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Distress and unmet needs in cancer patients

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1 Introduction

1.1 Psychological impact of a cancer diagnosis

Despite major advances in the detection of cancer and medical treatment, receiving a cancer diagnosis can trigger various negative emotions. Initially, patients may experience anxiety and uncertainty, but also anger and feelings of guilt about supposed responsibility for the onset of the disease can exist (1). In the treatment phase, patients may experience problems related to coping with temporary (e.g. hair loss) or definitive body mutilation (e.g. breast amputation) and other side effects of treatment (1). At the time treatment ends, the so-called *re-entry phase*, patients often face remaining psychosocial challenges that may extend into longer survivorship (2,3). This phase has been reported as one of the most difficult periods, as patients may lose the support and sense of security associated with treatment and its regular contact with health care professionals. Patients may still have to deal with side effects of treatment, may suffer from fear of recurrence and may have difficulties reintegrating into former family and social roles (3). After the first year after completion of medical treatment, many patients will regain emotional balance (2,4). However, for a subgroup of patients emotional problems remain present for a longer period of time, and they can have a disruptive effect on the patients' quality of life (2,5).

There is consistent evidence that the prevalence of cancer patients experiencing psychological complaints as a result of their diagnosis ranges from 30-45% (6-8). However, clinicians often fail to detect these complaints in their patients (9). Also, not much is known about the percentage of patients in need for support for these problems. While some studies do report percentages of patients considering a referral to psychosocial services (8,10), only few studies give information about the actual uptake of these interventions (11). Moreover, with the dissemination of evidence-based recommendations for clinical practice, there is a call for improving the quality of psychosocial interventions patients are receiving (12).

The current thesis aims to add to the existing knowledge about the percentage of cancer patients experiencing psychological problems, in the rest of the thesis labeled with the term 'distress', and about their willingness to accept psychosocial services and to participate in psychosocial intervention research. Moreover, the thesis will focus on the feasibility of one specific intervention, called 'Problem-Solving Therapy' (PST), as a promising study in the USA found it to be a highly effective treatment to reduce distress in cancer patients (13).

In this first introductory chapter, some general information about the incidence and medical treatment of cancer will be presented (box 1.1), as well as a description of psychological distress and the development of several guidelines for distress screening (1.2). Furthermore, we will outline the PST intervention (1.3) and give a summary of our research and the different study aims (1.4).

Box 1.1 Cancer diagnosis and treatment

In the Netherlands, every year approximately 90.000 patients receive a first diagnosis of cancer and about 40.000 cancer patients will die as a result of cancer. The term cancer refers to over a 100 types of diseases, all having in common an uncontrolled multiplying of cells resulting in a tumor. The number of new cases of cancer still increases every year, mainly due to growth and ageing of the population. The prognosis of cancer patients varies greatly by cancer type and stage of the disease. Fortunately, nowadays 50%-60% of patients diagnosed with cancer get cured. In addition, survival rates of cancer patients gradually increase due to a diagnosis of cancer in an earlier stage, improved treatment and decrease of the incidence of several cancer types with low survival rates, such as lung cancer and cancer of the stomach (14).

Cancer treatment generally falls into four major categories: surgery, radiation, chemotherapy and biological therapy. Any of these approaches can be used as a *primary* treatment, which is the major intervention. Many patients will then receive *adjuvant therapy* as part of a comprehensive treatment protocol. Most cancer types are treated with a multi-modal approach. Major *surgery* involves removing the tumor, surrounding tissue, and lymph nodes. *Chemotherapy* is a systemic intervention and acts by altering the cancer-cell life processes and functioning in various ways. Because cells are constantly dividing and are in various phases of the cell cycle, several types of chemotherapy are used to provide the maximum effect. However, the drug agents of chemotherapy do not have the ability to select only the malignant cells, therefore normal cells can also get damaged. The most common side effects of chemotherapy include hair loss, low white-cell count, low platelet count, nausea, vomiting, diarrhea, and a sore mouth. *Radiation* therapy works on the cellular level by using high-energy waves or particles. The cancer cells die because of the damaging effects of radiation on the cells' DNA molecules. Normal cells within the field of treatment are also killed by radiation, which can lead to side-effects, such as nausea, vomiting, diarrhea, hair loss, and anemia, depending on the site location of treatment. The most common side effect of radiotherapy is fatigue. Other treatment modalities include *hormone therapy* and *immune therapy* (1,15)

1.2 Distress**1.2.1 Distress or depression**

To recognize the variety of emotional problems that may arise after receiving a diagnosis of cancer, psycho-oncology professionals recently invoked the term 'distress'. The idea was that the use of this term, instead of the terms 'depressive symptoms' or 'depression', would be less stigmatizing and appeal to common sense, as most individuals have a good idea of what feeling 'distressed' entails (16). It was also introduced with the expectation that patients who were labeled distressed would be

more willing to accept treatment than if they were told they were depressed. However, distress is, in contrast to depression or depressive symptoms, not recognized as a diagnostic category in clinical care, and it is difficult to argue for specific symptoms associated with a diagnosis of being 'distressed'. The National Comprehensive Cancer Network (17) has labeled distress as an:

"unpleasant emotional experience of a psychological (cognitive, behavioral, emotional), social, and/or spiritual nature that may interfere with the ability to cope effectively with cancer, its physical symptoms, and its treatment. Distress extends along a continuum, ranging from common normal feelings of vulnerability, sadness and fears to problems that can become disabling, such as depression, anxiety, panic, social isolation, and spiritual crisis (p. 6, DIS-2) (17)."

There is evidence that the prevalence of distress in cancer patients ranges from 30-45%, depending on the measure used and the point of assessment (6-8). It should be noted that distress in cancer patients is often measured with tools combining anxiety and depression items, such as the Hospital Anxiety and Depression Scale (HADS) (18) or the Brief Symptom Inventory (BSI) (19), so the distinction between distress and depression in research is not always well-defined. Accumulating evidence suggests that the presence of distress is associated with reduced health-related quality of life (20), poorer satisfaction with care (21) and possibly reduced survival after cancer (22). As already mentioned before, unfortunately, it is found that oncologists often fail to detect distress in their patients, so that distress frequently remains unaddressed (23,24).

1.2.2 Screening for distress: detection of unmet needs

During the last decades, interest in psychosocial oncology has grown significantly. In 2008, the Institute of Medicine (IOM) published a report titled *"Cancer Care for the Whole Patient: Meeting Psychosocial Health Needs"* in order to promote greater awareness of the need for psychosocial care for patients with cancer (25). The report summarized evidence about the deleterious effects of unmet psychosocial care needs of patients, as well as the beneficial effects of providing psychosocial services. The report stated that:

"Attending to psychosocial needs should be an integral part of quality cancer care. All components of the health care system that are involved in cancer care should explicitly incorporate attention to psychosocial needs into their policies, practices and standards, addressing clinical health care. These policies, practices, and standards should be aimed at ensuring the provision of psychosocial health services to all patients who need them (p. 8-9) (25)".

Before publication of this report, other countries also published guidelines with regard to psychosocial oncology: for example, the United Kingdom (26), the United States (17), Australia (27) and Canada (28). In 2009, the Dutch Health Care Inspectorate examined the quality of oncology care. One of their conclusions was that interest in and attention to psychosocial care in the Netherlands was unsatisfactory (29). This resulted in the recommendation that routine screening for psychosocial problems in cancer patients had to be incorporated as a standard in all hospitals in the Netherlands by 2010. In the same period, the Dutch Society for Psychosocial Oncology formulated and published a guideline regarding the need for psychosocial care in cancer patients, with the aim that every adult cancer patient who receives ambulatory hospital care should be routinely screened for psychosocial distress (30).

Although guidelines for routine screening of distress are widely disseminated, there is evidence that most physicians working with cancer patients do not use a screening instrument to identify patients with emotional problems. One study evaluated the implementation of the distress management guidelines of the National Comprehensive Cancer Network (NCCN) by NCCN member institutions and found that only 20% of member institutions routinely screened all patients as recommended by the guidelines and many of the institutions that screened patients did not use standardized assessment methods (31,32). One of the barriers to the implementation of screening appeared clinicians' lack of time, as most clinicians were having only 20 minutes or less for a consultation with their patients. Other barriers included clinicians' lack of training and low personal skills and confidence about giving a distress or depression diagnosis (32).

In our opinion, it is noteworthy that screening for distress should not be seen as an end in itself. Often overlooked is that screening should be implemented as a means toward the goal of identifying patients with an unmet need for psychosocial services, in order to offer them those services. There is still a lack of consistent information about the actual uptake of psychosocial services after the implementation of screening for distress. Two observational studies in newly diagnosed cancer patients reported that respectively only 23% and 47% of patients screening positive for distress accepted a referral to existing psycho-oncological services (33,34). In addition, large scale well-designed trials establishing the effects of screening on patients wellbeing are still scarce (35,36) and many studies do not find a direct effect of psychosocial screening on patients' health related outcomes (36-40).

1.2.3 Screening for distress: targeting intervention research

Screening for distress is not only recommended in clinical practice, as was discussed in the previous paragraphs, it is also part of a scientific rationale. Several meta-analyses and systematic reviews still question the efficacy of psychosocial interventions to reduce distress among cancer patients (41-43). In 1999, Sheard and Maguire were among the first to comment that most trials did not select patients with significant psychological distress (41). Psychosocial intervention trials that do not select patients for distress run the risk of failing to demonstrate the efficacy of the intervention, because a majority of

patients with low distress may not register a clinically significant effect (a floor effect). Recently, another meta-analysis and a 'review of reviews' came to the same conclusion, stating that interventions targeted at patients high at risk for suffering significant distress are found to show much stronger clinical effects than interventions with unscreened patients (44,45).

1.3 Problem-Solving Therapy: the 'gold standard' for distress management?

Given the various emotions cancer patients may experience, the importance of developing and evaluating effective interventions to affect positively their psychological distress appears obvious. A promising study in this context came from Nezu *et al.* (2003), publishing the results of their study into the efficacy of Problem-Solving Therapy (PST) for distressed adult cancer patients (13). The basic premise of PST is that when patients learn to identify and resolve problems, they will gain an increased sense of self-efficacy, control, and confidence. According to the theory of problem-solving, such changes would reduce symptoms of distress and depression (Box 1.2).

In the study of Nezu *et al.*, 132 patients were randomized into one of three conditions: a) a PST group, b) a PST-SO group with a significant other, and c) a waiting list control group. At post-treatment, participants in both treatment conditions (PST and PST-SO) were found to have improved quality of life, decreased psychological distress and depressive symptoms, as well as more effective problem-solving ability. These effects were maintained at 6-months and 1-year post-treatment. Patients in the waiting list condition did not experience any significant changes. The authors noted that the effect sizes on distress identified in the study were substantially larger than the mean effect sizes noted earlier in a meta-analysis conducted by Meyer and Mark (46), suggesting that PST appeared to be a particularly robust intervention.

PST has documented efficacy for various other diagnoses within medical care settings (see for an overview (47)). A number of systematic reviews and meta-analyses also concluded that PST was a feasible and effective intervention for depressive disorders (48-51), and PST was even labeled as the '*gold standard*' for the treatment of depression in primary care (49).

Box 1.2 Problem-Solving Therapy

In the PST sessions the following five components are stepwise addressed:

- 1) *problem orientation*: a motivational technique that includes viewing problems as inevitable, normal and predictable part of life that can be resolved or coped with effectively when confronted appropriately;
- 2) *problem definition*: the process of analyzing a problem, understanding what specifically makes the situation difficult, and establishing realistic and attainable goals to cope with or resolve the problem;
- 3) *generation of alternatives*: brainstorming about the many possible ways to reach the goals;
- 4) *decision-making*: the process of evaluating each of the potential ideas to determine which one will meet the desired goal;
- 5) *solution implementation and verification*: developing a plan, carrying it out, and evaluating its success.

The PST protocol is recommended to be delivered in a structured and sequential method, occurring over approximately 10 sessions. In the first session a comprehensive list of the current problems in the patients' life is established, which may include physical/health related problems, emotional/personal problems, family/relationship problems, problems with friends, and problems with finances/work, hobbies or daily activities. The next four sessions are guided by this problem list, and the patient is educated to apply the problem solving components of defining a problem, generating alternative solutions, selecting the best solution, developing a plan, and evaluating whether this has solved the problem. The last sessions are designed to practice and to increase generalizability and maintenance of skills. Throughout all the sessions, there should be attention for the development of a positive problem orientation, thereby strengthening the patients' ability to cope effectively with his or her problems (15).

1.4 The research

This overview shows that the impact of a diagnosis of cancer can result in various negative emotional reactions, recently given the label of being '*distressed*'. In literature, one can find numerous psychosocial intervention trials evaluating their efficacy in reducing the distress patients encounter. Many of these trials are targeted towards cancer patients in the early diagnostic and treatment phase. Less studies have been directed towards patients after the completion of medical treatment (3,52), although it is found that in this phase still a percentage of 25-30% of patients remains to experience depression and distress (2,53). Psychosocial interventions are especially relevant in this period, when regular contact with health care professionals declines. In this context, the study of Nezu *et al.* (2003) was highlighted as it showed promising results (13).

1.4.1 The study aims

One of the original aims of the project was to replicate the study of Nezu *et al.* (2003) and examine the efficacy of Problem-Solving Therapy in a Dutch sample of adult cancer patients selected for heightened distress. As the study of Nezu *et al.* was carried out in the USA, generalizability to the Dutch healthcare setting needed to be assessed before recommendations for clinical implementation could be formulated. In contrast to the study of Nezu *et al.*, we decided to include patients short after completion of active medical treatment, as we wanted to offer them support in a period in which patients may be confronted with long-term symptoms including persistent fatigue, fear of recurrence and decreased social support. To be able to recruit a sufficient number of patients we approached multiple hospital sites to join the study.

Due to difficulties in the implementation of the screening and the recruitment of patients, less patients than expected were screened and included in the study. We therefore decided to describe our experiences with screening and recruitment in a number of papers, focusing on the distress screening results, the implementation of the screening and the retention of patients in the PST intervention. Based on the low recruitment rate, we also decided to investigate this topic more thoroughly, by systematically reviewing the literature on recruitment rates of psychosocial intervention studies for cancer patients.

In Chapter 2 of this thesis, we will address the contradictory evidence of the benefits of screening for patients' distress. More specific, we will examine the question if screening for distress is an efficient means to uncover unmet needs in cancer patients. Importantly, much of the screening literature implicitly assumes that screening positive for distress represents an unmet need for psychosocial services. This assumption has not yet been adequately tested. In Chapter 3, we further comment on a large and adequately powered clinical trial of Carlson *et al.* (2010) evaluating the efficacy of screening on subsequent distress in outpatients with breast and lung cancer (54). The authors concluded that routine screening was feasible in a large cancer center and reduced distress levels in both patient groups. However, looking closer to their findings, we raised doubts about the proposed efficacy of their screening intervention and about some methodological issues. In our commentary we therefore question if, based on this study, it can be concluded that screening helps to reduce distress levels in cancer patients.

The next two chapters focus on the recruitment and retention of distressed cancer patients in a psychosocial intervention study, and the challenges we encountered in these important research phases. In Chapter 4, we will concentrate on the question if implementing screening for distress is an efficient means to recruit cancer patients to a psychological intervention trial. As we encountered substantial challenges in the implementation of the screening, we examined the extent to which distressed patients had an unmet need for psychosocial services and were willing to participate in an

intervention study. We describe patient characteristics associated with enrollment in the study, the investment of time in screening, and the implementation challenges of screening for distress. In Chapter 5, we will address the problems to be solved in the implementation of a randomized controlled intervention trial, taking into account our experiences with replicating the Problem-Solving Therapy intervention trial of Nezu *et al.* (2003).

Finally, as we did not succeed in recruiting sufficient patients into our study for an adequately powered trial, we decided to undertake a systematic review examining the recruitment rates and the completeness of reporting of the recruitment process of 97 other psychosocial randomized controlled trials for cancer patients (Chapter 6). Most journals reporting clinical and psychosocial intervention trials endorse the use of the guidelines of the Consolidated Standard for Reporting Trials (CONSORT). These guidelines represent *'an evidence-based, minimum set of recommendations for reporting RCTs, and offer a standard way for authors to prepare reports of trial findings, facilitating their complete and transparent reporting, and aiding their critical appraisal and interpretation'* (55). While some previous studies already discussed the completeness of reporting the recruitment process of clinical trials (56-59), the completeness of reporting of psychosocial RCTs for cancer patients was not earlier systematically reviewed.

In sum, as we encountered substantial challenges in the execution of our main goal – the replication of a psychosocial intervention trial concerning PST in Dutch oncology settings – we decided to shift our focus to more methodological and clinical issues regarding screening for distress and the execution and reporting of psychosocial interventions in oncological care. This shift in focus delivered valuable lessons for recent and future research, and can be found in the following chapters of this thesis.

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