any additional tasks for the patient or clinician, but didn't require the researcher to be present in the consultation. The private nature of the consultation room allowed this method to be used.

6.4.7.4 Patient interviews

At the end of the study, each patient was asked to take part in a semi-structured interview (appendix 7). The aim of the interview was to investigate if the patient experienced any social difficulties, and if so whether they requested and/ or were provided with help, how this was accomplished and the impact that this had on the difficulty. Additional questions were included for the intervention group, which elicited specific details on the use of the SSIP. The intervention group were also asked general questions on the acceptability and usefulness of the SSIP. The patient interview schedules were designed using information from previous staff and patient interview studies[54], as well as information obtained during the development of the SSIP. To facilitate discussion without having to discuss each individual item on the SDI-21, the subscales of the SDI-21 were used as a foundation for the questioning. The semi-structured format allows more discussion than a closed interview, allowing for detailed qualitative analysis, whilst ensuring that pertinent questions were answered and potentially allowing quantitative analysis [160, 161].

6.4.7.5 Staff interviews

Selected team members were asked to take part in a brief interview at the end of the study (appendix 8). Doctors were selected from each discipline according to the frequency of contact with study participants, i.e. those with higher levels of contact with study patients were selected. All nurses who participated were asked to take part in the interview. The staff interviews were based on initial analysis of nurse checklists and audio-recordings of consultations, and examined the help requested or provided by patients, actions that were taken, and the impact the staff member felt this had on themselves and the patient. The potential influence of the SSIP was also explored.

6.4.8 Outcome measures

The aim of the outcome measures was to assess any patient self-reported change in social difficulties and/ or an impact on psychological distress (although the pilot was not powered to detect a difference, but to give an estimate of effect sizes for a future RCT). Three self-reported instruments were selected that would measure psychosocial difficulties, quality of life, and the presence and severity of anxiety and/ or psychological distress.

6.4.8.1 CARES-SF

The Cancer Rehabilitation Evaluation System – Short Form (CARES-SF – appendix 12) was used to provide comparable measures of quality of life and day to day problems. The CARES-SF is a 59-item questionnaire, on which patients complete between 38 and 57 items. Patients rate problems on a 5-point scale, ranging from 0 (not at all/ no problem) to 4 (very much/ severe problem), therefore the higher the score the more severe the difficulties. A global CARES-SF score can be calculated along with scores for each of five domains; physical, psychosocial, medical interaction, marital and sexual difficulties[162].

6.4.8.2 HADs

The Hospital Anxiety and Depression Scale (HADS – appendix 4) was used to detect levels of anxiety and depression in patients. This is a 14-item instrument, with two subscales for anxiety and depression. Scores range from 0 to 21 on each scale, with higher scores indicating more distress, providing measures of severity[141].

6.4.8.3 SDI-21

The Social Difficulties Inventory (SDI-21 – appendix 1b) is described in detail in chapter 1. It is a 21-item questionnaire designed to detect the presence and severity of social difficulties. Items are rated between 0 (no difficulty) to 3 (very much difficulty). Sixteen of the 21 items can be summed to provide an interval scale of social distress, with scores ranging from 0 to 44 [43, 70] (the higher the score, the greater the level of social distress and severity of social difficulties). These sixteen items can also be used to generate three subscale scores, covering Everyday Living, Money Matters and Self and Others, with the remaining five items scored individually.

6.5 Analysis

6.5.1 Data checking

The data collected from patients via paper documents was inputted onto a study-specific Access database throughout the progress of the study. The accuracy of this data inputting was assessed by selecting a random 10% of cases from each dataset and comparing the inputted data against the original questionnaire.

6.5.2 Reliability checking

PW conducted reliability testing on a random 10% (n=7) of interviews to check that coding applied to audio-recordings produced the same findings as that applied to transcribed data. This was done by listening to an audio-recording that had previously been transcribed and checking that the results were the same regardless of whether it was done on paper or by listening to the audio.

Due to time constraints, it was not possible to transcribe every patient interview. Seventy per-cent of completed patient interviews were transcribed (n=50). The remainder were listened to and coded into a Microsoft® Excel sheet, using the same framework as had been applied to the transcribed interviews

6.5.3 Patient characteristics

Counts were taken of the number of patients who were approached, consenters, decliners, drop-outs and those who declined but allowed consent to collect socio-demographic and clinical data. Descriptive analyses were used to describe the clinical and socio-demographic profiles of consenting patients and those who declined but provided consent for this data to be collected. The Consolidated Standards of Reporting Trials (CONSORT) recommendations were followed to describe patient's pathways through the trial and monitor numbers of participants at each stage[163].

Chi-squared and T-Test analyses were used to assess any associations between socio-demographic and clinical differences between patients who consented, declined and dropped-out, and between patients in each randomisation arm.

6.5.4 Outcome measures

Global and subscale scores for the **CARES-SF**, the **HADs** and the **SDI-21** were calculated according to the guidance from their respective developers [56, 70, 141, 164]. Scores from the CARES-SF data were calculated as recommended; an average severity score, a global score and number of problems endorsed were calculated for the six summary scales (CARES-SF overall score and the five higher-order factors of physical, psychosocial, medical interaction, sexual and marital). For the SDI-21, this included transformation of responses for four of the items according to guidelines produced after Rasch analysis[56].

The mean and standard deviation for each global score and subscale were calculated by randomisation arm and for all patients. Independent samples t-tests were used to compare baseline global CARES-SF scores, HADS anxiety and depression subscale scores and SDI-21 global social distress scores between the randomisation arms prior to the introduction of the intervention.

One-way between-groups analysis of covariance (ANCOVA) was conducted to assess the impact of receiving the intervention on each of the outcome measures described. In each case the independent variable was the receipt of the intervention, the dependent variables were the end of study scores for each measure, and the covariates were the corresponding baseline scores. Effect sizes were calculated for all outcome measures, calculated using the following equation;

$$\text{Effect size} = \frac{[\text{Mean of intervention group}] - [\text{Mean of control group}]}{\text{Total standard deviation[165]}}$$

6.5.5 Process of care measures

6.5.5.1 Patient checklists

Descriptive analyses were used to assess frequency of access to support services at baseline and at the end of the study. Counts were taken of whether each service had been used at baseline, at the end of the study, at both time points, or not at all. Chi-squared analysis was used to explore any significant differences in the use of services by randomisation arm, gender, age group, deprivation category, disease site and ethnicity at baseline, and by randomisation arm at the end of the study.

6.5.5.2 Nurse checklists

Nurse checklists were developed in order to measure levels of informal contact between nurses running outpatient clinics and the patients waiting to see the doctor (described in section 6.4.7b). The intention had been to use simple counts to describe which social difficulties were raised in this situation, who initiated these discussions, and any actions taken as a result of these encounters. None of this expected contact was observed in the study, and no nurse checklists were completed.

6.5.5.3 Audio-recordings of clinical consultations

Content analysis was undertaken on the audio-recordings of the patient-oncologist interaction during consultations. A coding framework was developed using the subscales and items from the SDI-21. Each recording was listened to and the following items were coded:

- Details of the consultation and who was present;
    - Date
    - Length
    - Clinician
    - Who else was present;
        - Relative
        - Nurse
        - CNS
        - Other (e.g. surgeon, speech and language therapist)
- Whether any issues for each subscale/ item were raised within the consultation and if yes;
    - Details of the nature of the issue
    - Who raised the issue
    - Any action that was taken in response to the issue
    - Who took the action

For each of the four time-points, frequencies at which issues were raised were calculated.

For the baseline recordings Chi-squared analysis was used to assess any significant association between whether issues were raised and the variables of randomisation arm, age group, gender, clinic, deprivation category and ethnicity. Chi-squared analysis was used to assess if the presence of another person in the consultation was associated with the frequency at which issues were raised at baseline, and to explore any association between frequency of discussion and randomisation arm at the end of

the study. A mean frequency of discussion was calculated for each randomisation group, for each subscale and single item, and where feasible independent samples t-tests were used to compare means between the randomisation groups. Independent t-tests were employed to check for any association between subscale scores and whether any issues categorised within that subscale were raised, at the baseline time point.

6.5.5.4 Patient interviews

The SDI-21 subscales and single items were again used to develop a framework for coding the information within patient interviews. Interview data was coded to identify;

- The nature of problems patients experienced
- Whether it was currently a problem, had been a problem previously, or was anticipated to become an issue in the future
- Which subscale or single item of the SDI-21 this issue most closely related to
- What resources or services were accessed to deal with the problem
- Whether the SSIP had been used, at any stage or in relation to a specific issue (for the intervention group only)
    - If it wasn't used, any reason for this if given

It became clear during the process of conducting the interviews, but prior to the formal analysis, that few patients were using the SSIP.

6.5.5.5 Staff interviews

The staff interview schedule (appendix 8) was amended to include a question on why the informal contact expected between nurses and patients in the waiting room was not observed, and why patients were not using the SSIP. The interview schedule was used to develop the content framework, which elicited the staff member's thoughts on these issues, as well as;

- What factors they felt were important in the delivery of information to patients
- Whether the staff member remembered anyone referring to the SSIP
- Typical practice in identifying and dealing with social difficulties
- How CNS contact was arranged for patients
- What formal methods for assessing social difficulties were currently in place

6.6 Results

6.6.1 Participants

Figure 6.2 demonstrates the pathways of patients throughout the study and availability of data at each stage (adapted from the CONSORT recommendations)[163]. In total, 165 patients were approached. Nine of these were approached but became ineligible due to changes to their treatment plan. Seventy patients declined to participate (42%). Of all those who declined, the majority (n=54) provided consent for their socio-demographic and clinical data to be collected.

Eighty-six of those approached consented to participate; of these, ten dropped out at various stages of the study. Participants were classified as having dropped out of the study if they left the trial prior to completing the end of study questionnaires. The reasons for dropping out of the study were that the patient passed away (n=1), were 'lost to follow-up' (n=6, referring to patients who returned to only attending regional cancer units when radiotherapy had ceased, meaning insufficient appointments at the local Cancer Centre were available at which patients could be accessed to collect data), moved away (n=1) or chose to discontinue participation (n=2). Where the patient decided to leave the trial, in both cases this was due to progression in disease/ deterioration in health status. Eighty-eight per-cent (n=76) of consenters had data collected at all four time-points throughout the study. Seventy patients agreed to take part in the end of study interview.

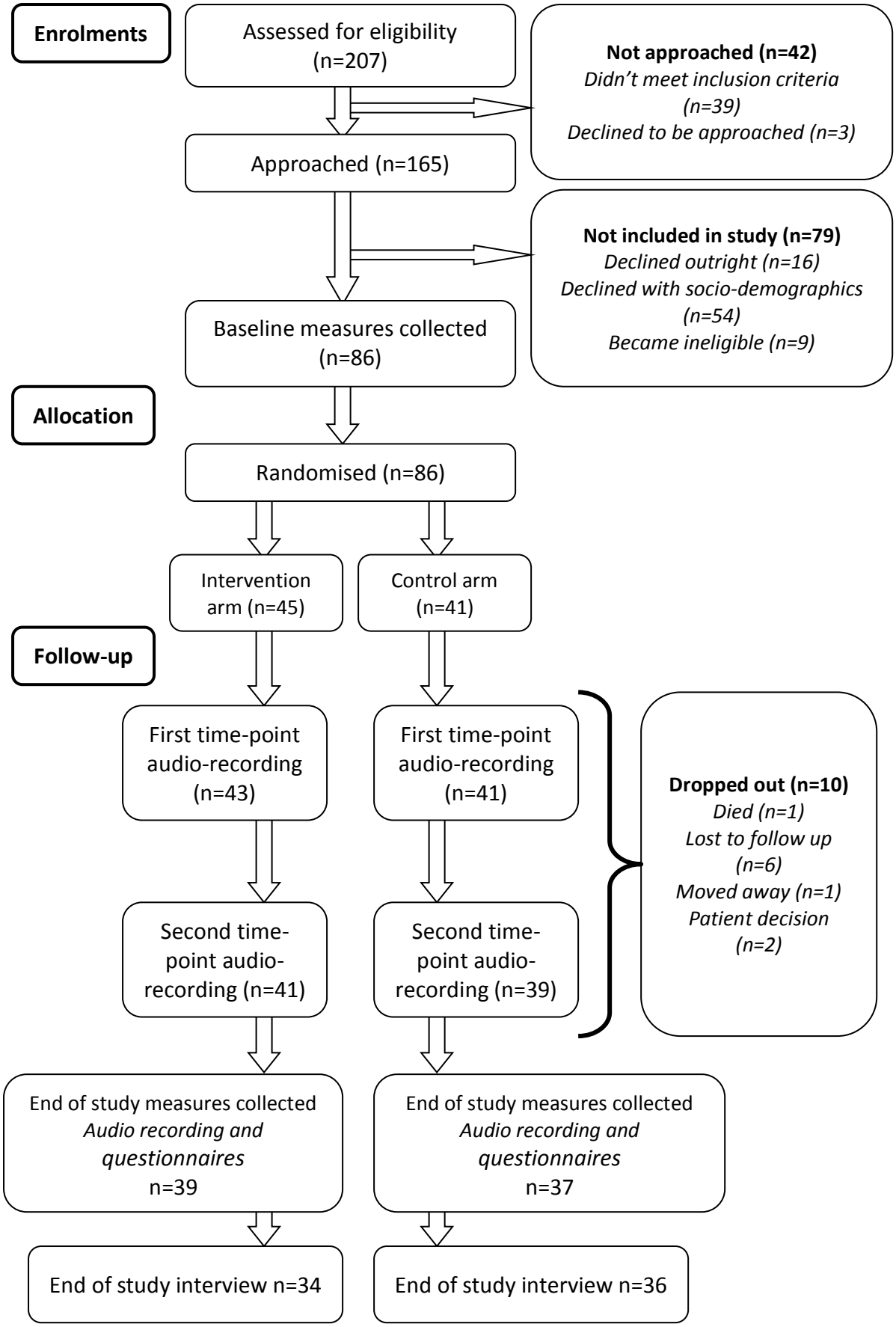


Figure 6.2: Participants pathway through the trial

There were no significant differences in socio-demographic or clinical profiles between the groups of patients who consented, declined or dropped out, and no significant difference between the randomisation groups (tables 6.2a and b). All socio-demographic and clinical data were available for all consenters, drop outs and the 54 decliners who provided consent for this to be collected, except for in one case where a completed patient's IMD score and rank could not be calculated. This was because the postcode could not be recognised despite attempts to double-check and locate the address on Royal Mail's Postcode Finder.

Table 6.2a: Baseline sociodemographic and clinical profiles of participants by randomisation arm

		Intervention (n=45)		Control (n=41)		Total (n=86)		Decliners (n=54)	
		n	%	n	%	n	%	n	%
Gender	Male	30	67	24	57	54	63	30	55
	Female	15	33	17	43	32	37	24	45
Age	Group 1: ≤60 years	27	59	19	43	46	53	25	46
	Group 2: ≥61 years	18	41	22	57	40	47	29	54
	Range & mean (SD)	18 to 78 - 52.3 (16.4)		22 to 89 - 58.8 (15.9)		18 to 89 - 55.6 (16.2)		21 to 83 - 60.8 (13.6)	
Clinic Group	Haematology	12	31	13	35	25	29	11	20
	Head and Neck	22	46	16	35	38	44	27	50
	Sarcoma	11	23	12	30	23	27	16	30
Ethnicity	Not given	2	5	1	3	3	3	4	7
	Pakistani/ other Asian	0	0	1	3	1	1	1	2
	White	41	92	39	90	80	94	49	91
	Black	2	0	0	0	2	2	0	0
Deprivation category	20% Least affluent	20	41	15	35	35	41	29	54
	20% Middle	6	15	8	16	14	16	8	15
	20-40% Most	19	44	17	46	36	42	17	31
	Missing	0	0	1	3	1	1	0	0
Stage of disease	Disease free	0	0	1	3	1	1	0	0
	Primary local	32	72	24	59	56	65	34	63
	Local recurrence	7	18	4	11	11	13	6	11
	Metastatic	6	10	12	27	18	21	14	26
Treatment	Biological therapy	1	3	2	5	3	4	1	2
	Chemotherapy	18	41	23	59	41	48	23	43
	Chemo-radiotherapy	8	15	7	13	15	17	10	18
	Radiotherapy	18	41	9	23	27	31	20	37

Table 6.2b: Baseline sociodemographic and clinical profiles of participants who dropped out, by randomisation arm

		Drop-outs		
		Intervention (n=6)	**Control (n=4)**	**Total (n=10)**
Gender	Male	4	3	7
	Female	2	1	3
Age	Range mean (SD)	26 to 76 49.5 (18.8)	36 to 63 53.8 (12.1)	26 to 76 51.6 (15.5)
	≤60	4	3	7
	≥61	2	1	3
Clinic Group	Haematology	0	0	0
	Head and Neck	4	3	7
	Sarcoma	2	1	3
Ethnicity	Not given	0	0	0
	Pakistani/ other Asian	0	0	0
	White	4	4	8
	Black	2	0	2
Deprivation category	20% Least	4	2	6
	20% Middle	0	2	2
	20-40% Most	2	0	2
	Missing	0	0	0
Stage of disease	Disease free	0	0	0
	Primary local	4	2	6
	Local recurrence	0	0	0
	Metastatic	2	2	4
Treatment	Biological therapy	0	0	0
	Chemotherapy	2	1	3
	Chemo-radiotherapy	2	2	4
	Radiotherapy	2	1	3

6.6.2 Baseline results

6.6.2.1 Outcome measures

Table 6.3 shows mean scores for all outcome measures and their subscales, for each intervention group and for all patients.

Table 6.3: Baseline outcome measures

	Intervention	Control	Total
	Mean, SD	**Mean, SD**	**Mean, SD**
CARES-SF	**n=37**	**n=33**	**n=70**
Global CARES-SF score	4.8, 2.78	4.6, 2.70	4.7, 2.72
HADS	**n=36**	**n=35**	**n=71**
Anxiety subscale	6.4, 4.05	6.1, 3.64	6.2, 3.82
Depression subscale	5.0, 3.73	5.6, 3.02	5.3, 3.38
Global HADs score	11.4, 6.12	11.6, 6.04	11.5, 6.29
SDI-21	**n=36**	**n=35**	**n=71**
SD-16	10.7, 7.32	8.4, 8.33	9.5, 7.86
Everyday living subscale	5.2, 4.13	3.9, 3.52	4.6, 3.86
Money matters subscale	3.9, 2.65	1.9, 2.89	2.5, 2.81
Self and others subscale	2.4, 2.63	2.5, 2.77	2.5, 2.68

CARES-SF

Of all the patients who completed the study in full, 70 complete datasets were available for analysis. Thirty-three of these patients were in the control arm, and 37 in the intervention arm. Independent-samples t-tests showed no significant difference in the Global CARES-SF severity scores between randomisation arms at baseline (intervention group mean 4.8, SD 2.78, control group mean 4.6, SD 2.70; $t(68) = -0.22$, $p=0.83$).

HADS

Five of 76 completing patients had unusable HADs data, in that there were too many scores missing in each domain to permit calculation of missing scores in line with the guidance from the developers. This meant that 71 datasets were available for analysis (35 in control arm and 36 in intervention arm). Subscale scores for anxiety and depression at baseline were calculated. Independent samples t-tests showed no significant differences in severity of anxiety or depression for either randomisation group at baseline [$t (69) =-0.35$, $p=0.73$].

SDI-21/SD-16

Seventy-one complete datasets were also available to calculate mean SDI-16 global social distress scores and subscales (35 in control arm and 36 in intervention arm). Five patients had too many missing responses to permit calculation of missing scores. Independent samples t-tests showed no significant difference in global social distress scores between the randomisation groups at baseline [$t (69=-1.22$, $p=0.23$, two-tailed). These results show that there were no significant existing differences in well-being as

reported through any of the outcome measures between patients in the intervention group and the control group prior to the introduction of any intervention.

6.6.2.2 Process of care measures

Patient checklist data – use of services

Seventy-six patients provided complete patient checklist data at baseline (table 6.4). For all services, the majority of patients reported not having accessed them within the previous month prior to completing the checklist (64% to 87%). The highest rates of use were for Government or local council services (e.g. Department for Work and Pensions to seek benefits), and charities or voluntary services, with 32% and 33% of patients reported having accessed these prior to completion of the checklist respectively. 'Other' services were least frequently accessed (1%). Services that patients incorrectly classified as 'other' included District Nurses, Sarcoma/ GIST (gastro-intestinal stromal tumour) Support Groups, York Against Cancer Transport Service, and a Macmillan Counsellor; these were re-classified into the appropriate category prior to analysis.

Chi-squared analysis showed significant associations between the following variables and use of services at baseline:

- Government services and deprivation, with those at lower levels of affluence accessing the services more frequently;
- Charity and use of other hospital services and disease site – those in the haematology group accessed both services more frequently than head and neck and sarcoma patients;
- Randomisation arm and hospital services; fewer in the control group used these services
- Use of websites and age of patient (younger patients accessing more frequently)

It was not possible to conduct Chi-squared analysis for healthcare-related services and any of the following variables; ethnicity, website against disease site and deprivation category. It was only possible to explore an association between others and randomisation arm. This was due to violations of assumptions in terms of cell count, i.e. the numbers were too small.

Table 6.4: Frequency of use of services at baseline (patient checklist)

	Intervention (n=39)		Control (n=37)		Total (n=76)	
	n	**%**	**n**	**%**	**n**	**%**
Healthcare-related	10	26	7	19	17	22
Government or local council	12	31	12	32	24	32
Charity/ voluntary	14	26	11	30	25	33
Other hospital-based	10	26	17	46	27	36
Websites	11	28	4	11	15	20
Other	0	0	1	3	1	1

Audio-recording data – frequency of discussion within consultation

Only patients who had a complete set of four recordings were included in this analysis (n=67). Reasons for incomplete datasets included: if the patient was missed in clinic, if a clinician refused to be recorded, or if the audio file became corrupted and was therefore unusable. One patient had no speech at all, but communicated during consultations by writing down what he wanted to say, and allowed the research team to take photocopies of these responses. By audio-recording the consultation and using these notes it was still possible to conduct the analysis.

Reliability checks

Checks were carried out on all four consultation recordings for 10% of patients (n=7). PW listened to and coded these consultations using the same framework as EJI had originally. Coding was compared and agreement calculated only on issues that were recorded as being raised in the consultation at all. Original agreement was 63% overall. A discussion then took place to reach consensus on the areas where there had been disagreement in coding. This was typically where one researcher had coded and the other had missed an issue, rather than disagreement in what conversations were classed as which issue from the social difficulties subscales and single items.

Figure 6.4 shows the frequency with which each subscale/ single item was raised in baseline consultations, between randomisation groups and overall. The most frequently raised subscales and items were everyday living and other areas of everyday life, raised in 79% and 64% of consultations respectively. The everyday living subscale includes single items of independence, domestic chores, personal care, care of dependents getting around and recreation.

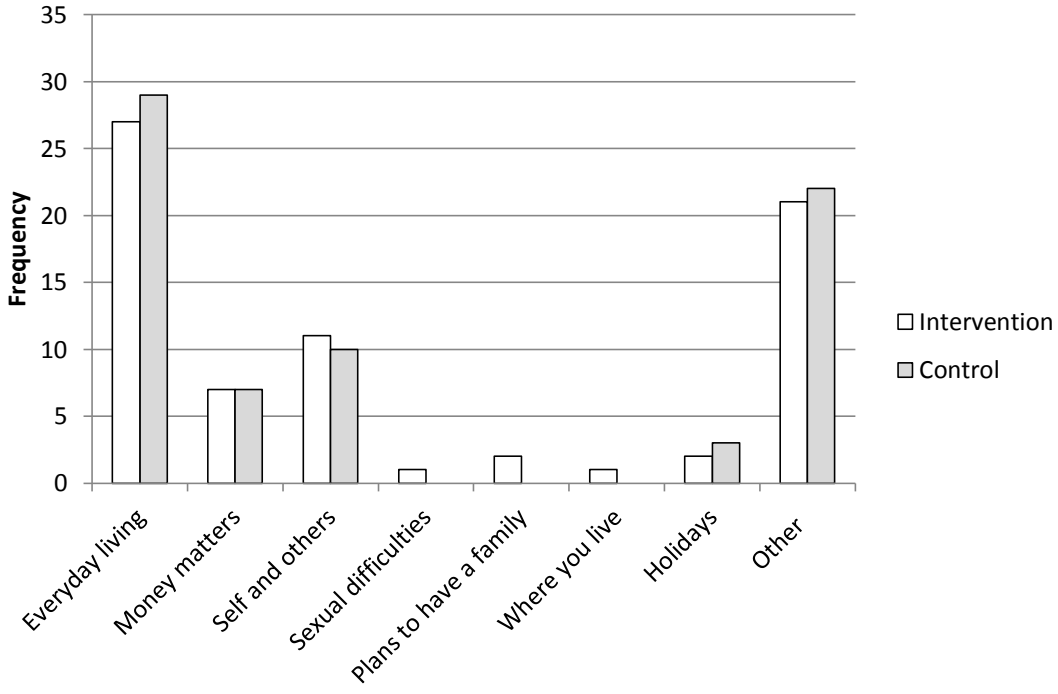


Figure 6.3: Frequency with which issues were raised in baseline consultations by randomisation arm

Chi-squared analysis was not feasible to explore association between the following variables because the low frequencies violated the assumptions for chi-squared in terms of cell counts:

- Ethnicity and frequency of any issue
- Frequency of raising of sexual difficulties, plans to have a family, where you live, holidays and any socio-demographic variables
- Money matters and deprivation category

A significant association was found between the frequency of money matters being raised and the age of the patients, with younger patients having a higher frequency of money matters being raised in the consultation. A significant association was also discovered between the frequency of 'other' issues being raised in the consultation, with head and neck patients raising issues classed as 'other' more frequently.

6.6.3 End of study results

6.6.3.1 Outcome measures

Table 6.5 shows mean scores and standard deviations for each outcome measure, for each randomisation arm and overall.

Table 6.5: End of study outcome measures

	Intervention	**Control**	**Total**
	Mean, SD	**Mean, SD**	**Mean, SD**
CARES-SF	**n=37**	**n=33**	**n=70**
Global CARES-SF score	4.9, 2.6	4.8, 3.1	4.9, 2.9
HADS	**n=36**	**n=35**	**n=71**
Anxiety subscale	6.5, 3.3	5.9, 4.1	6.2, 3.7
Depression subscale	5.6, 4.1	6.0, 4.7	5.8, 4.4
Global HADs score	12.1, 6.2	11.9, 8.3	11.9, 7.3
SDI-21	**n=36**	**n=35**	**n=71**
SD-16	10.8, 7.8	8.7, 7.5	9.7, 7.7
Everyday living subscale	5.4, 4.4	4.8, 4.0	5.1, 4.2
Money matters subscale	2.8, 3.2	1.5, 2.3	2.2, 2.9
Self and others subscale	2.6, 2.4	2.3, 2.6	2.5, 2.4

The results of ANCOVA analyses (tables 6.6 a to e) demonstrated that, after adjusting for baseline scores, there was no significant difference in scores for any of the selected outcome measures (global CARES-SF, HADs or SD-16 global distress score) between the two randomisation arms after delivery of the intervention (shaded grey). Details are presented in tables 6.6a to e. In all cases there was a strong relationship between the pre and post-intervention scores (highlighted in **bold**).

Table 6.6a: ANCOVA results for global CARES-SF

Dependent Variable: End of study global CARES-SF score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	225.181a	2	112.590	22.033	.000	.397
Intercept	54.889	1	54.889	10.741	.002	.138
Baseline global CARES-SF score	224.529	1	224.529	43.938	.000	.396
Arm	**.174**	**1**	**.174**	**.034**	**.854**	**.001**
Error	342.382	67	5.110			
Total	2241.410	70				
Corrected Total	567.563	69				

a. R Squared = .397 (Adjusted R Squared = .379)

Table 6.6b: ANCOVA results for HADs – anxiety subscale

Dependent Variable: End of study HADs-A anxiety subscale score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	476.321a	2	238.160	34.483	.000	.504
Intercept	73.852	1	73.852	10.693	.002	.136
Baseline HADS_A	469.397	1	469.397	67.963	.000	.500
Arm	**2.983**	**1**	**2.983**	**.432**	**.513**	**.006**
Error	469.651	68	6.907			
Total	3648.000	71				
Corrected Total	945.972	70				

a. R Squared = .504 (Adjusted R Squared = .489)

Table 6.6c: ANCOVA results for HADs – depression (HADs – D) subscale

Dependent Variable: End of study HADs - D depression subscale score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	584.411a	2	292.206	26.749	.000	.440
Intercept	32.521	1	32.521	2.977	.089	.042
Baseline HADS_D score	581.572	1	581.572	53.238	.000	.439
Arm	**.175**	**1**	**.175**	**.016**	**.900**	**.000**
Error	742.828	68	10.924			
Total	3718.000	71				
Corrected Total	1327.239	70				

a. R Squared = .440 (Adjusted R Squared = .424)

Table 6.6d: ANCOVA results for global HADs score

Dependent Variable: End of study global HADs score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	1851.881a	2	925.940	33.887	.000	.499
Intercept	105.683	1	105.683	3.868	.053	.054
Baseline global HADs	1850.985	1	1850.985	67.741	.000	.499
Arm	**3.488**	**1**	**3.488**	**.128**	**.722**	**.002**
Error	1858.063	68	27.324			
Total	13886.000	71				
Corrected Total	3709.944	70				

a. R Squared = .499 (Adjusted R Squared = .484)

Table 6.6e: ANCOVA results for SD16 scores (global social difficulties score)

Dependent Variable: End of study SD16 score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	2837.724a	2	1418.862	75.721	.000	.690
Intercept	115.436	1	115.436	6.161	.016	.083
Baseline SD16 score	2757.916	1	2757.916	147.182	.000	.684
Arm	**1.479**	**1**	**1.479**	**.079**	**.780**	**.001**
Error	1274.192	68	18.738			
Total	10837.000	71				
Corrected Total	4111.915	70				

a. R Squared = .690 (Adjusted R Squared = .681)

Tables 6.7a to e show adjusted mean scores and confidence intervals for all end of study outcome measures, by randomisation arm.

Table 6.7a: Adjusted means and confidence intervals – end of study CARES-SF

End of study – global CARES-SF adjusted means

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	4.837[a]	.394	4.052	5.623
Intervention	4.937[a]	.372	4.195	5.679

a. Covariates appearing in the model are evaluated at the following values: CARES_Global = 4.6957.

Table 6.7b: Adjusted means and confidence intervals – end of study HADs-A

End of study – HADs – A (anxiety subscale)

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	5.967[a]	.438	5.092	6.841
Intervention	6.377[a]	.444	5.490	7.264

a. Covariates appearing in the model are evaluated at the following values: HADS_A = 6.21.

Table 6.7c: Adjusted means and confidence intervals – end of study HADs-D

End of study – HADs – D (depression subscale)

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	5.754[a]	.552	4.652	6.855
Intervention	5.853[a]	.560	4.736	6.970

a. Covariates appearing in the model are evaluated at the following values: HADS_D = 5.30.

Table 6.7d: Adjusted means and confidence intervals – end of study global HADs

End of study – global HADs score

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	11.753[a]	.871	10.015	13.492
Intervention	12.197[a]	.884	10.433	13.960

a. Covariates appearing in the model are evaluated at the following values: HADS_T = 11.51.

Table 6.7e: Adjusted means and confidence intervals – end of study SD-16

End of study – global social difficulties (SD-16)

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	9.584[a]	.736	8.116	11.052
Intervention	9.876[a]	.725	8.429	11.323

a. Covariates appearing in the model are evaluated at the following values: SD16 = 9.55.

Effect sizes were calculated for each of the outcome measures (table 6.8). Cohen's guidance for assessing the effect size was employed, which showed a small effect on all outcomes (≤0.2 = small, ≤0.5 = medium, ≤0.8 = large)[166].

Table 6.8: Effect sizes for all outcome measures

CARES-SF	**Effect size**
Global CARES-SF score	0.03
HADS	
Anxiety subscale	0.16
Depression subscale	-0.09
Global HADs score	0.03
SDI-21	
SD-16	0.3
Everyday living subscale	0.14
Money matters subscale	0.4
Self and others subscale	0.12

6.6.3.2 Process of care measures

Patient checklist data – use of services

Table 6.9 demonstrates how many patients used each service, split by randomisation arm and shown for both time-points. Only patients with a complete checklists at both baseline and end were included in this analysis (n=70).

Table 6.9: Use of services as reported on Patient Checklists

	Baseline		End	
	Control (n=33)	**Intervention (n=37)**	**Control (n=33)**	**Intervention (n=37)**
Healthcare-related	4	11	4	5
Government/ local council	10	10	10	10
Charity	7	9	7	9
Other hospital	10	8	10	8
Websites	3	10	3	10
Others	0	4	0	4

Use of service data was combined to calculate the number of patients in each group who used any service at baseline and at the end of the study. The aim was to use this data to conduct a Cochran-Mantel Haenzel Chi-Squared (CMH) analysis. This demonstrated (table 6.10), that patients who were not using any services at baseline were also still not using any services at the end of the study, and those who were using services were continuing to do so at the end of the study. Due to the nature of these data, it was not possible to conduct the CMH test.

Table 6.10: Use of any service at baseline and end of study

		Use of any service at the end of the study		
Use of any service at baseline		**No (n=35)**	**Yes (n=35)**	**Total (n=70)**
No (n=35)	**Control arm**	18		18
	Intervention arm	17		17
	Total	35		35
Yes (n=35)	**Control**		15	15
	Intervention		20	20
	Total		35	35
Total (n=70)	**Control**	18	15	33
	Intervention	17	20	37
	Total	35	35	70

Nurse checklist data – informal contact between nurses/ patients

It became apparent as the study progressed that the expected observation of informal contact between nurses and patients in the waiting area before and after consultations was not seen. Only one form was completed because the researcher witnessed a conversation loosely based around social difficulties. In one clinic (haematology), there were no staff nurses running the clinics. It was planned that the Clinical Nurse Specialists (CNSs) would complete the nurse checklists should they have unplanned

contact with patients in the waiting room, but again, this was not observed. In head and neck clinics the nurses are more involved in the patient's consultations with the doctors and see patients regularly at weekly nurse-led clinics. The staff interview conducted at the end of the study was amended to include a question about why this activity was not seen as expected.

Audio-recording data – frequency of discussion within consultation

Figure 6.5 shows the frequency with which issues were raised in the last of four recordings, by randomisation arm and overall. The areas of Everyday Living and Any other area of everyday living were raised most frequently. Self and others and 'other' issues were raised more frequently in the intervention arm, and holidays more frequently in the control arm.

Forty-six patients had one or more issues discussed during their consultation that were coded as 'other' (figure 6.6). These included:

- Anxiety relating to fear of progression and/ or a patient who was awaiting scan or blood results (n=20)
- Difficulty eating or lack of appetite; includes issues relating to maintaining weight (n=25)
- General coping (n=4)
- Pain (n=3)
- Sleep (n=11)
- Lack of energy, visual difficulties and concerns around continuity of care (all n = 1).

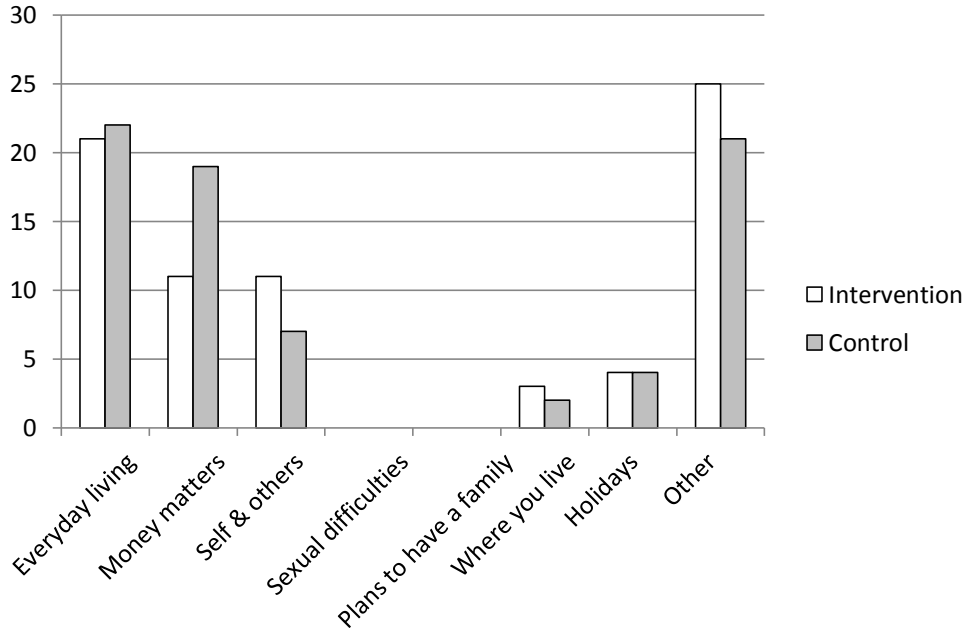


Figure 6.4: Frequency with which issues were raised in end of study consultations by randomisation arm

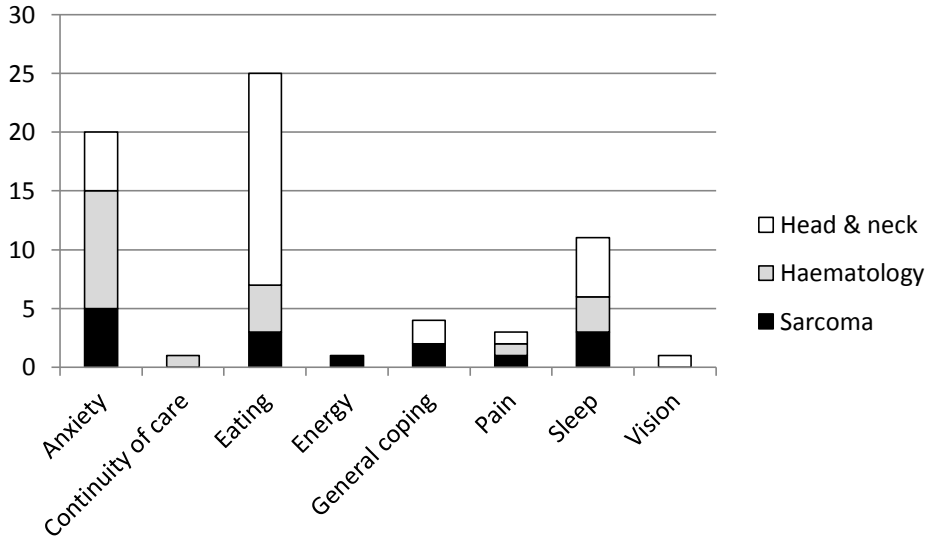


Figure 6.5: Frequency of issues coded as 'Other' by diagnosis group

Difficulties relating to eating, appetite and weight maintenance accounted for most of the discussions classified as 'Other'. This issue was mainly of concern to head and neck patients, accounting for 18 out of 25 incidences of this issue being raised. This is likely to be related to the nature of head radiotherapy to the head and neck, which can leave the patient with a sore mouth and lack of taste. Sleep was also mainly an issue for head and neck patients. Anxieties relating to fear of progression (particularly when

patients were awaiting scan or blood results that would demonstrate response to treatment) were second most frequently raised, mostly from patients within the haematology diagnosis group.

Comparison of subscale scores and frequency of discussion

Tables 6.11a and b demonstrate the differences in mean SDI-16 subscale scores and whether the corresponding issues were raised in the consultation for the control group and intervention group respectively. The data from table 6.12b suggests that patients who scored highly (indicating higher difficulties) with money matters also tended to have these issues discussed in the consultation. There were no significant relationships between mean subscale score and whether issues were raised for the control group.

Table 6.11a: Comparison of subscale scores and frequency of discussion - control group

		Mean subscale score	SD	t-test	p
Everyday living raised	Yes	4.07	3.72	t(31)=-0.56	0.58
	No	3.17	2.93		
Money matters raised	Yes	2.57	3.55	t(31)=-0.64	0.53
	No	1.77	2.78		
Self & others raised	Yes	2.40	2.63	t(31)=0.16	0.86
	No	2.57	2.79		

Table 6.11b: Comparison of subscale scores and frequency of discussion - intervention group

		Mean subscale score	SD	t-test	p
Everyday living raised	Yes	4.86	3.72	t(28)=0.92	0.37
	No	6.38	4.75		
Money matters raised	Yes	5.00	1.09	t(28)=-3.34	0.003
	No	2.63	2.72		
Self & others raised	Yes	3.44	3.43	t(28)=-1.01	0.32
	No	2.33	2.46		

Influence of others in consultation

Chi-squared analysis was carried out to assess whether patients who had others present in the consultation more frequently raised each of the issues in question. No significant associations between presence of another person and whether the issues were raised were found. No significant difference in frequency of raising issues against randomisation arm was found at the end of the study.

Patient Interviews

Patient interviews were conducted at the end of the study, in most cases less than 14 days after obtaining the end of study outcome measures. Seventy-one patients took part in the interview in total. The interviews were used to assess what difficulties patients had faced throughout the period of the study (and therefore the main period of their active treatment), whether these issues were still a problem, and what resources, if any, had been accessed in an attempt to resolve the situation. Patients who were in the intervention group and therefore had received the SSIP were also asked about whether and how they had used it for each particular area.

Reliability checks

For 7 patient interviews coding was compared and agreement calculated only on issues that were recorded as being raised in the interview responses. Discrepancies between researchers' coding was discussed and consensus agreed. Following this process overall agreement was 93%.

Difficulties reported during interviews

Patients reported that they were experiencing difficulties in most areas at the time of the interview, regardless of intervention arm (figure 6.7). They reported accessing a wide number of services (table 6.13) during the interview, higher than that observed from the results of the patient checklists, including some that had not been noted on the checklists, e.g. friends and family.

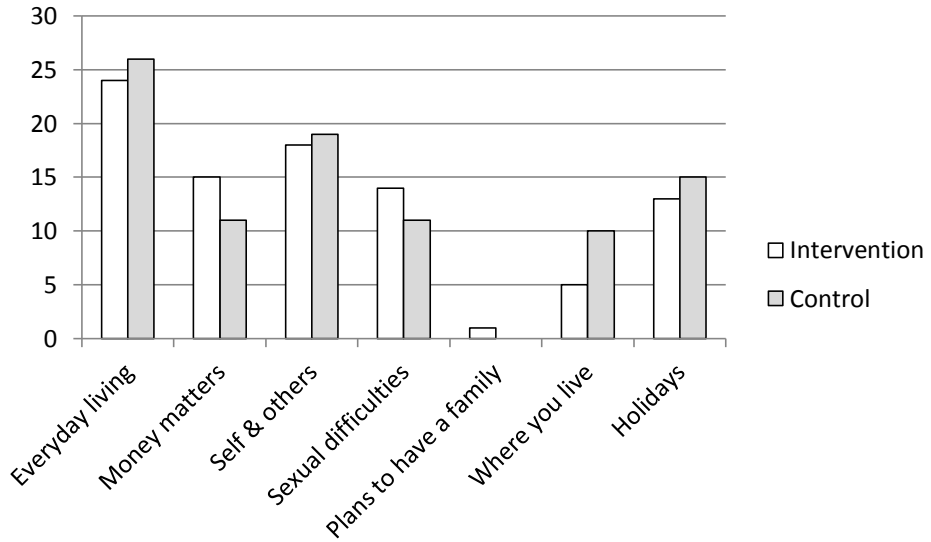


Figure 6.6: Difficulties experienced by patients at the time of interview, categorised by SDI-16 subscales and single items

Table 6.12: Typical resources accessed for each area of difficulty, as reported in end of study interview

	Everyday living	Money matters	Self & others	Sexual difficulties	Where you live	Plans to have a family	Holidays
Adaptations/ assistance at home	3		1		11		
Cancer Centre Hotel	2						
Blue Badge	6	2					
Clinical advice (non-CNS)	14	4	14	6			8
Clinical intervention	17				4	6	2
Community/ Primary Care (District Nurse, GP)	4	1	3		2		
CNS	4	7	9				3
Support group (including Church)	4		1				
Rehabilitation Team (non-SW)	7		3		1		1
Family & friends	41	9	48	15	9		1
Hospital transport	4	3					
Macmillan Cancer Support	4	12	4		2		5
Self	26		12	2	6		10
Other charity (non-Macmillan, e.g. local charity groups)	1	35			1		3
Social Worker	4	16			1		
Benefits advice		28					
Personal finances (e.g. pension)		41			2		10
Employer		15					
Other (e.g. MP)		1	14		6		8

Use of the SSIP

None of the 31 patients in the intervention group reported using the SSIP in any significant way, i.e. accessing a service or resource as a result of obtaining the information booklet. The majority (n=21) read through it when they received it, but then did not refer to it again. Nine patients reported not looking at it at all, or couldn't remember it, and one person was not directly asked about the use of the SSIP during the interview.

Participants were asked for reasons for not using the SSIP. The majority of people felt they had already accessed this information elsewhere (n=9), or that they were managing to deal with issues on their own (n=9). One patient felt they were provided with too much information, and others felt that they had not yet required the SSIP but would keep it "…as a back-up" (n=2). A further 9 participants gave no specific reason for not using the SSIP and one was not asked this question.

Patients were asked what they thought of the timing of the delivery of the intervention, i.e. would it be more useful if delivered earlier in their cancer journey. Three patients reported that it would have been more use to them if they could have accessed the information earlier, ideally at their first diagnosis.

Staff interviews

Participants

Eleven staff interviews were conducted, including staff nurses (n=2), CNSs (n=3), consultant (n=3), and specialist registrars (n=3).

Lack of use of SSIP by patients

Staff provided the following reasons why they thought patients did not use the SSIP (eleven staff interviewed provided 24 possible reasons):

- Patients already have the information (n=4)
- Patient are overloaded with information (n=5)
- Patients are already well supported (n=6) or didn't need the information (n=1)
- Patients only need key contacts or have other priorities (n=4)
- Patients prefer to speak to staff directly (n=1)

Lack of expected informal contact with nurses

The staff members were also asked to consider why the expected informal contact with staff in the waiting room was not observed. The eleven interviewees provided 16 possible reasons, which were:

- Patients are already well supported (n=3)
- There is a lack of space in clinic to provide such support (n=2)
- There is a lack of staff to provide such support (n=3)
- There is insufficient time during the clinic to provide such support (n=5)
- Patients do not open up (n=3)

6.7 Summary of findings

The key finding was that none of the patients who had been provided with the SSIP reported using it in any significant way. Other findings were;

- Both staff and patients acknowledged the large volume of information available to patients
- None of the patient-reported outcome measures suggested any influence of the SSIP on well-being, but this pilot was not powered to detect differences
- Estimates of effect size were calculated for all outcome measures and demonstrated a small effect in all cases; this suggests that a large RCT would be required to detect small differences
- A higher number and range of services and resources were reported as being used during the patient interview when compared with those reported via the patient checklist
- Some significant associations were found between socio-demographic characteristics and use of services, e.g. age and use of websites
- Everyday living and self and others were the areas of social difficulty most frequently discussed during the consultation
- Age had a significant influence on the discussion of money matters (more frequently raised in younger patients' consultations)
- An association was shown between discussion of financial issues and mean scores on the SDI-21 Money Matters subscale
- Issues relating to 'Self and others' and 'Any other area of everyday life'' were more frequently raised in the consultations of those in the intervention group

- Holidays were discussed significantly more frequently in the consultations of patients who did not receive the SSIP
- Informal contact between staff and patients in the outpatient setting was not observed as predicted; staff all reported similar reasons for this during the interview, e.g. lack of time

6.8 Discussion

Evidence suggests that information may have a key role in assisting with social difficulties and its provision may be lacking[36]. Despite this, when provided with an information intervention in this case patients failed to use it in any meaningful way. The main reason for this as reported by patients and suggested by staff, is that they already have the information, in one way or another. Staff more specifically referred to 'information overload', suggesting not only do patients have sufficient information, but in some cases there is too much, and patients will prioritise what they feel they need at that time. For example, at the height of treatment and the most severe side effects, the contact number for the CNS may be the only information the patients feel they need at that time. In Models of Diffusion (MoD) terms, the SSIP is too compatible with existing interventions[73], and therefore offers little perceived *relative advantage* over what is already available. As observed in this study, these factors result in a lack of adoption. The overall aim of this pilot was to estimate effect sizes and confidence intervals, and was not powered to demonstrate a difference in outcomes for patients. The function of the SSIP was reliant on patients reading it and accessing services, which did not happen. The small effect sizes observed suggest a large RCT would be required to detect only small differences. Considering the cost and resource implications associated with most large RCTs[167], this is probably not advisable.

Use of services was measured using the study-specific Patient Checklist. There was no difference in access to services regardless of randomisation arm. Patients receiving the SSIP had no greater awareness of availability of services than those in the control arm; this may be explained by the interview data that showed a lack of use. The patient interview at the end of the study elicited a greater range of resources accessed than the Patient Checklist. This included resources such as family and friends, pensions and personal savings. Although the 'Other' section on the Patient Checklist

was designed to capture these additional resources to the main five listed, patients did not report these using the checklist.

Despite the reported lack of use, the findings suggest a significant influence on randomisation arm on discussion of areas relating to 'Self and others' and 'Any other area of everyday life' (those in the intervention arm discussed these more frequently) and 'Holidays' (those in the control arm raised this issue more frequently). This may seem anomalous given that patients reported not using the SSIP in any significant way, and may suggest a more subtle influence of the intervention. It is also possible that this was a chance finding, and further testing would be required to show a definite association.

The majority of patients in the intervention group reported reading through the SSIP on receiving it, but then not referring to it again. It may be possible that the SSIP had simply raised awareness of some issues, which may have been sufficient to influence patients' discussion of issues, e.g. having read and had it acknowledged that relationships may be affected, this may have legitimised discussion during post-intervention consultations. Similarly, those in the intervention group raised the issue of holidays significantly less frequently than those in the control group. It may be possible that these patients had been able to access the information they required, and therefore did not need to raise it with their doctor.

Evidence from previous interview studies[60] suggested that there would be observable informal contact between nurses and patients within the setting of the outpatient clinic. The Nurse Checklist was designed to try and capture this, but this contact was not seen. When asked about this, staff suggested a variety of reasons, including lack of space, time and staff. This expected observation was based upon previous in-depth interview studies[60]. It is possible that the nurses in these interviews may have been describing the best case scenario, or that the characteristic of the clinics they were working in at the time allowed more of this contact to occur.

The findings from this pilot RCT echo those from other studies[168]; patients living with cancer will require information throughout their diagnosis, treatment and beyond, but these information needs will vary between individuals and as they progress through their personal cancer journey [169]. Kazimierczak et al (2013)[170] suggest information provision can be conceptualised as a "support for navigating

through the knowledge landscape", and that healthcare professionals need to recognise that each patient's journey through this landscape will be different. As such, a 'uniform distribution' of generalised information is unlikely to be effective [168, 170], as witnessed in the pilot described here. This increasing trend towards personalised information provision is evident from initiatives such as Information Prescriptions in the UK[171, 172]. This suggests that although information has a vital role in dealing with social difficulties, it will be much more effective as part of a larger, multi-faceted approach, than as a stand-alone intervention.

Although there is a huge amount of literature on the role and impact of information giving, there is a lack of randomised controlled trials, specifically within the area of social difficulties; most research around information giving focusses on treatment options and clinical interventions[168]. Therefore one of the key strengths in the pilot presented here is its randomised controlled design. The intervention was also based on evidence of patient-reported need and was designed with patient involvement throughout. Although the utility of the RCT design in studies of complex interventions is under debate, in the testing of one simple element of a proposed complex intervention, as in this case, this was a feasible method[173]. This provided robust evidence about the impact of the information component of the proposed complex intervention. The inclusion of the qualitative interviews also added to the value of the study, in understanding why the intervention did not work as well as the fact that it didn't work, in line with MRC guidelines[1].

During this pilot, the number of required participants was exceeded, with patients recruited successfully from three different clinical settings. Although the additional participants were not sufficient to offer additional power to the analysis, this did result in additional data for the patient interviews and process of care measures. Data were also successfully obtained from a patient who had no speech, but who was keen to take part in the study, by modifying the data collection methods to ensure they could be included as they wished.

A limitation was the design of the Patient Checklist, the aim of which was to collect data on services that patients had accessed at baseline and again at the end of the study. The information on the checklist was deliberately vague, to ensure patients weren't primed at baseline by having received a comprehensive list of available

services. However, more instruction may have been useful to the patients, e.g. asking them to consider and report on access and use of other resources such as friends and family. This would have allowed a better comparison of baseline data from the checklist and findings from the patient interview.

6.9 Conclusion

In terms of the original primary aim of the study, the evidence demonstrates that a generalised information resource, delivered without any guidance, may not be effective in assisting patients to deal with their social difficulties. The overall message from this chapter is that oncology patients undergoing active treatment are typically in receipt of sufficient information; in some cases they are overwhelmed with information. Therefore the addition of another information resource, even one designed specifically to target a known information gap, is not effective, as it is too generalised and too *compatible* with existing interventions that the patient is receiving[73]. The timing of delivery may be a factor in the lack of use. This will be explored in the second pilot study. The lack of impact of information and the finding that patients may already receive too much information, along with evidence from the literature, suggests that a more tailored approach may be necessary. The real benefit of information giving is likely to come when it is delivered as one component of a more personalised intervention, which is explored in the second pilot study.

Chapter 7: Development and evaluation of a Nurse Training Package (NTP) to facilitate delivery of an assessment for social difficulties

7.1 Overview

The previous chapter explored the impact of an information booklet, specifically designed to support patients with their social difficulties. Earlier evidence suggested that information alone may have the potential to assist patients in dealing with their social difficulties. As described in chapter six, patients who were provided with the information didn't use it, despite still reporting that they were experiencing difficulties. This suggests that the need was still there, but the simple information provision was not effective in helping patients deal with their social difficulties. A number of reasons for this were explored during staff and patient interviews. One of the most widely suggested reasons for lack of use was the amount of information that patients were already in receipt of, meaning that the Support Services Information Pack (SSIP – attached as additional material), became "…just another leaflet…". Another suggestion was that the social difficulties information was simply provided at the wrong time.

The lack of impact of the information booklet suggests that simple provision may be too compatible with existing practice. When an innovation is too compatible, this will prevent its uptake[73]. Patients are provided with and can access a huge amount of written information, in hard copy and via the internet. Information provision may be more effective when provided in response to specific difficulties, elicited by means of personalised, detailed assessment.

The next stage of the programme of work was to design a way to train nurses to provide such an assessment for patients, to check for the presence and severity of social difficulties, and evaluate the impact of this assessment on processes of care and patient outcomes, as compared with standard care. This chapter explains how the nurse training was developed, delivered and evaluated.

7.2 Background

Previous research into the roles and responsibilities of the clinical team has suggested that nurses naturally take a lead in the discussion of a range of issues, including social difficulties. Patients have also reported feeling that the nurses are the most

appropriate team members to deal with supportive care issues[60]. As a result of these findings, nurses were selected as the assessors for the purposes of this project.

Through discussion with nursing staff, it was known that, depending on their specific role, most nurses would have had some experience of carrying out formal assessments, so the concept in general would not be new to them. However, using the SDI-21 is not part of standard practice (the nurses were unlikely to have seen it), and its delivery via touchscreen and links to the electronic records system (patient pathway manager – PPM) were new concepts. Therefore for the nurses, the idea of assessing for and dealing with social difficulties via the touchscreen and within the context of the outpatient clinic were considered innovative. As a result, and in line with diffusion of innovation theory, some level of uncertainty regarding the practice did exist, which had the potential to hinder its adoption[73]. To counteract this, and increase the likelihood of adoption, nurses were provided with comprehensive training on the process (with the understanding that individuals may react differently to the innovation in comparison with others in their social system).

Another important attribute of an innovation is *compatibility* with existing working practices. Therefore the training needed to be acceptable to staff in terms of the time commitment required and flexibility, to fit in with their existing working patterns and limiting any disruption to their day to day activities. If this could be achieved it would increase the compliance with training and therefore increase the likelihood of the adoption of the new practice[73].

7.3 Aims

The aim of the work described in this chapter was to develop a Nurse Training Package (NTP) that was acceptable to staff and could fulfil required learning objectives, facilitating the delivery of an assessment of social difficulties for patients. A second aim was to develop an appropriate method by which to evaluate the effectiveness of the training.

7.3.1 Objectives of the NTP

The goal of the nurse training was to provide staff with the skills to successfully administer the SDI-21, interpret the results efficiently, and manage difficulties that become apparent through the assessment, e.g. provide information on appropriate

referral pathways and intervention strategies. The overall goal of the training was to facilitate the nurses in independently accessing the touch-screen system for the relevant patient, instruct the patient on how to complete the questionnaire on the touch-screen, access the results via the electronic record system (Patient Pathway Manager – PPM), interpret the results and manage any emergent difficulties. The proposed process was as follows.

1. Participating patient attends for outpatient appointment
2. Nurse brings up relevant patient details and prepares the SDI-21 on screen
3. Nurse brings patient into room, explains SDI-21 and facilitates completion
4. Nurse accesses responses; graphs, tables, individual responses or a combination
5. Nurse utilises guidance/ training and experience to decide best course of action depending on results
6. Nurse provides interventions at appropriate level as per guidance/handbook
7. Nurse records contact and interventions on PPM

7.4 Development of the Nurse Training Package (NTP)

The staff involved needed to be able to carry out the assessment for social difficulties in routine practice. They needed to be able to recognise significant scores and select appropriate interventions in response to issues being highlighted. The training programme needed to fit in with existing working practice as closely as possible without overburdening staff. For the purposes of the study the staff were not trained to recognise changes over time and clinically meaningful changes in scores over time, as they were only be carrying out the assessment once for each patient. Although they were made aware the SDI-21 has this capability, training them fully in this for the purposes of this study was unnecessary, and might have been confusing, time consuming and counter-productive.

7.4.1 Aims and methods

The aim of this section of work was to develop a Nurse Training Package (NTP), to fulfil the learning objectives outlined in table 7.1. The goal of the NTP was to facilitate the delivery of a formal assessment of social difficulties by providing nurses with the required skills.

Table 7.1: Required learning objectives

Area	Learning objective
Background	Ability to define social difficulties
	Understanding impact of unresolved social difficulties
	Basic understanding of the development of the SDI-21
SDI-21: Practicalities	Understanding how the SDI-21 works
	Ability to use the touch-screen
	Ability to access and understand the results/scores
	Ability to record contact and interventions on PPM
Resolving difficulties	Understanding levels of intervention
	Knowledge of appropriate services
	Knowledge of appropriate information resources

Specific aims and the methods used to develop a training package are outlined in table 7.2. Exploration of the literature was used to identify types of training or teaching delivery methods and their appropriateness to this context and type of training to be delivered. Meetings with Senior Nursing Staff (Lead Cancer Nurse and Matron) were conducted to introduce the research and gain permission to utilise nursing resource. These meetings were also used to find out if completing this training would have any benefit to the nurses in terms of fulfilling existing training competencies. After meeting with the Lead Cancer Nurse and Matron, the Sisters in the relevant departments were approached, again to introduce the study and establish appropriate times and locations for training, and gain permission to approach individual nurses and ask them to participate in the study. The results of the findings from the methods outlined in table 7.2 and their contribution to the Nurse Training Package are described in section 7.4.2.

Table 7.2: Aims and methods for designing a Nurse Training Package (NTP)

Aim	Method
Explore training delivery techniques and their effectiveness	Literature scoping
Establish what permissions are required to utilise nursing resource	Meetings with Lead Cancer Nurse and Matron with Line Management responsibility for Sisters in relevant departments and the nurses in their teams
Establish if completing the training will fulfil existing competencies	
Establish best locations and times for delivery of training	Meetings with Sisters in relevant departments
Identify and/or develop existing resources that can be used in teaching	Explore in-house documents and previous publications

7.4.1 The Nurse Training Package (NTP)

Table 7.3 demonstrates the structure of the training package, the delivery methods to be used and required resources that were used to achieve the learning objectives outlined in table 7.1.

Initial discussions with nursing teams suggested that shorter sessions, carried out over a number of days/ consecutive weeks may be more constructive than one long session. The training was therefore designed with three smaller components, which could be delivered over three separate occasions, or as one longer session, depending on the staff requirements. This allowed greater flexibility of delivery, allowing it to fit in with the nurses' busy schedules.

Findings from the literature suggested that active learning, particularly learning by doing, and immediate utilisation of skills are demonstrated as being the most effective teaching techniques in terms of knowledge retention (3 to 5). Lecturing and demonstration was kept to a minimum, and active learning techniques were employed where possible[130, 174].

Evidence suggests that limiting the time between training and utilising skills is beneficial[174]. The timing of the training was dependent on nurses' availability, and was done as close as possible to the start of the recruitment process so that nurses had the skills when they needed them, but also limiting the time between training and using the skills as far as possible.

Table 7.3: Structure of the NTP

Stage	Learning objectives	Timing & method of delivery	Resources
I - Background	Ability to define social difficulties Understanding impact of unresolved social difficulties Basic understanding of the development of the SDI-21	15 minute presentation 15 minute question and answer session	Presentations Papers
II - SDI-21-Practicalities	Understanding how the SDI-21 works Ability to use the touch screens Ability to access and understand the results/ scores Ability to record contact and interventions on PPM	30 minute practical session	Touchscreens Scoring guidance Case studies
III - Resolving difficulties	Understanding levels of intervention Knowledge of appropriate services Knowledge of appropriate information resources	30 minute practical session	Output from Stage II Guidance ICSS Staff Directory Case studies SDI Handbook

Although lecture-style presentations were kept to a minimum, it was felt that PowerPoint presentations would be most effective in delivering stage I of the NTP, the background information. Nurses were provided with hard-copies of the slides to refer to later, as well as relevant papers that would inform them about the development of the SDI-21, and the work preceding this study. Presentations were to be delivered in a structured but informal manner, with time allocated for questions and answers. This would allow key information to be delivered to a number of people (where necessary), but left individuals the option to access the papers should they be interested in further reading.

Practical sessions were considered to be the most crucial element of the NTP and the most effective learning technique. These sessions allowed nurses an opportunity to go through the process of completing the SDI-21 on the touch-screen computer, generating and analysing output, before doing this in a real clinic situation with real patients. This provided an opportunity to access the technology using 'dummy' data, and with the direct support of the research assistant. All nurses had the opportunity

to do this. These practical sessions also included instruction on how to record interventions and contact with the patient following the assessment on PPM.

All nurses were provided with a handbook to keep with them throughout the training and the period of the study. This included:

- General 'refresher' information regarding the SDI-21 (based on the content of the presentation)
- Scoring guidance[175]
- Hierarchies of intervention[60]
- Recording contacts and interventions on PPM
- Contact details for the research team

This handbook was developed from existing guidance on use of the SDI-21[60, 175]. Nurses were also provided with copies of the SSIP, to be used as a resource for patients in the intervention group if this was felt to be appropriate. All contact details and websites within the SSIP were checked for accuracy and updated as necessary. Information, Care and Support Services (ICSS) also provided each department with a Staff Directory, containing useful contacts both within and outside of the hospital.

The handbook was designed as a step-by-step guide, which nurses could use to take them through the whole process. The sections within the handbook were clearly labelled and dividers used so that nurses could access the relevant pages quickly. Instructions were illustrated with screen shots from the touch-screen and PPM to help clarify the steps involved. A flowchart was included to demonstrate what steps should be taken depending on the overall scores from the SDI-21, as well as by subscales. These were adapted from existing in-house guidance created by Dr Penny Wright.

In order to support the nurses, it was important that they were aware that this was a pilot study, the key objective of which was to test the feasibility and acceptability of including the assessment in standard practice. They were encouraged throughout to feed back any concerns regarding the study or conducting the assessments. The handbook included reassurance that a member of the research team would always be present in clinics when participating patients were attending. Although it was important to support the nurses, it was also important to ensure that the researcher would not be carrying out the assessment on behalf of the nurses, as this would not be

an accurate reflection of the impact of introducing such an assessment into practice. Contact details for the research team were also included. The handbook included materials provided during the training. Refresher sessions were offered on an ad-hoc basis, either for new members of staff or those who wanted a reminder. The handbook and offers of refresher sessions were felt to be particularly important, as relatively low numbers of patients would be requiring the assessment. This meant that it was likely some nurses would conduct fewer assessments than others.

7.5 Development of an evaluation method

The value of the proposed training added an additional variable to consider, i.e. if the assessment is not shown to be effective, this could be confounded by inadequate training. Therefore it was important that all learning objectives were met by the nurses prior to them actively assessing participating patients. A formal evaluation of the training was achieved using pre and post-course questionnaires, similar to those employed in communication skills training for clinicians, specifically the Connected © ACST Course Evaluation Questionnaire.

The Kirkpatrick Model is a four-level training evaluation model (table 7.4), which is employed in a number of fields to assess the effectiveness of training[176]. It is often used for measuring the impact of and evaluating training outcomes in healthcare settings, and was applicable in this scenario [176].

There were two options for evaluating the effectiveness of the staff training. The first was to use a formal evaluation tool at the end of the training programme and before the start of the research programme, e.g. a formal assessment of staff knowledge. There are a number of forms this could have taken, e.g. questions (exam or quiz). A more practical approach was also an option, e.g. role play, which could be assessed by the trainer/ facilitator and others in the group. This option would have highlighted any problems prior to the start of the project, but it would have extended the length of the training programme, and staff may have felt they were being tested and may not have enjoyed doing this.

Table 7.4: The Kirkpatrick Model for evaluation of training outcomes [176]

Level	Details	Possible methods
1 – Reaction	Post-course evaluation of the training Does not measure what trainees have learned Assess interest, motivation and attention from participants	Surveys
2- Learning	Measures what participants have learned Allows participants to demonstrate their knowledge	Written assessments Role plays
3 - Behaviour	Assessment of ability to use the learned skills and knowledge Determines whether participants use the skills in practice	Observation
4 – Results	Impact that the training has had overall, including financial and morale impacts	Observation

The second option was to evaluate during the research project, as staff were assessing participating patients. The main disadvantage to this method was that if there had been any failings in the training they would only be highlighted during the actual research project, which may cause delays and may impede the success of the assessments. One solution to this may have been to increase the number of patients required, which would carry time and resource implications. It would have given staff the opportunity to practice carrying out the assessments in 'real life', thus highlighting any practical difficulties that could not be accounted for during training. This would also have fitted with the active learning and problem-based techniques that are demonstrate increased retention of information and skills[130, 177].

7.5.1 Aims

The aim was to develop an NTP-specific evaluation questionnaire to formally evaluate the effectiveness of the nurse training.

7.5.2 Methods

Pre and post-course questionnaires were drafted. Item generation was achieved using the Connected © ACST Course Evaluation Questionnaire and NTP-specific learning objectives. The questionnaires were reviewed by Research Nurses from the Patient Reported Outcomes Group.

7.5.3 Results – the evaluation questionnaire

The full questionnaires are provided as appendices 16 and 17. The pre-course questionnaires were completed on one occasion, prior to any training being provided. The post-course questionnaire was completed immediately after training and intended to be repeated mid-way through the study. In the questionnaires, nurses were asked to indicate levels of confidence in dealing with social difficulties, by responding to a series of statements on a scale of 1 to 5 (1=strongly disagree, 5= strongly agree), e.g. "I am uncomfortable about raising some personal topics with patients (e.g. sexual matters, finances)".

Both questionnaires included a series of questions on the nurses' skills and abilities in dealing with social difficulties, and understanding of why it was important to do so. These questions were repeated in the pre and post questionnaires, in order to demonstrate increased confidence/ ability following training. The pre-course questionnaire then asked about any training already received, and what areas of carrying out routine assessments the nurses would perceive to be the most difficult. There is also a section where nurses could raise any specific issues they wanted more information on during the training. The post-course questionnaire included very specific questions relating to the learning objectives to be met during the training, e.g. "I am able to instruct a patient on how to complete the SDI-21". The post-course questionnaire also included a section where nurses could raise any existing concerns regarding the assessment.

7.6 Delivery and evaluation of the NTP

7.6.1 Participants

In the planning of the two pilot studies described in this thesis, it had been set out that the patient populations for the two pilot studies ideally should be the same (haematology, head and neck and sarcoma). The nurses who care for these patients in the outpatient setting were therefore the target participants for the training and would be the ones to conduct the assessments with participating patients. It was not possible to conduct the second pilot study in haematology as there is no Staff Nurse support in the outpatient clinic, which is run by CNSs and Healthcare Assistants.

Melanoma was selected as an appropriate alternative, as the treatment regimens are similar and the patient population also includes younger people as in haematology.

7.6.2 Difficulties in delivering the NTP

7.6.2.1 Time

The NTP was designed to be as flexible as possible, in order that it could be delivered within the constraints of the nurses' existing working routines. All of the nurses approached had responsibility for the running of a variety of outpatient clinics, and had a limited number of 'free' sessions in which the training could ideally be carried out. Despite the flexibility of the package and the ability to deliver one 30-minute section at a time, it was very difficult for some of the nurses to find the time to take part. Some of the nurses only worked part-time, and often their free sessions were taken up, as they were required to take part in mandatory clinical training or cover clinics for colleagues, e.g. in the case of absence. When the training sessions were conducted, they were typically rushed as the nurses dealt with these time pressures.

7.6.2.2 Concerns raised during training

In one clinic, the Sister raised significant concerns about the potential impact of conducting the assessment with their patients. This was during the delivery of the presentation and question and answer session, which was intended to provide the nurses with background information on the SDI-21. During this presentation, examples were given of the types of difficulties that may emerge as a result of conducting the assessment. Some of these issues, particularly sexual difficulties, alarmed the Sister, who felt that conducting the assessment would 'open a can of worms', increase the patients' expectations of what the nurses' were capable of helping them with, and ultimately pose a risk to the well-being of the patients. The issues were raised during the delivery of the presentation, which involved the whole outpatient nursing staff for that department. Although reassurance was given, i.e. the nurses would receive training on how to deal with difficulties, and that their role was to signpost patients to the appropriate service (if the nurses didn't have the capacity/ skills to deal with this), the Sister requested that the delivery of the training be stopped, and that further discussion should take place with her line manager and the research team.

Members of the research team met with the Sister and Matron, to discuss the concerns further. The Sister's concerns were addressed, reassurance given and the research was able to continue. The Matron was key in adding her support to the project (on behalf of herself and the Lead Cancer Nurse), but at the same time understood Sister's concerns.

In terms of diffusion of innovations theory, this is an example of how the unknown elements of an innovation may cause concern and prevent adoption, and how increasing knowledge and reducing uncertainty in an appropriate way can help to alleviate these concerns and result in the adoption of the innovation; described by Rogers as the "…uncertainty reduction process…"[73]. It also demonstrates the Matron's role as fitting Roger's description of an 'opinion leader'; an individual who is able to influence the behaviours and attitudes of others, but who are not necessarily an innovator. Their status as opinion leader is rarely a result of any formal role within the system. Their influence is generally earned by their knowledge or technical ability, approachability and accessibility, and their ability to conform to the accepted norms of the system. They tend to be at the centre of a number of interpersonal networks and therefore may have a wide range of influence[73].

7.6.3 Effectiveness of training

Eight nurses were responsible for the running of the relevant clinics from which patients would be recruited for the pilot randomised controlled trial. All eight nurses consented to take part in the study and therefore the training. One nurse left the post just after the training had been delivered. Due to an administrative error one nurse had completed the training without completing the pre-course evaluation questionnaire. Pre-course data was therefore available for six nurses. Post-course data at the first time point, i.e. immediately after the training was available for seven nurses, but only three completed the questionnaire at a second time point, after they had conducted four or five assessments.

As will be discussed in chapter eight, some nurses did not conduct this number of assessments and therefore were not asked to complete a second post-course questionnaire. Due to low numbers these data have not been included. Table 7.5 demonstrates mean scores in questions that were repeated in both questionnaires. Changes in mean scores are highlighted, and the asterisk indicates where questions are

negatively worded, i.e. a reduction in score is an improvement. Slight improvements are seen in perceived ability to assess social difficulties, selecting appropriate interventions and recognising which issues require specialist referral. A very minor reduction was seen in how disruptive nurses felt conducting the assessment would be.

Table 7.5: Impact of training on nurses' perceived capabilities and understanding

	Pre-course mean score (Range = 1 to 5) n=6	**Post-course mean score (Range = 1 to 5) n=7**
I understand what is meant by the phrase 'social difficulties'	4	4
I am aware of what issues would be classed as social difficulties	4	4
I am uncomfortable about raising some personal topics with patients (e.g. sexual matters, finances)*	3	3
It is important that social difficulties are dealt with	5	5
I am able to deal with a patient's social difficulties	3	3
I am able to adequately assess a patient's social difficulties	3	4
I am able to choose appropriate interventions to deal with social difficulties	3	4
I am able to recognise which issues I need to deal with myself and which require a specialist referral	3	4
I have knowledge of information for patients, locally and nationally	3	3
I have knowledge of available support services that are available for patients, locally and nationally	3	3
I am able to explain to patients why it is important to assess their social difficulties	4	4
It would be disruptive to carry out routine assessments of social difficulties during outpatient clinics*	4	3
Key **Denotes a negatively-worded item – a reduction in score is an improvement* *Shaded rows indicate an improvement in score*		

The **pre-course questionnaire** asked about previous training relating to social difficulties. Only three nurses reported having received any training related to social difficulties;

"Most courses I have completed have had some sort of social care on the agenda, but nothing specifically for social difficulties"

"In regards to completing holistic assessments and referral"

"As part of nurse training in general"

Prior to the training participants were also asked to identify which aspects of carrying out the assessment within routine practice they would find most difficult;

"Not having enough time due to busy clinic or only staff member running clinic so not giving the patient the time they require."

"Depends on the patient. Some give lots of info then don't wish to take further or are resistant (sic) to help. Others give little info but you know they need help."

"Time element and complexity of assessment."

"None in particular."

"Don't know yet."

The pre-course questionnaire also provided the nurses with the opportunity to share any queries or pressing concerns that could be addressed during the training, but nothing was reported on the evaluation form.

The **post-course questionnaire** (appendix 17) asked seven specific questions about the competencies and skills that should have been delivered in the training. Again, the range of scoring was 1 to 5 (1=strongly disagree, 5= strongly agree). There were no negatively worded questions. Mean scores of four were reported for ability to use the touch-screen, understanding of how the SDI-21 works, ability to instruct a patient to complete the SDI-21, ability to access the responses via PPM, and ability to provide appropriate interventions. Mean scores of three were given for ability to interpret the scores from the SDI-21 output and ability to record contact and interventions in PPM.

The final question asked what specific aspect (if any) the staff were most concerned about;

"Only slight concern until have used it once or twice with a patient."

"I think when the first patient is done it will all fall into place."

*"Referring to qs 1.14 to 1.20 - this will become more familiar and easy to use once we start. At present I can't really remember a lot of the session, sorry. Can't remember very much about session. Need to do it again possibly before starting to use it."**

*Referring to questions on; ability to use touchscreen, understanding of how SDI-21 works, ability to instruct patient, ability to access responses from PPM, ability to interpret scores, ability to provide interventions, ability to record contact.

"Just unfamiliar with it."

"Not sure yet if I can remember which boxes to click on screen. Hopefully it will come with practice and support."

7.7 Discussion

The aim of the work presented in this chapter was to develop a Nurse Training Package that could be delivered in a flexible and efficient manner, and provide ample opportunities for the nurses to raise any concerns regarding the assessment process and the pilot study. The goal of the NTP was to reduce the level of uncertainty around the new practice, thereby increasing its likelihood of adoption.

This process of uncertainty reduction can be observed in the situation that arose with the Sister who was concerned about potential negative consequences of conducting the assessment. After she had raised these concerns, she sought reassurance and guidance from her 'opinion leaders' – the Matron and Lead Cancer Nurse. In order to achieve uncertainty reduction and thereby engage her in the study, the research team worked closely with the Sister and her opinion leaders. In turn, the Sister was the opinion leader for the nurses within her department, and once she had her concerns addressed, her staff in turn were happy to take part.

The results from the evaluation demonstrated that the training alone has little influence on levels of confidence among the staff. The nurses anticipated that only having the opportunity to conduct the assessments would increase their skills and confidence, which is in line with teaching and learning theory[130, 177]. This suggests that engaging staff in 'role play' with members of the research team acting as patients may have had more of an impact on the nurses' confidence in conducting the interviews.

The next chapter (chapter 8) describes the piloting of the NTP and assessment versus standard care.

Chapter 8: Feasibility, acceptability and impact of an assessment of social difficulties in routine practice

8.1 Overview

Previous chapters have demonstrated that while information is important, generic, non-tailored information provision designed for a general patient population may not be effective in helping individuals deal with their social difficulties. The findings from chapter 6 also demonstrate that patients receive a lot of information, and in some cases were overwhelmed by it. In terms of Models of Diffusion (MoD) theory, the Support Services Information Pack (SSIP) trialled in chapter 6 may be too *compatible* with existing available information interventions, which may explain why it was not taken up by the patients. An innovation that is too *compatible* with what is already available offers no *relative advantage* to the user [2]. A more tailored approach may be more effective, and a greater benefit of information provision may be witnessed when delivered as a personalised intervention, in response to an identified need. This chapter explores the feasibility and acceptability of an intervention designed to enable this.

The previous chapter (chapter 7) described the development of a Nurse Training Package (NTP) to enable nurses to provide an assessment of social difficulties in routine practice, using the Social Difficulties Inventory (SDI-21). The current chapter describes the randomised pilot study that tested the feasibility and acceptability of conducting such an assessment within existing working practice, using the MoD framework to explain and describe the nurses' responses to the innovation. Any impact on patient well-being was also explored.

8.2 Aims

The primary aim of this pilot study was to investigate the feasibility and acceptability of delivering an assessment of social difficulties in a routine practice setting. Secondary aims were;

- To investigate the potential impact of the assessment on
    - processes of care and
    - patient well-being

- To calculate estimates of the effect size of this intervention for use in a future randomised controlled trial (RCT)
- Explore the optimum time for the delivery of an information intervention, specifically the Support Services Information Pack (SSIP, the trial of which is described in chapter 6)

8.3 Hypothesis

It was expected that in comparison to standard care, a social difficulties assessment, including nurse training and provision of information to patients, would have the following effects:

1. improve detection of social difficulties
2. lead to a change in the process of care
3. increase support accessed
4. enhance patient well-being when compared with standard care

8.4 Methods

Where possible, the methods used and described in the initial pilot study (comparing the SSIP and standard care – chapter 6) were duplicated. The same process and outcome measures were used, except in the pilot study described here the SDI-21 was used as an intervention and therefore not used as an outcome measure. Due to lack of expected data collected in the first pilot study from the Nurse Checklist (appendix 13), the Nurse Checklist was not used in this study.

8.4.1 Study design

The study followed a randomised parallel group design, intervention versus standard care. Processes of care and outcome measures were used. Randomisation was selected to allow the best estimate of the potential effect size of the intervention by comparing the two arms (figure 8.1).

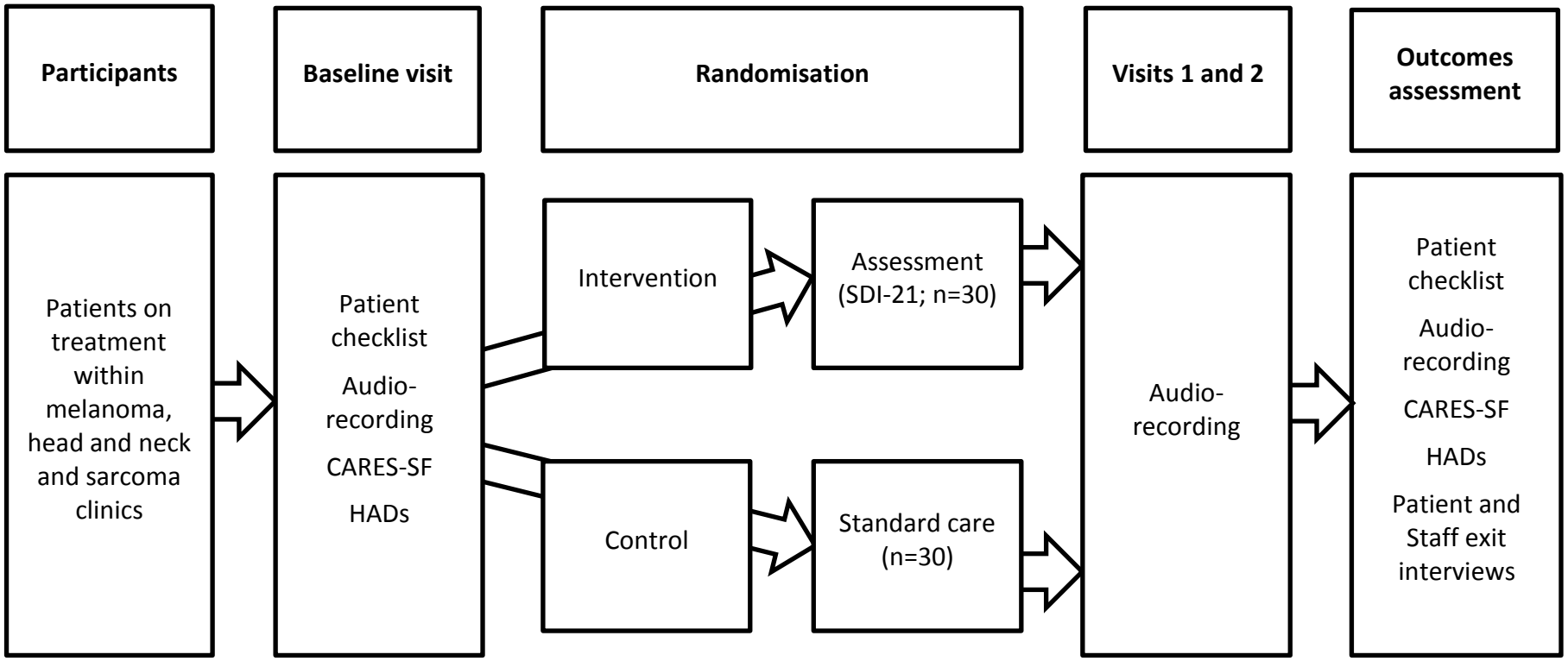


Figure 8.1: Study design

Key

CARES-SF: Cancer Rehabilitation Evaluation Scale (Short Form) [appendix 12]
HADs: Hospital Anxiety and Depression Scale [appendix 4]
SDI-21: Social Difficulties Inventory (21 items) [appendix 1b]
SSIP: Support Services Information Pack [included as additional material]

8.4.2 Setting

As described in chapter six (section 6.4.2), this pilot study was conducted at a large regional cancer centre. Participants were accessed and recruited from a general oncology outpatient clinic and a specialist radiotherapy clinic, serving patients with the diagnoses described in table 8.1.

8.4.3 Participants

As in the previous pilot study, in order to detect a change as a result of the intervention, the sample needed to include patients who were most likely to be experiencing social difficulties. As it is known that these are more common in younger patients and those on active treatment[44], the target disease groups were those described in the first pilot study (chapter 6 - head and neck, sarcoma and haematology).

It was not possible to conduct this study within the haematology clinics because there were no staff nurses employed within the outpatient setting. This meant that the intervention could not be delivered by the nurses as intended. As an alternative, patients were recruited from the melanoma clinics. This permitted delivery of the intervention through the staff nurses that ran the outpatient clinic, as well as including younger patients and those undergoing active treatment; these are patient populations likely to be experiencing a range of social difficulties [44].

For logistical reasons head and neck patients were recruited from, and all process and outcome measures taken throughout their appointments within the Nurse Led Clinic rather than the Consultant's outpatient review (as in the first study). This was done after discussion with the Senior Sister responsible for the care of the head and neck radiotherapy patients; she felt it would be too burdensome for nurses to conduct the assessments during the running of consultant-led outpatient clinics.

Eligible participants were again those who had received at least one of a minimum of four cycles of chemotherapy, or who had commenced radiotherapy with the intention for treatment to continue for a minimum of four weeks, and would be attending the hospital for a minimum of four consecutive appointments over a 3 to 6 month period.

Other eligibility criteria were;

- Ability to read and understand English
- Have the capacity to give informed consent and complete the questionnaires
- Non-participation in other psychosocial studies or clinical trials with a significant psychosocial or quality of life element
- Be on active treatment and planning to attend the hospital for a minimum of four consecutive appointments over a period of 3 to 6 months.

For the purposes of this pilot, all documentation associated with participation was again published only in written English, and was not made available in any other language or format, e.g. Braille, large font or audio. Patients were randomised to study arm (intervention or control) following consent. Randomisation was stratified by age, gender and disease site (table 8.1). Randomisation was achieved using the telephone service provided by the Leeds Institute of Clinical Trials Research.

Table 8.1: Stratification criteria

Age group (years)	Male			Female			Total
	Head & neck	Sarcoma	Melanoma	Head & neck	Sarcoma	Melanoma	
≤ 50	5	5	5	5	5	5	**30**
>51	5	5	5	5	5	5	**30**
Total	**10**	**10**	**10**	**10**	**10**	**10**	**60**

8.4.4 Sample size

As in pilot study 1 (chapter 6), there was no formal sample size calculation. In order to obtain data to fulfil the secondary aim of estimating the effect size of the intervention, and assist in the selection of primary outcome measures for a future randomised trial, the sample size was maintained at 30 patients per arm, as in pilot study 1[159]. Allowing for a 13% drop-out rate as observed in the first pilot study, a minimum of 34 patients per arm were required to obtain complete data on 60 patients in total. Recruitment would cease when data had been collected on 30 patients per arm.

8.4.5 Intervention

The intervention in this pilot study was a one-off assessment of the patient's social difficulties, using the SDI-21 (appendix 1b), administered via a touch-screen computer.

For patients randomised to receive the intervention, the one-time assessment was carried out by a nurse from the relevant outpatient clinic who had undergone the Nurse Training Package (NTP), the development, delivery and evaluation of which is described in chapter 7. This involved completion of the SDI-21 on a touch-screen computer, under guidance from the nurse. The SDI-21 (appendix 1b) and the scoring methods are described in detail previously in chapters 1 and 6 (sections 1.6.3 and 6.4.8.3) [43, 70]. Score interpretation guidance, including subscales and clinically meaningful differences have been developed for the SD-16 (figure 1.1)[178, 179]. Only patients who were randomised to the intervention arm underwent this assessment following baseline, when they attended for their second on-study appointment. This was only carried out once during the study (figure 8.1).

Once the SDI-21 had been completed, the nurses could access the results either directly from the touch-screen system or via the electronic Patient Pathway Manager system (PPM). Responses were available in a variety of formats, including a full printout of the whole questionnaire, graphical outputs or summarised by subscale. These results were then used to facilitate a discussion with the patient regarding any difficulties they may have reported. The SSIP from the first pilot study (chapter 6) was made available to the nurses, to be provided to the patients if they thought it would be appropriate. Although findings showed it was not widely used in the first pilot study, no concerns regarding the acceptability of the SSIP were raised; therefore it was made available to the nurses.

8.4.6 Procedure

1. Senior nursing staff were approached to obtain permission to approach nurses and utilise nursing resources and time during the period of the research
2. Nurses were provided with information sheets
3. Consent to participate was obtained from nurses
4. Consent to have NLP Clinic appointments and assessments audio recorded was obtained from nurses
5. Nurses who consented to participate were trained as outlined in the Nurse Training Package (NTP - described in chapter 7)

6. Consultants responsible for the care of the patients were provided with information sheets
7. Permission to invite patients to participate was obtained from consultants within the multi-disciplinary teams (MDTs) responsible for their care
8. Consultants who were to see patients at their review appointments were identified and approached separately as participants themselves, in order to obtain their consent to participate in the study
9. Posters explaining the research activity within the unit were displayed, and leaflets provided to patients in the clinics from which participants were required
10. Eligible patients were identified using the electronic patient notes and clinical trials management system (PPM)
11. Researchers checked the names with the clinic staff to ensure that there were no reasons why the potential participants should not be approached (e.g. if they were too ill, anxious, or had recently received bad news)
12. The list of potential participants was taken to the relevant outpatient clinic
13. The details of the study were fully explained by the researcher and the patient presented with an information sheet
14. Patients were given up to four weeks to consider whether participation
15. Verbal consent to approach again at next visit or contact by telephone was obtained
16. Patients who were not returning to clinic within 4 weeks were telephoned at home
17. Patients who were returning within 4 weeks were approached again at their next visit
18. When they had decided to participate, patients were asked to read and sign a consent form, which was posted out with a return envelope to those who made the decision at home

19. Following consent, patients were asked to complete the baseline measures (patient checklist, CARES-SF and HADS [appendices 14, 12 and 4 respectively), and have their consultation recorded during the clinic visit
20. Clinical and socio-demographic data was collected using the PPM system using a clinical data form
21. Patients were randomised via telephone by the Leeds Institute of Clinical Trials Research.
22. Those patients randomised to the intervention group received the assessment by a trained member of staff prior to their second visit, which included completing the SDI-21 and discussing the results with the nurse*.
23. The subsequent consultation was audio-recorded.
24. Patients were monitored and seen next at their first post-treatment follow-up appointment, which was also audio-recorded.
25. Head and neck radiotherapy patients had both of their first post-treatment NLP appointment and doctor's review appointments recorded.
26. Patients were sent outcome measures after this appointment by post (patient checklist, CARES-SF, and HADS [appendices 15, 12 and 4]).
27. Once these were been completed and received, patients in the control group were provided with the SSIP.
28. A suitable time for the semi-structured exit interview was also arranged, within four weeks of receipt of the completed outcome measures, and four weeks following receipt of the SSIP for the control group.
29. Interviews with participating nurses were also arranged for within 8 to 12 weeks of the end of the study.
30. Patients who declined to participate were asked to complete a Declined to Participate Patient Consent Form and provide their socio-demographic information
31. This form permitted the research team to keep an anonymised record of the patient's basic socio-demographic and clinical information. This was used to

explore demographic differences between participants and non-participants at the end of the study.

32. If patients did not wish to sign this form, only a record of the number of patients on whom no basic demographic information was available was kept.
33. During the study recruitment and follow-up a secure record of the names of patients who declined to participate or withdrew from the study was kept on the PPM system, so they were not approached again.

**Following a substantial amendment, the assessment and subsequent discussion were audio recorded following further consent from the nurses to do this.*

8.4.7 Acceptability and feasibility; staff interviews

At the end of the study, all nurses who participated were interviewed using a semi-structured interview schedule (appendix 9).

The aims of these interviews were;

I. to elicit their thoughts on the acceptability and feasibility of conducting the assessment within their current working practice
II. to explore what factors may influence their likelihood to adopt a new practice (such as the assessment) in the future
III. to assess the suitability of the training and support provided

For both **patient** and **staff interviews** the semi-structured format allowed more discussion than a closed interview, facilitating detailed qualitative analysis, whilst ensuring the pertinent questions are answered and potentially allowing quantitative analysis of some of the responses [160, 180].

8.4.8 Processes of care measures

The same process of care measures were employed in this study as in pilot study 1 (chapter 6), apart from nurse checklists.

8.4.7.1 Patient checklists

The study-specific patient checklist (appendices 14 and 15) were used again as in the first pilot study. The aim of the checklist was to assess patient awareness of and use of support services. Two versions were generated; one for baseline and end of study

(appendices 14 and 15 respectively), and were developed in conjunction with the SSIP using the same sources of information. The aim of these checklists was to identify if undergoing an assessment with the nurse had alerted any patients within the intervention group to specific services, and by what other means the standard care group may become aware of services during the period of their treatment.

At baseline (appendix 14) patients were asked if they had used a variety of services within the last 3 months, with a simple tick-box to respond yes or no. The number of services listed in detail was kept to a minimum to reduce the risk of patients being 'primed' to services before they started the study.

The end-of-study patient checklist (appendix 15) listed the same services, but asked the patient in more detail about their use of these services and reasons why they had accessed or not accessed them. The content and acceptability of the checklists was evaluated during the first pilot study, and no changes were made for the second pilot study.

8.4.8.2 Audio-recording of clinical consultations

Audio-recordings were selected to monitor the discussion between patients and oncologists or nurses during review appointments. They were used to identify discussion of psychosocial difficulties and support services, initiation of the discussion, information provided and actions taken on these issues. Audio-recordings allowed subsequent careful analysis of all these factors and did not burden the staff or patients with any additional tasks. As these discussions took place in a private room separate from patient waiting area this method was feasible.

8.4.8.3 Patient interviews

Patients completing all stages of the study were asked to take part in a semi-structured patient interview (appendices 10a and b) following completion of the end of study questionnaires and audio-recordings. This was conducted face-to-face at a location convenient to the patient, or over the telephone. The aim of this was to investigate the nature of any difficulties faced, what help was requested or provided, how this was accomplished and the impact that this had on them. There were additional questions for the intervention group, enabling the interviewer to elicit specific details on the assessment process.

The patient interview schedules were designed using information from previous staff and patient interview studies[54], and that collected and used in the development of the SSIP. Areas for discussion were based on the sub-scales of the SDI-21, which are groups of items that were shown to fit with each other following factor analysis. This allows discussion on similar issues without having to discuss each individual item on the SDI-21. This was also used to explore the use of the SSIP and patients' thoughts on the timing of this intervention.

8.4.9 Outcome measures

The aim of the outcome measures was to assess any patient self-reported change in social difficulties and/ or impact on psychological distress. As the SDI-21 was the intervention in this study, it was not included as an outcome measure. As in pilot study one the Cancer Rehabilitation Evaluation System – Short Form (CARES-SF – appendix 12) and Hospital Anxiety and Depression Scale (HADS – appendix 4) were used to provide outcome measures.

8.4.9.1 CARES-SF

To provide comparable measures of quality of life and day to day problems, the CARES-SF (appendix 12) was used. It is a 59-item questionnaire, on which patients complete between 38 and 57 items. Patients rate problems on a 5-point scale, ranging from 0 (not at all – no problem) to 4 (very much – severe problem). This can provide a Global-CARES-SF score and scores for each of five domains; physical, psychosocial, medical interaction, marital and sexual [162].

8.4.9.2 HADs

The **Hospital Anxiety and Depression Scale (HADs)** was chosen to detect any patients with anxiety and depression. It is a 14-item instrument, with two subscales for anxiety and depression. Scores range from 0-21 on each scale with higher scores indicating more distress, providing valid measures of severity [141].

8.4.10 Assessment data

Audio-recordings were taken of the interaction between the nurse and the patient during the assessment. For head and neck patients the assessment and the first post-

intervention audio recording took place at the same time. Data from the SDI-21 completed by patients during the assessment was extracted from PPM.

8.5 Analysis

8.5.1 Acceptability and feasibility; staff interviews

Framework analysis was used to analyse the staff interviews. Framework analysis is a qualitative analysis method commonly used within health-services research[72]. It provides an opportunity to develop an *a priori* framework which can be added to as the analysis progresses and additional themes or findings are discovered. It involves the following standard five-step process;

1. **Familiarisation**: the stage at which the analyst becomes familiar with the data and gains an overview of general emerging themes
2. **Identifying framework**: this is typically the development of a framework using the themes identified within the familiarisation stage.
3. **Indexing**: the stage at which the text from the interviews is coded or allocated to the relevant headings of the framework
4. **Charting**: at this point the indexed data is organised by headings within the framework
5. **Mapping and interpretation**: the sections of data from stage four are used to populate a matrix, based on the original framework[72, 181]

Familiarisation in this context began during data collection as the interviews were being conducted. Notes were taken during the interviews and any emergent themes/ areas of questioning added as appropriate (e.g. if something came up in first interview it was added to subsequent ones). **Identifying the framework;** in this context key elements of the MoD conceptual model[2] had already been identified as the *a priori* framework. This is shown as table 8.2, which also includes details of how each element of the framework was applied to the interview data. The elements of *assimilation by the system, implementation and routinisation, linkage among components*, *system antecedents* and *readiness for innovation* were related to the long-term implementation of innovations and therefore were not included as part of the *a-priori* framework.

The **indexing** stage involved listening to and making detailed notes on each of the interviews conducted, then **charting** and **mapping** was achieved by using an Excel spread sheet to organise the data under the relevant headings (framework items). The interview schedule was developed based on the MoD model[2], which was also then used as the framework for analysis. Due to significant differences in working practices between the two types of clinic in which the study took place the two locations were considered separately during the analysis.

Table 8.2: *A-priori* analysis framework and definitions described in context (examples in *shaded italics*) – taken from models of diffusion framework[2]

Element	Definition as described in MoD framework[2]	Application in this context
The innovation	The new, unfamiliar technology and/ or practice.	The practice of assessing patients for the presence and severity of social difficulties, using the SDI-21 (delivered on a touch-screen system), interpreting results and dealing with issues raised.
Relative advantage	The extent to which the innovation or new technology is perceived as offering an improvement over existing practice [2, 73].	Whether the assessment using the SDI-21 offered an advantage over existing methods of identifying and dealing with social difficulties.
On the *relative advantage* of using the SDI-21 in comparison with existing assessment methods; *"…it's another perspective isn't it, a different viewpoint…because it is patient-reported rather than you asking a question and then writing that down."* (S38)		
Compatibility	Refers to how closely an innovation fits with current values and needs of the potential adopters [2, 73].	How compatible conducting the assessment was with the existing working practices in the specified clinics.
On the *compatibility* of using touch-screen technology in clinic; *"…go back to paperwork…it's more transferable…transportable than a computer... (because) some clinics, there is no free room to take a patient in and find an empty computer…"* (S77)		
Complexity	How difficult the innovation is to understand and use [2, 73].	How easily the nurses could learn to use (and maintain the knowledge) to enable them to conduct the assessments.
On the *complexity* of the online system and difficulties retaining knowledge post-training; *"I was a bit frightened of by the idea of it…remembering how to go through it because it was* 'click this button, click that button' *and so when we actually went to do it, because we did our training months and months (before) the first person came up…I'd forgotten all about it."* (S77)		
Trialability	How much opportunity there is for the potential adopters to practice or *trial* the innovation [2, 73]?	As this was part of a research project the context was within a trial setting, and also refers to how many opportunities the nurses had to 'practice' carrying out the assessments.
On the lack of opportunity to practice during the study; *"…If I'd had done more of them and I was proficient enough and it was automatically in the back of my head…that would have been fine but…I only did it once…"* (S81)		
Observability	Relates to the extent to which the outcomes of an innovation can be seen by potential adopters [2, 73].	Whether the nurses could *observe* the impact of conducting the assessment for the patients, whether positive (helping them deal with social difficulties) or negative (e.g. significantly affecting the running of the clinic).

Element	Definition as described in MoD framework[2]	Application in this context
On *observing* how the use of the assessment identified a problem for a patient and allowed the nurse to help them find a solution; *"…it was very revealing and helpful for this particular gentleman, it was excellent…he just seemed like an ordinary person/ patient slightly anxious but keeping it altogether and stuff and it was going through that where you opened up all sorted of things for him…I just though brilliant because it's troubling you and if he'd just been sat, sent off his bloods and sat in the awaiting room then that wouldn't have been picked up."* (S77)		
Reinvention	The potential for the adopters to adapt and refine the innovation to fit their *needs* more effectively [2, 73].	Any suggestions or requests from the staff to adjust the delivery of the intervention.
Fuzzy boundaries	Innovations are often described as having a *hard core* (the fixed components) and a *soft periphery* (the organisational structure and system required for implementation). *Fuzzy boundaries* refers to the adaptability of the soft periphery [2].	The *hard core* in this context was the fixed components (i.e. the SDI-21, the web-based delivery). The *soft periphery* was the nature of the clinic into which the assessment process was being introduced. This links to *reinvention*; how the assessment process can be adapted to fit with the soft periphery of the clinic procedures.
On *reinventing* the process around the *fuzzy boundaries* to increase its *compatibility* with existing resources; *"…it might be one solution for the… (healthcare assistant) could give them the booklet to fill in…patient takes it into the doctor…go through and see what the difficulties are…"* (S39)		
Risk	How risky the innovation is to the potential user/ adopter, i.e. the degree of uncertainty of outcome or impact associated with an innovation[2].	Perceived risk for the nurses would include a negative impact on the smooth running of the time-pressured clinics, or the risk of 'opening a can of worms' by asking patients about specific, potentially sensitive items (e.g. sexual difficulties).
On the *risk* that conducting a formal assessment will increase patients' expectations; *"We can't sort everything out…some people…will have unrealistic expectations of about what the nursing team can do for them…how much are we trying to fix…?"* (S58)		
Task issues	How relevant the innovation is to the adopter's day to day work and whether it can assist them in improving their performance[2].	How relevant the assessment process was to the day to day running of the clinics and how it could assist the nurses in improving or streamlining provision of psychosocial care for patients.
On how the SDI-21 would legitimise discussion for some patients, assisting in identifying difficulties; *"…some (patients) are easier to talk to than others...(here) you have a format where…that opens that door having a format like that…does help…it breaks the ice sort of thing…"* (S01)		
Knowledge required to use it	How efficiently the knowledge necessary for implementing the innovation can be transferred from one context to another[2].	How efficiently the knowledge required in delivering the assessment and interpreting the results was imparted to the nurses.

Element	Definition as described in MoD framework[2]	Application in this context
On how the effectiveness of the training to provide the *knowledge required* was hampered by the delay between the training and conducting the assessment; *"…you might have done the training but it might have been three or four weeks before actually then you got to use it for the first time… I would have been thinking, hang on a minute, what do I do now because you've had the training but then it's gone because you've not used it."* (S01)		
Augmentation/ support	Whether the innovation is provided along with customisation, training and technical support[2].	All the nurses were trained in how to conduct the assessment, interpret the results and deal with any difficulties raised. Support was available throughout the period of the pilot.
On how a lack of *support* in conducting the assessments would have caused uncertainty; *"…you gave us a lot of help and I think that helped and I think the fact that you did set it up for us and all we had to do then was with the patient…without that I probably might have gone, woo, and because I didn't do it on a regular basis…"* (S41)		
Adoption by individuals		
General psychological antecedents	Individual traits associated with the likelihood of trying innovations (e.g. motivation, values)[2].	How likely each of the individual nurses were to engage in trialling the assessment process.
General psychological antecedents relating to use of computers; *"I hate them, I do not like them at all. I've got basic computer skills…and they are using them throughout the hospital now…so you can't get away with not using it, so yes I do use computers but they are not my favourite thing. I don't have anxieties, they are just so bloody slow…"* (S77)		
Context-specific psychological antecedents	How the individual's traits (general psychological antecedents) are expressed or respond within the specific context [2].	How the *general psychological antecedents* of the individual nurses was expressed in the context of the specific trial.
Context-specific psychological antecedents relating to use of computers; *"…don't use a bloody computer, you could get all of that stuff down in using pre-assessment in a booklet thing…patient can be sat there in a waiting area…they could fill it in, you could come in, tally up the scores, see what they've written down and take it from there…"* (S77)		
Meaning	The meaning attached to the innovation by the individual [2].	How the nurses felt about conducting such assessments generally, and how much importance they attached to gathering social difficulties information in a standardised way.
The *meaning* the nurse attaches to having the opportunity to provide holistic support; *"…if I've asked questions of someone and I've managed to sort out financially or whatever, social services need to be involved, the district nurses or the Macmillan, I do have a sense of satisfaction if I've sorted it all and it's all happened and the patient comes in next and says, oh, yes, all that worked out...I…get a feeling of job satisfaction that I've managed to do all that…I think it would improve how I felt about what I was doing because a lot of things are being taken away from us so I suppose if we still have something like that would ..."* (S01)		

Element	Definition as described in MoD framework[2]	Application in this context
The adoption-decision	Includes c*ontingent* (depending on a decision made by someone else), co*llective* (the individual has a certain amount of choice but must ultimately comply), or a*uthoritative* (individual is told whether or not to adopt the innovation) [73] [2].	The decision seemed to be *collective.* Although the Senior Sisters and staff nurses were able to refuse to participate, they were aware that in a research active institute they understood the importance of conducting research and had been involved in research previously.
Concerns-based adoption model	Any concerns the potential adopters have regarding the use of the innovation, either prior to adoption (concerns in pre-adoption), during initial use (concerns during early use) or once users become familiar with the innovation (concerns in established users) [2, 77].	This was expanded to include all nurses' feelings about the innovation and the trial as a whole.
On *concerns* relating to identifying problems that can't be dealt with promptly; *"…my biggest concern was what might come out of it… I could see the value of what we were trying to do in terms of improving patient care and getting more information to help us deal with what comes along for the patient…the biggest worry for me was so what do we do about this…we'll ask this question, but if the patient answers this, then where do we go with that because then…resources are limited…we're left with identifying a problem with a patient…(they) may think well you've asked me…and now you're saying there's nothing you can do about it…"* (S58)		
Diffusion and dissemination	Influences on how the innovation may be adopted via "pure diffusion" (unplanned, informal, decentralised, and mainly mediated by peers) and "…active dissemination…" (planned, formal, centralised)[2].	The SDI-21 assessment was *actively disseminated*. It was *planned* and *formally disseminated* from the research team to the clinical staff via formal channels established within the research-active Institute of Oncology.
Network structure	Refers to the quality and structure of social networks[2].	There 'horizontal' network structure of nursing staff, as described by Greenhalgh et al[2] was observed in this setting. The Lead Cancer Nurse had overall responsibility via Matrons, who in turn manage Senior Sisters, staff nurses and HCAs. This appeared to be a supportive network with mechanisms for feedback at all levels.
Homophily	How similar the potential adopters are in terms of factors such as educational and cultural background and socioeconomic status [2, 73].	Data on years' experience, age and gender were collected to enable assessment of *homophily* amongst the nurses.

Element	Definition as described in MoD framework[2]	Application in this context
Opinion leaders	Those who may have influence over other potential adopters, either through status and authority, or they may be *peer opinion leaders*, who can exert influence via representativeness and credibility[2].	Opinion leaders and champions would be identified as the pilot progressed.
Champion	Key individuals who are engaged with the innovation, but may not necessarily be in a position to influence other potential adopters[2]	
Outer context	The *outer context* – inter-organisational networks and collaborations; may include informal networks, the wider environment and political directives [2].	The clinics in the context of the wider hospital and in comparison with each other, included the logistics of the running of each clinic in this case.

8.5.2 Data checking

The data collected from patients via paper documents was inputted onto a study-specific database throughout the progress of the study. The accuracy of this data inputting was assessed by selecting a random 10% of cases from each dataset and comparing the inputted data against the original questionnaire.

8.5.3 Reliability checking

For consultation and interview data, a random sample of 10% of each relevant dataset was coded separately by PW to check reliability. In this case, patient interviews were not transcribed, but were listened to and coded into an Excel sheet, using the same framework as had been applied to the interviews from the first pilot study.

8.5.4 Patient characteristics

Counts were taken of the number of patients who were approached, consenters, decliners, drop-outs and those who declined but allowed consent to collect socio-demographic and clinical data. Descriptive analyses were used to describe the clinical and socio-demographic profiles of consenting patients and those who declined but provided consent for this data to be collected. The Consolidated Standards of Reporting Trials [CONSORT] recommendations were followed to describe patient's pathways through the trial and monitor numbers of participants at each stage[163].

T-Tests were used to check if there were any significant differences in the socio-demographic and clinical profiles of patients who consented, declined, and those who eventually dropped out. Where assumptions relating to cell size were not violated, Chi-squared analysis was used for age group, gender, disease site, stage of disease, ethnicity, treatment during trial and independent samples T-Tests for ages. This was also done to assess any significant clinical or socio-demographic differences between patients who were randomised to the intervention or control groups.

8.5.5 Outcome measures

Global and subscale scores for the **CARES-SF** and **HADs** were calculated according to the guidance from their respective developers [56, 70, 141, 164]. Scores from the CARES-SF data were calculated as recommended; an average severity score, a global

score and number of problems endorsed were calculated for the CARES-SF overall score.

The mean and standard deviation for each global score and subscale were calculated by randomisation arm and for all patients. Independent samples t-tests were used to compare baseline global CARES-SF scores, HADS anxiety and depression subscale scores between the randomisation arms prior to the introduction of the intervention. One-way between-groups analysis of covariance (ANCOVA) was conducted to assess the impact of receiving the intervention on each of the outcome measures described. In each case the independent variable was the receipt of the intervention, the dependent variables were the end of study scores for each measure, and the covariates were the corresponding baseline scores.

As the pilot study was not powered to show a difference between the groups, effect sizes were calculated for all outcome measures, using the following equation;

$$\text{Effect size} = \frac{[\text{Mean of intervention group}] - [\text{Mean of control group}]}{\text{Total standard deviation}[165]}$$

Effect size results were interpreted using Cohen's guidance (≤ 0.2 is small, 0.2 to 0.5 is medium, 0.5 to 0.8 is large) [166].

8.5.6 Process of care measures

8.5.6.1 Patient checklists

Descriptive analyses were used to assess frequency of access to support services at baseline and at the end of the study. Counts were taken of whether each service had been used at baseline, at the end of the study, at both time points, or not at all.

Where cell-size assumptions would not be violated Chi-squared analysis was used to explore any significant differences in the use of any service at all and each specific service by randomisation arm, gender, age group, deprivation category, disease site and ethnicity at baseline, and by randomisation arm at the end of the study.

8.5.6.2 Audio-recordings of clinical consultations

Content analysis was undertaken on the audio-recordings of the patient-oncologist and patient-nurse interaction during consultations. A coding framework was

developed using the subscales and items from the SDI-21. Each recording was listened to and the following items were coded:

- Details of the consultation and who was present;
    - Date
    - Length
    - Clinician
    - Who else was present;
        - Relative
        - Nurse
        - CNS
        - Other (e.g. surgeon, speech and language therapist)
- Whether any issues for each subscale/ item were raised within the consultation and if yes;
    - Details of the nature of the issue
    - Who raised the issue
    - Any action that was taken in response to the issue
    - Who took the action

For each of the time-points, frequencies with which issues were raised were calculated.

For the baseline recordings Chi-squared analysis was used to assess any significant association between whether issues were raised and the variables of randomisation arm, age group, gender, clinic, deprivation category and ethnicity. Chi-squared analysis was also used to assess if the presence of another person in the consultation was associated with the frequency at which issues were raised at baseline, and to explore any association between frequency of discussion and randomisation arm at the end of the study.

A mean frequency of discussion was calculated for each randomisation group, for each subscale and single item. Where feasible, independent samples t-tests were used to compare means between the randomisation groups. Independent t-tests were employed to check for any association between subscale scores and whether any issues categorised within that subscale were raised, at the baseline time point.

8.5.6.3 Patient interviews

The SDI-16 subscales and single items were again used to develop a framework for coding the information within patient interviews. Interview data was coded to identify;

- The nature of problems patients experienced
- Whether it was currently a problem, had been a problem previously, or was anticipated to become an issue in the future
- Which subscale or single item of the SDI-21 this issue most closely related to
- What resources or services were accessed to deal with the problem
- Whether the SSIP had been used, at any stage or in relation to a specific issue (for the control group only, who were provided with it after end of study measures and prior to interview)
    - If it wasn't used, any reason for this if given

8.5.7 Assessment data

The audio-recordings of the consultations were used to time the length of each recorded assessment. In the case of the head and neck patients the assessment was done during the first post-baseline consultation to be recorded. The assessment recordings were analysed in the same way as other audio-recording of consultations. Data from the SDI-21 were used to calculate mean global distress scores and subscale scores, and assess how many patients reached or exceeded the cut-off point of 10 for the SD-16[147]. Comparisons were made between the SD-16 subscale scores and whether the issue was raised in the consultation.

8.6 Results

For a number of reasons (outlined below) this study did not reach the target number of patients and was not completed as intended (figure 8.2) which also resulted in an imbalance in the randomisation arms.

8.6.1 Participants

Although the previous study had recruited well (chapter 6), there were a number of problems in recruiting patients to this pilot and staffing issues that impacted the study.

There were difficulties specifically in recruiting patients from the melanoma and sarcoma clinics, which did not come to light until the study had started.

8.6.1.1 Melanoma clinics

A number of melanoma patients receiving active treatment were doing so as part of a clinical trial. Many of these trials included significant psychosocial outcome measures as well as clinical measures. It was decided that these patients should be considered ineligible for this pilot study, for a number of reasons. Firstly, these patients were completing a variety of measures as part of their clinical trial protocol, and to ask them to participate in this additional study and undertake further study-related tasks including questionnaires and recording of consultations would have added to their burden significantly. Secondly, completing the psychosocial outcome measures as part of their clinical trial may have increased their awareness of psychosocial issues and therefore biased their response.

Due to the nature of the disease, melanoma patients who were not on trial and receiving standard treatment typically saw deterioration in their condition and progression in their disease within a period of a number of weeks. This meant that a high number of patients involved in the study passed away before they completed all elements of the study.

8.6.1.2 Sarcoma clinics

Sarcoma patients receiving radiotherapy were excluded from the study. During radiotherapy, patients with any diagnosis are seen in the specialist radiotherapy unit (SRU), staffed by the radiotherapy nurses. The radiotherapy sister felt that it would not be feasible to conduct the assessments prior to the patients' appointment with doctor during the consultant-led clinics. Unlike the melanoma clinic, in the SRU the nurses running the clinic sit in on the consultation for every patient. This means that there would be no time for them to sit with a patient and conduct the assessment. This meant the study was not feasible in this setting, and led to the pilot taking place in the nurse-led head and neck clinics rather than consultation-led clinics. This left very few eligible patients within the sarcoma clinic (i.e. receiving chemotherapy).

These clinic-specific issues were compounded by a reduced pool of eligible patients, as those involved in the previous pilot were excluded from participation (18 patients were considered ineligible because they were a participant in the first study).

8.6.1.3 Staffing issues

During the time of the study, the author (EJI) was managing the trial and its administration, which included undertaking the majority of the recruitment and follow-up tasks in each of the relevant clinics. EJI was on maternity leave from December 2011 to August 2012. Although the Patient Reported Outcomes Group team attempted to maintain recruitment and follow-up, this became unsustainable. Patients already involved in the study were followed up but no new patients were recruited after January 2012. It was hoped that recruitment could re-start following the end of maternity leave in August 2012, but this was not possible for the reasons outlined below:

The study was complex to run, often requiring at least two researchers to be present in two separate clinics and conduct the necessary study tasks, e.g. audio-recording of consultations between patients and staff, delivery and collection of questionnaires. Each clinic ran in different clinical areas of the local cancer centre. This meant the study required the equivalent of two full-time equivalent researchers on the study at all times to screen for eligibility, track patient progress, recruit and follow-up in clinics and conduct administrative tasks (e.g. updating records, correspondence with patients, enter data). By August 2012, this level of staffing was no longer available, which was compounded by my returning to work part-time following my maternity leave.

The main grant on which this study was partially supported came to an end in March 2012. Although the plan had been to complete the study at least to the follow-up phase by this time, due to my maternity leave this was not possible. Other members of the Patient Reported Outcomes Group were by this time committed to another programme of work and so were unable to provide any support. Due to the time-gap between the last study activity (January 2012 and August 2012), any nursing staff involved in the study would require re-training in use of the assessment tools, which again would not have been possible with the level of staffing available.

Changes in staffing had also occurred in the participating clinics during my maternity leave, which had led to changes in the working methods, and meant that it was no longer to conduct the study in the format in which it had been designed. Figure 8.2 shows the pathways of patients throughout the study and availability of data at each stage (adapted from the Consolidated Standards of Reporting Trials [CONSORT] recommendations)[163].

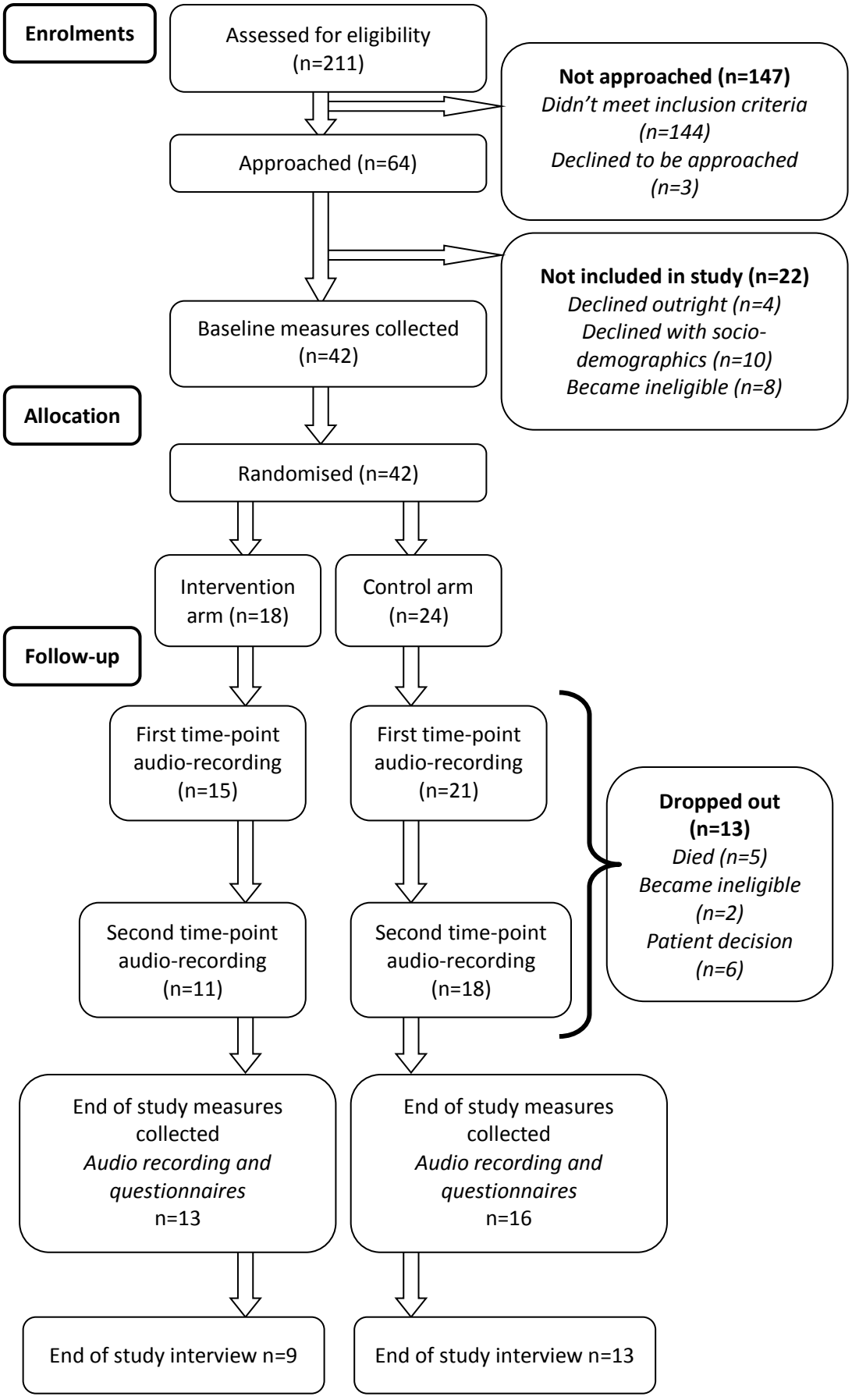


Figure 8.2: **Participants' pathways through the trial**

Two hundred and eleven patients were assessed for eligibility to participate in the study. Of these 147 were not approached, for the following reasons;

- Patients declined to be approached by a researcher following initial contact from the clinic nurse (n=3)
- Participating in a clinical trial with significant quality of life element (n=43)
- Ineligible treatment type or regimen (n=79)
- Participated in the first pilot study (n=18)
- English was not their first language (n=2)
- Died prior to approach (n=2)

Of the 64 patients who were approached, 22 were not included in the study. Of these, 14 declined to participate, 10 of whom provided consent for socio-demographic and clinical details to be collected. Eight patients agreed to participate but became ineligible due to changes in their treatment regimen. Forty-two patients were randomised. Over the course of the study, a further 13 participants dropped out, the reasons for which were that the patient passed away (n=5), became ineligible (n=2), or chose to discontinue their participation (n=6 - total drop-outs 33%).

Chi-squared analysis was used where feasible to explore any significant differences in socio-demographic and clinical details between patients' participation category (participants, decliners and those who dropped out - tables 8.3a and b). Due to cell-count violations (i.e. cell count of less than 5) this was not feasible for diagnostic group, deprivation category, stage of disease and treatment at the time of the study. However, the majority of participants were of white-British origin (97%), and had metastatic disease (41%). There were significantly more men than females in all participation categories (p=0.001). There were no significant differences in age between the participation categories. Patients who declined to take part had similar socio-demographic and clinical profiles. There were more decliners from the head and neck clinical group, but more patients were eligible for approach in this group.

There were no significant differences between randomisation group and diagnostic group, gender, deprivation category and age at baseline. The Chi-square analysis was not feasible between ethnicity, stage of disease, treatment and participation category, but it is clear in table 8.3a that the majority of patients are of white-British origin,

within the ‘other’ stage of disease category and were receiving chemotherapy at the time of the study.

Table 8.3a: Baseline sociodemographic and clinical profiles of participants by randomisation arm

		Intervention (n=18)		Control (n=24)		Total (n=42)		Decliners (n=10)
		n	%	n	%	n	%	n
Gender	Male	12	80	15	63	27	64	7
	Female	6	20	9	37	15	36	3
Age	Group 1 ≤60 years	10	55	12	50	22	52	2
	Group 2 ≥61 years	8	45	12	50	20	48	8
Range and mean (SD)		31 to 78 57.1 (11.9)		36 to 79 58.4 (12.4)		31 to 79 58.3 (12.7)		39 to 79 65.4 (12.1)
Ethnicity	Not given	1	1	0	0	1	2	1
	Pakistani	0	0	0	0	0	0	0
	White-British	17	99	24	100	41	98	9
Deprivation category	Least affluent	4	22	8	33	12	28	5
	Medium level of affluence	6	33	7	29	13	31	3
	Most affluent	8	45	9	38	17	41	2
Disease site	Head and neck	9	50	10	42	19	45	4
	Melanoma	7	39	9	38	16	38	5
	Sarcoma	2	11	5	20	7	17	1
Stage of disease	Primary local	8	44	5	21	13	31	4
	Local recurrence	4	22	1	4	5	12	0
	Metastatic	6	34	16	67	22	52	4
	Missing	0	0	2	8	2	5	2
Treatment at trial	Biological therapy	0	0	1	4	1	2	2
	Chemotherapy	9	50	11	46	20	48	4
	Chemo-radiotherapy	6	33	4	17	10	24	2
	Radiotherapy	3	17	6	25	9	21	2
	Not recorded	0	0	2	8	2	5	0

Table 8.3b: Baseline sociodemographic and clinical profiles of participants who dropped out by randomisation arm

		Drop-outs		
		Intervention (n=7)	**Control (n=6)**	**Total (n=13)**
Gender	Male	6	4	10
	Female	1	2	3
Age	Group 1: ≤60 years	3	4	7
	Group 2: ≥61 years	4	2	6
	Range and mean (SD)	31 to 78 58.3 (15.4)	41 to 67 52.5 (9.8)	31 to 78 55.6 (12.9)
Ethnicity	Not given	1	0	1
	Pakistani	0	0	0
	White-British	6	6	12
Deprivation category	Least affluent	1	2	3
	Medium level of affluence	2	3	5
	Most affluent	4	1	5
Disease site	Head and neck	2	2	4
	Melanoma	4	3	7
	Sarcoma	1	1	2
Stage of disease	Primary local	2	1	3
	Local recurrence	0	0	0
	Metastatic	5	5	10
	Missing	0	0	0
Treatment at trial	Biological therapy	0	0	0
	Chemotherapy	5	2	7
	Chemo-radiotherapy	1	2	3
	Radiotherapy	1	2	3
	Not recorded	0	0	0

The rates at which patients dropped-out were roughly equal between the randomisation groups, but more male patients, those with metastatic disease and on chemotherapy or chemo-radiotherapy dropped out in comparison to other groups.

8.6.2 Acceptability and feasibility - staff interviews

Participants

Eight nurses completed the training. The only male nurse to participate in the study completed the training and conducted two assessments, but then left to work in a different department and so was not available to take part in the interview. The remaining 7 nurses participated throughout the duration of the study and completed the interview; five were from the Specialist Radiotherapy Unit (SRU), two were from a

general oncology outpatient department (OD). All the remaining participating nurses were female, with an average age of 52 years (range 40 to 60). Six participants were NHS Band 5 Staff Nurses; one participant was a Senior Sister (NHS Band 7/8). The average number of years as a qualified nurse was 13 years (range 5 to 25), with an average of 8 years' experience in oncology (range 4.5 to 17). The average number of assessments conducted by each nurse was 1.8 (minimum 1, maximum 4).

There was a time delay between the completion of training and conducting the first assessment; this was the case for all participants in both departments. This was between 3 to 6 weeks. There was also a delay of approximately 9 months between participating in the study and taking part in the interviews (due to EJI's maternity leave), which led to some difficulties in recalling events during the study for some of the nurses.

Overview

Due to small numbers of patients and the randomised design of the pilot, the participating nurses had few opportunities to conduct the assessments. This limited the *trialability* of the innovative process. As a research study, this was intended as an opportunity to encourage experimentation; in practice the design of the study and the difficulties with recruitment and retention of patients limited this significantly.

The clinics in which the nurses were working were considered in the analysis as separate locations. The two different departments vary in their working practices, in terms of the specific tasks and responsibilities of the nurses, and therefore the level of contact they had with patients. The two departments differed in terms of their *network structure.* Throughout the process of the interviews it became clear that the current *socio-political climate* varied between the departments, as did the impact this was having on the *environmental stability* of each location.

In this context, the innovation was *actively disseminated*; it was *planned* and *formally disseminated* from the research team to the clinical staff. This was done via formal channels established within the environment of the research-active institute in which they were based. As Greenhalgh et al propose, once the innovation has been introduced to the adopting unit (the nurses involved in the study), the predominant diffusion mechanism becomes the *social networks* and lines of communication[2].

8.6.2.1 General Oncology Outpatient Department (OD)

Both nurses who participated in the study from this department took part in the interview. One of the nurses only conducted one assessment, the other conducted 3 in total. Table 8.2 demonstrates the framework and definitions used to conduct framework analysis.

Outer context

This department was where ambulatory patients typically attended the for an outpatient review with a doctor. This was usually once every fortnight to four weeks if they were on treatment, or every few months if on longer-term treatment or off-treatment follow-up. These were scheduled appointments which were booked well in advance.

For the nurses running the clinics in this setting, they were typically the only nurse on duty in any given clinic. These nurses felt it was important that they were 'visible' in the clinic, for the patients and the other staff members involved, e.g. healthcare assistants (HCAs), research nurses and doctors. They had a wide range of tasks that they were responsible for, ranging from chasing up scan results to taking observations, and occasionally more specialised clinical tasks such as flushing Hickman or PICC lines (used to deliver chemotherapy, which sit under the patients' skin). Although many of the tasks were planned, the nurses often had to deal with other issues and queries that arose during the clinic. The major concern for both nurses was that conducting the assessments took them away from the clinic for a significant amount of time.

In standard practice, any contact with the nurses tended to be brief, depending on the observations or tasks that were required. This contact was usually within the waiting room of the clinic and offered no private space. Prior to the pilot study, both nurses reported occasionally dealing with social difficulties but not in any routine or standardised way. Some patients did not have any contact with the nurse. It was rare for nurses to sit-in on consultations with the doctor in this setting.

A sense of *environmental instability* became apparent during the interviews with the two nurses from this department; the number of staff nurses in the department was due to be reduced, and so they were facing a potential change in location and role. There was a high degree of uncertainty at the time of the interviews.

Adoption by individuals

Diffusion and dissemination

In terms of s*ocial networks*, the nurses and staff in this department were overseen by a Sister, but the staff nurses tended to work individually on their designated clinics, usually with assistance from the HCA. The clinic areas are logistically separate from one another, with a communal reception area serving two clinics. Although the Sister with responsibility for the department gave permission for the relevant staff to be approached, she was not involved in the study beyond this. There was no clear *champion* or *opinion leader* within the nurses' *social network,* the presence of which is associated with increased likelihood of innovation adoption[2]. The nurses reported that knowing others were trialling the assessment (albeit in a different department) didn't affect their willingness or intention to use the system.

Concerns and emotions in pre-adoption

In this case, only the first two stages were relevant (pre-adoption and early use). The nurses were explicitly asked about any emotions they had prior to the pilot, not just *concerns*, and were asked to recall how they felt when they heard about the pilot and the proposed process. During the training period, prior to the start of the study, both nurses expressed *concerns (in pre-adoption)* about "…being away from the clinic…". This highlighted that the assessment as carried out in the trial (i.e. with the nurse sitting in a separate room with the patient whilst they completed the SDI-21 and dealt with the responses) was *incompatible* with the current practice of the clinic, and continued to cause the nurses *concerns during use* that whilst they were sitting with the study participant conducting the assessment, they were not present in the clinic. They also had *concerns* about any additional workload generated by the assessment (if actions were required following it), and what jobs were building up in the clinic whilst they were with the participating patient.

General and context-specific psychological antecedents

In terms of meaning, both nurses reported a general sense of cynicism regarding many initiatives, particularly those that "…come from upstairs…" referring to Trust Management.

In terms of *general psychological antecedents*, and *homophily* the two nurses were similar in terms of their previous experience; both had been in oncology for 4/5 years,

with over 10 years' experience in other areas of nursing prior to that. Both worked part-time, which involved very little time when they were not responsible for the running of a designated clinic. In terms of their feelings towards computers in general, one nurse reported that she "…hate(s) them (computers) with a passion…" the other was more confident and able with computers. Despite a lack of confidence with computers, the same nurse reported a higher level of capability in dealing with a range of social difficulties; she attributed this to her previous role in Accident and Emergency (A&E), during which time she experienced a wide range of people and situations; "…I'm older and working in A&E you see all sorts…"

Both of the nurses were also similar in terms of their *context-specific psychological antecedents*. Time was a constant issue within the clinics they had responsibility for; this was compounded by the unpredictability of what might occur during the clinic, which often overran. These nurses felt they had to be 'visible' and accessible within the clinic, for both their colleagues (doctors and HCAs) and for the patients. They were also regularly required to deal with telephone calls. For this reason, the nurses rarely sat in on consultations with patients and doctors, although this was something they both reported they would like to do more of.

Conducting the assessment in this environment also required finding a private room with access to a PC, which wasn't too far from the clinic. This could occasionally be difficult as there were other staff who required the spare rooms, e.g. clinical research nurses, clinical nurse specialists, an element of the process which was *incompatible* with their usual practice.

Attitudes towards the innovation

Both nurses had concerns about the assessment, in terms of using the technology. Although the training package (chapter 7) was designed to provide the nurses with the necessary skills and knowledge to carry out the assessment, the time lag between the training and the first opportunity to do so was approximately 4 to 6 weeks. In line with evidence from the literature, attempts were made to limit the time between training and utilising skills as this is known to be beneficial in terms of retaining knowledge [17]. Unfortunately, due to the nature of the recruitment process and the design of the study, it was not possible to achieve this. This meant that at the time of conducting the assessments, the nurses had lost the required *knowledge* required to

use the system, and found trying to remember the steps required very complicated. Perhaps due to the perceived *complexity* associated with accessing the results, none of the nurses utilised the facilities within PPM to view the output from the SDI-21 as graphs or results summarised by subscale. All of the nurses instead opted to receive a print out of the full questionnaire with individual responses listed next to each question. Only one of the nurses expressed concerns about the knowledge required to use the assessment in terms of the issues that may be raised during the assessment, and this was specifically in relation to one item, which was sexual difficulties.

The training provided at the beginning of the study was a key part of the *augmentation and support* provided with the innovation, which is associated with increased likelihood of adoption [2, 73]. A high level of practical support was provided by the research team throughout the study; this included setting up the PCs within clinic to conduct the assessment and provision of a hand-held guide. The intention had been for this level of *support* to reduce as the study progressed and each nurse gained more experience and confidence with the system. However, due to the small numbers of patients and early cessation of the study, this wasn't possible. This meant that all of the assessments carried out were done so with a significant level of support from a member of the research team. As the figures on numbers of assessments conducted shows, the nurses had little opportunity to utilise the skills acquired during training. This limited the *trialability* of the assessment process.

Despite some *concerns* relating to the practical side of conducting the assessment, and how *compatible* it would be with their current working practice, both of the nurses reported positive experiences when they got the opportunity to do so. Their roles at the time permitted very little time to provide psychosocial support to their patients, and both nurses reported feeling that these sorts of tasks had "…been taken away from them…" As such, they saw the assessment as offering *relative advantage* over their current roles in terms of their chances to provide this sort of care for their patients. Both nurses also reported an observable effect of the assessment, in that they were able to provide help and support for patients, resolving specific concerns and establishing a closer relationship with the specific patients.

Both of the nurses from this unit had one very positive experience of conducting the assessment. Both reported that due to the nature of their current roles they have very

little time and opportunity to build meaningful relationships with patients, and that they missed that element. In both cases, the nurses felt they had helped the patients to deal with issues that were concerning them, offer reassurance, and also that it helped to forge a more meaningful relationship with the patient. They reported feeling that the patients were more likely to talk to them at subsequent appointments. Despite the *concerns* raised around *compatibility* with their clinic processes (namely lack of time), both nurses felt that the experience of conducting the assessments was a generally positive one, and therefore had the potential to help them attain gains in terms of job satisfaction and patient care. Overall the nurses felt that doing the assessments was positive for both them and the patient, but in the current context and situation within clinic it was difficult.

8.6.2.2 Specialist Radiotherapy Unit (SRU)

All five nurses who participated in the study from this unit took part in the interview. The minimum number carried out by one nurse was and the maximum was four.

Outer context

The radiotherapy unit was where patients typically attended to receive treatment every day for a number of weeks. Once a week they had a scheduled appointment to see their doctor as part of an outpatient review clinic. They also had a weekly appointment at a nurse-led review clinic. The nurses were also available throughout the day for any patient who was experiencing problems, who could be referred on an ad-hoc basis by the radiotherapists. Some patients were seen by the nurses every day if they required treatment for skin reactions or other side effects caused by the radiotherapy.

The nurses had a large shared office and were therefore working in the same room when they were not seeing patients. One nurse had responsibility for running a specific doctor's review clinic, but these were based within the same department and set of treatment rooms. The nurses within this unit had more patient contact in comparison to their colleagues in general oncology outpatients, and undertook more clinical tasks such as dressings and offering mouth-care and dietary advice. Before the patients started treatment one of the nurses conducted an assessment. This could take up to an hour and covered some elements of the patient's social situation and any related difficulties.

In this setting the assessments were included as part of the scheduled nurse-led clinics, which involved the patients having a dedicated appointment in a private room with the nurse. The rooms used all had a PC with access to the internet and the PPM system. This meant the assessment was more *compatible* with their usual practice than that of general oncology outpatients.

Adoption by individuals

Diffusion and dissemination

The social network within SRU differed from that observed in the general oncology outpatient. Although the hierarchy of staff was essentially the same (staff nurses managed/ led by a Senior Sister), in SRU the Senior Sister worked more closely alongside with the nurses she managed. The nurses and their Senior Sister worked physically close together, sharing the same environment, and, with the exception of the Sister's management tasks, the same role. While those on OD worked more independently on individual clinics, the set-up and organisation of SRU meant the nurses shared an office, and other than specific clinics they had main responsibility for, would see any patients through the Nurse-Led clinics as required.

The Senior Sister was a clear o*pinion leader* within the SRU team; evidence from the interviews and from observations made during the study demonstrated that all the staff nurses working with the Senior Sister looked to her for advice and support and respected her as a colleague and a manager. This meant that when the Senior Sister expressed serious *concerns in pre-adoption* about the impact of the assessment, the other nurses in the team echoed these *concerns*. *Social influence* generally seemed more salient for staff within the SRU than OD, specifically the influence of the Sister on the other staff. Two of the nurses said that it helped knowing "…they were all in the same boat…" Two said they would do it if asked by the appropriate person, regardless of who else was taking part.

Concerns and emotions in pre-adoption

In this setting the first phase of the nurse training package (NTP) was delivered to the whole team at one time. During this session the Senior Sister expressed grave *concerns* over the kind of issues that may be raised and how the staff would be able to deal with them. Her concerns were such that she asked to postpone the training and the involvement in the study until further discussions could take place with the

research team and the Matron. The other nurses acquiesced to this decision and made no attempts to have any more involvement in the study until the issue was rectified.

The Senior Sister reported that she "…had to think very carefully before taking part…" Her main concerns were about raising issues that they then would not be able to deal with effectively. She was anxious that conducting the assessment would raise expectations for the patient, expectations that could not be met with the services available. This was compounded by her feelings that much of what is covered in the SDI-21 was already discussed during the first full assessment that the head and neck patients underwent. Other nurses felt the overlap between the SDI-21 and what they already covered was reassuring. *Concerns* expressed by the other nurses tended to be around the technical side of accessing the assessment and use of the computer to obtain the results.

General and context-specific psychological antecedents

All of the SRU nurses used computers during their day-to-day work, although they varied in levels of ability and confidence. Three of the nurses reported that they only really used the computers "…because they have to…" The main pressures faced by the SRU department were time and the volume of patients. There was also a level of unpredictability. This unpredictability was caused as the nurses provided a 'walk in' service (in addition to their scheduled appointments) for all radiotherapy patients, regardless of their diagnosis, and any patient requiring dressings, advice or other nursing care could drop in as and when required. The nurses reported that they often saw 3 to 4 times the planned number of patients.

This was compounded by to the nature of the radiotherapy treatment department. Radiotherapy treatment was provided using a series of linear accelerators (referred to as 'the machines'). The timings for delivery of treatment on these machines were very specific, but due to the complexities of treatment these appointment times were often delayed. This meant that the nurses' scheduled appointments with patients were often "…at the mercy…" of the machines and how they were running on a given day. Patients were often very late for their scheduled appointment time.

The closure of an inpatient ward to which radiotherapy patients were typically admitted also added pressure to the SRU team. They were frequently faced with

acutely ill patients, who required admission, but due to the shortage of beds were left waiting in the department, sometimes from 9am in the morning until 7pm at night. These patients were often very ill, and required nursing care throughout this time and the nurses had to stay with the patient until a bed could be found. This prompted the development of a small two-bed unit within SRU where proper nursing care could be provided. The key aim for all of the SRU nurses was to prevent unplanned admissions.

In terms of meaning attached to the SDI-21 and the assessment process, all of the nurses shared a level of cynicism towards such initiatives; they felt that 'they' (DoH/ NHS Management) 'keep reinventing the wheel', re-badging the same processes. The Senior Sister had a previous bad experience with another assessment tool, and also had the greatest level of *concern* regarding the perceived *risks* she associated with using the SDI-21. She didn't feel her previous negative experience had contributed to her feelings towards the SDI-21 and the assessment process.

Attitudes towards the innovation

In terms of *compatibility*, the nurse-led radiotherapy clinics were more conducive to fitting in the assessment within their existing routine. All the nurses felt the technical infrastructure provided to conduct the assessments was good. They felt that the immediacy of results via the PPM system was "…vital to its success…" The process was very *compatible* within this setting. The nurses had access to a private room with a PC and a designated appointment with the patient. They already dealt with a lot of the issues listed on the SDI-21 and already refer to a lot of specialist services. They already used PPM, often to check on the status of patients before seeing them. They didn't have to be as 'visible' as those on OD. Only the Senior Sister thought it didn't fit with their current set up.

In terms of *augmentation and support*, including the training and support throughout the study, many of the nurses could not remember completing the training, but seemed to remember it was helpful. Most of the nurses reported that doing the assessments was more effective and memorable than the training. As in OD, there was a high level of support provided throughout the study by the research team. Due to small numbers of patients requiring assessment the nurses did not have enough opportunity to become confident to a point where the level of support could be reduced.

When considering *relative advantage*, all the nurses felt that the SDI-21 covered areas already discussed throughout the patients' journey. Three nurses felt that the assessment process trialled here offered any improvement on the service already provided, in that it would standardise the discussion that already occurs, and permit monitoring of the patients' social wellbeing over time. There was also a concern by all of the nurses that conducting the assessment would "open a can of worms". Some expressed concerns that the assessment may raise patients' expectations about what the department could support them with. Although in OD the assessment was felt by the nurses to be an improvement on existing practice in terms of patient care, and job satisfaction for the nurses involved, in SRU, most of the staff felt that the assessment added little to their existing practice (or that it offered no r*elative advantage* in terms of MoD theory).

Some could see the benefit of formalising what they already do; contrariwise they are also aware that they may be opening a 'can of worms'. Only the Senior Sister saw no advantage at all. One nurse could see the benefit of "…getting it from the patient's point of view..."

A lack of *trialability* was an issue within SRU as well as OD. Although there were more head and neck patients in the trial to be seen by SRU staff, there were also more trained nurses available to conduct the assessment. Again, there was a lack of opportunity for the nurses to use the system without direct support from a member of the research team, so limiting their ability to overcome the *complexitie*s associated with its use. All of the nurses reported that they had a basic understanding of how to use the system, but were impeded by difficulty in remembering the instructions. Typical *task issues* included how to remember to set up the online system and find the results within PPM. There were some concerns relating to where they would go next when certain issues were raised. One of the nurses expressed concerns about the complexity for patients who were not used to using computers, although this situation never occurred during the trial.

Greenhalgh et al propose *reinvention* as an important attribute of an innovation (whether there is the possibility of adapting the innovation to increase its *compatibility*)[2]. Only one nurse suggested an option for *reinvention*, which was the use of a hand-held device such as a tablet or iPad would streamline the process, as the

patient could use the tablet and then the nurse could access the results on the PC as soon as they had finished, rather than both the patient and the nurse trying to use the same PC.

In terms of *observability*, none of the SRU nurses could remember any specific experiences, either positive or negative, associated with conducting the assessment. One nurse remembered a patient who was not on the trial, but who she felt would have benefited from the assessment.

8.6.3 Baseline results

8.6.3.1 Outcome measures

Mean scores for baseline outcome measures and their subscales are shown in table 8.4, shown by intervention arm and for all patients. One person dropped out prior to randomisation.

Table 8.4: Baseline outcome measures

	Intervention	**Control**	**Total**
	Mean, SD	**Mean, SD**	**Mean, SD**
CARES-SF	**n=18**	**n=24**	**n=42**
Global CARES-SF Score	0.7, 0.44	0.6, 0.35	0.6, 3.96
HADS	**n=18**	**n=24**	**n=42**
Anxiety subscale	6.4, 4.57	5.1, 3.92	5.6, 4.49
Depression subscale	7.1, 5.89	4.7, 2.89	5.6, 4.35
Global HADS score	13.6, 8.28	9.9, 6.25	11.3, 7.12

CARES-SF and HADS data was available for 42 patients at baseline. Independent samples T-test showed no significant difference between global CARES-SF scores or total HADS scores between the randomisation groups at baseline [t (40) = -5.03, p=0.6] and [t (40) =-0.98, p=0.34] respectively.

8.6.3.2 Process of care measures

Patient checklist data – use of services

Table 8.5 shows frequency of use of services (within the previous month), as reported by patients on the baseline patient checklist. Forty-three patients completed the checklist at baseline, but one dropped out prior to randomisation and has therefore not been included. Patients who reported using 'other' services were asked to provide details. Where possible, any services listed in the 'Other' category were re-classified as

one of the original checklist options, e.g. a patient had not reported using healthcare-related services, but had checked the 'Other' box and listed their GP or District Nurse in the details section; this was reclassified as healthcare-related. In total, 9 instances of reporting in 'other' were reclassified in this way. These corrected data on frequency of access to services is shown in table 8.4.

Table 8.5: Frequency of use of services at baseline (patient checklist)

	Intervention (n=18)	**Control (n=24)**	**Total (n=42)**
Healthcare-related	5	4	9
Government or local council	6	9	15
Charity/ voluntary	6	6	12
Other hospital-based	3	5	8
Websites	3	6	9
Other	0	2	2
NHS Business Services Authority	*0*	*1*	*1*
Family	*0*	*1*	*1*

Chi-squared analysis was used to explore any associations between use of services and socio-demographic and clinical variables. Due to the small sample size it was not possible to conduct Chi-squared analysis for many of the variables as this caused a violation of assumptions of the test in relation to cell counts. It was possible in the following cases but no significant associations were found;

- Age group and
    - use of government/ local council services (p=0.11)
    - use of charity/ voluntary services (p=0.51)
- Gender and
    - use of government/ local council services (p=0.81)
    - use of charity/ voluntary services (p=0.49)
- Intervention group and
    - use of government/ local council services (p=0.35)
    - use of charity/ voluntary services (p=1.0)

Audio-recording data – frequency of discussion within consultation

Reliability checks

Reliability checks were carried out for all consultation recordings for approximately 10% of patients (n=3). PW listened to and coded these consultations using the same framework. A comparison of coding was undertaken, with agreement calculated only

on issues that were raised in the consultation. PW and EJI met to discuss disagreements in coding and reach consensus. Disagreement tended to arise where one coder had missed an issue and one had coded it, rather than what elements of a conversation should be coded as which item from the SDI-21.

Figure 8.4 shows the frequency with which issues were raised within the baseline consultation, by randomisation arm and overall. The most frequently raised subscales were everyday living and 'other' areas of everyday life, which were raised in 70% and 58% of consultations respectively.

'Other' areas of everyday life included…

- Anxiety relating to fear of progression (n=4)
- Difficulty eating or lack of appetite; includes issues relating to maintaining weight (n=11)
- General coping (n=4)
- Sleep (n=1)
- Queries about novel treatments that had featured in the media (n=2)
- Anxiety/ claustrophobia whilst on radiotherapy machine (n=1)

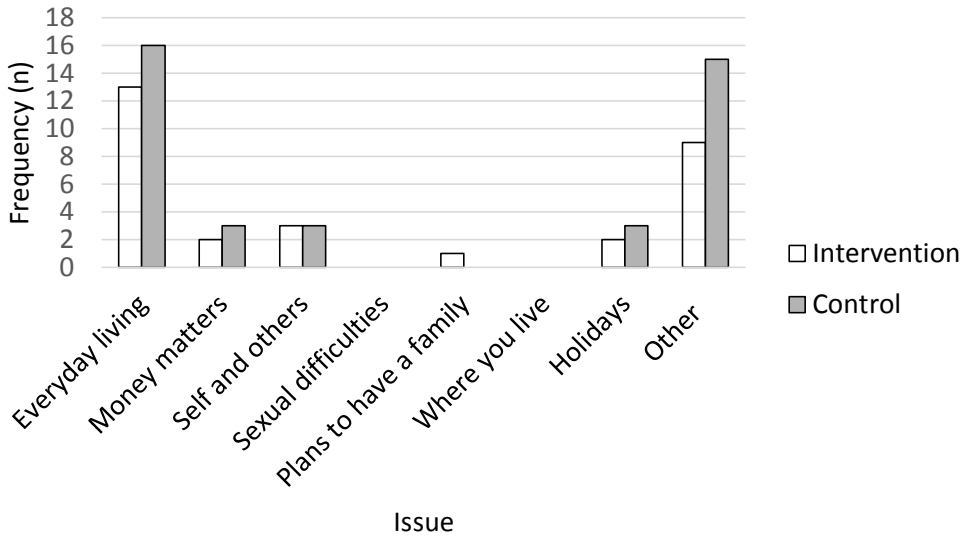


Figure 8.3: Frequency with which issues were raised in baseline consultations, by randomisation arm

It was not possible to conduct Chi-squared analysis to check for associations between sociodemographic and clinical details and the frequency with which issues were raised. This was due to very small numbers, resulting in violation of assumptions regarding cell

sizes. In some cases this was because the issues had not been raised at all (sexual difficulties and where you live).

8.6.4 SDI-21 scores for intervention patients

Delivery of the assessment intervention

Three patients in the intervention group dropped out prior to their assessment being complete. Fifteen completed the SDI-21. Table 8.6 describes the scores for the global social distress score (SD-16), and the three subscales (everyday living, money matters and self and others). Table 8.7 shows the median scores for the five single items.

Table 8.6: Results from SDI-21; global social distress score (n=15)

	Range	**Mean**	**Std. Deviation**
SD16	0 to 44	9.1	7.62
Everyday living	0 to 16	4.5	3.80
Money matters	0 to 13	2.0	3.44
Self & others	0 to 15	2.6	1.96

Table 8.7: Results from SDI-21; median single item scores (n=15)

Difficulties with…		
		Median
Sexual matters	0 to 3	0
Plans to have a family	0 to 1	0
Where you live	0 to 2	0
Plans to take a holiday	0 to 3	1
Any other area of life	0 to 3	0

Six patients (40%) scored a global social difficulties score (SD-16) of ten or more; this is considered the score above which a patient should be considered socially distressed[147]. A score of ten or more would have warranted additional discussion with the nurses. Overall these results suggest relatively low levels of social distress, and are similar to those seen in all participants from the first pilot study at baseline (chapter 6, table 6.3).

8.6.5 End of study results

8.6.5.1 Outcome measures

Table 8.8 shows end of study outcome measure scores.

Table 8.8: End of study outcome measures

	Intervention	**Control**	**Total**
	Mean, SD	**Mean, SD**	**Mean, SD**
CARES-SF	**n=11**	**n=18**	**n=29**
Global CARES-SF score	0.7, 0.52	0.6, 0.41	0.6, 0.45
HADS	**n=11**	**n=18**	**n=29**
Anxiety subscale	6.4, 4.57	5.0, 4.04	5.5, 4.22
Depression subscale	6.5, 8.61	4.7, 3.48	5.3, 5.89
Global HADs score	12.9, 10.83	9.8, 6.97	10.9, 8.59

The results of ANCOVA analysis demonstrated no significant difference in outcomes scores for any of the selected outcome measures (global CARES-SF, HADs anxiety and depression scales and global HADs score) between randomisation arms post-intervention (shaded pale grey). Details are presented in tables 8.9a to d. In all cases, except the HADs depression subscale, there was a strong relationship between the pre and post-intervention scores (shown in **bold**). Details are presented in tables 8.10a, b, c and d.

Table 8.9a: ANCOVA results for global CARES-SF

Dependent Variable: End of study global CARES-SF score

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	2.584[a]	2	1.292	11.183	.000	.462
Intercept	.117	1	.117	1.010	.324	.037
Baseline global CARES-SF score	2.506	1	2.506	21.694	.000	.455
Arm	**9.503E-5**	**1**	**9.503E-5**	**.001**	**.977**	**.000**
Error	3.004	26	.116			
Total	17.504	29				
Corrected Total	5.587	28				

a. R Squared = .462 (Adjusted R Squared = .421)

Table 8.9b: ANCOVA results for HADs – anxiety subscale

Dependent Variable: End of study HADs anxiety subscale score (HADs-A)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	495.546[a]	2	247.773	1743.246	.000	.993
Intercept	.162	1	.162	1.141	.295	.042
Baseline HADs-A score	482.850	1	482.850	3397.169	.000	.992
Arm	**.060**	**1**	**.060**	**.420**	**.523**	**.016**
Error	3.695	26	.142			
Total	1382.000	29				
Corrected Total	499.241	28				

a. R Squared = .993 (Adjusted R Squared = .992)

Table 8.9c: ANCOVA results for HADs – depression subscale

Dependent Variable: End of study HADs depression subscale score (HADs-D)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	32.652[a]	2	16.326	.454	.640	.034
Intercept	203.554	1	203.554	5.655	.025	.179
Baseline HADs-D score	10.828	1	10.828	.301	.588	.011
Arm	**13.058**	**1**	**13.058**	**.363**	**.552**	**.014**
Error	935.899	26	35.996			
Total	1797.000	29				
Corrected Total	968.552	28				

a. R Squared = .034 (Adjusted R Squared = -.041)

Table 8.9d: ANCOVA results for global HADs score

Dependent Variable: End of study global HADs

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared
Corrected Model	841.315[a]	2	420.657	8.938	.001	.407
Intercept	43.137	1	43.137	.917	.347	.034
Baseline global HADs score	774.370	1	774.370	16.454	.000	.388
Arm	**1.044**	**1**	**1.044**	**.022**	**.883**	**.001**
Error	1223.651	26	47.063			
Total	5552.000	29				
Corrected Total	2064.966	28				

a. R Squared = .407 (Adjusted R Squared = .362)

Tables 8.10a to d show adjusted mean scores and confidence intervals for all end of study outcome measures, by randomisation arm. Table 8.10 shows estimated effect sizes for all outcome measures, and Cohen's method for assessing the effect size showed a small effect size for all outcome measures (≤0.2 = small, ≤0.5 = medium, ≤0.8 = large)[166].

Table 8.10a: Adjusted means and confidence intervals – end of study CARES-SF

End of study – global CARES-SF

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	.639[a]	.104	.426	.851
Intervention	.642[a]	.081	.477	.808

a. Covariates appearing in the model are evaluated at the following values: Baseline global CARES SF= .6483.

Table 8.10b: Adjusted means and confidence intervals – end of study HADs-A

End of study – HADs–A (anxiety subscale)

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	5.576[a]	.114	5.341	5.811
Intervention	5.481[a]	.089	5.298	5.665

a. Covariates appearing in the model are evaluated at the following values: Baseline HADs–A (anxiety subscale) = 5.59.

Table 8.10c: Adjusted means and confidence intervals – end of study HADs-D

End of study – HADs–D (depression subscale)

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	6.236[a]	1.852	2.429	10.044
Intervention	4.800[a]	1.435	1.851	7.750

a. Covariates appearing in the model are evaluated at the following values: Baseline HADs–D (depression subscale) = 5.62.

Table 8.10d: Adjusted means and confidence intervals – end of study global HADs

End of study – global HADs score

Arm	Mean	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound
Control	10.812[a]	1.637	7.448	14.177
Intervention	11.216[a]	2.110	6.879	15.554

a. Covariates appearing in the model are evaluated at the following values: Baseline global HADs score = 11.31.

Table 8.11: Effect sizes for all outcome measures

Outcome measure	Effect size
Global CARES-SF	0.2
HADS - anxiety	0.3
HADS – depression	0.3
HADS - total	0.3

8.6.5.2 Process of care measures

Table 8.12 demonstrates how many patients used each service, split by randomisation arm and shown for both time-points. Twenty-eight patients completed the end of study checklist.

Due to small numbers, it was not possible to conduct Chi-squared analysis to explore associations between use of individual services and any clinical or socio-demographic details. Data on use of services was combined to provide a count of use of **any** service, and to check for associations between use of any given service and randomisation arm at baseline [(1, n=42), 0.93, *p=0.3*, phi=0.15] and end [(1, n=42), 0.74, *p=0.7*, phi=0.13], but no significant associations were found. The general trend demonstrates a reduction in the number of services accessed by the end of the study.

Table 8.12: Use of services as reported on Patient Checklists

	Baseline			End		
	Control (n=24)	**Intervention (n=18)**	**Total (n=42)**	**Control (n=17)**	**Intervention (n=11)**	**Total (n=28)**
Healthcare-related	2	2	4	2	2	4
Government/ local council	10	6	16	5	4	9
Charity	7	6	13	6	2	8
Other hospital	4	3	7	2	0	2
Websites	6	3	9	4	2	6
Others	7	4	11	0	0	0

Use of service data was combined to calculate the number of patients in each group who used any service at baseline and at the end of the study. The aim was to use this data to conduct a Cochran-Mantel Haenzel Chi-Squared (CMH) analysis. This demonstrated (table 8.13), that after allowing for use at baseline there was no difference in usage between the treatment arms [(1, n=28) =0.51, *p=0.47*].

Table 8.13: Use of any service at baseline and end of study

Use of any service at baseline			Use of any service at the end of the study: No	Use of any service at the end of the study: Yes	Total
No	**Intervention arm**	**Intervention**	3	2	5
		Control	3	2	5
	Total		6	4	10
Yes	**Intervention arm**	**Intervention**	1	5	6
		Control	5	7	12
	Total		6	12	18
Total	**Intervention arm**	**Intervention**	4	7	11
		Control	8	9	17
	Total		12	16	28

Audio-recording data – frequency of discussion within consultation

Comparison of subscale scores and frequency of discussion

Figure 8.5 shows the frequency with which issues were raised in the end of study recording by randomisation arm and overall. The areas of everyday living and any other area of everyday living were raised most frequently (in 48% and 34% of consultations respectively).

Unfortunately due to small numbers it was not feasible to conduct Chi-squared analysis to check for associations between frequency of discussion and intervention arm.

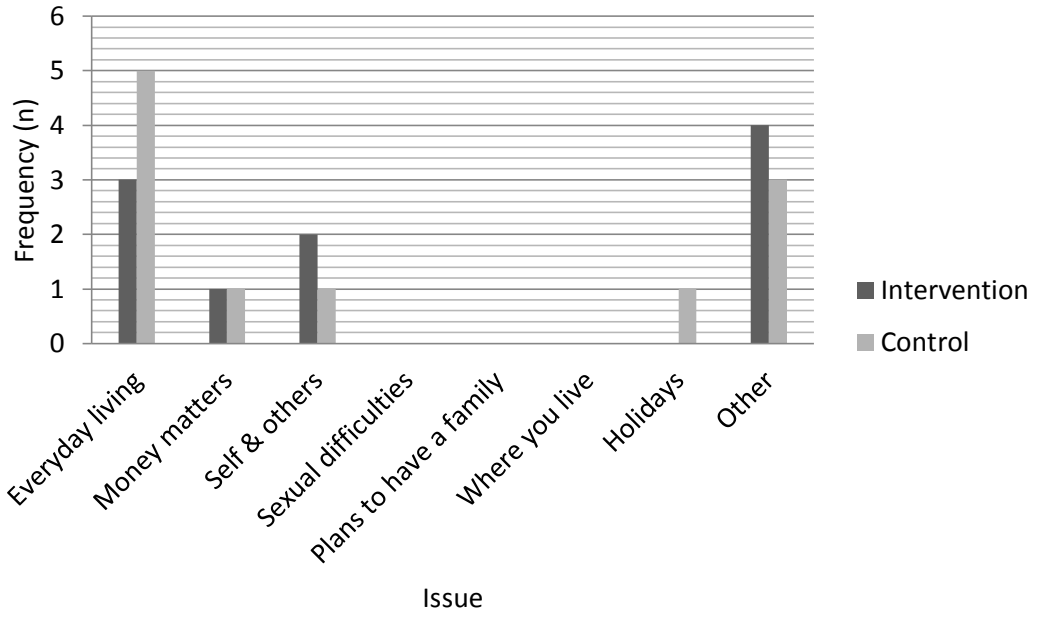


Figure 8.4: Frequency with which issues were raised in end of study consultations by randomisation arm

Comparison of subscale scores and frequency of discussion

Table 8.14 demonstrates the differences in mean subscale scores provided during the assessment, and whether or not these issues were raised in the consultation that took place directly afterwards. There were no significant differences in mean subscale scores from the SDI-21 between those who had the issue discussed and those who did not.

Table 8.14: Comparison of SDI-16 subscale scores and frequency of discussion

		Mean subscale score	SD	t-test	p
Everyday living raised	**Yes**	5.2	3.4	t(13)=-0.96	0.36
	No	3.2	4.7		
Money matters raised	**Yes**	5.3	4.9	t(13)=-2.09	0.06
	No	1.2	2.6		
Self & others raised	**Yes**	2.7	1.5	t(13)=-0.06	0.95
	No	2.6	2.1		

Table 8.15 compares patients who were considered to be socially distressed (SD-16 score of 10 or more) and those who were not, with whether issues were raised in the post-assessment consultation.

Table 8.15: Comparison of whether issues were raised in the post-assessment consultation and level of social distress

	Considered socially distressed	
	No (SD16 score ≤9)	Yes (SD16 score ≥10)
Everyday living raised	5	5
Money matters raised	0	3
Self & others	2	1

Due to small numbers it was not feasible to conduct Chi-squared analysis to check for associations between whether the issue was raised and if the patient was considered socially distressed. The average length of assessment was 23 minutes.

Patient Interviews

Patient interviews were carried out within two weeks of obtaining the end of study outcome measures. Twenty-two patients took part in the interview, either face-to-face or over the telephone. The end of study interviews were used to assess what difficulties patients had been facing throughout the period of the study (during the

main period of their active treatment), whether these difficulties were still a problem, and what resources (if any) had been accessed in an attempt to resolve the situation. All patients were provided with an updated copy of the Support Services Information Pack (SSIP) at the time of obtaining the end of study outcome measures. They were asked during the end of study interview whether they had used the SSIP or not, and for feedback on the SSIP.

Reliability checks

Reliability checks were carried out for approximately 10% (n=3) of patient interviews. PW listened to and coded three patient interviews using the same framework. A comparison of coding demonstrated 91% agreement. Agreement was only calculated on issues that were recorded as being raised in the interview responses.

Difficulties reported during interviews

Twelve of the 22 patients who took part in the interviews reported current difficulties in at least one of the areas drawn from the SDI-21 subscales or single items (figure 8.6). The areas in which most patients reported difficulties were everyday living and holidays. Although Chi-squared analysis was not possible due to small numbers, there seems to be no major differences between randomisation arms.

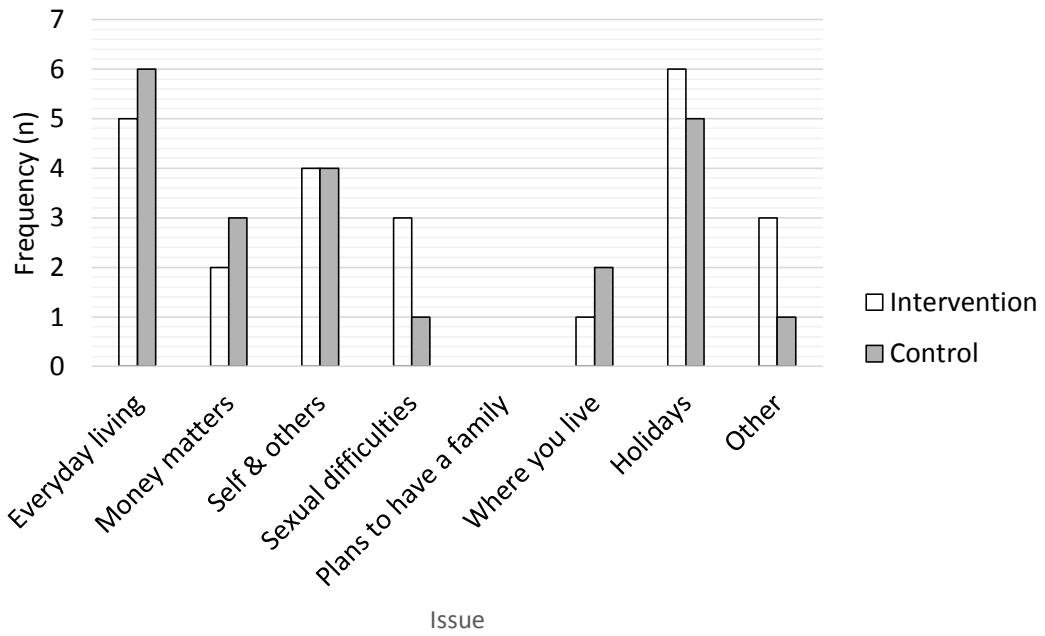


Figure 8.5: Difficulties experienced by patients at the time of interview, categorised by SDI-21 subscales and single items and by intervention arm

Table 8.15 shows which resources patients were accessing for support. This demonstrates a greater variety of resources than those identified via the patient checklist. The most frequently accessed resources were friends, family and colleagues and 'self', which included any attempt by the patient to manage the situation themselves, e.g. pacing themselves during tasks when fatigued.

Table 8.16: Typical resources accessed for each area of difficulty, as reported in the end-of-study interview

	Everyday living	Money matters	Self & others	Sexual difficulties	Plans to have a family	Where you live	Holidays	Other
Adaptations/assistance at home	1							
Benefits		1						
Clinical advice (non-CNS)	4		2				2	
Clinical intervention			1					
Community/ Primary Care (District Nurse/ GP)	2							
Employer		2						
Friends and family, including spouse and colleagues	8		5	1				
Internet							1	
Macmillan	2	2	4					
Mobility aids	4							
None stated		1	1	3		3	5	
Other	2	1	1					4
Other charity (non-Macmillan)	1							
Personal finances (pension/ insurance policy)	1	4						
Rehabilitation Team (non-SW)	3		1					
Self	8	1	3				3	

Use of Support Services Information Pack (SSIP)

Patients in the control arm were provided with a copy of the SSIP at the point at which end of study outcome measures were collected (n=9). They were then asked about their use of the SSIP at the subsequent interview, approximately two weeks later. None of the nine patients reported using the SSIP in any meaningful way, i.e. using it to seek out appropriate services for a specific problem and then accessing the service through the information provided. Four patients said they read through it, and five patients could not remember receiving or reading through the booklet.

Four patients said they felt the SSIP would be more useful had they received it earlier. Only one person thought the timing was appropriate, one said they would have preferred it later, and two patients were not specifically asked about the timing of delivery.

Two patients thought the SSIP would be particularly useful to guide internet research, and would help navigate the huge amount of information online, avoiding the misleading or inappropriate sites. Many of the patients reported receiving a large amount of information already, particularly a variety of leaflets. As found in the first pilot study (chapter 6), the information booklet was reported as being just one of a high number of written booklets or leaflets, and therefore offered no significant advantage over and above what is already provided.

Reflections on the assessment

Four of the nine intervention arm patients who completed the interview provided specific feedback on their experiences of the assessment, and whether they felt it was beneficial. Quotes are provided in figure 8.7. One patient couldn't remember the assessment and three patients didn't provide specific feedback on their experience. Three patients were very positive about their experience of the assessment with one person reporting how it specifically helped with one particular issue (fear and anxiety about recurrence). Another patient felt it offered no advantage over and above what was usually discussed. Both of these patients were from the head and neck clinic.

"Did you find the assessment useful?"
"…I did actually…found it easier to talk to the…[nurse]…than I probably have anyone else over the whole period…because she was obviously up to speed and she appreciated what I was going through…she had first-hand information and she was saying things and I thought yes that's right that's what I feel…yes she was really good…she was making me see sense…put things into perspective…it was good to have a good heart to heart without thinking who am I talking to, should I be saying this…will I upset somebody…"
1054, male, sarcoma patient

"…call it useful or not…covered a variety of things…would imagine…if things had come up that I wanted to discuss…given me the opportunity…was helpful in that sense…"
1144, male, head and neck patient

"I can barely remember it…not sure if I found it useful to me…how strongly did you feel about this…about that…not sure if it was meant to benefit me…felt it was just giving information…no (didn't deal with any specific difficulties)…no (nothing that hadn't already been raised)…overall thoughts…I never felt that it was beneficial to me…it just felt like an assessment of me…how I felt to other people…
1112, female, head and neck patient

"I think there would be a lot of people that store up problems that wouldn't ask and it would be really useful for the nurses…they deal with people day in day out they can give them the information first hand straight away…"
1017, female, melanoma patient

"Could you discuss things in the assessment you wouldn't usually raise in a typical consultation?"
"Yeah probably, more informal…more of a one to one chat….doctors bit more specific and technical…they're pushed for time…"
1054, male, sarcoma patient

"Do you feel the assessment was conducted at an appropriate time?"
"…very start too early…mind's still whirring…when I had it…fully aware of what was happening…talk to the nurse fully without having to ask questions…cut to the chase…two or three weeks in…still new…wouldn't have taken it all in…my mind would've been elsewhere…ideal time for me…"
1054, male, sarcoma patient

"…I would imagine…about right time…by the time they…assessment…had treatment for a week or so…came into the zone where any issues had been relevant at that time for me I could have brought them up…clinic…yes better than having to go specifically somewhere else…"
1144, male, head and neck patient

"…it [the assessment] doesn't need to be at the beginning…people need to go through a certain amount of experiences…"
1017, female, melanoma patient

"Do you feel the clinic was the most appropriate place to conduct the assessment?"
"…clinic is fine because it becomes part of your life going to clinic…really useful doing it in clinic time…just think it could be really useful…I'm just getting on with things, there will be people that need a lot of support and help…"
1017, female, melanoma patient

Figure 8.6: Patient feedback about the assessment

8.7 Summary of findings

For various reasons, only half of the target number of participants for this pilot study were not be achieved; all findings must be considered with this in mind.

- The nurses had few opportunities to conduct the assessments
- This led to difficulties in remembering the instructions
- Nurses differed in their views about the assessment between the two departments involved in the study
- There was some concern about 'opening a can of worms'
- Of the few patients who underwent the assessment, they generally felt it was a positive experience
- Results from the SDI-21 assessment showed relatively low levels of social distress, comparable with those from the first pilot study
- Estimates of effect size were calculated for all outcome measures and demonstrated a small effect in all cases
- The intervention seemed to have no significant impact on the outcome and process measures for patients
- Few of the patients provided with the SSIP used it in any meaningful way

8.8 Discussion

The overall aim of this pilot study was to assess the acceptability and feasibility of introducing the formal SDI-21 assessment into existing practice. This pilot has demonstrated that the acceptance and feasibility of an innovation to any given unit is influenced by the complex relationship between the individuals, the organisation and the innovation itself. This pilot confirms that many of the factors proposed by Greenhalgh et al[2] as influencing adoption can be observed in different departments of the same unit.

Although randomised controlled trial design is seen as the 'gold standard'[182], in this case a feasibility study rather than a randomised pilot design would have been more appropriate. This would have highlighted the difficulties experienced (see below) that led to limitations in understanding the impact of the intervention, and richer data on the impact of the intervention could have been obtained. It was intended to be a pilot

but due to the unexpected challenges the results were more about the feasibility of trialling the assessment at all rather than its impact as an intervention

Unfortunately due to difficulties in recruitment and staffing throughout the study, it was not possible to reach the target number of participants (n=60). The study started with a reduced pool of eligible patients, and experienced a higher rate of attrition than in the previous study. The first issue was the limit in the number of eligible patients who could be approached for the study. Due to the poor prognosis associated with melanoma, many of the patients who consented to participate sadly passed away. The only reason for non-completion of the study within the melanoma group was that they had died. Due to staffing issues and changes to clinical practice in the departments the study had to be halted early and it was not possible to restart. Although this pilot was not powered to detect differences between the randomisation arms, this limited the ability to draw conclusions from the effect-size data presented here. The majority of patients included were from the head and neck group, a diagnostic cohort with a quite distinct set of circumstances and needs.

Delivery of the Nurse Training Package (NTP) was challenging. The nurses involved were already working in time-pressurised environments; especially those from the OD who had very little time in their working day when they were not responsible for running a clinic session. The NTP had been designed to be delivered in a number of smaller sessions, to facilitate more flexible delivery of the training. Despite this, it was still difficult to find a time during which the staff could sit and focus on the training and learn the new skills required. In most cases this was done during their lunch break. Once the training was complete, there was a delay, often of weeks, until they had to conduct an assessment in practice. This was because they had to wait until patients had to be recruited and until one was recruited to the intervention arm, and arrived for the relevant appointment; this presented challenges for the nurses in retaining the new information and skills. This was demonstrated in the nurses' use of only one of the possible formats for viewing the SDI-21 responses; they lacked awareness of the alternative options, and only used the full list of questions and responses; this meant they were not utilising the subscale scoring facilities, which would have made reviewing the issues more efficient.

Although effect sizes were calculated, the ability to use these to calculate estimates for effect size for a future randomised trial have been limited by the small patient numbers. The limited qualitative evidence from the patients suggested they found the experience of doing the assessment a positive one, and it gave them an opportunity in a private environment outside of the clinical consultation to discuss any concerns. The positive results of conducting the assessment were more clearly seen in the general oncology outpatient department (OD), where the nurses and patients have very little opportunity for private interaction and development of relationships.

During the first pilot study, the lack of use of the SSIP prompted a question of the timing of delivery of support services information. Patients in the control group for the pilot study reported here were provided with the SSIP as their end of study measures were taken. Interviews conducted at the end of the study again demonstrated a lack of use; and views on the best time for delivery of such information were mixed, and the sheer volume of information available was raised again. Despite small numbers, this supports previous findings that it is tailored information, delivered in a different manner that may be required.

Despite limitations expressed in the first study (chapter 6), the Patient Checklist was not amended prior to its use in this pilot. The limitations related to discrepancies between reporting of use of services on the checklist versus those reported during the patient interview; a greater variety and number of services were reported as being accessed by patients during the interviews in comparison to what was reported via the checklist. The aim of the Patient Checklist was to identify any change in use of services following delivery of the intervention. The Patient Checklist was designed as a way to make a brief, quantifiable assessment of the number of services accessed at baseline, with the End of Study version providing the same assessment post-intervention. The challenge in this element of data collection was providing enough detail so that the patients could understand the checklist, but without 'priming' the patients to the range of services available. Although the checklist did not provide as much detail as the patient interviews, this reflects the data-collection method; the checklist was intended to be simple and collect quantitative data – counts of use of services, whereas the patient interview was designed using more open questions to assess the full range of all supportive resources, including friends and family.

Even when the physical and practical nature of the environment and existing work processes allow relatively easy integration of a new process, there are still a number of factors that may prevent its uptake. This was demonstrated in the Specialist Radiotherapy Unit (SRU), where the assessment process could be easily introduced into the practice within the nurse-led clinics, its uptake was still affected by the nurses' perceptions of how much *relative advantage* it offered, over and above what they already did. Despite very small numbers of patients, the *relative advantage* offered by the assessment was more apparent in OD than in SRU, as it was so different to existing practice in terms of the opportunities the nurses on OD had to provide this sort of care. This *advantage* may have been negated with increasing numbers of assessments due to the *incompatibility* with existing practices in this department.

This pilot work has highlighted the complexities often experienced when introducing a new practice into a healthcare environment; however, the impact on outcomes for patients is not clear from the results presented here. Although the staff members were interviewed in detail about their experiences, the lack of opportunity to conduct assessments, and the time delay between the trial and conducting the interviews meant that there were difficulties in recalling experiences. This meant that a true measure of any positive impact for staff was not possible.

8.9 Conclusions

In terms of the original primary aim of the study, the evidence demonstrates that a lack of *trialability* is a key issue in introducing innovations. The findings from this small pilot have demonstrated a number of potential barriers to implementing new practices in complex healthcare settings. Utilising models such as the MoD framework in planning implementation strategies may assist in pre-empting some of these barriers.

Although the numbers were small, the very positive response from patients and nurses to have an opportunity to spend more time focussing on the holistic care of the patients suggests this is important to both staff and patients.

Due to the small effect sizes and the number of barriers encountered during this pilot, it would not be recommended to move the implementation of the SDI-21 forward with a large randomised controlled trial. Other strategies such as on-going service quality improvement initiatives, observational studies or quasi-experimental designs may

offer an appropriate alternative for evaluating the effectiveness of this complex intervention.

Chapter 9: Staff and patient responses to a pilot of an electronic Holistic Needs Assessment (eHNA); a service evaluation

9.1 Overview

In the context of the pilot study described in chapter 8, use of the innovation (the SDI-21 assessment) was voluntary; the nurses had a choice to participate or not. Some behavioural models propose the voluntariness of use of an innovation (i.e. whether the individual has a choice to use it or use is mandated) as a moderator of behavioural intention and use behaviour. For example, in the Unified Theory of Acceptance and Use of Technology (UTAUT) model, Venkatesh et al propose that the construct of Social Influence, although insignificant in voluntary settings, becomes significant when use of a technology is mandated [84]. In DoI theory, Rogers discusses incentives and mandates rather than voluntariness, considering them part of the *relative advantage* of an innovation:

"Mandates for adoption are a mechanism through which the system exerts pressure on an individual to recognise the relative advantage of an innovation…"[73]

In order to explore the potential impact on the voluntariness of use of an innovation, this chapter describes the roll-out of a government-mandated holistic needs assessment within one department of a local Teaching Hospitals NHS Trust, and a subsequent service evaluation of the uptake of the assessment and staff and patients' experience of participation. Ethical approval for this section of work was not required as it was part of a wider service improvement initiative. Nurses' responses to an innovation were explored within a mandatory context; the Models of Diffusion (MoD) Conceptual Model [3] has been used as a framework to describe the events in the case of this service evaluation.

9.2 Background

Holistic care is defined as;

"…a system of comprehensive or total patient care that considers the physical, emotional, social, economic, and spiritual needs of the person; his or her response to illness; and the effect of the illness on the ability to meet self-care needs…"[183]

The concept of holistic care is not a new one for the nursing profession; it was present in the work of Florence Nightingale [184] and has been throughout the history of

medicine [185]. As outlined in Chapter 1 (Section 1.8) The Holistic Common Assessment (HCA) of Supportive and Palliative Care Needs for Adults with Cancer [62] was developed in order to help healthcare providers adopt a unified approach to delivering holistic care as a response to the NICE Guidance (2004) on Supportive and Palliative Care Needs for Adults with Cancer, which states;

"6.18: Teams should ensure that social care needs of each patient are identified as part of initial routine assessment and, are then assessed on an on-going basis." [12].

The HCA guidance suggested five domains for holistic assessments; background information and assessment preferences, physical needs, social and occupational needs, psychological well-being and spiritual well-being.

Since the publication of the Cancer Reform Strategy in 2007 [63], care providers have been required to provide evidence of implementation of the HCA guidance. A Trust-specific implementation steering group was set up to apply the guidance with oncology out-patients. The steering group members included the Lead Cancer Nurse, other Senior Nursing Staff, Psychosocial Oncologists and members of the POG.

The aim of the steering group was to select an appropriate holistic need assessment tool, and a procedure to pilot this in practice. The objectives of the steering group were to decide the following:

- The assessment instrument to be used, considering;
    - The domains to be covered
    - Potential to monitor changes over time
    - Acceptability to patients and staff
    - The time and staff resource required to complete the assessment
    - Potential to be delivered online or on paper
- How the available electronic patient record system (Patient Pathway Management - PPM) could be utilised to securely record and monitor the assessment responses and any actions and outcomes resulting from these results (e.g. referral to another service)
- Which specific patient groups and clinics would be involved
- How and when the assessment would be delivered (i.e. on paper, online, whilst in clinic or at home prior to the appointment)

- How other healthcare providers, e.g. General Practitioners (GPs) could be made aware of the assessment findings and actions

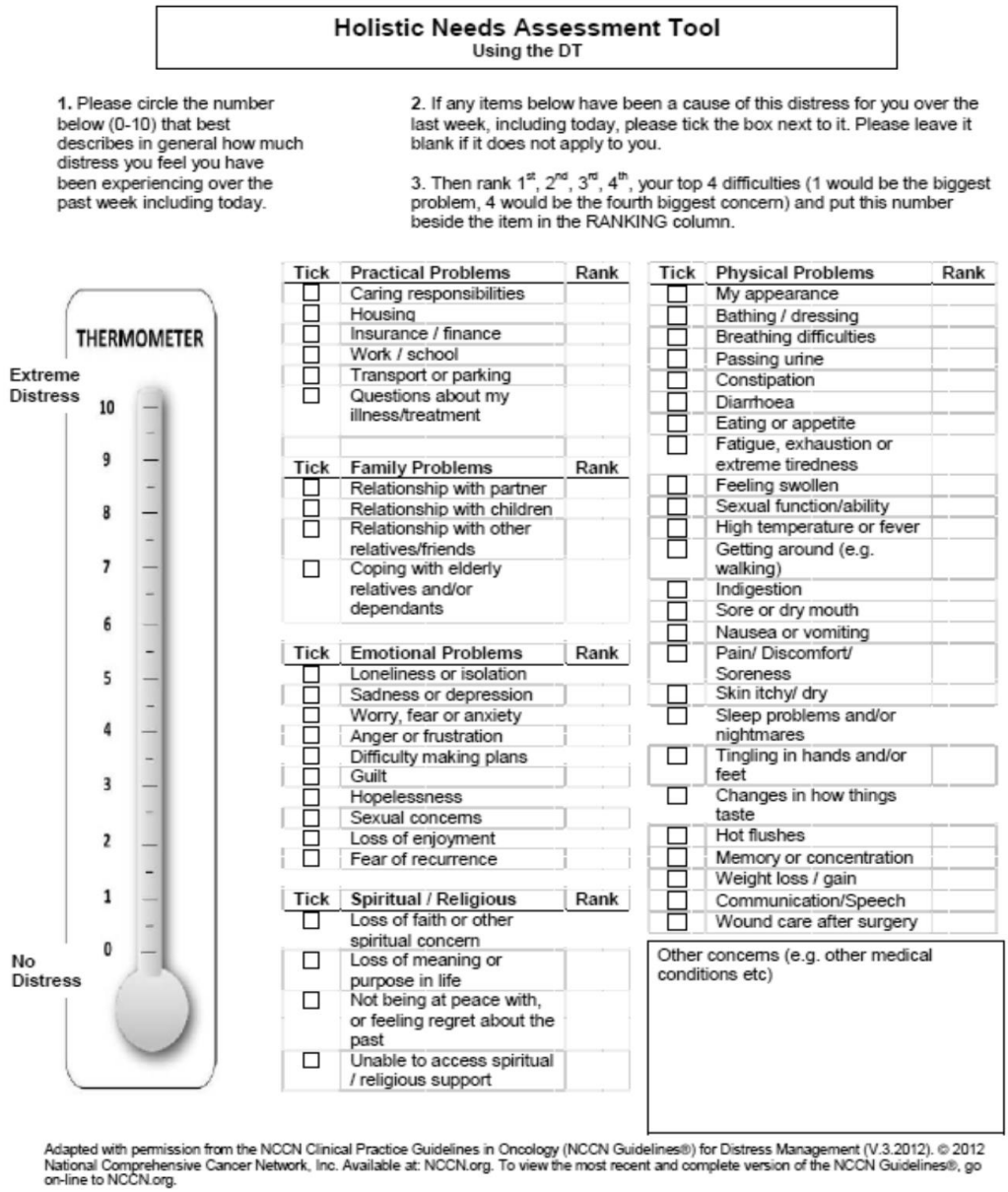
9.3 The pilot

9.3.1 The intervention

During consensus meetings with the steering group members, The Distress Thermometer with Problem Checklist (DTPL, figure 9.1) [186, 187] was eventually selected as the most appropriate instrument with which to conduct the holistic assessment within an oncology outpatient setting.

The intervention comprised a number of components, including the delivery of the DTPL via an online system. The DTPL was developed by the National Comprehensive Cancer Network (NCCN) as a "…rapid means for oncologists to identify patients with significant distress…" [186, 188]. The 'thermometer' element of the instrument is a patient-reported measure used to assess levels of distress; the patient is asked to use a visual analogue scale (VAS) to identify a number from 0 to 10 which they feel best describes the level of distress they have felt over the last week (0 being none, 10 being extreme distress). A cut off of ≥4 is considered the optimum for defining a person who is distressed in a general cancer population (i.e. those with a score of 4 or above are considered distressed) [189].

Patients are then presented with the 'Problem List', which is a checklist of typical problems, covering practical, family, spiritual, emotional and physical difficulties; this has been adapted for use within the UK context [190]. Patients are simply asked to tick which items "…have been a cause of distress for you over the last week" (figure 9.1). In this context, the generic 'Problem List' was supplemented with additional questions that the clinical team felt were relevant for their specific patient group at the Yorkshire Cancer Network (YCN) level (now the Yorkshire and Humber Strategic Clinical Network for Cancer). The YCN made a number of these different versions of the DTPL available within the network. Each version included additional or alternative problems, designed to reflect the issues facing specific clinical groups (e.g. lung cancer, sarcoma)[191]. Geographical site-specific versions were also available. For the purposes of this pilot, the version of the DTPL used was site-specific but was not specific to any clinical group (figure 9.1).



Holistic Needs Assessment Tool
Using the DT

1. Please circle the number below (0-10) that best describes in general how much distress you feel you have been experiencing over the past week including today.

2. If any items below have been a cause of this distress for you over the last week, including today, please tick the box next to it. Please leave it blank if it does not apply to you.

3. Then rank 1st, 2nd, 3rd, 4th, your top 4 difficulties (1 would be the biggest problem, 4 would be the fourth biggest concern) and put this number beside the item in the RANKING column.

THERMOMETER

Extreme Distress 10 9 8 7 6 5 4 3 2 1 0 No Distress

Tick	Practical Problems	Rank
☐	Caring responsibilities	
☐	Housing	
☐	Insurance / finance	
☐	Work / school	
☐	Transport or parking	
☐	Questions about my illness/treatment	

Tick	Family Problems	Rank
☐	Relationship with partner	
☐	Relationship with children	
☐	Relationship with other relatives/friends	
☐	Coping with elderly relatives and/or dependants	

Tick	Emotional Problems	Rank
☐	Loneliness or isolation	
☐	Sadness or depression	
☐	Worry, fear or anxiety	
☐	Anger or frustration	
☐	Difficulty making plans	
☐	Guilt	
☐	Hopelessness	
☐	Sexual concerns	
☐	Loss of enjoyment	
☐	Fear of recurrence	

Tick	Spiritual / Religious	Rank
☐	Loss of faith or other spiritual concern	
☐	Loss of meaning or purpose in life	
☐	Not being at peace with, or feeling regret about the past	
☐	Unable to access spiritual / religious support	

Tick	Physical Problems	Rank
☐	My appearance	
☐	Bathing / dressing	
☐	Breathing difficulties	
☐	Passing urine	
☐	Constipation	
☐	Diarrhoea	
☐	Eating or appetite	
☐	Fatigue, exhaustion or extreme tiredness	
☐	Feeling swollen	
☐	Sexual function/ability	
☐	High temperature or fever	
☐	Getting around (e.g. walking)	
☐	Indigestion	
☐	Sore or dry mouth	
☐	Nausea or vomiting	
☐	Pain/ Discomfort/ Soreness	
☐	Skin itchy/ dry	
☐	Sleep problems and/or nightmares	
☐	Tingling in hands and/or feet	
☐	Changes in how things taste	
☐	Hot flushes	
☐	Memory or concentration	
☐	Weight loss / gain	
☐	Communication/Speech	
☐	Wound care after surgery	

Other concerns (e.g. other medical conditions etc)

Figure 9.1: The DTPL employed in the pilot

Technology created in locally for research (QTool) enabled electronic delivery of the DTPL[192]. QTool is a secure web-based questionnaire management system that allows patients to report outcomes (symptoms, side effects and quality of life) to their healthcare professionals via instruments such as the distress thermometer and other measures (for more information please see www.qtool.net). Once questionnaires are completed, their responses are immediately fed into the patients' electronic records on the Patient Pathway Manager (PPM), ready to be viewed by the clinician, in this case the CNS for subsequent discussion with the patient.

9.3.2 The setting and participants

Following a call for volunteers from the Lead Cancer Nurse, a specialist CNS team elected to trial the eHNA. The service provides care for one of the largest oncology patient populations. For many of these patients their cancer becomes a chronic disease, and they survive with it for many years. For example, one specific cancer follow-up protocol timescale is 10 years, and there is an ever-increasing volume of patients year-on-year. Although surviving, these patients often have complex needs, including long-term treatments and long-term side effects of treatment.

This pilot was conducted by the CNS Team, and supported by the Macmillan Information Team from the local Macmillan Centre and the members of the implementation steering group, including POG. At the time of the pilot, the team of four CNSs were providing the whole-time equivalent (WTE) of three full time CNS posts. Their role being provision of support for patients, including holistic support, treatment option counselling and long-term information and support until transfer to palliative phase, via nurse-led and telephone clinics. The nurses were also required to fulfil a number of clinical duties, and deliver treatments (e.g. injections), and support consultant-led clinics.

The pilot specifically took part with a selected group of patients attending one nurse-led outpatient clinic. This clinic took place on a Tuesday afternoon, led by the CNSs and supported by a healthcare assistant. The appointments are booked as 30-minute sessions. Patients who had recently received a diagnosis, or received confirmation that their disease had advanced were invited to complete the online assessment. Some of these patients may have already had surgery. This group of patients were selected, as the HCA Guidance recommends such events as an appropriate time at which to conduct the holistic assessment[62]. One of the aims of this clinic, and a key role of the CNS, is to give patients the opportunity to discuss potential treatment options. Other patients attending this clinic included patients receiving treatment with injections.

9.3.3 Pre-pilot methods of assessment

Prior to the pilot, there were two ways in which a holistic needs assessment could be conducted. Firstly, a template had been created within PPM that generated a free-text

box with headings to reflect the five key holistic needs assessment domains (physical, social, occupational, psychological and spiritual). This was then typically used as a guide for the nurses during the consultation, who could then add text under each heading to outline any concerns and problems discussed in that domain. This could be used for any patient as the CNS thought necessary and appropriate.

Within the urology clinic in which the pilot took place, the DTPL had also been provided on paper, either via post with their invitation to the appointment, or whilst they were waiting in the clinic. The patients were then requested to bring the completed form with them into the appointment with the nurse, where the responses were discussed.

The intended pathway of completion (i.e. for the patient to complete prior to the appointment and the responses reviewed in consultation with the nurse) was intended to be the same for the online delivery of the DTPL (section 9.3.6, figure 9.2).

9.3.4 Training

9.3.4.1 Clinical Nurse Specialists (CNSs)

A Consultant Clinical Psychologist who was a member of the implementation steering group offered training for the CNSs in communication skills and how to recognise patients in distress. Members of the POG team provided at-desk training for two CNSs on the use of the QTool online system, and how to view the results in PPM after completion. They were also instructed on how to use PPM to generate letters for individual patients, which included unique login details to allow them to complete the DTPL online and ensure the link to their specific records within PPM. One of the CNSs had been involved in a previous research project utilising QTool, and therefore required minimal training on how to use the system. Two of the CNSs did not undergo the training provided by POG due to time constraints, and instead received informal training from the CNS who had had prior experience of use of the system. All of the CNSs had access to a training manual provided by the POG team, which included instructions and screenshots.

9.3.4.2 Macmillan Information Staff and Volunteer

In order to support the pilot by offering pre-pilot testing and support for patients in clinic, the Macmillan Information Support Staff team and volunteer within the local Macmillan Centre also underwent the at-desk training to enable them to use the system. The Macmillan staff then asked drop-in patients and members of support groups at the centre to trial the online system, for usability to patients and to test the reporting mechanism between QTool and PPM.

9.3.4.3 Secretary

A urology team secretary was selected and trained by the POG team to enable the generation of the patient letters with unique login details from PPM, to be sent along with the invitation to clinic. The patients were identified for her on the clinic list by the CNS.

9.3.5 Procedure for pilot

I. Patients with newly diagnosed prostate cancer, or a newly diagnosed progression in their disease were identified using PPM.
II. The trained secretary used the system within PPM to generate a letter.
III. This letter included instructions for accessing the QTool website and their unique login details – these login details ensured the link between their responses on PPM and their individual patient record within PPM.
IV. This letter also requested that the patient attempt to complete the online assessment at home prior to their appointment where possible.
V. It stated that if they were not able to complete the assessment at home, they should arrive 20 minutes early for their appointment and there would be the opportunity to access a PC and complete it in clinic before seeing the CNS.
VI. For any patients reporting a level of distress of four and above, an automated email was delivered to the CNS team to alert them.
VII. When patients arrived for their subsequent appointment, they were asked if they needed to complete the assessment by the receptionist.
VIII. If they needed to do so, the Macmillan Volunteer would make herself known to the patient and direct them to the PC.

IX. At this point the Macmillan Volunteer asked if the patient would like any assistance with logging in and/ or completing the online assessment.

X. The patient was instructed as necessary to allow them to complete the assessment.

XI. Once the assessment was complete, the patient could return to the waiting room to await their appointment with the nurse.

XII. When they went in to see the nurse, the results of their assessment would be available via their PPM record for the nurse to discuss as required.

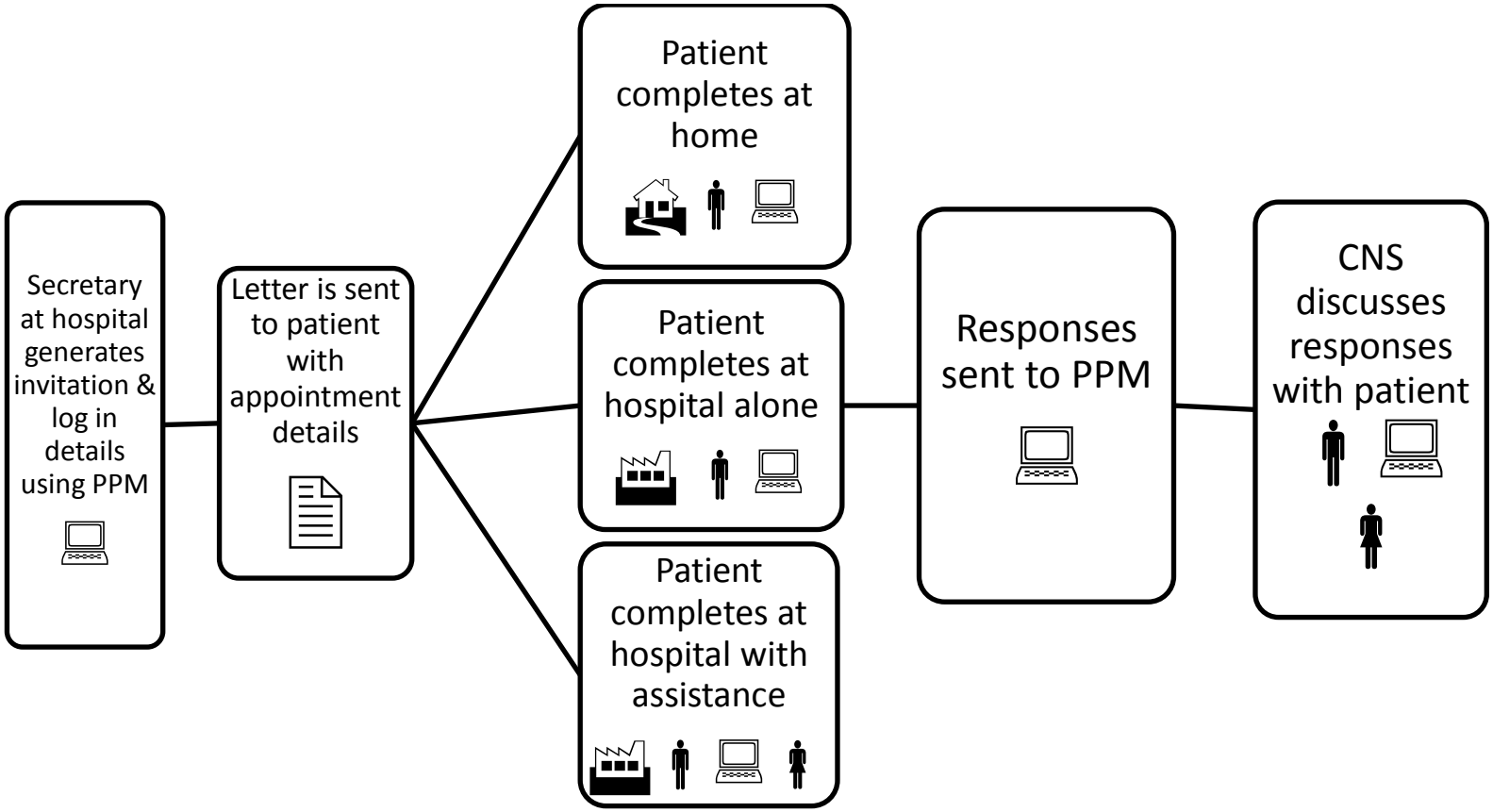


Figure 9.2: Procedure for delivery of the pilot intervention

9.4 Evaluation Phase I: Interviews with staff and Macmillan Volunteer

All nursing staff, the Macmillan Information Staff (involved in the pre-pilot) and the volunteer who assisted in clinic were interviewed about their experience of the pilot process, using a semi-structured interview (appendix 11).

9.4.1 Aims

The overall aim of this phase was to describe the staff responses to and perceptions of the innovative process of the eHNA, using the MoD Framework[2] to describe what was observed.

Specific aims were;

i. to obtain background information about the staff, e.g. experience,
ii. to elicit their thoughts on the acceptability and feasibility of conducting the assessment within the constraints of everyday working practice,
iii. to obtain their views on what may make the process more effective in the future, and
iv. to assess the suitability of the training and support provided throughout the process of the pilot

9.4.2 Methods

9.4.2.1 Data collection

An interview schedule was developed and reviewed by members of the POG and the Lead Cancer Nurse. The semi-structured format allowed more discussion than closed-questioning, facilitating detailed qualitative analysis, whilst ensuring the pertinent questions are answered [160, 161]. The interviews took place in November 2012, four months after the start of the pilot. All interviews were audio-recorded to facilitate analysis.

9.4.2.2 Data analysis

Framework analysis was used to analyse the staff interviews, the methods for which are described in chapter 8, section 8.5.1 (page 229). **Familiarisation** in this context began during data collection as the interviews were being conducted. Notes were taken during the interviews and any emergent themes/ areas of questioning added as

appropriate (e.g. if something came up in first interview it was added to subsequent ones). **Identifying the framework;** in this context, as in chapter 8 (table 8.2), the elements of the MoD Conceptual Model[2] had already been identified as the *a priori* framework. As in chapter 8, table 8.2, the *a priori* framework elements and their definitions are shown in table 9.1, with applications in context updated for the service evaluation dataset (highlighted in **bold).** The **indexing** stage involved listening to and making detailed notes on each of the interviews conducted, then **charting** and **mapping** was achieved by using an Excel spread sheet to organise the data under the relevant headings (framework items), and grouping the data into responses by staff group, i.e. CNS, Macmillan Information Staff and the volunteer and by looking at the different intervention element versus the framework item, as it became clear that the different elements of the intervention were being considered separately by the staff.

Table 9.1: *A-priori* analysis framework and definitions described in context – taken from models of diffusion framework[2]

**Unchanged from table 8.2*

Element*	**Definition as described in MoD framework[2]***	**Application in this context**
The innovation	The new, unfamiliar technology and/ or practice.	**The practice of conducting the holistic assessment using the DTPL (delivered on a touch-screen system), interpreting results and dealing with issues raised.**
Relative advantage	The extent to which the innovation or new technology is perceived as offering an improvement over existing practice [2, 73].	**Whether the holistic assessment using the DTPL offered an advantage over existing methods of conducting holistic assessments.**
On how the new process offers *relative advantage*; *"…too many (patients) for us to see…there's not very much continuity because there's not enough of us…so using the holistic needs assessment… is really good because there is some quality there…because we're able to sit with them and talk to them…whereas in other clinics I don't feel that happens…"* (01)		
Compatibility	Refers to how closely an innovation fits with current values and needs of the potential adopters [2, 73].	How compatible conducting the assessment was with the existing working practices in the specified clinics.
On how the method piloted was not *compatible* with the standard clinic practice; *"…when I see these patients the things that have been highlighted are nothing to do with the cancer diagnosis…it's delaying everything and again I don't have the time to wait and hang around on a corridor waiting for X to finish (that) conversation…"* (04)		
Complexity	How difficult the innovation is to understand and use [2, 73].	How easily the nurses could learn to use (and maintain the knowledge) to enable them to conduct the assessments.
On the *complexity* of using the system; *"It was a nightmare trying to get the letter off PPM, and it slowed me down terribly in clinic, and X had to come and help me and it was a few emails before I got the letter out…"* (03)		
Trialability	How much opportunity there is for the potential adopters to practice or *trial* the innovation [2, 73]?	**The assessments were being *trialled* as part of a pilot. This may also refer to how many opportunities the nurses had to 'practice' carrying out the assessments.**
On lack of *trialability* caused by minimal use of the system*; "I'm one where if I'm using something like a new system…I need to use it consistently over and over again before I can get it, and I think that's where I found the difficulty because I might use it I think I've done it a few times and that would be spread over 2 or 3 months and that's just not enough for me to remember."* (03)		
Observability	Relates to the extent to which the outcomes of an innovation can be seen by potential adopters [2, 73].	**Whether the nurses could *observe* the impact of conducting the assessment for the patients, whether positive (helping them deal with issues of concern) or negative (e.g. significantly affecting the running of the clinic).**

Element*	Definition as described in MoD framework[2]*	Application in this context
Observing positive impacts of taking part in the pilot for patients; *"…there has been some really positive feedback about learning about support services, and the support (the volunteer) has being providing, that's come from the CNS…the patients have enjoyed that extra time…the patients have benefited from that."* (08)		
Reinvention	The potential for the adopters to adapt and refine the innovation to fit their *needs* more effectively [2, 73].	Any suggestions or requests from the staff to adjust the delivery of the intervention.
Fuzzy boundaries	Innovations are often described as having a *hard core* (the fixed components) and a *soft periphery* (the organisational structure and system required for implementation). *Fuzzy boundaries* refers to the adaptability of the soft periphery [2].	**The *hard core* in this context was the fixed components (i.e. the DTPL, the web-based delivery). The *soft periphery* was the nature of the clinic into which the assessment process was being introduced. This links to *reinvention*; how the assessment process can be adapted to fit with the soft periphery of the clinic procedures.**
On *reinventing* the process around the *fuzzy boundaries* to increase the effectiveness of the assessment process; *"I didn't know where these people were at in their diagnosis, and I really think that is an area for looking at, if you know where people fit in and then you can adjust the questionnaire to that particular group you can get much more out of them…one guy was about to get some bad news…the only reason I know that is because the nurse came in before…it put a different slant on it altogether because…I was a little bit more careful with him…"* (05)		
Risk	How risky the innovation is to the potential user/ adopter, i.e. the degree of uncertainty of outcome or impact associated with an innovation[2].	Perceived risk for the nurses would include a negative impact on the smooth running of the time-pressured clinics, or the risk of 'opening a can of worms' by asking patients about specific, potentially sensitive items (e.g. sexual difficulties).
On the *risk* that sending the invitation to assessment to patients prior to key appointments may break bad news regarding their diagnosis in an inappropriate way; *"So they're being sent out these letters…generated by an admin person who perhaps doesn't know much about them, she's just going off a clinic list… they are then sitting down in a room with the volunteer who's saying tell me about your concerns…and they might say 'I don't know what my diagnosis is yet, are you telling me I've got cancer?', and it's not appropriate.* (04)		
Task issues	How relevant the innovation is to the adopter's day to day work and whether it can assist them in improving their performance[2].	How relevant the assessment process was to the day to day running of the clinics and how it could assist the nurses in improving or streamlining provision of psychosocial care for patients.
On *task issues* around how much support the patients needed to complete the assessment in clinic; *"…if you need a good amount of conversation to complete it online then I'm thinking it's not an online assessment is it really…"* (03)		
Knowledge required to use it	How efficiently the knowledge necessary for implementing the innovation can be transferred from one context to another[2].	How efficiently the knowledge required in delivering the assessment and interpreting the results was imparted to the nurses.
On how technical difficulties impacted the sharing of *knowledge*; *"…my learning experience has*		

Element*	Definition as described in MoD framework[2]*	Application in this context
never been smooth, quite a few times when someone's said 'oh you do this', and even X has shown me sometimes and she went 'oh that's never supposed to happen'…so it's never been smooth…" (03)		
Augmentation/ support	Whether the innovation is provided along with customisation, training and technical support[2].	All the nurses were trained in how to conduct the assessment, interpret the results and deal with any difficulties raised. Support was available throughout the period of the pilot.
On technical *support* during the pilot; *"I felt very supported by X and X...I would just pick up the 'phone and they would tell me what to do."* (02)		
Adoption by individuals		
General psychological antecedents	Individual traits associated with the likelihood of trying innovations (e.g. motivation, values)[2].	How likely each of the individual nurses were to engage in trialling the assessment process.
Context-specific psychological antecedents	How the individual's traits (general psychological antecedents) are expressed or respond within the specific context [2].	How the *general psychological antecedents* of the individual nurses was expressed in the context of the specific trial.
How *general psychological antecedents* are expressed in relation to the pilot; *"I do find it a little patronising…I consider myself to be quite a good clinician…I can do a holistic assessment as part of my consultation anyway and will cover the necessary concerns when I see a patient in those kind of settings and it's almost like a tick-box exercise to me…"* (04)		
Meaning	The meaning attached to the innovation by the individual [2].	**How the nurses felt about conducting holistic assessments generally, and how much importance they attached to gathering holistic needs data in a standardised way.**
On how holistic care of patients should be a part of the nursing ethos; *"Holistic assessment is something that I've always done anyway and it's something that we should be doing as nurses…"* (01)		
The adoption-decision	Includes c*ontingent* (depending on a decision made by someone else), co*llective* (the individual has a certain amount of choice but must ultimately comply), or a*uthoritative* (individual is told whether or not to adopt the innovation) [73] [2].	**The decision seemed to be *collective.* The nurses had the opportunity during the pilot to trial the assessment and give feedback, but as this was a government policy it would be likely they would have to formally adopt it at some stage.**
On how the *adoption-decision* was driven by one staff member in this context; *"I've always done HNA…and when I was a lung cancer nurse…we chose 5 different needs assessment tools to pilot and the distress thermometer came out actually as the one that we all liked to use, so then I brought that with me when I started here…and then so I was up for it really, so when (lead cancer nurse) was talking to us as CNSs about the holistic needs assessment and using the distress thermometer I sort of volunteered our team to work with it."* (02)		

Element*	Definition as described in MoD framework[2]*	Application in this context
Concerns-based adoption model	Any concerns the potential adopters have regarding the use of the innovation, either prior to adoption (concerns in pre-adoption), during initial use (concerns during early use) or once users become familiar with the innovation (concerns in established users) [2, 77].	This was expanded to include all nurses' feelings about the innovation and the trial as a whole.
On feeling optimistic in *pre-adoption*; *"Holistic needs is something we need to be doing better and I wanted it to be more formalised so we weren't doing it wrong, and we'd have somewhere for it to be documented and it would be a lot clearer. I felt optimistic that it would make a difference to paperwork and increase our understanding of patients' problems."* (01)		
Diffusion and dissemination	Influences on how the innovation may be adopted via "pure diffusion" (unplanned, informal, decentralised, and mainly mediated by peers) and "…active dissemination…" (planned, formal, centralised)[2].	**The holistic needs assessment was *actively disseminated*. It was *planned* and *formally disseminated* from the Lead Cancer Nurse, with assistance from the research team, to the clinical staff via formal channels.**
Network structure	Refers to the quality and structure of social networks[2].	There 'horizontal' network structure of nursing staff, as described by Greenhalgh et al[2] was observed in this setting. The Lead Cancer Nurse had overall responsibility via Matrons, who in turn manage Senior Sisters, staff nurses and HCAs. This appeared to be a supportive network with mechanisms for feedback at all levels.
Homophily	How similar the potential adopters are in terms of factors such as educational and cultural background and socioeconomic status [2, 73].	Data on years' experience, age and gender were collected to enable assessment of *homophily* amongst the nurses.
Opinion leaders	Those who may have influence over other potential adopters, either through status and authority, or they may be *peer opinion leaders*, who can exert influence via representativeness and credibility[2].	Opinion leaders and champions would be identified as the pilot progressed.
Champion	Key individuals who are engaged with the innovation, but may not necessarily be in a position to influence other potential adopters[2]	

Element*	Definition as described in MoD framework[2]*	Application in this context
Outer context	The *outer context* – inter-organisational networks and collaborations; may include informal networks, the wider environment and political directives [2].	The clinics in the context of the wider hospital and in comparison with each other, included the logistics of the running of the clinic in this case.

9.4.3 Findings

9.4.3.1 Problems encountered during the pilot

In order to make arrangements to conduct the evaluation, informal discussions took place prior to the formal interviews with the staff involved. During these conversations, the CNSs raised a number of difficulties that had been experienced with the pilot intervention, including;

1. Difficulties in administration of the invitation letter to patients
2. High numbers of patients completing the assessment in clinic
3. In-clinic completion taking longer than expected

As part of the development of the evaluation, EJI attended a Tuesday afternoon clinic to have an informal chat with patients who had completed the assessment that day in clinic. In line with what the CNSs reported, four of them had completed the assessment, but none of them had received the letter inviting them to take part in the assessment and providing instructions on how to do so. This meant that the staff within the clinic had been required to generate the letters in clinic. It was reported that the letters had not been sent with the clinic appointment because the secretary who had been trained to complete these tasks had been on annual leave, and no one else had picked it up in her absence.

In addition, one of the same patients said that it wasn't immediately obvious to him who the volunteer was, and he wasn't sure what her qualifications were, although it became clear as the assessment progressed. This patient reported having a very specific reason for attending that day (injection) and he said it seemed strange to be asked such questions at this time.

It was evident quite quickly that not all of the CNSs were engaged with the eHNA process, and there were huge variations in attitudes and experiences relating to the process within the small team. The process had not become part of the routine

practice of the clinic, and some of the staff were experiencing lack of knowledge and confidence with the system; overall it was not being used consistently throughout the team.

As the interviews progressed it became apparent that all of the members of staff viewed the process as a number of separate elements, including the volunteer who had more experience of the online completion of the DTPL. These elements were;

- The visual analogue scale (VAS – the 'thermometer' itself)
- The problems checklist
- The ranking exercise that patients are asked to complete

The main focus of the findings were relating to the CNSs as the adopting individuals, and the various elements of the innovation.

9.4.3.2 Adoption by individuals

Diffusion and dissemination

The MoD Model proposes that the factors influencing the uptake of the adoption can be placed on a continuum between "pure diffusion" (unplanned, informal, decentralised, and mainly mediated by peers) and "…active dissemination…" (Planned, formal, centralised) (figure 9.3), and that the predominant diffusion mechanism is *social networks*, ("…the pattern of friendship, advice, communication, and support which exists among members of a social system.")[2], referred to as *social influence* in the DoI theory [73]. Figure 9.4 demonstrates how the observed dissemination and diffusion of the eHNA occurred within this context.

The innovation was introduced to the team via *active dissemination* as part of a *formal dissemination programme* instigated by the DoH, NICE and the National Cancer Action Team[62, 63] and subsequently actioned by the Lead Cancer Nurse within the Trust. In terms of the MoD model these can be described as the *external change agency*. As Greenhalgh et al propose, once the innovation has been introduced to the adopting unit (the CNS team), the predominant diffusion mechanism becomes the *social networks* and lines of communication between the *champion* (CNS 02)

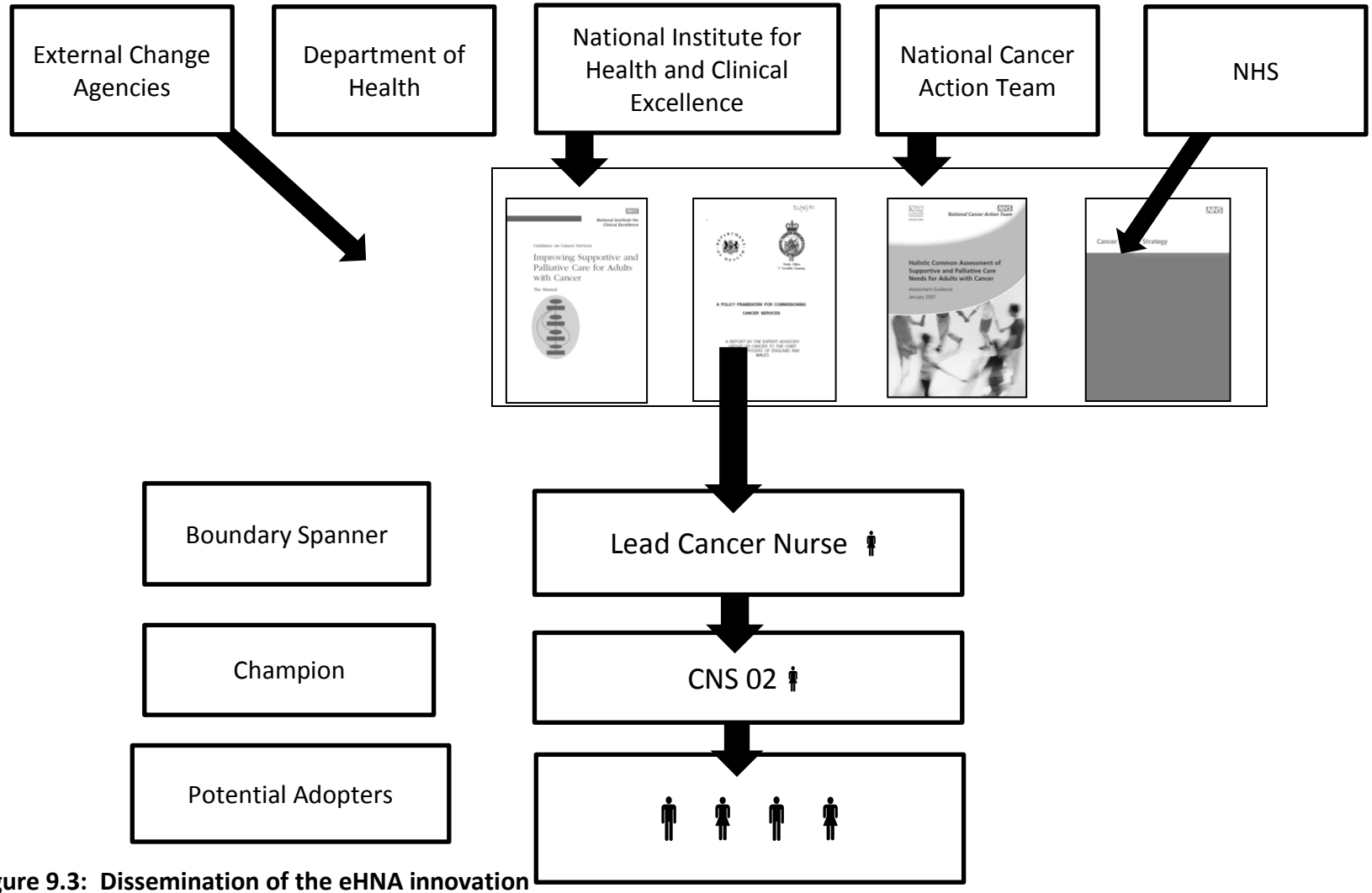


Figure 9.3: Dissemination of the eHNA innovation

CNS 02 had previous positive experiences with both the QTool online system and the DTPL as an instrument. Although CNS 02 as the *champion* differed significantly in her positive attitude towards the pilot compared with her colleagues, it seemed that they were all willing to attempt the pilot and respected her decisions regarding this. CNS 02 was aware of the others' thoughts on the process and the DT, and her thoughts on her colleagues' views on the process were accurate when compared with their responses during the interview. None of the CNSs perceived that they were influenced by the attitudes of their colleagues. Those who were unsure of the process found it comforting to know that others had similar concerns, but at the same time felt that having "…a positive person…" within the team also helped motivate them to try.

Concerns and emotions in pre-adoption

In place of Rogers' original five stages of adoption (awareness, persuasion, decision, implementation and confirmation)[73] the evidence from Greenhalgh's review suggests that the Concerns Based Adoption Model (CBAM) "…better explained the findings of empirical studies of complex service innovations in an organisational context" [2]. The CBAM considers three stages of the adoption process; preadoption, early use and established use, and outlines what factors will assist the adoption of an innovation at each stage. Staff awareness of the adoption, whether they have sufficient information about what it does and the correct knowledge to use it, and are aware about what impact it might have, are all important prerequisites for successful adoption. In this case, only the first two stages are relevant (pre-adoption and early use). The staff were explicitly asked about *any* emotions they had prior to the pilot, not just concerns, and were asked to recall how they felt when they heard about the pilot and the proposed process.

Three of the four CNSs used phrases/ words such as 'excited', 'hopeful', 'enthusiastic'. One nurse (04) could not recall how she felt prior to the start of the pilot. All of the nurses acknowledged that the standardised assessment and recording of holistic care was something "they could be doing better". They reported being hopeful that it would speed things up and help them to provide a higher level of care in a more efficient manner, despite the pressures faced. Of the four members of the Macmillan Information Team, three also reported positive feelings about the process prior to the pilot; one gave no specific answer to this question.

Despite the generally positive attitude amongst the CNSs prior to the pilot commencing, only one of the nurses (02) had any real experience of the DTPL and QTool, and this was the same individual who had been the only one of the team to be a member of the steering group. This suggests that only this staff member had all the relevant information and experience to allay any concerns. This presents a picture of a team of staff with an imbalance in their awareness and knowledge and therefore their experience; this pattern would continue throughout the other areas of analysis.

General and context-specific psychological antecedents and meaning

General psychological antecedents refer to the characteristics of the individuals that are associated with a predisposition for adopting and accepting innovations or new practices (e.g. tolerance of ambiguity, ability and learning style). *Context-specific antecedents* refer to how motivated and able the adopter is, and whether the innovation meets any requirements they have. *Meaning* refers to the meaning attached to the innovation by the potential adopter[2]. If an individual has characteristics associated with adoption, if they are motivated and able to use the innovation, and it has positive meaning for the individual, adoption has an increased chance of success by that individual. It became clear during the evaluation that the context in which the pilot was being conducted was having an influence on the adoption of the process.

The team were facing a number of pressures during the pilot and at the time of the interviews. The team already served a very high volume of patients with diverse and complex needs; amongst a population that would live for a long period (e.g. for one diagnostic group follow-up was 10 years). A recent peer review (within the last 5 years) had led to the creation of an additional CNS post, taking them up to the current three whole-time equivalent CNS posts, such was the volume of their patient population. Significant changes to their work plan had been made, which meant their sessions were increasingly taken up with clinical duties, rather than making contact with patients, i.e. time to contact patients by phone to respond to their queries. On top of these existing issues, nurse 02 was working her notice period and was due to leave within a number of weeks. Staff reported that this was due to Trust and service-wide financial issues, there was no guarantee that she would be replaced.

This nurse was the most senior of the four, and was also the exception in terms of both her attitude towards technology in general and her general feelings towards the DTPL and the eHNA initiative in general. In terms of general technology she described herself as 'engaged' and she had previous very positive experiences both with the distress thermometer and with the QTool online delivery facility. This nurse was the person who had been driven to volunteer the team for involvement in the pilot, which she reported was partly because of her previous positive experiences with both the DT and the QTool system, but also because she felt that the pilot would give the team an opportunity to receive some support in providing holistic care in a more consistent manner. Whereas the remaining three nurses felt the current workload and pressures were a reason not to get involved, the most senior nurse saw it as a way to provide more consistency and quality of care to their patients who they all perceived to be under-served. She was therefore a loss not only in terms of their workload coverage, but also as the *champion* of the pilot process and the person to which the other nurses went to when they had any problems with any aspect.

The impending loss of this staff member, on top of the existing pressures, was having a significant impact on the remaining nurses. One described it as having a destabilising effect. Another considered the team to already be at crisis point.

Two of the nurses had concerns regarding the DTPL before the pilot began (CNS 01 and 04), and one was very negative about the initiative as a whole (04). She found it patronising and felt that holistic care was an integral part of her service to patients and she did not require an assessment tool/ process to help her provide this care, particularly in view of the pressures – she felt that learning something new and introducing a new practice was too much in the current climate for them. Therefore the *meaning* attached to the DT for nurse 02 compared with her team members was very different.

These events (i.e. work plan change and leaving of 02) happened after the start of the pilot and are likely to have some bearing on the lack of success. However, existing negativity and lack of confidence amongst some of the nurses, heightened by this event, plus difficulties with the process/ innovation (see 9.3.4b) combined to reduce the success of the implementation.

The Macmillan Volunteer

As a non-clinician and a cancer survivor, the volunteer's *general psychological antecedents* differed from the CNSs and Macmillan staff – particularly the Macmillan staff who had previous experience in nursing. The volunteer was "…keen to move things forward…" and was excited and enthusiastic about the pilot. In terms of *context-specific psychological antecedents* the whole experience was a new one for her, and she had no preconceptions about any aspect of the process, but was keen to get things working. She was not aware initially of the difficulties and pressures the team were facing. The *meaning* she attached to the process was related to her personal experience of being a patient, and she saw the potential addition to the service delivered to patients as a positive one.

9.4.3.3 Attitudes towards the innovation

It became clear through the interviewing process that some of the staff considered the whole process as a set of individual components, even going so far as to consider the main elements of the DT (the VAS, the problem checklist and the ranking exercise), to the point where the interview data could be separated into headings in relation to each of the separate components of the process. In line with findings from Greenhalgh et al's work, considering an innovation as a number of component parts can make it manageable for the potential adopters and increase its likelihood of adoption [3].

There were a number of *concerns (in early use)* expressed by all of the staff. Only the champion did not express any major concerns about any of the process, but acknowledged some of the *concerns* that the other nurses had (i.e. can see how sometimes it may take longer).

The overall process - general concerns and emotions

Overall the nurses felt that there was a lack of standardisation in terms of the process; sometimes the nurse had to generate the letter 'there and then' in clinic in order for the patient to complete the assessment, sometimes the volunteer was there and completed it prior to the appointment, and sometimes, particularly if letters needed generated and the volunteer wasn't present, it was not done at all.

The intended process was to have patients completing the DTPL online at home, so that the results were stored in the PPM system ready for the nurse to view during the

appointment. This did not happen as expected, and the perception by all of the nurses was that a very high percentage of the patients were completing the DTPL in clinic, and many patients also requested assistance from the volunteer in clinic. The original intention was for the volunteer to simply provide practical support and guide the patients through log in and be on hand should problems occur while they were completing the DTPL online. On a number of occasions this process led to a lengthy conversation between the volunteer and the patient, sometimes holding up the clinic as the nurses were left waiting for the patients. The CNSs became frustrated at having their already busy clinic held up and disrupted.

One of the nurses felt that making the assessment in its piloted form part of the typical consultation was very difficult; meaning it was seen to be incompatible with their standard practice. Another CNS felt they were "more than capable" of prioritising patients' difficulties without the aid of the DTPL, suggesting that to her it offered no *relative advantage*. Suggested figures regarding rates of completion from the same nurse backed up this lack of advantage; she quoted that whilst using hard-copies of the DTPL, provided via post or in clinic, response rates were significantly higher at approximately 75% and 100% respectively. There was unfortunately no data available to back up these suggested figures.

Only the champion felt that the use of this process could offer advantage, especially considering the current pressurised environment in which the Urology CNSs were working. She felt that the pilot offered a way to provide quality and consistency of care without increasing the staff workload.

DTPL – Distress Thermometer VAS and Problems Checklist

The VAS section of the DTPL (the thermometer) did not cause any concern to any of the staff or patients. Most of the staff could see the benefit of the problems checklist as a 'prompting' tool, and one member of the Macmillan team thought it was useful to encourage staff to bring up issues they may otherwise avoid.

There were a number of concerns regarding the problems checklist, which even the champion acknowledged. The overarching sense was that the checklist was too generic, "…too much one cap fits all…" All the CNSs and some of the Macmillan staff commented that the patients can tick "too many problems", or indeed all of them. This would generate a lengthy discussion. There was also a concern that being

presented with a list of problems may cause the patients to think about problems that they weren't previously concerned about or hadn't thought of, or force them to face issues they'd rather not consider. Both CNSs and Macmillan staff felt that the wide range of problems may "open a can of worms" or even "put words into peoples' mouths". Although the questionnaire specifies that the patient only consider the last seven days, and consider only issues relating to their diagnosis, it is often difficult to ensure the patient does so. Some specific questions caused more concern than others, e.g. the sex question was difficult for both the patients and the staff, particularly considering the age of the patients and that they were all men and the volunteer was a younger female. The regrets question was seen to be very emotive and some patients brought up incidents and issues that had happened or affected them many years ago. Therefore the opinions of the staff suggest that not only does this element of the DTPL offer no *relative advantage*, it also increases the *complexity* for the staff, in that it offers more information than may usually be obtained during the consultation, but this is not necessarily relevant to their current care and may even be causing harm to some patients who become distressed whilst completing the checklist.

The nature of the questions seemed to be a particular concern in the context of the timing of delivery. Some of the patients invited to participate were aware of their diagnosis but not the extent of it or what their next stage in the pathway was. Patients were being asked to consider all concerns, when actually for many of them there may have been only one over-riding concern, which was the extent of their diagnosis and what would happen to them next; and all other issues would be impacted by this. Due to this many of the staff were concerned that the delivery of the DTPL at this time was not appropriate.

DTPL - Ranking activity

Following the completion of the problems checklist, patients are then asked to rank each of the problems they have ticked in terms of how much of a concern they pose at that particular time. This caused major problems for both the staff and the patients. It became clear from interviewing the volunteer and another Macmillan staff member who had helped patients in clinic that this was the cause of the lengthy conversation that had caused so much concern and disruption in clinic. They thought the conversation required to help the patients complete this section almost rendered the

task pointless because the patients need so much assistance to complete the task. Patients needed a high level of support. The volunteer expressed concerns that this meant the answers were not genuine. Again, this activity increased the *complexity* of the process, without offering any *relative advantage*.

Volunteer

One of the CNSs admitted that if the volunteer wasn't present she just avoided the process altogether and didn't ask the patients to complete the DTPL. One nurse felt having the volunteer to help may have reduced concerns for the patients regarding the practicalities of using the computer, and the benefits of having the opportunity to sit with an information professional and discuss concerns.

The presence of the volunteer was considered by all of the nurses to be the cause of the lengthy conversations when the patients completed the assessment in clinic. On interviewing the volunteer and the other Macmillan team member who had helped the patients, it became clear that the ranking activity within the DTPL was considered the major cause of these conversations which were sometimes the cause of disruption and hold ups in clinic. It was also noted that the presence of family members could compound this issue and extend the conversation even more.

All of the staff, including the volunteer herself, expressed concerns about the nature of some of the conversations and issues raised as a result of completing the checklist and particularly the ranking exercise. The burden for both the patient and the volunteer, caused by these often lengthy and potentially sensitive conversations, was a concern for all of the staff. As even the CNSs acknowledged that they wouldn't ordinarily raise some of these issues without the DTPL, they wondered if it was appropriate for the volunteer who does not have a "therapeutic relationship" with the patient.

Staff expressed concerns that the presence of the volunteer may cause over-reporting or affect patient responses, which the volunteer had already acknowledged. There was a worry that the patients would end up reporting/ discussing things twice
Both the volunteer and another Macmillan team member who had been involved in helping patients felt they could have "done a better job" had they known more about the patients, e.g. what stage they were at in the pathway, what they knew about their diagnosis; they felt this would help them tailor the questions.

Online/ QTool

The generation of the letters via PPM caused significant practical problems for three of the four CNSs (only 02, the champion had no practical difficulties with this due to her prior experience). This letter provided the unique log in details for the patient to enable them to use the QTool system, but more essentially these details ensured their DTPL online responses linked directly with their individual record on PPM. Therefore without this letter and details it was not possible to complete the process. The three nurses who had experienced difficulties with this had been limited in their access to training due to existing workload and time pressures – in most cases 02 had shown them 'on the job'. Due to the lack of standardisation they did not have many opportunities to use the knowledge, because they were not regularly required to generate the letters. Although many of the staff considered the online system to potentially be faster, this speed advantage may be reduced or less observable in the face of such technical complexity.

Two of the staff thought that huge assumptions were made about patients' access to and abilities with computers, especially considering that the patient group was of an older age group. This was the reason for offering the service in clinic where required. The major benefits of the online system were recognised as no risk of losing information (as with paper), and the improved accuracy of recording; the link to the patients' individual records was seen as an essential and highly advantageous facility. It was also reported that when using the paper versions, many patients did not undertake the ranking exercise; whether this was deliberately ignored by them or whether the instructions were not clear was not ascertained – accurate figures for how many patients failed to do this on paper are also not available. Considering the staff thoughts on the ranking exercise, it is not clear whether this lack of completion of the exercise would be considered an advantage or not.

Reinvention

Both in Rogers' original DoI theory, and in the MoD model, opportunities for reinvention of an innovation by the potential adopters will increase the likelihood of adoption. Throughout the interviews a number of suggestions were made for how the process may be adjusted to make it more compatible with the existing practice, and reduce its complexity. Some of the suggestions were:

- To have the patient complete the DTPL on paper and have the volunteer input the responses on the computer
- To fully train and engage the nurses before involving the volunteer; this would ensure the nurses had the skills to conduct the full process (i.e. generating letters, helping patients complete the assessment online)
- Increasing the number of patients completing the assessment at home
- Use of tablets/ iPads in the waiting room to offer more flexibility within clinic
- Additional staff
- Improved administration of letters
- Dedicated Macmillan information person in each clinic
- Removal of the ranking activity from the process

From the data collected during the interviews, the removal of the ranking activity would remove the most complex component of the process. This would also be one of the most workable solutions to implement. Unfortunately, these *reinvention* ideas were not discussed between the team members as the pilot progressed. Had the team had the opportunity to meet and discuss any difficulties during the pilot they would have become aware of what specifically was causing the problem and had the opportunity to implement some of their *reinvention* ideas. The nurses would have had a better understanding of the problems the volunteer was facing and the fact that they all had concerns about the ranking element of the checklist would have come out.

9.4.4 Summary of findings

Any existing negativity (*context-specific psychological antecedents*) towards the process or any of the elements of the innovation is heightened by the issues associated with the process/ innovation, i.e. lack of perceived *relative advantage*/ lack of *observability*, and the *complexity* associated with the process.

9.5 Evaluation Phase II: Patient survey

All patients recorded as having been invited to participate in the pilot were sent a postal survey to obtain their views and experiences of the pilot. Anonymous data on their DTPL responses were also obtained from the PPM system. Patients were included to add to the *observability* of the process, i.e. if the patients found it a particularly positive experience this could be fed back to the staff involved and

demonstrate the *relative advantage* and potentially impact the *meaning* of the process to the staff involved.

9.5.1 DTPL Data

9.5.1.1 Aims

Analysis of the DTPL data was conducted to fulfil the following aims:

- Assess how many of the invited patients had completed the assessment
- Assess how many completers had done so within clinic or at home
- Summarise the levels of distress and nature of the problems being faced by the patients

9.5.1.2 Methods

Data collection and analysis

Anonymous patient data was extracted from PPM. Simple counts were taken of how many patients had completed the DTPL online. The day of the week they had completed it was also recorded. This gave an indication of where the DTPL had been completed. If completed on a Tuesday afternoon, the time of the clinic, it was likely that the patient had done it in clinic, and at home if completed at any other date or time. Mean levels of distress were calculated, and counts taken of problems reported.

9.5.1.3 Findings

Between 17th July 2012 and 25th March 2013, 136 patients were considered eligible to take part in the pilot. Of these, 88 were recorded as having completed the assessment when the data was extracted, resulting in an overall response rate of 65%. Unfortunately due to a lack of accurately recorded response rates from previous methods, it cannot be certain that this response rate offered any *relative advantage* in terms of the number of patients completing the DTPL in comparison to other methods.

The day on which the assessment was completed was used to gauge whether it had been completed in clinic or in another location; 53% of completers were recorded as doing so on a Tuesday afternoon, the day and time of the clinic. This makes it extremely likely that it was done in clinic. The remainder did it on another day, and therefore probably in another location. Although the nurses perceived very high

numbers of patients completing in clinic, whereas these figures suggest 53% were; this over-estimate may be due to those that were doing it in clinic being more visible because they were taking a long time and disrupting the clinic.

Levels of distress

Complete data was available for 86 patients who had completed the online DTPL. The mean level of distress was 3.3 (SD 2.81, range 0-9, figure 9.5).

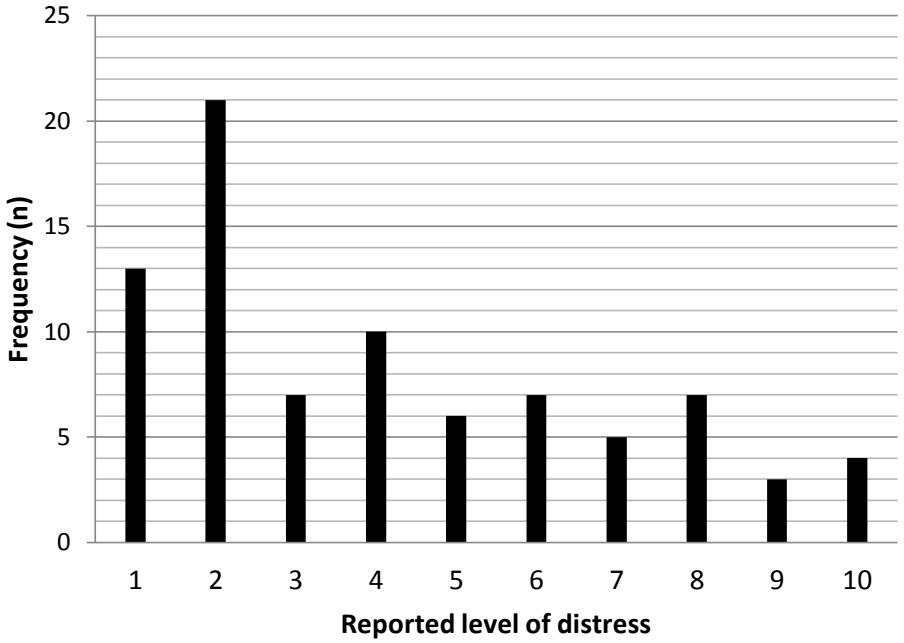


Figure 9.4: Levels of distress reported on DTPL

Thirty-four of the 86 patients scored 4 or more on the DT section of the DTPL (40%), and would therefore be considered distressed [189].

Problems reported

Figure 9.6a shows how many times each specific item within the practical problems section of the problem list was endorsed by patients within the pilot. The most frequently reported problem was “Questions about my illness/ treatment”, which was ticked on the problems list by 29 patients.

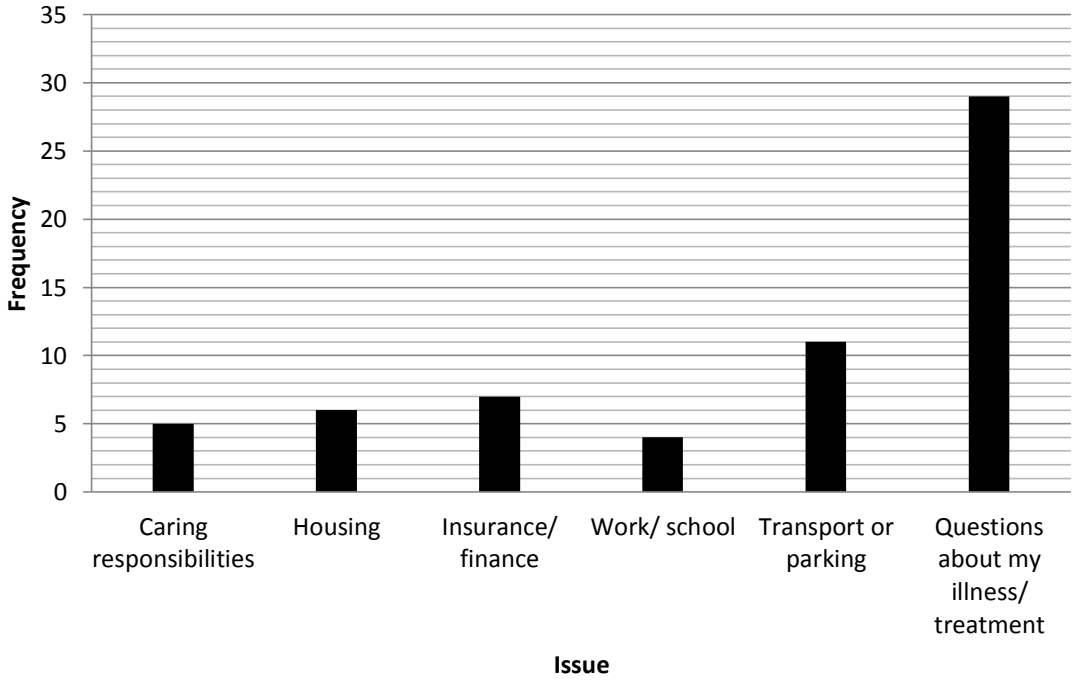


Figure 9.5a: Frequency with which practical problems were endorsed

Figures 9.5b and 9.5c demonstrate how frequently family problems and emotional problems were endorsed by patients. The most frequently endorsed family problem was "Coping with elderly relatives and/ or friends". Within the emotional problems list, the most frequently endorsed problems are "Worry, fear and anxiety" and "Fear and recurrence".

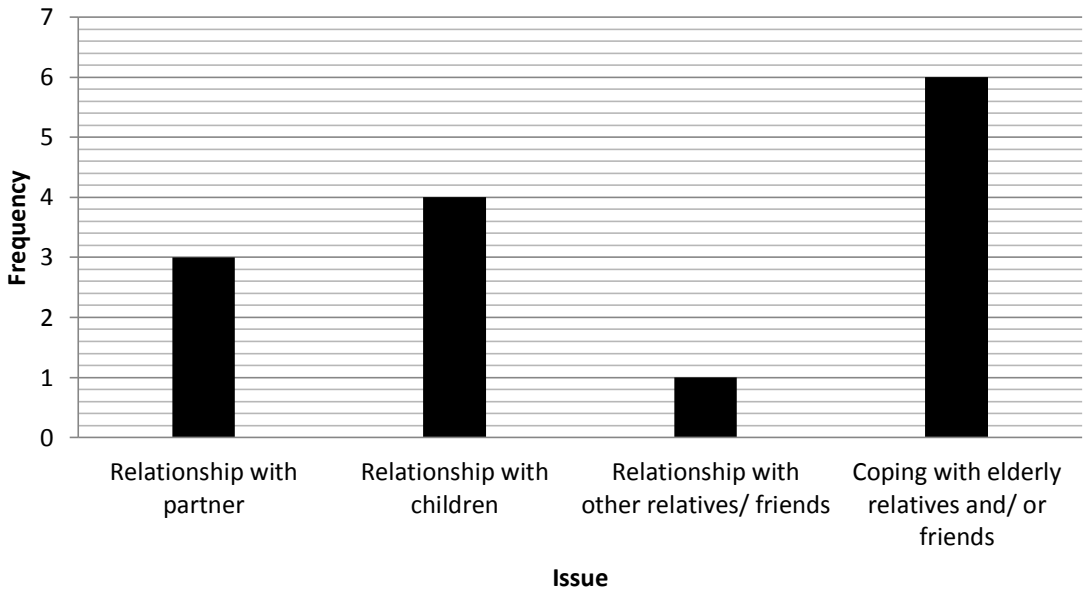


Figure 9.5b: Frequency with which family problems were endorsed

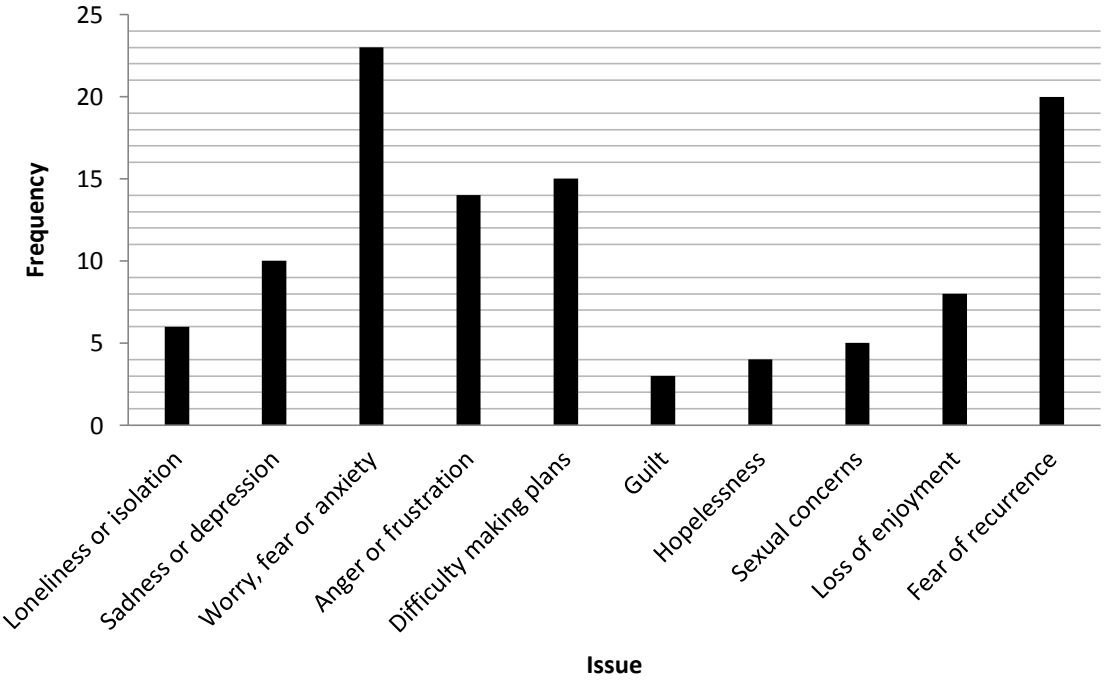


Figure 9.5c: Frequency with which emotional problems were endorsed

Spiritual problems were the least frequently endorsed of all the problem areas and items. These are presented in figure 9.6d.

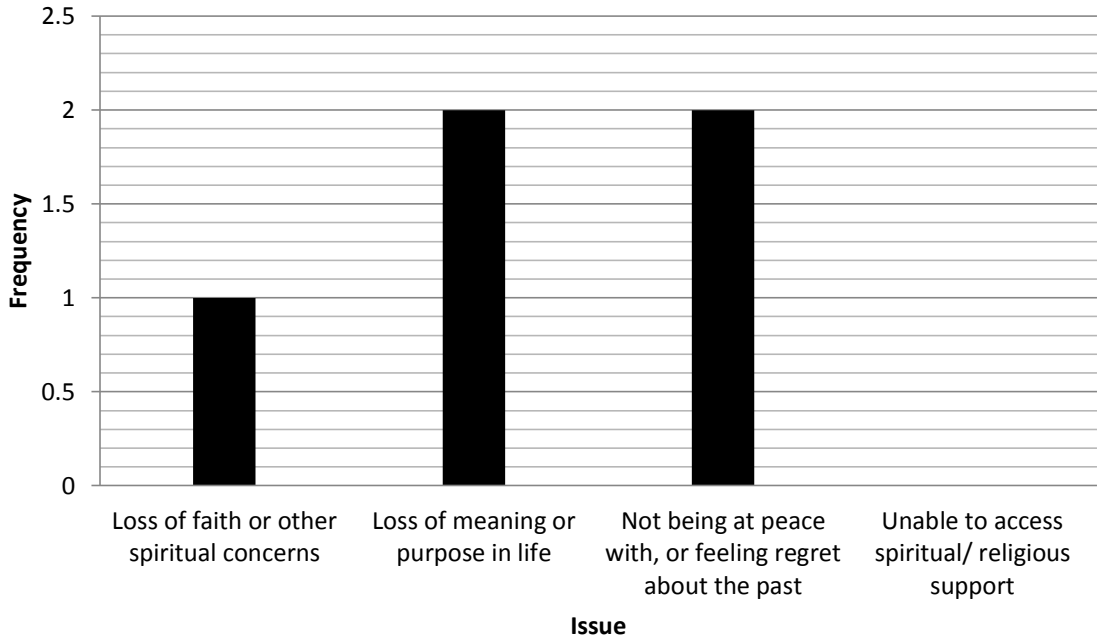


Figure 9.6d: Frequency with which spiritual problems were endorsed

Physical problems were the most frequently endorsed of all the problem items (figure 9.6d). The most frequently ticked difficulty was “Passing urine”.

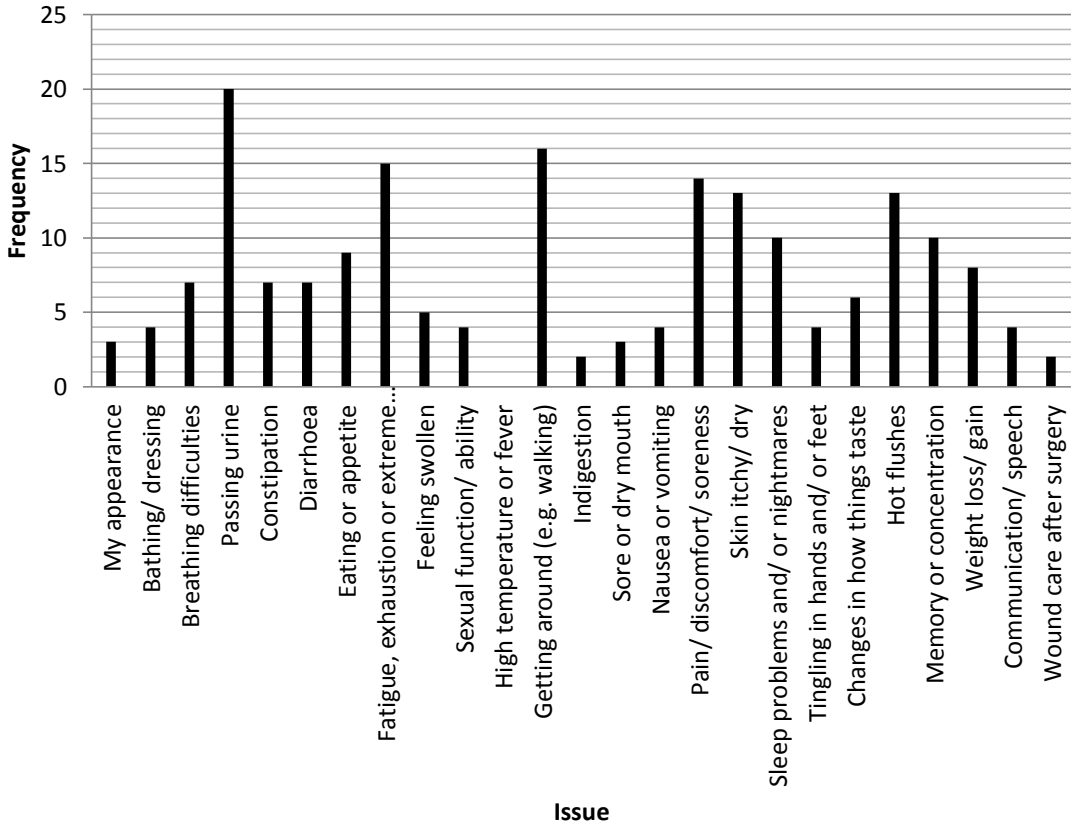


Figure 9.6e: Frequency with which physical problems were endorsed

Nineteen patients added comments to the 'Other concerns' free-text box at the end of the problems list. Eleven of these additional concerns were reporting additional, non-related health issues, such as diabetes, glaucoma and stroke. Six of these patients used the free-text box to elaborate on issues already covered by the problems list, e.g. difficulty with mobility due to arthritis, fatigue caused by disruption to sleep due to problems with urination. One patient queried the length of time between surgery and being asked to complete the assessment;

"Today (11th MARCH 2013) I received the request to do this survey about my assessment for cancer treatment. I had my [surgery] on 3rd JANUARY 2013! So does the right hand actually know what the left hand is doing where you are???"

One patient used this free-text space to ask a question about whether radiotherapy would be an appropriate treatment option.

9.5.2 Patient survey

9.5.2.1 Aims

The patient survey was designed to obtain feedback directly from patients on the following;

- Their memories of receiving the initial invitation letter
- If they had completed the assessment;
  - Where they completed it and if they required support
  - Their satisfaction and experience of the assessment
  - Whether taking part in the assessment had been useful to them
- If they hadn't completed the assessment, reasons for this

9.5.2.2 Methods

Data collection

Patients who were recorded on PPM as having been invited to participate in the assessment pilot were sent a patient survey through the post to find out about their experience of taking part in the pilot.

Patient feedback surveys were developed in collaboration with the Lead Cancer Nurse and members of the POG team. The aims of the survey were discussed informally with a small group of patients attending the PSUC, and their ideas on any pertinent questions sought. An initial version was reviewed by the Lead Cancer Nurse, the Urology CNSs and other members of the POG Team, before being briefly piloted on a small number of patients in the PSUC. The finalised survey was sent to all patients who were registered on the PPM system as having been invited to complete the eHNA. They were asked to complete the survey and return in a stamped addressed envelope, which was provided. No reminder letters were sent to non-responders.

Data analysis

Basic content analysis and counts were taken to assess:

- Number of patients who did not complete the assessment
  a. Reasons why they didn't complete it
- Number of patients who did complete the assessment
- Where they completed the assessment

- If they experienced any difficulties
- Views on the assessment (whether it was useful/ helped them deal with difficulties)
- Satisfaction with help received in clinic if applicable

9.5.2.3 Findings

The results below are based only upon those patients invited to participate in the online DTPL assessment who also returned a completed survey.

Survey participants

At the time of the survey distribution, only 136 patients were recorded on PPM as having been invited to participate in the pilot and complete the assessment, and were therefore sent a survey and return envelope. Of these, 66 returned completed survey forms (48%). One returned the survey with a note reporting that they did not wish to participate in the survey. Sixty-nine of the original 136 did not respond to the survey at all.

DTPL completion among survey respondents

Of the survey respondents, 31 reported not completing the DTPL online assessment. Of these, 25 responded that they had never received an invitation letter, four were not sure whether they had received the letter and/ or were unsure if they had completed the DTPL, and two patients remember receiving the letter but did not attempt to complete the assessment at home, and this was not followed up with them in clinic. One of these patients had not received a cancer diagnosis and was therefore provided with a clinic appointment and subsequently invited to participate in the pilot in error. No explanation was provided for why the other patient received an invitation but was not then followed up.

Only 34 of the 66 survey respondents reported completing the online DTPL assessment (25% of 136 invited to participate in the pilot, 51% of all survey respondents). Of the 34 survey respondents who reported completing the DTPL, 15 completed it at home, 17 completed it in clinic, and 2 attempted to complete it at home but were unable to, but completed it in clinic. Of the 34 patients who responded to the survey having completed the DTPL online, only 26 of them provided usable survey data.

Ability to complete at home

Eleven patients attempted to complete the DTPL online at home and provided complete survey responses. Ten of these completed it at home successfully. The remaining patient attempted to complete it at home but ultimately completed it in clinic. No reason for their inability to complete it at home was provided.

Completion in clinic

Including the patient who attempted to complete the DTPL online at home but eventually did it in clinic, 16 survey respondents completed the DTPL in clinic.

Option for help

Standard practice when patients were completing the DTPL in clinic was that the volunteer would offer them the option of attempting to complete it alone (with some practical help logging in), or to have some assistance throughout the assessment. In the survey, patients were asked if they remembered being given the option of help. Only one patient reported they were not given the option, and five were not sure. Ten patients remembered being given the option for assistance.

Patients requiring help

Only two survey respondents reported that they were able to complete the DTPL online in clinic without assistance. The majority (n=12) completed it with the assistance of the volunteer (n=7), or the CNS (n=5). Two survey respondents were not sure who had helped them.

Satisfaction with help

Patients who received help in clinic were asked to rate their satisfaction with help on a scale of 0 to 10 (0 being not satisfied at all, 10 being very satisfied). The average satisfaction score was 8.5 (n=12). The minimum score given was 5. Patients were asked to give reasons for their reported level of satisfaction. Positive responses included:

"Although not expecting this when I attended clinic, I did feel it helped me to talk through questionnaire with volunteer."

"Felt I was talking to someone who cared."

"The reasons behind the questionnaire were well explained and where I felt there was ambiguity this was discussed and agreed before answers were entered."

Two patients, (including the patient who provided the first quote above) were satisfied with the help they received but felt surprised at being asked to complete the DTPL online. One patient who had not completed the assessment at home reported that they did not wish to do so, as they didn't feel the questions concerned them. They went on to complete in clinic but felt "pushed" into doing so;

"Felt I was slightly pushed into giving answers to aspects that didn't concern me, the reason I didn't complete online was that I wasn't particularly bothered about any of the topics."

Another patient reported that they had only received the forms a few days before clinic, and although willing to complete the DTPL online, had wanted more time to do it at their leisure and this patient was not happy at having to complete it in clinic;

"Forms received Saturday morning - in clinic they had wanted it all completed. Not happy at having to try in clinic."

Views on assessment

Overall usable survey data were available for 26 patients who had completed the DTPL online either at home or in clinic. These responses have been used to provide the results below.

Explanation of assessment

Patients were asked if they felt the assessment and what it involved was explained fully. Five patients were not sure, 19 reported that it was. Two patients did not answer this question. Patients were asked to give reasons for their responses, some of which are given below;

"Did not totally understand why I was doing it."

"I thought the questionnaire was self-explanatory and can't remember being offered help to complete it."

"I didn't particularly feel the need for the interview rather did I think I was being a 'volunteer' to enable the lady to fulfil her function. If this sounds rude and arrogant I apologise and I do not want nor mean it to be."

"I knew what she was asking me to do and why."

Usefulness of assessment

Patients were asked if they thought the assessment experience had been useful to them. One patient did not answer this question. Only three patients reported that they did not feel it was useful; their explanations for which are given below;

"My treatment had just started; I believe it will be helpful as my treatment progresses."

"Not really - there wasn't anything that was particularly bothering me. I could get all the info I needed from internet/ staff at clinic."

"It did not relate to my needs or requirements."

Most survey respondents who had completed the assessment (n=15/26) felt that it was useful, with some of the reasons given below;

"I did not feel so quite alone it helped me realise it was just not me with certain feelings."

"Explained a lot of things. Settled my mind."

"It seemed to cover all the things I was concerned about."

Seven patients said they were not sure if the assessment had been useful to them. One of these patients said this was because they were never given any feedback/ follow up after completion- this was a patient who had completed it at home. Some reasons for their response are given below;

"I was/ am aware of my feelings and thought processes in relation to my diagnosis, the discussions did not offer much more insight."

"Did not feel it was useful to me - but it may be useful to someone else involved in my care."

Help in dealing with concerns

Patients were then asked a more specific question about whether the assessment experience had helped them discuss their concerns and worries. One person did not respond to this question. Five patients said it did not – with one patient reporting that they felt they "…had to give answers when nothing was concerning me…" Four patients said they were not sure, one of whom was the patient who had completed the DTPL online at home but had not received any follow up. The majority of patients (n=16/26) reported that it had helped them;

“There was a different "slant" to "the insights" as there would be when having discussion with another person - which is always helpful.”

“Even though I did not have any worries I think that it is good to have a way to express our concerns without making it too official.”

“Discussed with my wife whilst completing.”

9.5.3 Summary of key findings

For some patients the survey was sent out some months after they received the original welcome letter and/ or completed the assessment; this may limit the usability of this data due to problems with recall. The number of respondents reporting receiving a letter was the same as those who did not (n=27). The number of respondents who had completed the DTPL online versus those who had not were similar (n=34, n=32 respectively). Of those who had not completed the DTPL online, the majority reported not receiving a letter/ not being aware of the assessment as the reason. The number of respondents completing at home or in clinic was similar (n=17, n=19 respectively). This is in line with the data extracted from the PPM system. The majority of respondents recalled being given the option of assistance with the DTPL online in clinic. Those who received help were satisfied with the assistance they received, and most respondents felt the process was explained properly. The majority of respondents felt the assessment was useful and helped them deal with their concerns.

9.6 Discussion and Conclusions

The key finding from the staff interviews was that for the majority of the staff involved, the piloted process was too *complex* and did not offer sufficient *observable relative advantage* when compared with other methods they had been using. A combination of factors contributed to this lack of adoption, both in terms of the potential adopters and their context, and characteristics of the innovation itself.

There was variation between the CNSs in their uptake of the innovation; there was a clear *champion* within the team, but despite this uptake was not uniformly spread. The observed events and feedback from the staff interviews can be explained in terms of the Models of Diffusion theory. The CNSs considered one element of the innovation (the volunteer) as a particular problem area, which was the involvement of the

volunteer; however, further analysis demonstrated that it was actually a different element of the process (the ranking activity on the DTPL) that was generating lengthy discussions with the volunteer and holding up the process, instilling negativity towards the process from the CNSs.

Ideas for *reinvention* of the process were expressed during the interviews but had not been shared between the staff members throughout the pilot. Although they came to the same conclusion regarding the 'sticking point' of the ranking activity on the DTPL, this *concern* had not been shared during the early stages of the pilot, meaning that the opportunity for *reinvention* was lost. In line with MoD theory, the opportunity to *reinvent* and adapt the intervention can increase its likelihood of adoption. This may also have enabled the nurses to feel more ownership over the process, but the lack of communication about the issues meant this didn't occur. The *context* of the pilot was an already pressurised team; the anticipated increase in workload and loss of the pilot *champion* when she left was already reported as being destabilising for the team. Although data from the patient survey was limited, concerns expressed by the staff about the suitability of the DTPL for the chosen patient group were echoed by some of those that completed the survey.

The question of the suitability of the DTPL within this context and for the patient group in question was raised throughout the staff interviews, and was echoed by the patients and the volunteer. One anecdotal report from an interview involved a quote from a patient – "…my levels of distress can change every five minutes…" This illustrates an emerging concern regarding psychological screening; a 2015 review of research and policy literature by Salmon et al explores the benefit of any psychological screening for the patient, and suggests that the typical focus on improving the diagnostic accuracy of screening instruments should be shifted to a framework more common in a public health setting. This would consider other perspectives, including redefinition of what healthcare professionals should be screening for, and what happens following the screening. Salmon's proposed changes including managing the uncertainty and unpredictability of an individual's psychological well-being, as demonstrated by the patient who reported his distress levels could "…change every five minutes…"[193].

The staff involved in the evaluation described here expressed concerns about the resource implications of carrying out a needs assessment using the DTPL. Hollingworth

et al (2013)[194] conducted a randomised controlled trial that provided evidence that the DTPL was not shown to be cost effective in improving patient mood when compared to standard care. Although generally thought to be relatively inexpensive, the assessment in this case was calculated to cost £19 per patient, but did not lead to any improvement in patient mood or lower subsequent health costs [194]. In view of the ideas regarding *reinvention* found during this evaluation, ideas for future research may be include a modified, shorter DTPL. The volunteers who assisted the patients during completion of the DTPL found the ranking element to be the most burdensome. Removal of this may increase the efficiency of the instrument.

The key strength of this evaluation was the detailed and honest feedback from the staff during their interviews. Without the depth of the detail provided by the range of staff involved, the true difficulties preventing successful adoption may not have been discovered. This level of detail, when considered within the robust framework provided by Greenhalgh et al has made it possible to drill down to the various elements of the process and start to understand the dynamic between them.

The flexibility and range of the data collected and the analysis conducted was beneficial in drilling down to the issues causing most concern for those involved. In line with Greenhalgh's MoD model, this provides the opportunity to identify the specific components within the innovation (or *technology cluster* as Rogers' may have defined it), and therefore the chance for reinvention, both of which are associated with increased likelihood of adoption. Although a rich dataset was obtained from the CNSs and the Macmillan staff directly involved, interviews with the other individuals involved may also have shed more light on specific barriers, e.g. the secretary and the Lead Cancer Nurse would have offered further perspectives.

Qualitative data about the nurses' experience of the impact of the assessment on their clinic was vital in understanding why it was not seen as *compatible* with existing practice. However, a lack of ethnographic data on the process means that these findings regarding the additional time and impact on the clinic cannot be verified. Although some observations were made, these were brief and sometimes based on existing knowledge of the typical running of the clinic (section 9.4.3.1). The robustness of the evaluation findings may have been improved by employing more systematic data collection, such as those described in ethnographic methodologies[195], e.g.

systematic data collection on standard ethnographic observational dimensions such as the activities carried out (events) or the sequence of events during the clinics (time)[195]. Any observations made and noted were incidental to other research activities during clinic, e.g. waiting to speak to the nurses to arrange interviews or informal chats with patients.

The patient data was also limited, for both in terms of the DTPL response data and the patient survey. The latter was also limited in both volume and potentially in accuracy, due to the time period between their invitation to complete the eHNA and the time they received the survey. The patients overall saw the experience as a positive one; this feedback may offer the staff some evidence of *relative advantage*. Unfortunately there was no pre-pilot data available with which to make comparisons to add to this evidence base. Only 48% of patients responded to the survey sent as part of this evaluation, therefore it cannot be guaranteed that this is a representative sample of all those who took part. Those who did not respond to the survey may also be the same patients who struggled most with participation in the pilot, and therefore their views will not be represented here.

Not all of the elements included in Greenhalgh's MoD model were considered in the analysis; the population of the framework using the data was driven by the emergent issues that were most pertinent to the staff themselves. This should not be considered a weakness; Greenhalgh et al state that the model is not intended to be prescriptive, but rather offer guidance for the range of issues that may be considered in implementing innovations[2].

9.7 Implications for practice

The findings from this evaluation demonstrate the importance of *reinvention;* closely linked to this in this context was the perceived *complexity* of the process as a whole. When the process was considered as a number of component parts, the staff began to pinpoint the cause of the difficulties and consider opportunities for *reinvention.* Although all the staff had similar concerns and many had pinpointed, the lack of communication about this meant that they each had their individual concerns but had not been able to share these and decide on a course of action to implement their reinvention ideas. Had the team communicated more effectively, the nurses would have obtained a better insight into the problems the volunteer was facing (i.e. people

needing a lot of support). This opportunity to reinvent the process would have made it more acceptable and increased its likelihood of adoption.

Greenhalgh et al's review and the findings presented here demonstrate how applicable the MoD model is to healthcare research, and how it can be used to explore barriers to uptake and from there propose solutions. Despite this, the implementation of innovations is still challenging, with gaps between evidence and implementation in practice. Case studies such as this can provide 'real-life', pragmatic applications of the wide-ranging and perhaps overwhelming diffusion theories[196].

Chapter 10: Discussion

10.1 Overview

A cancer diagnosis and subsequent treatment have significant consequences, not just for the patient, but for their family and extended social network [30, 31]. The effects can be felt in all areas of life and be present in one form or another, through diagnosis and treatment and often into survivorship [9, 33, 34]. These effects are not always recognised in routine oncology practice, and information provision for patients on psychosocial difficulties may be delivered in an ad-hoc manner[52]. Living with unresolved social difficulties may undermine patients' ability to deal with the diagnosis and treatment[39].

The overall aim of the work presented in this thesis was to explore implementation of a programme of social difficulties assessment, including staff training and provision of information to patients, into routine practice. The specific aims of the work presented in this thesis were to establish gaps in the provision of psychosocial care, identify possible interventions that may help to bridge these gaps, and the mechanisms by which they may be adopted by patients and staff. This work was conducted in line with the MRC framework and updated guidance for developing and evaluating complex interventions[1, 135].

Pre-clinical/ Theory Stage

Two potential gaps in the provision of psychosocial care were identified by exploring the current literature (chapter 1). These were; a lack of support services information and a lack of a standardised method to assess the presence and severity of social difficulties. Along with the secondary analysis of data presented in chapters 3 (frequency of discussion of related issues during outpatient appointments) and chapter 4 (levels of unmet need and impact of routine assessment), this fulfils the theory/ pre-clinical phase of the original MRC Framework[135], known as the development stage in the new guidance[1], and contributed to the justification of a need for the intervention.

In conducting the literature search and secondary analyses described above, two possible interventions were identified as; 1) information provision and 2) a formal

assessment of social difficulties, by a nurse trained to use the Social Difficulties Inventory (SDI-21).

Phase I/ Modelling Stage

A Support Services Information Pack (SSIP-included as additional material) was developed and evaluated (chapter 5), and then tested in a pilot randomised controlled trial to assess its impact on processes of care and patient well-being in comparison to standard practice (chapter 6). In order to assess patients for the presence and severity of social difficulties (using the SDI-21), a Nurse Training Package was developed and delivered to nurses. A pre and post-course evaluation was also developed and completed (appendices 16 and 17), in order to assess the utility of the training package in achieving the objectives (chapter 7).

This intervention was then tested in a second pilot (chapter 8). For a number of reasons, including low recruitment and high attrition rates, the target number of patients was not reached. The nurses had few opportunities to practice the new skills learned during the training. Despite this, the interviews conducted with the nurses provided insightful qualitative data on the acceptability and feasibility of the new practice, which was the primary aim of this pilot. Delivery of this intervention was particularly challenging as the nurses were already working in time-pressured environments, and engagement in the study required an additional task during their busy clinic sessions. These two pilots testing the two interventions fulfilled the modelling phase of the MRC Framework[135], known as the feasibility/ piloting stage in the new guidance[1].

Phase II/ Exploratory Stage

The implementation of an electronic Holistic Needs Assessment (eHNA) was the subject of a service evaluation, in which patients were surveyed via post and Clinical Nurse Specialists (CNSs) were interviewed (chapter 9). This fulfilled in part the phase II (exploratory trial) stage of exploration recommended by the original MRC Framework[135], and the evaluation phase described in the updated MRC guidance[1].

10.2 Summary of results

The original hypothesis was that successful diffusion of a technology cluster (comprised of social difficulties assessment using the SDI-21, including staff training

and provision of information to patients), if developed in line with suggested innovation attributes from the models of diffusion framework [2] would have the following effects:

- Increase patient awareness of and access to services
- Help patients to resolve their social difficulties
- Increase detection of social difficulties by staff
- Increase communication between staff and patients about social difficulties
- Increase staff awareness of services and interventions made
- Improve patient well-being, when compared with standard care.

In reality neither intervention was adopted to a level where any impact on patient well-being could be successfully assessed (although the pilots were not powered to show any difference, but rather demonstrate estimates of effect sizes for a future trial). The information intervention appeared to offer no *relative advantage* in comparison to what was already available to the patients. It was not tailored to the patients' specific information needs, which may vary in the timing and nature of the information required [197].

The assessment using the SDI-21 was difficult to implement. *Trialability* is an important characteristic for successful adoption of an innovation, but due to the difficulties in recruiting the target number of patients (described in chapter 8) this was not possible; the nurses did not have sufficient opportunity to practice. Some of the nurses felt it was too close to what they already do in practice; therefore offering them no perceived *relative advantage*.

The nurses in the second of the two pilot studies (chapter 8) and the service evaluation (chapter 9) seemed to have experienced no significant *relative advantage* of being provided with a standardised assessment tool. For some it was too *incompatible* with standard practice and too disruptive to their practice, or too *compatible* with care already provided. In all cases the new *knowledge and skills required to use it* were too *complex* to understand or were difficult to deliver in terms of training. In all cases workload and time as a resource were huge factors, leading to problems both in the delivery of training and in conducting the assessments during clinic. When asked about the *meaning* they attached to holistic care, all of the nurses felt it was their role,

but it was something they were losing the ability to provide, even in the case of the CNS whose role was developed specifically to provide such care.

These findings may reflect a deeper-rooted NHS and Government-wide organisational issue regarding the identity of the nursing role. Health service reform and initiatives such as the HCA were undertaken by the Government in order to improve patient-led care, while at the same time improving efficiency and cost-effectiveness[59]. This led to changes in working patterns and skill-mix for nurses. Although mainly positive for specialist nurses, has had negative impacts for staff nurses and ward sisters in terms of reduction in patient care and increased workload intensity. Perhaps more importantly these frontline nurses now experience more defined role delineation; this has led to task-orientated day-to-day schedules with little room to develop their caring relationship with patients[59]. The descriptions of the nurse's day to day work in chapter 8, level 1 demonstrates this in practice. This raises the question of the validity of standardised assessment tools in enhancing nurses' practice in relation to provision of psychosocial care.

In terms of the original hypotheses, none of the expected effects of the interventions were demonstrated by the findings of the pilot studies. Qualitative interview data from the pilot of the assessment intervention did suggest a positive experience of the assessment; two nurses and the patients they assessed reported feeling like unresolved issues had been dealt with, and reassurance had been provided for the patient.

A further aim of this thesis was in identifying the mechanisms by which these interventions may be adopted by patients and staff. As described in chapter 2, Greenhalgh et al's adaptation of Rogers' Diffusion of Innovations theory[73], the models of diffusion framework[2], was useful in developing the interventions and for retrospective analysis of what was observed in the pilot studies of the social difficulties interventions and the service evaluation of the eHNA pilot.

The statistical results in terms of the effect sizes and the qualitative results do not support development of a full randomised controlled trial. The small effect sizes, when considered along with the difficulties implementing the assessment intervention (e.g. difficulties engaging the staff in training and maintaining the knowledge required

to use the system) suggest that moving to a large-scale randomised trial would not be appropriate, and that other trial designs should be considered.

10.3 Strengths and limitations of the work conducted

Strengths

The underpinning theory for the work presented in this thesis is Greenhalgh et al's models of diffusion framework, which was based on Rogers' Diffusion of Innovations theory. The models of diffusion framework was developed following an extensive systematic review, and provides a comprehensive evidence-based model for use in the healthcare services setting [2].

During this study two interventions were developed; the Support Services Information Pack (SSIP), and the Nurse Training Package (NTP) that would enable nurses to administer the SDI-21, interpret the results and provide interventions as appropriate to the patients' needs. Both of these interventions were developed with a strong theoretical basis, and in the case of the SSIP, guidance was sought from information specialists from the Information Care and Support Services and the Information for Oncology Patients Group (INfOP), with engagement from the patient involvement group throughout.

The SSIP was created with involvement from key stakeholders or their representatives, (i.e. the User Partnership Group representing patients), who informed the initial content and format. It was evaluated using an iterative process, where developing drafts of the document were circulated for comment from all stakeholders, in line with NHS guidance on producing patient information[198]. Alternative, more formal methods of evaluation were considered but not utilised in this case, the DISCERN instrument[199] and the EQIP (ensuring quality information or patients) scale[200]. In both cases, the instruments focus on information on treatment choice, and are only partially relevant in this context. For example, although some of the items on the DISCERN instrument can be applicable to any patient information (e.g. "Is it clear when the information used or reported in the publication was produced"[199]) many of the items were only relevant to treatment choice information and not so to the content and aims of the SSIP (e.g. "Does it refer to areas of uncertainty?"[199]). The items covering generic aspects of good information were covered by the guidance obtained from INfOP[151] and the NHS[198]. As the SSIP was considered a relatively low-level

intervention and was not related to treatment decisions it was not considered necessary to conduct a formal evaluation.

The primary aim of the first pilot study (chapter 6) was to investigate the impact of the information booklet (the SSIP) on processes of care, patient behaviours and well-being. This study was successful, in that the target number of patients was exceeded, and the findings demonstrated clearly that few of the intervention patients used the SSIP. Despite this negative result, this highlighted important issues around the overwhelming volume of information available to patients, and supported the justification for the need for an intervention that would help to identify specific difficulties and tailor information giving and other interventions appropriately.

Although the second pilot was not successful in terms of reaching the target number of patients, detailed qualitative data were collected on the acceptability, feasibility and issues around introducing new practices and innovations into real clinical settings. This study also highlighted the complexities of introducing a new practice into routine systems.

Findings from context-specific research and current evidence in the literature were used to establish an evidence base for the research presented. This added to the relevance of the work conducted to fulfil the pre-clinical/ theory stage of the MRC framework. The pilot studies and the service evaluation described in this thesis were all carried out in real, everyday NHS clinical settings, again adding to the relevance and generalisability of the findings presented. In order to conduct the research in these settings it was vital to foster excellent relationships with all the staff involved, to enable the recruitment of patients, and also to obtain honest and insightful results from the staff during their interviews.

A service evaluation was used to explore staff and patient responses to an electronic Holistic Needs Assessment pilot. This provided a wealth of detailed qualitative data to explore the issues that prevented the successful uptake of the process. This highlighted that the perceived difficulties (e.g. that the volunteer was spending too long with the patients because she was getting too involved), and the actual problem (that the patients found the ranking exercise on the distress thermometer too difficult and needed a lot of assistance from the volunteer).

Randomised controlled trials are a powerful tool in evaluating the effectiveness of healthcare interventions, and despite criticism are still considered by most to be the gold-standard[182]. Their value in evaluating complex interventions is the subject of much debate, and the focus on the RCT was a criticism of the original MRC framework [135, 182, 201, 202]. The latest MRC guidance attempts to acknowledge this criticism and emphasises the importance of modelling and use of qualitative and mixed methods approaches to fully understand the mechanism of action[1]. The mixed-methods approaches presented here are an example of how qualitative data can illuminate issues not considered during the development of a study, such as the kind of variables that can impact the success of an intervention outside its own characteristics.

Although Hawe et al (2004) considers RCTs still valid where the function of the intervention is stable even if the context does change[203], Mackenzie argues that variations are bound to occur for interventions implemented 'in real life'[201], limiting the validity and the generalisability of the intervention tested within the 'black box' of an RCT. The debate around both the MRC framework and the utility of RCTs in complex interventions continues, and currently there are no alternative evaluation approaches fit for all purposes[201].

Limitations

During the pilot study comparing an assessment of social difficulties and standard care (chapter 8), participating nurses experienced a delay between the completion of the nurse training package and the first opportunity to conduct an assessment with a participating patient. In line with the theories on retention of information over time (figure 2.12 [129]), this meant that they had lost the knowledge and skills required when they time came to conduct the first assessment, and subsequently relied on the researcher for support. Again, this limits the *trialability* of the intervention.

The primary aim of the assessment pilot study (chapter 8) was to obtain information on the feasibility and acceptability of the assessment process. Although a wealth of qualitative data were collected during interviews with the nurses, their experiences and the *trialability* of the intervention were reduced due to the lack of patients involved in the study. There was also a delay of a number of months between the nurses completing their last assessment with a patient and taking part in the interview,

which limited their recollections of how they experienced the assessments and may have introduced recall bias.

Although training involved practising with 'dummy' patients, more on the job training/ role play would have been better. This was recognised early in the design of the training package, but due to the time pressures for the staff it was very difficult to engage them in additional activities[129]. With greater initial confidence and practice the effects of the time delay between the end of training and starting the study could have been minimised, as the nurses may have been confident enough to practice on their own (if they had the time). A high level of support was required in order to keep the nurses engaged with the study. Although the intention was to reduce this as the study progressed, the low numbers of patients and early termination of the study meant this was never possible. As a result, and due to the need for the researcher to be there to collect data, it was never possible to assess how motivated the nurses would be to conduct the assessments without a member of the research team present to remind and assist them.

Due to the nature of the recruitment and data collection methods employed during the clinics, a great deal of time was spent waiting for patients to arrive for their appointments, for them to go in to see the doctor or nurse to enable audio-recording, or for the appointment to be over to collect the recording device at the end. During these periods of little research activity in clinic, an opportunity to collect ethnographic observation data was missed. As the researcher was 'immersed' in the clinic due to the amount of time spent there, it would have been an opportunity to collect ethnographic data and increase understanding of the actions and interactions within the clinic setting[195]. When considering the complexity of organisations such as the NHS and the departments within it, Pslek and Greenhalgh suggest "…the only way to know exactly what a complex system will do is to observe it…" [204]. This type of research would have been valuable prior to the pilot of the assessment intervention in this case. The primary aim of the pilot (to assess the acceptability and feasibility of introducing the SDI-21 assessment into routine practice), whilst achieved in part, was limited by the small numbers of assessments that actually took place. It may have been more appropriate to conduct action research or an ethnographic study prior to a randomised pilot of the assessment intervention.

10.4 Conclusions

Information has most benefit for patients when it is tailored to their specific needs at the given point in their pathway. Although general patterns can be seen in how patients' needs change over time, individual patients will vary, and this should be taken into account[197].

Eliciting what these needs are in terms of social difficulties is achievable using the SDI-21, evidenced by the findings from chapter 4. The original interpretation of this analysis is that information alone would be effective in dealing with social difficulties, but in light of the findings from the pilot testing of a generic information resource, it may be the case that the ideal intervention would be the use of the SDI-21 as a triage tool, and then tailoring the information provision (or other intervention) accordingly.

10.5 Implications for future research

The evidence presented here does not support a large randomised controlled trial for the more complex assessment intervention. Statistically, effect sizes are small, and the qualitative data highlights a number of barriers to implementation that may be magnified in a larger trial.

These findings highlight the importance of using the updated MRC guidance on evaluating complex interventions (2008)[1], and echo findings from other literature regarding the utility of the 'gold standard' randomised controlled trial design in the evaluation of complex interventions[167, 205-207]. Alternative designs may include; quasi-experimental design, observational studies, or quality improvement models [167, 207]. Mixed methods approaches, such as combining realist methods with RCTs[182], or the use of case-study approaches may also be useful alternatives to consider[208].

Regardless of the design of any future trial, the specific unit or department in which the research would be conducted must be carefully considered, with the elements within the models of diffusion framework taken into account. With the availability of online access increasing[209], and the availability of systems such as QTool[192], the option to have patients completing the assessment at home prior to an appointment (as planned in the eHNA pilot – chapter 9) should be considered, with the lessons highlighted through the eHNA service evaluation also borne in mind.

There is a myriad of theories available that aim to assist in implementation of complex interventions into organisations[210]. Attempts have been made to consolidate these theories into standardised, workable models that can assist in understanding how implementation occurs, and what actions can be taken to ensure implementation is effective, such as the Consolidated Framework for Implementation Research (CFIR), and the Unified theory of acceptance and use of technology (UTAUT) model [84, 210]. In a research context, Greenhalgh et al's model is useful for retrospective analysis of qualitative data to assess the mechanisms involved in the adoption process and the performance of an innovation. Although it is excellent in bringing together all possible factors to be considered in implementation, it offers little guidance on how to apply the framework and there is no evidence of its ability predict the impact or performance of an innovation, which is an area for future research [2, 211].

10.6 Implications for policy makers and service providers

The key finding from testing the information intervention (the SSIP) is that generic information, even on a specific topic such as social difficulties, is not necessarily useful to the patients. If they do not need the given information at the time of delivery, it is likely to be forgotten about. This fits with the evidence from other literature; patients' information needs will vary depending on their personal circumstances and their stage of the cancer pathway[197], i.e. newly diagnosed, completing treatment, returning to work.

In the UK the DoH and NHS England have responded to the growing body of knowledge on information needs, and are continuing to develop the Information Prescriptions service. While the concept of 'prescribed information' is not a new one [212], the UK's latest online adaptation was piloted in 2007, and an evaluation published in 2008[172]. An information prescription generator tool is now available via the NHS Choices Website[213], which is tailored to a specific condition and geographical area [214]. Further information provided on the site confirms the DoH's commitment to sustain and improve the service[214]. Healthcare providers can access the site and obtain condition and location-specific information to give patients. Much of the information is from NHS partners such as charities, in order to ensure the information is up to date. There is currently a need for evidence to demonstrate the uptake or cost-effectiveness of the information prescriptions service [172, 212].

When evaluating complex interventions in a setting such as the NHS, there needs to be a balance between ensuring scientific rigour and maximising useful findings and best use of resources [167, 206]. Evidence, suggests that, whilst it is seen as the 'gold standard' in most settings[215], the randomised controlled trial is not necessarily the best design to allow an understanding of the organisation, the individuals and the innovation that impact on the success of implementation. Embedding a qualitative element, or use of alternative designs such as quasi-experimental, or quality improvement methods may save resources and provide more understanding of the unique characteristics of all the elements involved. Engaging staff who work in the specific setting would be an efficient way to embed this knowledge within the implementation process, and fulfils both Rogers' and Greenhalgh's findings that engaging all types of potential adopters from an early stage in the implementation process will increase the likelihood of successful adoption[2, 73]

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Appendix 1a: History and development of the Social Difficulties Inventory (SDI-21)

History and development of the Social Difficulties Inventory (SDI-21)

In 1998 the Patient-Reported Outcomes Group (POG – previously known as the Psychosocial Oncology and Clinical Practice Research Group) were working on a research programme involving the development and evaluation of a system of routine patient centred assessment. As part of this Dr Penny Wright identified that there was a lack of clarity as to what constitutes social difficulties in oncology patients, and no existing instrument that could accurately assess the presence and severity of social difficulties within this population[9]. As part of this work the Problems Checklist[39] was psychometrically tested to explore its usefulness in this role, but was found to have limitations[45]. Dr Wright therefore undertook work to develop and test the SDI-21 [43].

Development and testing of the SDI-21

This development work was conducted following guidelines from the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Study Group[216]. This guidance outlines four stages of development for creating a questionnaire:

Item generation

The EORTC guidelines recommend three sources of research to compile an exhaustive and unbiased list of relevant issues; literature (including existing questionnaires), patients with the relevant condition and healthcare professionals. In line with these guidelines interviews and focus groups with 96 patients were undertaken (producing 32 items), focus groups with 49 members of staff (28 items), and a search of literature and existing questionnaires resulted in 105 further items. From these sources a list of 28 items were used to create the first draft of what would become the SDI-21 [9, 43].

Construction of the item list

This process required constructing the questions, considering layout, framing of questions and the response options. This was reviewed by a panel of experts and resulted in an initial 28-item questionnaire [9, 43].

Pre-testing

The aim of this phase was to identify and solve issues with the administration of the questionnaire, including phrasing and order of questions, and also identifying redundant items. Two studies tested the original SDI in 34 patients in total, which resulted in a new 22-item version[43].

Psychometric, clinical utility testing and scoring of the SDI-21

The EORTC guidance recommends a large, international group of patients to test the scale structure of a questionnaire. Psychometric testing of the 22-item SDI was conducted in 271 UK patients. This evaluated frequency of endorsement of each item, factor structure, reliability and validity. This resulted in a further item being removed and the current version, the SDI-21 (appendix 1b) [43]. Each item on the SDI-21 is scored by the respondent on a four-point scale, from 0 (no difficulty) to 3 (very much difficulty – figure 1.1). At the basic level, the score from each individual item could be used to alert staff to the level of difficulty in one of the 21 areas.

Rasch analysis identified 16 items within the SDI-21 that provide a global Social Distress Scale (SD-16, figure 1.1)[56]. With a defined cut point of ≥10, a score of 10 or above would suggest an elevated level of social distress, warranting further investigation. Further studies were undertaken to assess the clinical meaning and utility of the SDI-21[56, 70]. This has resulted in detailed scoring guidance (figure 1.1), identifying various ways to calculate and use a range of scoring systems. A clinically meaningful difference for the SD-16 score would be an increase of 3 or more. For the remaining five items individual scoring would be used. In addition, factor analysis derived three subscales with specific scores, and a clinically meaningful difference of 2 or more for each subscale.

The SDI-21 can be administered using touch-screen technology, with real-time provision of results to health care professionals (HCPs), and overcomes many of the practical difficulties associated with implementing assessment in routine practice [69]. Patients have found the questionnaire relevant and easy to understand, and the touch-screen computers have been found acceptable and easy to use [43, 44, 152]. This instrument could form the basis of an appropriate assessment process for social difficulties.

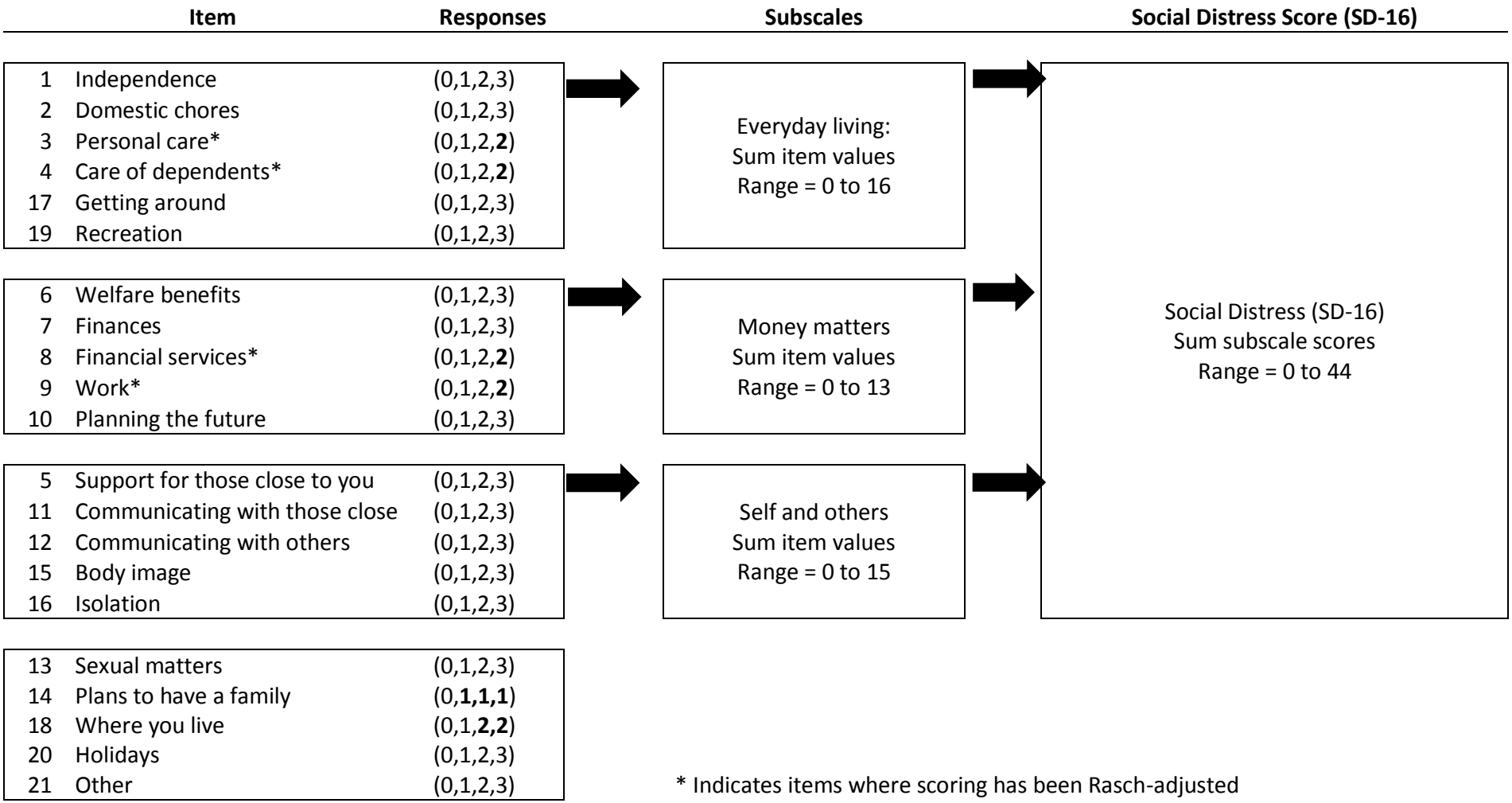


Figure 1.1: Scoring method for SDI-21

Recent applications of the SDI-21

The SDI-21 has been translated into Hindi, Punjabi and Urdu and tested in qualitative studies to assess its cultural relevance and usefulness within South Asian populations living within West Yorkshire [217]. It has been used within POG for two Macmillan Cancer Support Funded studies, the first of which was the Allograft Information Exchange (ALLINEX) Study, a study designed to develop and evaluated a website for stem cell transplant patients [218]. The second was in the electronic Patient-reported Outcomes from Cancer Survivors (ePOCS) feasibility study[192], the aim of which was to test a system for routinely and regularly collecting patient-reported outcome measure (PROMs) data from cancer survivors in the years after diagnosis and treatment, and linking this data to the National Cancer Data Repository.

The National Cancer Survivorship Initiative cited the SDI-21 as an instrument for use in a pilot survey describing the quality of life of cancer patients in England and Wales. It was included in the resultant PROMs pilot survey of 5000 cancer survivors, and was used in the full national PROMs survey of 50, 000 in 2013. The data from these surveys were used to inform future services [219-221].

The SDI-21 has been used in Canada within routine practice as one of a number of instruments forming an electronic Distress Assessment and Response Tool (DART), for assessing oncology outpatients, and in January 2013 had been used to assess over 12,000 patients [222, 223]. The SDI-21 and the SDI-16 received a positive evaluation as part of a systematic review conducted in 2012, which assessed the merits of available assessment tools [224].

Appendix 1b: The Social Difficulties Inventory (SDI-21)

SOCIAL DIFFICULTIES INVENTORY (SDI-21)

- Please read each question carefully and tick the response that best describes your answer
- Please answer each question as honestly as possible
- If you are not completely sure which response is the most accurate tick the box that you feel is the most appropriate
- Please tick the 'no difficulty box' if a question does not apply to you
- Do not spend too long on each statement
- There are 21 questions

ALL INFORMATION WILL BE TREATED CONFIDENTIALLY

During the past month		No difficulty	A little	Quite a bit	Very much
1	Have you had any difficulty maintaining your independence?				
2	Have you had any difficulty in carrying out your domestic chores? (e.g. cleaning, gardening, cooking, shopping)				
3	Have you had any difficulty with managing your own personal care? (e.g. bathing, dressing, washing)				
4	Have you had any difficulty with looking after those who depend on you? (e.g. children, dependent adults, pets)				
5	Have any of those close to you (e.g. partner, children, parents) had any difficulty with the support available to them?				
6	Have you had any difficulty with benefits (e.g. Statutory Sick Pay, Personal Independence Payments, Attendance Allowance, Universal Credit)				
7	Have you had any financial difficulties?				
8	Have you had any difficulties with financial services? (E.g. loans, mortgages, pensions, insurance)				
9	Have you had any difficulty concerning your work? (or education if you are a				

During the past month		No difficulty	A little	Quite a bit	Very much
	student)				
10	Have you had any difficulty with planning for your own or your family's future? (E.g. care of dependents, legal issues, business affairs)				
11	Have you had any difficulty communicating with those closest to you? (e.g. partner, children, parents)				
12	Have you had any difficulty communicating with others? (e.g. friends, neighbours, colleagues, dates)				
13	Have you had any difficulty concerning sexual matters?				
14	Have you had any difficulties concerning plans to have a family?				
15	Have you had any difficulty concerning your appearance or body image?				
16	Have you felt isolated?				
17	Have you had any difficulty with getting around? (e.g. transport, car parking, your mobility)				
18	Have you had any difficulty with where you live? (e.g. space, access, damp, heating, neighbours, security)				
19	Have you had any difficulty in carrying out your recreational activities? (e.g. hobbies, pastimes, social pursuits)				
20	Have you had any difficulty with your plans to travel or take a holiday?				
21	Have you had any difficulty with any other area of your everyday life?				

Appendix 2: Functional Assessment for Cancer Therapy – General

FACT-G (Version 4)

Below is a list of statements that other people with your illness have said are important. **By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.**

	PHYSICAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GP1	I have a lack of energy	0	1	2	3	4
GP2	I have nausea	0	1	2	3	4
GP3	Because of my physical condition, I have trouble meeting the needs of my family	0	1	2	3	4
GP4	I have pain	0	1	2	3	4
GP5	I am bothered by side effects of treatment	0	1	2	3	4
GP6	I feel ill	0	1	2	3	4
GP7	I am forced to spend time in bed	0	1	2	3	4

	SOCIAL/FAMILY WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GS1	I feel close to my friends	0	1	2	3	4
GS2	I get emotional support from my family	0	1	2	3	4
GS3	I get support from my friends	0	1	2	3	4
GS4	My family has accepted my illness	0	1	2	3	4
GS5	I am satisfied with family communication about my illness	0	1	2	3	4
GS6	I feel close to my partner (or the person who is my main support)	0	1	2	3	4
Q1	*Regardless of your current level of sexual activity, please answer the following question. If you prefer not to answer it, please check this box* ☐ *and go to the next section.*					
GS7	I am satisfied with my sex life	0	1	2	3	4

FACT-G (Version 4)

By circling one (1) number per line, please indicate how true each statement has been for you during the past 7 days.

	EMOTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GE1	I feel sad	0	1	2	3	4
GE2	I am satisfied with how I am coping with my illness	0	1	2	3	4
GE3	I am losing hope in the fight against my illness	0	1	2	3	4
GE4	I feel nervous	0	1	2	3	4
GE5	I worry about dying	0	1	2	3	4
GE6	I worry that my condition will get worse	0	1	2	3	4

	FUNCTIONAL WELL-BEING	Not at all	A little bit	Some-what	Quite a bit	Very much
GF1	I am able to work (include work at home)	0	1	2	3	4
GF2	My work (include work at home) is fulfilling	0	1	2	3	4
GF3	I am able to enjoy life	0	1	2	3	4
GF4	I have accepted my illness	0	1	2	3	4
GF5	I am sleeping well	0	1	2	3	4
GF6	I am enjoying the things I usually do for fun	0	1	2	3	4
GF7	I am content with the quality of my life right now	0	1	2	3	4

Appendix 3: European Organisation for the Research and Treatment of Cancer Quality of Life Questionnaire Core C30 (EORTC QLQ-C30)

Appendix 2

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

Please fill in your initials:
Your birthdate (Day, Month, Year):
Today's date (Day, Month, Year): 31

		Not at All	A Little	Quite a Bit	Very Much
1.	Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or a suitcase?	1	2	3	4
2.	Do you have any trouble taking a long walk?	1	2	3	4
3.	Do you have any trouble taking a short walk outside of the house?	1	2	3	4
4.	Do you need to stay in bed or a chair during the day?	1	2	3	4
5.	Do you need help with eating, dressing, washing yourself or using the toilet?	1	2	3	4

During the past week:

		Not at All	A Little	Quite a Bit	Very Much
6.	Were you limited in doing either your work or other daily activities?	1	2	3	4
7.	Were you limited in pursuing your hobbies or other leisure time activities?	1	2	3	4
8.	Were you short of breath?	1	2	3	4
9.	Have you had pain?	1	2	3	4
10.	Did you need to rest?	1	2	3	4
11.	Have you had trouble sleeping?	1	2	3	4
12.	Have you felt weak?	1	2	3	4
13.	Have you lacked appetite?	1	2	3	4
14.	Have you felt nauseated?	1	2	3	4
15.	Have you vomited?	1	2	3	4

Please go on to the next page

During the past week:		**Not at All**	**A Little**	**Quite a Bit**	**Very Much**
16.	Have you been constipated?	1	2	3	4
17.	Have you had diarrhea?	1	2	3	4
18.	Were you tired?	1	2	3	4
19.	Did pain interfere with your daily activities?	1	2	3	4
20.	Have you had difficulty in concentrating on things, like reading a newspaper or watching television?	1	2	3	4
21.	Did you feel tense?	1	2	3	4
22.	Did you worry?	1	2	3	4
23.	Did you feel irritable?	1	2	3	4
24.	Did you feel depressed?	1	2	3	4
25.	Have you had difficulty remembering things?	1	2	3	4
26.	Has your physical condition or medical treatment interfered with your family life?	1	2	3	4
27.	Has your physical condition or medical treatment interfered with your social activities?	1	2	3	4
28.	Has your physical condition or medical treatment caused you financial difficulties?	1	2	3	4

For the following questions please circle the number between 1 and 7 that best applies to you

29. How would you rate your overall health during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

30. How would you rate your overall quality of life during the past week?

1	2	3	4	5	6	7
Very poor						Excellent

Appendix 4: Hospital Anxiety and Depression Scale

HAD Scale

Name: Date:

Doctors are aware that emotions play an important part in most illnesses. If your doctor knows about these feelings he will be able to help you more.
This questionnaire is designed to help your doctor to know how you feel. Read each item and place a firm tick in the box opposite the reply which comes closest to how you have been feeling in the past week.
Don't take too long over your replies: your immediate reaction to each item will probably be more accurate than a long thought-out response.

Tick only one box in each section

I feel tense or 'wound up':

Most of the time.....
A lot of the time.....
Time to time, Occasionally.....
Not at all.....

I still enjoy the things I used to enjoy:

Definitely as much.....
Not quite so much.....
Only a little.....
Hardly at all.....

I get a sort of frightened feeling as if something awful is about to happen:

Very definitely and quite badly.....
Yes, but not too badly.....
A little, but it doesn't worry me.....
Not at all.....

I can laugh and see the funny side of things:

As much as I always could.....
Not quite so much now.....
Definitely not so much now.....
Not at all.....

Worrying thought go through my mind:

A great deal of the time.....
A lot of the time.....
From time to time but not too often..
Only occasionally.....

I feel cheerful:

Not at all.....
Not often.....
Sometimes .....
Most of the time.....

I can sit and feel relaxed:

Definitely.....
Usually.....
Not often.....
Not at all.....

I feel as if I am slowed down:

Nearly all the time.....
Very often.....
Sometimes.....
Not at all.....

I get a sort of frightened feeling like 'butterflies' in the stomach:

Not at all.....
Occasionally.....
Quite often.....
Very often.....

I have lost interest in my appearance:

Definitely.....
I don't take as much care as I should.
I may not take quite as much care.....
I take just as much care as ever.....

I feel restless as if I have to be on the move:

Very much indeed.....
Quite a lot.....
Not very much.....
Hardly at all.....

I look forward with enjoyment to things:

As much as I ever did.....
Rather less than I used to.....
Definitely less than I used to.....
Hardly at all.....

I get sudden feelings of panic:

Very often indeed.....
Quite often.....
Not very often.....
Not at all.....

I can enjoy a good book or radio or TV programme:

Often.....
Sometimes.....
Not often.....
Very seldom.....

Appendix 5: Close Persons Questionnaire

The Close Persons Questionnaire

This section concerns people in your life who you feel close to and from whom you can gain support (either emotional or practical) including close relatives and good friends.
How many people do you feel very close to? (It does not matter where they live or if you have seen them recently)
Please enter the number in this box ☐
For the person you are closest to, answer these questions about how well they have provided each stated type of support. Please circle the response you feel expresses your view best.

1) How much, in the last 3 months, did this person give you information, suggestions, and guidance that you found useful?

not at all	a little	quite a lot	a great deal

2) How much, in the last 3 months, could you rely on this person (was this person there when you needed them)?

not at all	a little	quite a lot	a great deal

3) How much, in the last 3 months, did this person make you feel good about yourself?

not at all	a little	quite a lot	a great deal

4) How much in the last 3 months, did you share interests, hobbies, and fun with this person?

not at all	a little	quite a lot	a great deal

5) How much, in the last 3 months, did this person give you worries, problems and stress?

not at all	a little	quite a lot	a great deal

6) How much, in the last 3 months, did you **want** to confide in this person?

not at all	a little	quite a lot	a great deal

7) How much, in the last 3 months, **did** you confide in this person?

not at all	a little	quite a lot	a great deal

8) How much, in the last 3 months, did you trust this person with your most personal worries and problems?

not at all	a little	quite a lot	a great deal

9) How much, in the last 3 months, would you have liked to have confided in this person more?

not at all	a little	quite a lot	a great deal

10) How much, in the last 3 months, did talking to this person make things worse?

not at all	a little	quite a lot	a great deal

11) How much, in the last 3 months, did he/she talk about his/her personal worries with you?

not at all	a little	quite a lot	a great deal

12) How much, in the last 3 months, did you need practical help from this person with major things(e.g. looking after you when you are ill, help with money, with children)?

not at all	a little	quite a lot	a great deal

13) How much, in the last 3 months, did this person give you practical help with major things?

not at all	a little	quite a lot	a great deal

14) How much, in the last 3 months, would you have liked more practical help with major things from this person?

not at all	a little	quite a lot	a great deal

15) How much, in the last 3 months, did this person give you practical help with small things when you needed it (e.g. chores, shopping, watering plants etc.)?

not at all	a little	quite a lot	a great deal

Is there another person who you are also close to?

Yes	No

If Yes, please answer these questions about the person you feel closest to other than the person you answered about earlier. (Then repeat the above questions 1 to 15)

After completion for the closest two people then proceed to Network questions below, 1 to 8.

1) How often do relatives outside your household regularly visit or you visit them?

almost daily	about once per week	about once every month	never / almost never	once every few months	No relatives outside the household

2) How many relatives do you see once a month or more

none	1-2	3-5	6-10	more than 10

3) How often do you see anyone you know through your work socially, out of work hours?

almost daily	about once per week	about once every month	once every few months	never / almost never

4) Do you have friends or acquaintances you visit or who visit you?(not necessarily the same person each time)

almost daily	about once per week	about once every month	once every few months	never / almost never

5) How many friends or acquaintances do you see once a month or more?

none	1-2	3-5	6-10	more than 10

6) How often do you attend religious services? (apart from weddings and funerals)

almost daily	about once per week	about once every month	once every few months	never / almost never

7) Do you belong to any clubs or organisations? (social or recreational groups, trade unions, commercial groups, professional organisations, political parties, sports clubs, cultural groups, pressure groups etc.)

Yes	No

If Yes, taking all the above, how often?

almost daily	about once per week	about once every month	once every few months	never / almost never

8) Does anybody live in your household besides you?

Yes	No

If Yes

Who lives in your household besides you ? **Mark Yes or No**

Spouse /partner	Your mother	Your father	Your partners mother	Your partners father
Yes / No	Yes / No	Yes / No	Yes / No	Yes / No

How many children under 5

0	1	2	3	4	>4

How many children 5-15

0	1	2	3	4	>4

How many children over 15

0	1	2	3	4	>4

How many other people

0	1	2	3	4	>4

Appendix 6: INfOP Checklist for Producing Patient Information

Checklist for Producing Patient Information

Please print this sheet for your use

We recognise it can be difficult and time consuming to produce patient information; the INfOP Group are here to help make the whole thing a less daunting experience.

When developing an information resource, planning is vital. There are lots of things to consider from storage of the resources to financing the venture. You may find the following checklist helpful when producing your own patient information resources. We suggest that you produce an initial draft copy and then use this checklist to make sure you have considered everything, before you forward it to the INfOP group for review.

	YES	NO
• Is it clear who the resource is designed for?	☐	☐
• Is the title clear and relevant?	☐	☐
• Have you started with an introductory paragraph?	☐	☐
• Are the aims of your resource clear?	☐	☐
• Does it achieve its aims?	☐	☐
• Have you used straightforward language?	☐	☐
• Have you included relevant & labelled diagrams or pictures?	☐	☐
• Are references included (where necessary)?	☐	☐
• Has a 'date of production' been included?	☐	☐
• Is the resource based on 'best practice'?	☐	☐
• Have patients been involved in the development?	☐	☐
• Have you included the MDT members in the process?	☐	☐
• Have you identified a funding source?	☐	☐
• Have you a suitable place to store final copies?	☐	☐
• Do you have a distribution plan?	☐	☐
• Have you built evaluation and review in to the process?	☐	☐
• Can you produce the information in other formats?	☐	☐
• Have you considered people who cannot read English?	☐	☐

Once you have considered all the points on the checklist, you are invited to send a hard copy or email a word document to either of the INfOP chairs (see below). Your information will be sent to Medical Illustration Services at Cookridge Hospital to be designed and will then go for review using best practice. You will then be given a summary sheet containing any recommendations for change. Once the changes have been made your resource will go for a final review and be signed off by INfOP.

Chair
Jane Garrud

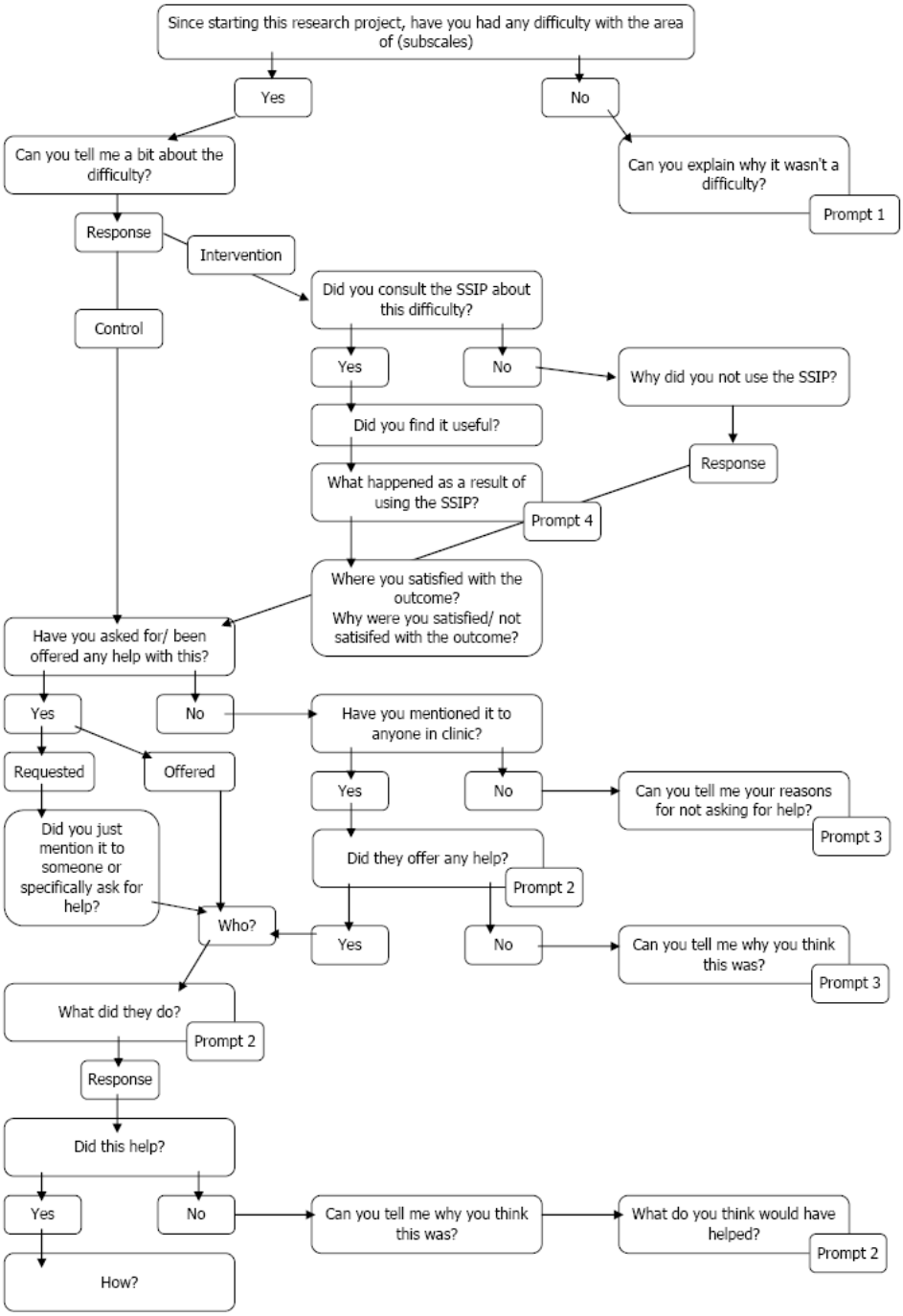
Tel: 0113 392 4385
jane.garrud@leedsth.nhs.uk

Chair
Karen Stocks

Tel: 0113 392 4091
karen.stocks@leedsth.nhs.uk

JG / KS Reviewed January 2006

Appendix 7: Patient Interview Schedule – Pilot Study 1



Final question: intervention group only
Do you think having the SSIP changed how you dealt with any difficulties? Did you use the booklet for any difficulties not discussed so far? What are your thoughts on the SSIP? Do you think it is useful? Do you like the layout/ format/ colours etc?

Prompt 1
i. Not applicable
ii. Something in place to deal with it before it became a problem, e.g. family support

Prompt 2
i. Provide information
ii. Discuss/ make practical suggestions
ii. Made referral
iii. Clinical response inc talk to doctors/ other staff
iv. Provide reassurance
v. Others - write letters, liaise with family etc

Prompt 3
i. Felt staff were too busy/ not enough time
ii. Embarrassed
iii. Feel it's not staff role
iv. Medical/ physical problems took priority
v. Didn't feel anything could be done

Prompt 4
i. Felt I could discuss the issue with staff
ii. Accessed one of the services in the book
ii. A referral was made on my behalf
iv. Other

Appendix 8: Staff Interview Schedule – Pilot Study 1

Initial findings suggest that the information pack may not have been used:

Do you have any thoughts on why the information pack may not have been used?

1. Yes
2. No (see prompts)
    a. Timing; concentrating on treatment, overwhelmed by information
    b. Delivery (i.e. just given to the patient by the RA with little guidance on how to use it)
    c. Patients already have sufficient information/ help with social difficulties

Do you remember anyone mentioning the information pack?

1. No
2. Yes (further questions)
    a. Can you remember what they said about it?
    b. Did this conversation develop into a discussion about their social difficulties?
    c. If so was any action taken?

Following findings from previous research, we expected to be able to record informal contact between the nurses and patients during the clinic; this was not the case:

Why do you think we didn't witness the informal contact between nurses and patients that was demonstrated in previous research?

How is it decided which patients have contact with the CNS?

How do you usually deal with social difficulties?

<u>For doctors only:</u>

How do you feel about having the consultations recorded for research purposes?

Do you feel that being recorded alters the consultation in any way?

- **E.g. increases doctor's or patient's awareness of social difficulties and therefore increases likelihood of these issues being raised?**
- **Does it alter yours or the patient's behaviour in any other way?**

Appendix 9: Nurse Interview Schedule – Pilot Study 2

BACKGROUND

	Question
1	Please can you give me some details about your past roles and how many years' experience you have in your current position?
2	Would you mind telling me your age (or age group)?
3	Please give me some general background about your role, thinking about; The kind of tasks your job entails, day to day Any pressures you face Any sources of support you have
4	Tell me how you feel about using computers generally…
5	Tell me about any concerns you have when using computers both generally and specifically at work

PROJECT - SPECIFIC

	Question
28	I'd like to tell you how I felt about approaching nurses about the study, and wondered if you could tell me (please be frank!) how you felt generally about taking part in the study, even just how you felt when I approached you about it? I felt it was difficult I knew we were asking a lot
6	Tell me how you felt about using the touch-screen/ online assessment system…
8	What do you feel are the pros and cons, for you, of the system being linked to PPM? For RT nurses; would you have felt differently about it had it been linked to MOSAIQ?
9	In what ways do you feel the assessment impacted on your contact with the patient, either positive or negative?
10	How did you feel about carrying out the assessment?
14	How do you feel your experience would differ if you could have done more assessments generally and/ or more with the same patients throughout their journey and seen how things changed?
15	What, if any, difficulties did you experience with any of the following elements of the assessment process; Technological/ practical side Understanding results Discussing issues with patients Finding solutions to difficulties raised
17	What impact did knowing that your colleagues were also carrying out the assessments have on your feelings towards doing the assessment?
19	What impact did knowing that your colleagues in other departments were also carrying out the assessments have on your feelings towards doing the assessment?
18	What impact would the knowledge that your management team were keen for you to use the assessment system have on your feelings towards it?
20	As part of a research project, you were aware that participation was voluntary.

	How do you feel this influenced your attitude towards carrying out the assessments?
24	Can you suggest any changes to the system tested that you think would make it better/ more acceptable/ more feasible?
25	Do you feel you had enough opportunities to carry out the assessments?
26	What impact do you feel doing more assessments would have on your feelings towards the assessments?

TRAINING AND SUPPORT

21	How useful did you feel the training was in preparing you to conduct the assessment?
22	Can you suggest any changes to the training that you feel would make it more effective?
27	Did you feel support was sufficient when you were carrying out assessments (both practical and in terms of scoring/ how to deal with difficulties)

ASSESSMENT - GENERAL

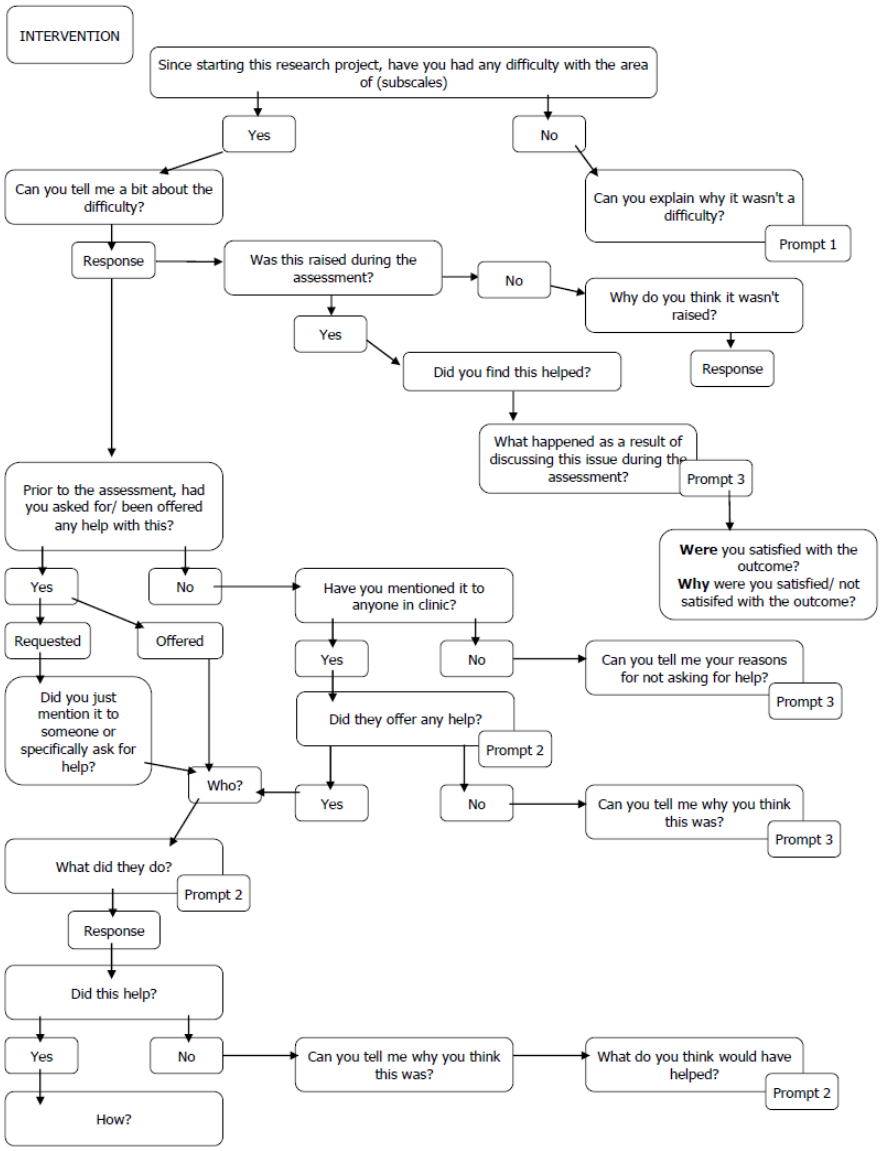
7	What do you feel are the pros and cons of using computer-based systems rather than pen and paper?
11	What do you feel are the pros and cons of carrying out a formal assessment such as the SDI Do you feel it would help you support the patient? In what ways?
12	In what ways do you feel such an assessment may affect; Patient experience Patient outcomes
13	In what ways do you feel such an assessment process may affect; Staff experience Job satisfaction
16	Do you think it would be practical to carry out this assessment for each patient? If yes, how often/ when do you think this should be carried out? If no, why not?
23	Do you feel members of staff in your specific role are the right people to provide this support? If yes, what do you feel would help you carry out the assessment more effectively in the future? If no, who do you feel should carry out the assessment?
29	How do you feel about asking patients about their social difficulties overall?
30	I'd like to ask you about what you feel about the Holistic Common Assessment; What is your understanding of what it entails? *Clarify at this stage if necessary* Has it been discussed with you in any way? How do you feel about it? Who do you think should be doing it? Should it be done at all?

FINAL QUESTIONS

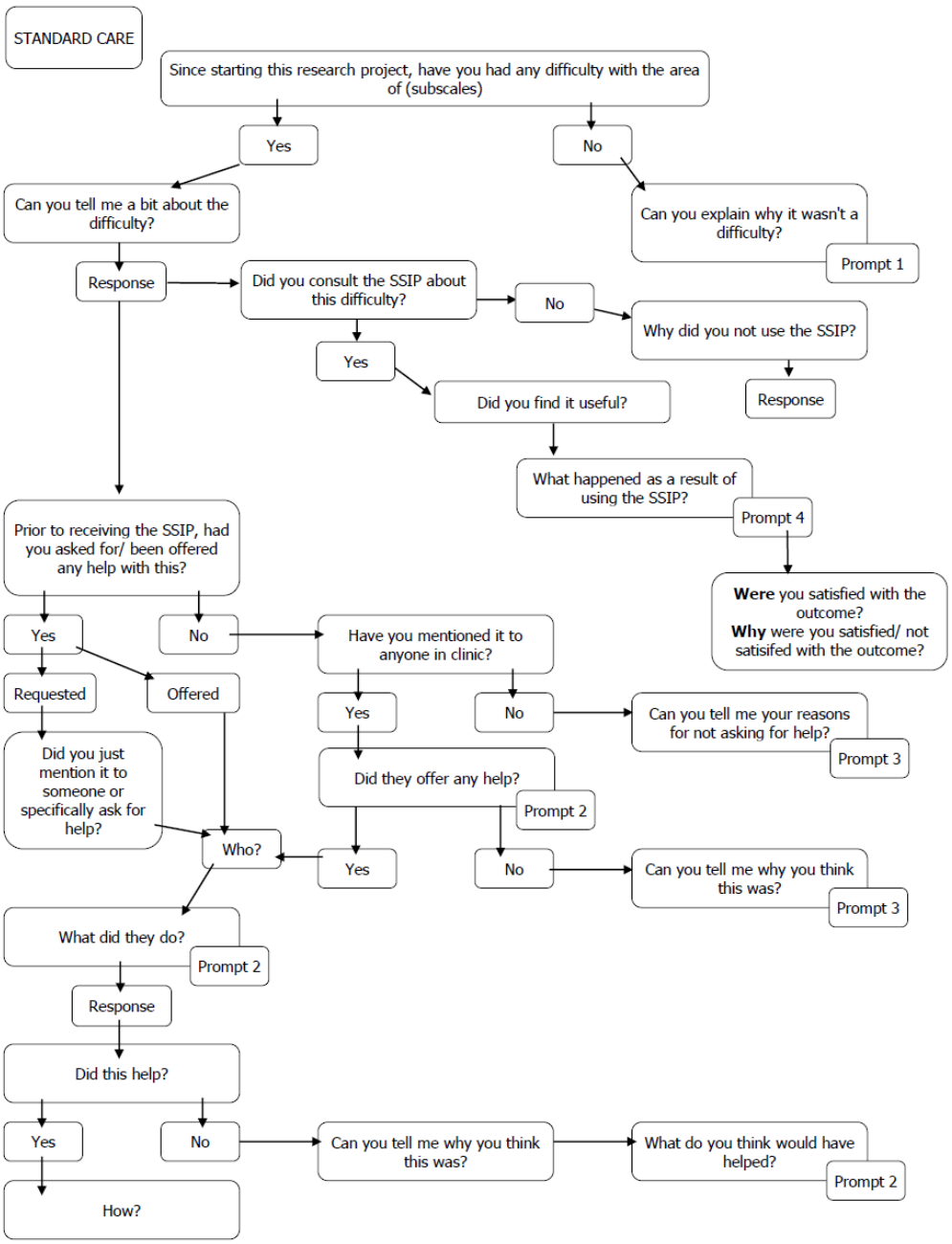
31	Please could you describe the clinic you work in and how it generally goes, thinking about; How does it run/ processes Typical numbers of patients/ staff How long does it usually last/ does it overrun Are electronic records used or paper based

32	Is there anything else you'd like to add about anything we've discussed?

Appendix 10a: Patient Interview Schedule – Pilot Study 2 – Intervention group



Appendix 10b: Patient Interview Schedule – Pilot Study 2 –control group



Final questions:
Did you use the booklet at all?
Did the booklet help you deal with any difficulties?
Do you think having the SSIP changed how you dealt with any difficulties?
Did you use the booklet for any difficulties not discussed so far?
What are your thoughts on the SSIP?
What are your thoughts on the **time** at which you were given the booklet - too late, too soon, just right?
Do you think it is useful?

Prompt 1
i. Not applicable
ii. Something in place to deal with it before it became a problem, e.g. family support

Prompt 2
i. Provide information
ii. Discuss/ make practical suggestions
ii. Made referral
iii. Clinical response inc talk to doctors/ other staff
iv. Provide reassurance
v. Others - write letters, liaise with family etc

Prompt 3
i. Felt staff were too busy/ not enough time
ii. Embarrassed
iii. Feel it's not staff role
iv. Medical/ physical problems took priority
v. Didn't feel anything could be done

Prompt 4
i. Felt I could discuss the issue with staff
ii. Accessed one of the services in the book
ii. A referral was made on my behalf
iv. Other

Appendix 11: Nurse interview schedule - service evaluation (chapter 9)

Background

1 Please can you give me some details about your past roles and how many years' experience you have in your current position?

2 Would you mind telling me your age (or age group)?

3 Please give me some general background about your role, thinking about;

The kind of tasks your job entails, day to day
Any pressures you face
Any sources of support you have

4 Tell me how you feel about using computers generally…

Prompts: *Confident *Enjoy it *Anxious *Do it because I have to *Don't fully understand them

5 Tell me about any concerns you have when using computers both generally and specifically at work

Project-specific

6 I'd like to tell you how I felt about approaching nurses about the study, and wondered if you could tell me (please be frank!) how you felt generally about taking part in the study, even just how you felt when I approached you about it?

I felt it was difficult
I knew we were asking a lot

7 Tell me how you felt about using the touch-screen/ online assessment system…

Prompts: *Worried I might break it! *Confident

8 What do you feel are the pros and cons, for you, of the system being linked to PPM?

9 In what ways do you feel the assessment impacted on your contact with the patient, either positive or negative?

Prompts: *Made it too long/ rushed *Made me distracted *Aided my understanding *Reassured patient

10 How did you feel about carrying out the assessment?

Prompts: *Enjoyed it *Didn't like it *Made me feel I was providing more holistic care

11 How do you feel your experience would differ if you could have done more assessments generally and/ or more with the same patients throughout their journey and seen how things changed?

12 What, if any, difficulties did you experience with any of the following elements of the assessment process;

Technological/ practical side
Understanding results
Discussing issues with patients
Finding solutions to difficulties raised

13 What impact did knowing that your colleagues were also carrying out the assessments have on your feelings towards doing the assessment?

Prompts: * None *More confident *Felt more willing

14 What impact did knowing that your colleagues in other departments were also carrying out the assessments have on your feelings towards doing the assessment?

Prompts:
* None *More confident *Felt more willing

15 What impact would the knowledge that your management team were keen for you to use the assessment system have on your feelings towards it?

16 As part of a research project, you were aware that participation was voluntary. How do you feel this influenced your attitude towards carrying out the assessments?

17 Can you suggest any changes to the system tested that you think would make it better/ more acceptable/ more feasible?

18 Do you feel you had enough opportunities to carry out the assessments?

19 What impact do you feel doing more assessments would have on your feelings towards the assessments?

Training and support

20 How useful did you feel the training was in preparing you to conduct the assessment?

21 Can you suggest any changes to the training that you feel would make it more effective?

22 Did you feel support was sufficient when you were carrying out assessments (both practical and in terms of scoring/ how to deal with difficulties)?

Assessment - general

23 What do you feel are the pros and cons of using computer-based systems rather than pen and paper?

24 What do you feel are the pros and cons of carrying out a formal assessment such as the SDI?

Do you feel it would help you support the patient?
In what ways?

25 In what ways do you feel such an assessment may affect;

Patient experience
Patient outcomes

26 In what ways do you feel such an assessment process may affect;

Staff experience
Job satisfaction

27 Do you think it would be practical to carry out this assessment for each patient? If yes, how often/ when do you think this should be carried out? If no, why not?

28 Do you feel members of staff in your specific role are the right people to provide this support?

If yes, what do you feel would help you carry out the assessment more effectively in the future?
If no, who do you feel should carry out the assessment?

29 How do you feel about asking patients about their social difficulties overall?

30 I'd like to ask you about what you feel about the Holistic Common Assessment;

What is your understanding of what it entails?

Clarify at this stage if necessary

Has it been discussed with you in any way?
How do you feel about it?
Who do you think should be doing it?
Should it be done at all?

Final questions

31 Please could you describe the clinic you work in and how it generally goes, thinking about;

How does it run/ processes
Typical numbers of patients/ staff
How long does it usually last/ does it overrun
Are electronic records used or paper based

32 Is there anything else you'd like to add about anything we've discussed?

Appendix 12: Cancer Rehabilitation Evaluation Scale – Short Form (CARES-SF)

CARES-SF
CAncer Rehabilitation Evaluation System
Short Form
For Research

Developed
by
Anne Coscarelli, Ph.D.
and
Richard L. Heinrich, M.D.

2118 Wiltshire Blvd, Suite 359, Santa Monica, California 90403 (310) 452-4152

CARES-SF
Cancer Rehabilitation Evaluation System
Short Form
For Research

Patient ID#: _____

Date: _____

Instructions

Below is a list of Problem Statements that describe situations and experiences of individuals who have or have had cancer. Read each statement and circle the number that best describes **HOW MUCH EACH STATEMENT APPLIES TO YOU** during the **PAST MONTH, INCLUDING TODAY.** Some sections will not apply to you. Please skip these sections and proceed to the next one as directed.

Example

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much
1. I have difficulty walking.....	0	(1)	2	3	4
2. I find that food tastes bad.....	0	1	2	3	(4)

How much does it apply to you?		Not at all	A little	A fair amount	Much	Very much
1.	I have difficulty bending or lifting	0	1	2	3	4
2.	I do not have the energy I used to	0	1	2	3	4
3.	I have difficulty doing household chores	0	1	2	3	4
4.	I have difficulty bathing, brushing my teeth or grooming myself	0	1	2	3	4
5.	I have difficulty planning activities because of the cancer or its treatments	0	1	2	3	4
6.	I cannot gain weight	0	1	2	3	4
7.	I find food unappealing	0	1	2	3	4
8.	I find that cancer or its treatments interfere with my ability to work	0	1	2	3	4
9.	I frequently have pain	0	1	2	3	4
10.	I find that my clothes do not fit	0	1	2	3	4
11.	I find that doctors don't explain what they are doing to me	0	1	2	3	4
12.	I have difficulty asking doctors questions	0	1	2	3	4
13.	I have difficulty understanding what the doctors tell me about the cancer or its treatments	0	1	2	3	4
14.	I would like to have more control over what the doctors do to me	0	1	2	3	4
15.	I am uncomfortable with the changes in my body	0	1	2	3	4
16.	I frequently feel anxious	0	1	2	3	4
17.	I have difficulty sleeping	0	1	2	3	4
18.	I have difficulty concentrating	0	1	2	3	4
19.	I have difficulty asking friends or relatives to do things for me	0	1	2	3	4
20.	I have difficulty telling my friends or relatives about the cancer	0	1	2	3	4

How much does it apply to you?		Not at all	A little	A fair amount	Much	Very much
21.	I find that my friends or relatives tell me that I'm looking well when I'm not.	0	1	2	3	4
22.	I find that my friends or relatives do not visit often enough.	0	1	2	3	4
23.	I find that friends or relatives have difficulty talking with me about my illness.	0	1	2	3	4
24.	I become nervous when I am waiting to see the doctor..	0	1	2	3	4
25.	I become nervous when I get my blood drawn.	0	1	2	3	4
26.	I worry about whether the cancer is progressing.	0	1	2	3	4
27.	I worry about not being able to care for myself.	0	1	2	3	4
28.	I do not feel sexually attractive.	0	1	2	3	4
29.	I am not interested in having sex.	0	1	2	3	4
30.	I sometimes don't follow my doctor's instructions.	0	1	2	3	4
31.	I have financial problems..	0	1	2	3	4
32.	I have insurance problems.	0	1	2	3	4
33.	I have difficulty with transportation to and from my medical appointments and/ or other places.	0	1	2	3	4
34.	I am gaining too much weight.	0	1	2	3	4
35.	I have frequent episodes of diarrhea..	0	1	2	3	4
36.	I have times when I do not have control of my bladder..	0	1	2	3	4
Do you have children? *If No, skip to next section.*				Yes		No
37.	I have difficulty helping my children cope with my illness.	0	1	2	3	4

How much does it apply to you?		Not at all	A little	A fair amount	Much	Very much
Are you working or have you been employed during the last month? *If No, skip to next section.*			Yes		No	
38.	I have difficulty talking to the people who work with me about the cancer	0	1	2	3	4
39.	I have difficulty asking for time off from work for medical treatments	0	1	2	3	4
40.	I am worried about being fired	0	1	2	3	4
Did you look for work during the past month? *If No, skip to next section.*			Yes		No	
41.	I have difficulty finding a new job since I have had the cancer	0	1	2	3	4
Have you been sexually active since your cancer diagnosis? *If No, skip to next section.*			Yes		No	
42.	I find that the frequency of sexual activity has decreased	0	1	2	3	4
Are you married or in a significant relationship? *If No, skip to next section.*			Yes		No	
43.	My partner and I have difficulty talking about our feelings	0	1	2	3	4
44.	My partner and I have difficulty talking about wills and financial arrangements	0	1	2	3	4
45.	I do not feel like embracing, kissing or caressing my partner	0	1	2	3	4
46.	My partner and I are not getting along as well as we usually do	0	1	2	3	4
47.	My partner spends too much time taking care of me	0	1	2	3	4

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much
48. I have difficulty asking my partner to take care of me.....	0	1	2	3	4
Are you single and not in a significant relationship? *If No, skip to next section.*			Yes		No
49. I have difficulty initiating contact with potential dates.....	0	1	2	3	4
50. I have difficulty telling a date about the cancer or its treatments.....	0	1	2	3	4
Have you had chemotherapy treatments in the last month? *If No, skip to next section.*			Yes		No
51. I become nervous when I get chemotherapy.....	0	1	2	3	4
52. I become nauseated during and/ or before chemotherapy.....	0	1	2	3	4
53. I feel nauseated after I receive chemotherapy.....	0	1	2	3	4
54. I vomit after chemotherapy.....	0	1	2	3	4
55. I have other side effects after chemotherapy.....	0	1	2	3	4
Have you had radiation therapy treatments in the last month? *If No, skip to next section.*			Yes		No
56. I get nervous when I get radiation treatments.....	0	1	2	3	4
57. I feel nauseous or vomit after my radiation treatments....	0	1	2	3	4
Do you have an ostomy? *If No, skip to next section.*			Yes		No
58. I have problems with ostomy care and maintenance.....	0	1	2	3	4

How much does it apply to you?	Not at all	A little	A fair amount	Much	Very much
Do you have a prosthesis? *If No, skip to next section.*		Yes		No	
59. I have difficulty with my prosthetic device (artificial limb, breast prosthesis etc.).....	0	1	2	3	4

Appendix 13: Nurse checklist from pilot study of information intervention versus standard care

Leeds Institute of Molecular Medicine

UNIVERSITY OF LEEDS

Psychosocial Oncology and Clinical Practice Research Group
St James's Institute of Oncology

Pilot study to assess provision of simple support services information versus standard care in managing social difficulties in routine oncology practice

Staff initials:	Staff study ID:	Patient initials:	Patient study ID:	New or completing participant (please circle):	
				New	Completing

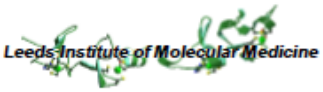
The aim of this checklist is to record what discussions around social issues you may have had with patients participating in the research study. The issues/ areas for discussion are organised according to the NHS National Cancer Action Team's Holistic Common Assessment Guidance[1].

Please look at each issue/ area (examples are shown to illustrate what each area may cover), and answer the questions that follow.

Issue/ area	**Did you discuss this issue with the patient?** **(Tick if yes, leave blank for no.)**	**If yes, did you bring up the conversation or did the patient?**	**Did you take any action regarding the issue?** **(Tick if yes, leave blank for no.)**	**If yes, please outline below, e.g. referred to information lounge**
Managing at home and in the community • Ability to prepare food and feed independently • Getting around the home/ key transfers • Other personal care and housekeeping				
Work and finance • Work issues • Day to day finances • Planning for the future				
Family and close relationships • Patient's close relationships, inc children • Sexual relations				
Social and recreational • Social interactions • Recreation and leisure				

1. Team, N.N.C.A., *Holistic Common Assessment of Supportive and Palliative Care Needs for Adults with Cancer: Assessment Guidance*, NHS, Editor. 2007: London.

Appendix 14: Baseline patient checklist from pilot study of information intervention versus standard care



UNIVERSITY OF LEEDS

Cancer Research UK Clinical Centre
Psychosocial Oncology and Clinical Practice Research Group
St James's Institute of Oncology
Bexley Wing
Beckett Street, Leeds
LS9 7TF

Pilot study to assess provision of simple support services information versus standard care in managing social difficulties in routine oncology practice

Patient Initials	Hospital No:	Study ID:	Study Group (circle as appropriate)	
			Intervention	Control

Service (examples)	**Have you used any of these services in: the last 3 months?** **(Tick if yes, leave blank for no)**
Healthcare-related E.g. Occupational therapy, physiotherapy	
Government or local council E.g. Blue Badge Parking scheme, Department for Work and Pensions	
Charity/ voluntary E.g. Bradford Cancer Support Centre, Macmillan Centres, support groups	
Other hospital-based E.g. Social Work, Clinical Psycho-Oncology Service, Bexley Wing Information, Care and Support Services	
Websites E.g. Cancerbackup/ Macmillan, Cancerhelp	
Others Please include any other services or resources you may have accessed that are not on this list	

Appendix 15: End of study patient checklist from pilot study of information intervention versus standard care

UNIVERSITY OF LEEDS

Cancer Research UK Clinical Centre
Psychosocial Oncology and Clinical Practice Research Group
St James's Institute of Oncology
Bexley Wing
Beckett Street, Leeds
LS9 7TF

Pilot study to assess provision of simple support services information versus standard care in managing social difficulties in routine oncology practice

Patient Initials	Hospital No:	Study ID:		Study Group (circle as appropriate)	
				Intervention	Control
		Have you used any of these services in since you took part in this study? **(Tick if yes, leave blank for no)**	**If yes, how did you find out about the service?**	**If no, why have you not accessed the service?** **(E.g. didn't need it, never heard of it)**	**Do you think you would use the service in future?** **(Tick if yes, leave blank for no)**
Healthcare-related E.g. Occupational therapy, physiotherapy					
Government or local council E.g. Blue Badge Parking scheme, Department for Work and Pensions					
Charity/ voluntary E.g. Bradford Cancer Support Centre, Macmillan Centres, support groups					
Other hospital-based E.g. Social Work, Clinical Psycho-Oncology Service, Bexley Wing Information, Care and Support Services					
Websites E.g. Macmillan, Cancerhelp					
Others Include any other services you may have accessed that are not on this list					

Appendix 16: Nurse Pre-training Evaluation Questionnaire from SDI-21 assessment intervention versus standard care

Leeds Institute of Molecular Medicine

UNIVERSITY OF LEEDS

Cancer Research UK Clinical Centre
Psychosocial Oncology and Clinical Practice Research Group, St James's Institute of Oncology, Bexley Wing, Beckett Street, Leeds, LS9 7TF

Pilot study to compare routine assessment versus standard care in managing social difficulties in routine oncology practice

Pre-Training Evaluation Questionnaire

- Many thanks for agreeing to take part in this research study.
- To allow you to participate fully in the study we would like you to take part in some educational sessions and training, to enable you to use the Social Difficulties Inventory (SDI-21) to carry out an assessment of patient's social difficulties, using a touch-screen computer
- To evaluate the effectiveness of this training we would like you to complete pre and post-training questionnaires
- Please complete this questionnaire as fully as possible and return **BEFORE** you complete the training
- Space has been provided at the end for you to write down any questions you may have; we will endeavour to address these fully during the training
- You do not need to put your name or any personal details on this booklet - you have been allocated a Study Number which the researcher will have written in the box below
- Your answers will be kept completely confidential. They will be stored in a secure file and only the research team will be able to access this.
- If you have any problems completing this booklet, or any queries about the research study in general, please do not hesitate to contact a member of the research team on **0113 2067548** or **0113 2067596**.
- Once completed, please hand back to the researcher or return in the envelope provided, to:
- SDI Research Team, Psychosocial Oncology and Clinical Practice Research Group, Level 3, Bexley Wing

FOR OFFICE USE ONLY:

Study Number		**Date inputted**	
Date of completion/ return		**Inputted by**	

Pre-Training Evaluation Questionnaire

Unless otherwise directed, please state the degree to which you agree or disagree with each of the following statements by circling the appropriate number on the scale; 1 is strongly disagree, 3 is neither agree nor disagree, and 5 is strongly agree

		Strongly disagree				Strongly agree
1.1	I understand what is meant by the phrase 'social difficulties'	1	2	3	4	5
1.2	I am aware of what issues would be classed as social difficulties	1	2	3	4	5
1.3	I am uncomfortable about raising some personal topics with patients (e.g. sexual matters, finances)	1	2	3	4	5
1.4	It is important that social difficulties are dealt with	1	2	3	4	5
1.5	I am able to deal with a patient's social difficulties	1	2	3	4	5
1.6	Are there any areas of social difficulties that you feel less confident in dealing with than others?	Yes ☐		No ☐		Not sure ☐
	If yes, please clarify: _____					
1.7	I am able to adequately assess a patient's social difficulties	1	2	3	4	5
1.8	I am able to choose appropriate interventions to deal with social difficulties	1	2	3	4	5
1.9	I am able to recognise which issues I need to deal with myself and which require a specialist referral	1	2	3	4	5
1.10	I have knowledge of **information** for patients, locally and nationally	1	2	3	4	5
1.11	I have knowledge of **available support services** that are available for patients, locally and nationally	1	2	3	4	5
1.12	I am able to explain to patients why it is important to assess their social difficulties	1	2	3	4	5
1.13	It would be disruptive to carry out routine assessments of social difficulties during outpatient clinics	1	2	3	4	5

Please continue to next page

1.14a Have you received any training that covered any aspect of recognising and/ or dealing with social difficulties? Yes ☐ No ☐ Not sure ☐

1.14b If yes or not sure, please describe

1.14 What aspects of carrying out routine assessments for social difficulties do you think you would find most difficult?

Please use this space to write any queries you may have that you would like to have addressed during the training:

Thank you for completing this pre-course questionnaire; please return to Emma or Ceri in the envelope provided to the address given on the front page

Appendix 17: Nurse Post-training Evaluation Questionnaire from SDI-21 assessment intervention versus standard care

Leeds Institute of Molecular Medicine

UNIVERSITY OF LEEDS

Cancer Research UK Clinical Centre
Psychosocial Oncology and Clinical Practice Research Group, St James's Institute of Oncology, Bexley Wing, Beckett Street, Leeds, LS9 7TF

Pilot study to compare routine assessment versus standard care in managing social difficulties in routine oncology practice

Post-Training Evaluation Questionnaire

- Many thanks for agreeing to take part in this research study
- You should now have completed the educational sessions and training
- To evaluate the effectiveness of this training we would like you to complete pre and post-training questionnaires
- Please complete this questionnaire as fully as possible and return **AFTER** you have completed the training
- You will also be asked to repeat this questionnaire at the half-way point of the study; after around 12 to 16 weeks
- You do not need to put your name or any personal details on this booklet - you have been allocated a Study Number which the researcher will have written in the box below
- Your answers will be kept completely confidential. They will be stored in a secure file and only the research team will be able to access this.
- If you have any problems completing this booklet, or any queries about the research study in general, please do not hesitate to contact a member of the research team on **0113 2067548** or **0113 2067596**.
- Once completed, please hand back to the researcher or return in the envelope provided, to:
  SDI Research Team, Psychosocial Oncology and Clinical Practice Research Group, Level 3, Bexley Wing

FOR OFFICE USE ONLY:

Study Number		**Date inputted**	
Date of completion/ return		**Inputted by**	

Post-Training Evaluation Questionnaire

Unless otherwise directed, please state the degree to which you agree or disagree with each of the following statements by circling the appropriate number on the scale; 1 is strongly disagree, 3 is neither agree nor disagree, and 5 is strongly agree

		Strongly disagree				Strongly agree
1.1	I understand what is meant by the phrase 'social difficulties'	1	2	3	4	5
1.2	I am aware of what issues would be classed as social difficulties	1	2	3	4	5
1.3	I am uncomfortable about raising personal topics with patients (e.g. sexual matters, finances)	1	2	3	4	5
1.4	It is important that social difficulties are dealt with	1	2	3	4	5
1.5	I am able to deal with a patient's social difficulties	1	2	3	4	5
1.6	Are there any areas of social difficulties that you feel more confident in dealing with than others?	Yes ☐		No ☐		Not sure ☐
	If yes, please clarify: _____					
1.7	I am able to adequately assess a patient's social difficulties	1	2	3	4	5
1.8	I am able to select appropriate interventions to deal with social difficulties	1	2	3	4	5
1.9	I am able to recognise which issues I need to deal with myself and which require a specialist referral	1	2	3	4	5
1.10	I have knowledge of **information** for patients, locally and nationally	1	2	3	4	5
1.11	I have knowledge of **available support services** that are available for patients, locally and nationally	1	2	3	4	5
1.12	I am able to explain to patients why it is important to assess their social difficulties	1	2	3	4	5

		Strongly disagree				Strongly agree
1.13	It would be disruptive to carry out routine assessments of social difficulties during outpatient clinics	1	2	3	4	5
1.14	I am able to use the SDI-21 touch-screen system	1	2	3	4	5
1.15	I understand how the SDI-21 works	1	2	3	4	5
1.16	I am able to instruct a patient how to use the SDI-21	1	2	3	4	5
1.17	I am able to access the responses and output from PPM	1	2	3	4	5
1.18	I am able to interpret the scores from the SDI-21 output	1	2	3	4	5
1.19	I am able to provide appropriate interventions to deal with problems highlighted by the SDI-21	1	2	3	4	5
1.20	I am able to record contact and interventions made from the SDI-21 in PPM	1	2	3	4	5

1.21 What aspects of using the SDI-21 assessment are you concerned about?

_____

_____

_____

_____

Thank you for completing this post-course questionnaire; please return to Emma or Ceri in the envelope provided to the address given on the front page