Distress and unmet needs in cancer patients
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Document Version
Publisher's PDF, also known as Version of record

Publication date:
2015

Link to publication in University of Groningen/UMCG research database

Citation for published version (APA):

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Chapter 7

General Discussion
7. General Discussion

A diagnosis of cancer can have a large impact on a patient’s life and wellbeing. The main aim of our study was to concentrate on the detection and treatment of psychological distress among patients with the replication of a randomized controlled psychosocial intervention trial, proven to be successful in the USA. As this appeared to be a challenging and complex job, we decided to shift our focus to the difficulties we encountered in the design and execution of our intervention trial and to more general methodological issues in conducting psychosocial intervention research in cancer patients. In this final chapter, we discuss our overall findings, concerning several aspects of screening for distress (7.1-7.4), the problems encountered in our replication study (7.5), suggestions for clinical practice and future research (7.6) and methodological issues, in which we take into account the strengths as well as the limitations of this study (7.7). Textboxes are presented to highlight specific recommendations resulting from this project and to offer a case example. The chapter will end with our final conclusions (7.8).

7.1. Screening for distress as a means to uncover unmet needs

In study 1 (Chapter 2), we questioned if screening for distress is the optimal means of identifying unmet need for psychosocial services among cancer patients (Box 7.1). On the one hand, there is evidence that screening for distress improves secondary outcomes related to patients’ wellbeing, such as improved communication between clinician and patient (4,5) and improved receipt of services (6,7). On the other hand, there is little evidence that screening for distress directly improves patient wellbeing in terms of reduced distress, and there is a lack of high quality trials assessing the direct effects of screening for distress on patients’ wellbeing (8). A systematic review into the effects of screening for psychological distress on patient outcomes found only one high quality RCT eligible to assess the effects of screening on cancer patients’ distress (4). This RCT showed that distress did not improve in screened patients versus those receiving usual care (5).

Recently, new scientific questions were elicited in literature about screening for distress, such as ‘what further information should screening seek about the context of distress and patients own needs’, and ‘how should a positive screen be responded to given that distress in a cancer context can indicate instrumental as well as psychological needs?’ (1). A recent study of Mackenzie et al. found that patient-perceived levels of anxiety and depression (single-item responses to the question: ‘What level of anxiety/depression have you been experiencing in the last week?’) were better indicators of whether patients were likely to accept psychosocial services than their clinical levels of distress assessed with the HADS (2). So, there is still little consensus about the optimal means to assess distress and unmet need for services of patients. In our opinion, the own perception of patients of their emotional problems and needs should be an essential part of this assessment.
Box 7.1 Screening for unmet needs

It should be worthy when clinical practice focuses more on patients’ perceived emotional problems and their unmet needs, instead of relying on their clinical levels of distress. Information about patients’ perceived emotional problems and possible unmet needs should be obtained at distinct stages of the treatment process. Depending on the perceived problems and unmet needs, patients should be directed to different types of services in- or outside the hospital. Thereby, the assessment of distress could promote patient-caregiver communication, and may promote the chance that patients are willing to accept services for the problems they encounter. However, practice has shown that this option is far from easy to implement, and thus should continue to get attention in the future.

7.2. Benefits of screening patients with cancer for distress

In our commentary (Chapter 3) on the large screening study of Carlson et al. (2010) (3), we argue that this study failed to demonstrate that screening for psychological distress significantly improved patients’ wellbeing. Although the Distress Thermometer scores 3-months post-randomization were significantly lower among patients receiving phone triage compared to the control condition, the magnitude of the effect was very small. There was no difference between the three screening groups on secondary outcomes of depression or anxiety three months post-randomization. A noteworthy finding was that the group that was offered a chance to discuss their screening score with staff, irrespective of their distress score, showed a small but significant reduction in distress compared to the full screening group and the control condition. As already discussed above, this again raises the question if screening for distress is the optimal means to uncover unmet needs of patients, as simply screening for distress did not demonstrate to improve patients’ wellbeing. There is still a patient-staff discussion needed about the problems encountered and the eventual need for a referral to psychosocial resources. Exclusively relying on screening for distress could even have a negative impact: patients with an unmet need for psychosocial care who do not meet some cut-off criterion on a distress measure might be ruled out from the support they wish or need to receive.

In addition, it was difficult to determine from the study how many patients screened positive for psychological distress and improved in their wellbeing as a result of screening. That is, patients were screened simultaneously for multiple problems (e.g. psychological distress, thoughts of suicide, transportation or parking problems, drug coverage, financial problems, pain, fatigue, or weight loss) with referral options to substantially different treatments (coping class, counseling, social worker, medical team, fatigue nurse, nutrition class). It should have been valuable if the authors of the study of Carlson et al. (2010) would have reported which treatment options distressed patients were referred to, a result that was absent in their paper. This information could have
delivered useful insight in the type of problems patients encountered and the impact screening for distress can have on existing psychosocial services (Box 7.2).

**Box 7.2 Uptake of psychosocial services by patients**

Apart from our thesis, there is still limited information available about the amount of cancer patients in need for, and accepting psychosocial services. We recommend that future studies assessing the benefits of screening for distress should incorporate and report in their study the actual need for and uptake of psychosocial services from patients being screened and receiving a referral. This information could then be compared with the use of psychosocial services in the absence of screening, to find out what the potential gains of screening are (6).

### 7.3. Screening for distress as a means to recruit patients for an RCT

In study 2 (Chapter 4), we showed that screening for distress for the recruitment of patients was inefficient, when implemented by clinical staff additional to their daily clinical tasks. Only 36 of the distressed patients (8%) consented to participate in our trial, representing 3.7% of all patients screened (figure 1).

![Figure 1. Distress level and need for psychosocial services of cancer patient screened for distress (n=970) with the HSCL-25 and interviewed by phone.](image-url)

We decided to implement systematic screening in a consecutive sample of patients and to approach all patients with elevated distress for participation. This method is considered to promote equal access to enrollment in trials and lead to a better representation of the patient population and is consistent with national (7) and international clinical guidelines (8). An alternative option for recruitment is the use of a convenience sample, based on clinician- or self-referral, with screening for distress only
after patients have shown interest in participation. A convenience sample is supposed to be relatively easy to recruit, but has been criticized for the risk of selection bias, by overlooking distressed patients who do not come forward to volunteer (9). Nonetheless, we found that distress screening in a consecutive sample of patients also involved selection bias (i.e. younger and higher educated patients were more likely to report a need for services and to participate in the trial). This was also supported by other research (10). On the other hand, two randomized controlled exercise trials for cancer patients found no differences in demographic and medical characteristics between consecutive and self-referred recruitment of patients (11,12). It might be that it is not the type of sample that matters, but just whether the recruited sample is representative of the target population to which the results of the trial have to be translated. It may even be that a convenience sample, emphasizing clinician- or self-referral, may more closely match to what would occur if the intervention is disseminated and implemented as routine care. We can learn from a number of randomized controlled intervention trials that the use of local media, clinical staff and/or cancer support groups can be successful means to recruit a powered sample of patients, either without (13) or with screening these patients after they have shown interest in participation (14,15) (Box 7.3).

Box 7.3 Patient recruitment: consecutive or convenience sampling

The choice for screening a consecutive or a convenience sample for the recruitment of patients should be based on several considerations. First, the availability of sufficient financial as well as personal resources for screening a full sample of patients. With sufficient resources, screening a consecutive sample of patients can be an attainable goal. Second, the amount of time that is available for recruitment; recruiting a convenience sample and screening after patients have shown interest may require less time than recruiting a consecutive sample with screening. Third, the commitment of several clinical staff members (nurses, physicians) to collaborate in the referral of patients to recruit a convenience sample, or to collaborate with screening for distress of a full sample of patients. And last, but not least, the purpose of the study. In general, a convenience sample is considered an attractive option for pilot and feasibility studies, allowing for a brief examination of the feasibility of an intervention or for more pragmatic trials testing the effectiveness of an intervention in the general population, whereas a consecutive sample is seen as a standard for efficacy studies, testing the effects of an intervention in a pre-defined sample of patients.

In line with our study, other researchers also reported that it was a challenge to screen a consecutive sample of patients visiting the hospital, and to achieve telephone interviews with those patients scoring high on the screening questionnaire. Compared to the number of interview completers and cases identified, the effort invested in screening often appears to be high (16). If one decides to follow the strong advocates of
methodological rigor, recommending a consecutive sample, several screening studies show that essential elements to recruit a sufficient number of patients include centralized project management, a person dedicated and trained to implement screening at each site, and commitment of involved staff members (17,18). If financially achievable, it might be helpful to shift to more automated data collection for screening, as research has shown that it reduces the investment of time (17). Once implemented, the use of automated data collection reduces the administrative costs of screening and may improve recruitment rates (19).

7.4. ‘Whether or not implementing routine screening in clinical practice?’

Our findings presented in Chapter 2, 3 and 4 made us critical about the use of routine screening for distress as a means to detect unmet needs in patients and as a means to refer those patients in need to adequate psychosocial services. However, whether or not implementing routine screening for distress in clinical practice is not a simple question that can be answered only based on the findings of this thesis. According to a recent review, a main barrier to the success of screening in many clinical settings is the lack of appropriate aftercare, as the proportion of cancer patients who received psychosocial care after a positive distress score was only 20% to 30% (3). However, it is the question if the main barrier is only a lack of psychosocial services available, or also a low need for services of many distressed patients, as was found in our thesis and other studies (20). Fact is that screening can only be successfully implemented in clinical practice when there is an adequate distress management plan that is supported by clinicians and staff (3).

Regarding the ‘secondary’ gains of screening for distress, other studies have shown that screening improved clinicians’ communication with the patient about psychosocial issues, and patients who were screened for distress accepted nearly 10 times more often a referral to psychosocial services. It also seemed that screening for distress facilitated early referral of patients to psychosocial services (21). In addition to these ‘secondary’ gains, it is also valuable that clinicians and staff who decide to implement screening demonstrate that they are willing to adopt a culture of patient-centered care instead of the more traditional physician/caregiver-centered approach (17). In our opinion, this can be an important side-effect of screening.
Box 7.4 Implementing routine screening for distress

Based on the current literature, we recommend that implementing screening in clinical practice can be a valuable option if:

a) there is evidence of poor detection of patients’ needs and a low referral to resources in the existing practice;

b) there are sufficient clinical resources available to implement the screening program and to adequately support patients with high distress; and

c) screening incorporates multiple domains, addressing perceived problems as well as unmet needs of patients.

In a well-functioning cancer care center where patients already routinely are referred to and access cancer care services, regardless of whether they are distressed, screening may be unnecessary (22). Also, when additional clinical resources are absent, introducing routine screening risks the negative effect of withdrawing resources from existing clinical activities (23).

7.5. Replicating an intervention study: problems to be solved

In study 4 (Chapter 5), we came to our main goal: a replication of the PST intervention trial of Nezu et al. (2003). This replication appeared to be a complex job; not only because the recruitment of patients was difficult, but also because the drop out of patients was high. Due to our small sample size, we were unable to draw conclusions about the effects that PST may have in a larger sample of patients in Dutch oncology settings. We were left with doubts about the feasibility of offering distressed patients with cancer, selected with screening of a consecutive sample, PST after completion of medical treatment. In the discussion section in Chapter 5, we gave a closer look to differences of the study of Nezu et al. with our study and identified a number of factors that may have explained why replicating the Nezu et al. study was problematic. One of the explications could lie in differences between the psychosocial healthcare system and between the general wellbeing in the Netherlands and in the USA. In the Netherlands psychosocial services are relatively easy accessible and to some extent financed by the Dutch healthcare system, which may have been a reason for patients dropping out and one of the main reasons for the low recruitment rate of the present study. Many patients experienced sufficient social support from family and friends, or the availability of professional psychosocial support nearby.

The study of Nezu et al. showed promising results, with patients in the intervention group showing improved quality of life, decreased psychological distress and depressive symptoms, as well as more effective problem-solving ability both short- and long-term. The authors noted that the effect sizes on distress identified in the study were substantially larger than the mean effect sizes that came from an earlier meta-analysis (4), suggesting that PST appeared to be a particularly robust intervention.
However, in the years following the start of our replication study, several meta-analyses came to the conclusion that the study of Nezu et al. reported unrealistically high effect sizes for their primary outcome, approximately 10 times those of other psychosocial interventions (24-26). Two of these meta-analyses, and a recent systematic review, excluded the study as an extreme outlier (4,24,25). In addition, a remarkable finding was that the intervention appeared to be much more effective when one of the PST developers participated in the study (26).

In the following paragraphs, we will discuss the implications of these findings for professionals in clinical practice who are looking for evidence-based interventions for cancer patients.

7.6. ‘Is PST a feasible and effective intervention for cancer patients?’

Although we cannot be conclusive about the feasibility and efficacy of the PST intervention from our replication study, we had the clinical impression that PST was beneficial for cancer patients who experienced mild practical or emotional problems due to the consequences of their illness.

‘I had to get used to the sessions, but afterwards it did work somehow.’

(Men, prostate cancer, after finishing PST)

We also found that only a small number of patients discontinued treatment because of the content of PST. As an example, we present a successful case of PST in box 7.5.

**Box 7.5 Case of PST**

Mrs. T. is 38-year old and diagnosed with breast cancer. One breast was surgically removed and she received chemotherapy and radiotherapy thereafter. For the next years she is prescribed hormone therapy. She has no children and is living alone. She lost her job due to the illness. Mrs. T. completed primary medical treatment before starting the PST sessions. She had no history of depression.

In the first session, mrs. T. mentions the following problems to put on her problem list:

1) she is unable to work in the house and the garden due to her fatigue;
2) she is puzzling about her fatigue and about the possibility of a cancer recurrence;
3) she feels unable to look at her breast and at herself in mirrors because it gives her the feeling of ‘not being the same person anymore’;
4) she sometimes feels alone and ignored by friends;
5) she is now unable to work and worried about finding a new job.

After discussing the problem list, Mrs. T. appears primarily concerned with her appearance, as she lost all her hair and does not feel the same person anymore. In the following sessions, one of her goals is that she wants to learn to care for the scar on her breast and to be able to look at it without being overwhelmed by emotions. Using the 5
steps of the problem-solving model, mrs. T. creates the plan to make some time during the week to care for her amputated breast and to look at herself, and to try to welcome eventual negative feelings with acceptance. In the following session, she mentions that she is content with the outcome of the exercise. She felt that she was able to look at herself and handle her emotions. After exercising with her other goals, mrs. T. recognizes at the termination of treatment that she has more positive feelings, feels more self-confident and that her puzzling decreased.

On the other hand, we experienced that some patients were not adequately supported with 8-10 PST sessions, focusing on their cancer-related problems. A qualitative study of Salander also found that many cancer patients wanted to talk about subjects not or only indirectly related to their cancer experience (2). It seemed as if these patients took the opportunity to deal with problems in life that had not been processed earlier, which were sometimes long-lasting contacts.

In many other randomized controlled trials, PST is found to be an effective intervention to reduce psychological complaints in patients with several diseases and disorders, such as diabetes, obesity, self-harm/suicide and generalized anxiety disorder (see for an overview (27)). Several meta-analyses and systematic reviews (26,28,29) also came to the conclusion that PST is equivalent to other evidence-based treatments and superior to control conditions in reducing depressive symptoms. However, there remains a critical note that more research is needed to determine the conditions and subjects in which these effects are realized (24).

In sum, we cannot be conclusive about the feasibility and efficacy of PST in the Dutch healthcare context and culture, although literature shows that PST may be as effective as other evidence-based treatments. A larger study, with a powered sample of patients screened for distress, and an intervention that is tailored to the individual needs of patients, is needed to evaluate this question.

7.6. Reporting of the recruitment process of psychosocial intervention studies
In study 5 (Chapter 6), we undertook a systematic review examining the recruitment rates and the completeness of reporting of the recruitment process of 97 psychosocial RCTs for cancer patients, including the study of Nezu et al. (2003). In many of the studies reviewed, we found incomplete reporting of the recruitment process and insufficient information about the method of recruitment, e.g. the recruitment strategy, the recruiter, the setting and the type of study sample. We emailed several authors for missing or unclear information about their recruitment process, and found that many did not reply, or replied that they had no longer access to their data. This lack of information makes it difficult for future researchers to gain access to recruitment data from interventions which they are planning to replicate or implement in clinical care.

During the review process, we also found that recruitment information was often described in an ambiguous way, sometimes leading to higher suggested recruitment
rates. Some authors for example reported the number of patients being referred to the study by a physician or who already consented to be screened for study participation as the full sample ‘approached’. Even more questionable, a number of studies reported randomizing 100% of eligible patients. It appeared that some of these studies included patients’ willingness to enroll in their eligibility criteria. An example: “Eligible subjects were cancer patients who (1) were adults (>18 years of age) who were aware of their cancer diagnosis, (2) had cancer-related pain during the 2-week study period, (3) could communicate verbally, and (4) agreed to participate in the study and signed a consent form after receiving a detailed explanation of the study” (30). Yet, when eligible patients declining to participate are defined as ineligible, this leads to a large overestimation of the acceptability of the intervention. To prevent similar bias in recruitment rates in reports of other intervention trials, these findings call for more explicit standards in reporting the recruitment process. Poorly reported recruitment strategies can lead to unlikely assumptions about the acceptability of interventions to patients, as well as unrealistic estimates of subsequent uptake of interventions.

Giving a closer look to the CONSORT checklist of items to be included in the reporting of a randomized clinical trial (31), we found that important items for external validity, such as the target population, counts of the patient recruitment process before randomization and the method of recruitment are not clearly prescribed. This was also noted by others (32) (Box 7.6). The CONSORT checklist also prescribes the use of a flow diagram to clarify the recruitment process. We indeed found an increase in the use of flow diagrams after the introduction of the CONSORT-statement in behavioural medicine (Davidson et al., 2003). However, the reporting of the recruitment process still remained incomplete in many of the papers using a flow diagram to describe their patient selection process. As an example, the first part of a flow diagram of a study of Anderson et al. is depicted below (figure 2)(33). In our opinion, the flow diagram does not give a complete picture of the flow of patients into the study. As being in pain was an inclusion criteria for this study, the flow diagram makes no distinction in the number and percentage of cancer patients reporting having pain or being eligible on other inclusion/exclusion criteria.
Box 7.6 Additions to the CONSORT-statement
We recommend to prescribe the number of patients assessed for eligibility and the method of recruitment as required items in the CONSORT checklist. We recognize that reporting the total number of patients assessed for eligibility may be a challenge for cancer trials with a combination of methods to identify patients, such as pre-screening of patient registries on eligibility criteria, assessing consecutive patients in a clinic combined with referrals of physicians, or making use of flyers. In those cases, a clear description of the recruitment method(s) should give insight in how the investigators calculated their recruitment rate. In addition, we suggest to develop a refined version of the CONSORT flow diagram (see Chapter 6). This flow diagram should provide more guidance for reporting the eligibility and screening criteria of the study which remain absent in the CONSORT version. For studies that select patients based on high physical or psychological complaints, we propose to distinguish between inclusion and screening criteria. This will deliver more insight in the percentage of patients with high complaints for whom the intervention is supposed to be effective. Also, details on the number of patients excluded and their reasons will provide insight in the selection process and, in turn, facilitate evaluation of external validity and clinical relevance.

We recommend that future research should continue evaluating the completeness of reporting of the recruitment process of intervention studies. Ongoing monitoring of this process will maintain attention to this important issue, which will in turn improve the quality of psychosocial intervention research in cancer patients and finally improve the quality of care for these patients.

Figure 2. Flow diagram of Anderson et al. (2006)
7.7 Methodological issues

7.7.1. Strengths

The strengths of our study are that we were able to screen a large sample of cancer patients, we used a multiscenter approach, and gained insight in patients’ willingness to participate and continue participation in psychosocial intervention research, especially in the PST intervention trial.

With the design of this project, we were able to collect screening data from a thousand of cancer patients visiting different treatment settings. In addition, we not only applied a screening questionnaire, but also interviewed almost all patients by phone about their complaints and potential needs (only those with low distress and no need for services were not interviewed). These interviews revealed that patients’ needs were related to a broad scope of physical, emotional and existential concerns.

A value of our multiscenter approach was that it gave us the opportunity to find out how screening for distress was implemented in various ‘real life’ settings and by various care providers. We learned that our screening approach had to be adapted to the health care context of each setting and that it could not be implemented in one uniform way.

A strength of the choice for our screening questionnaire, the Hopkins Symptom-Checklist-25, was that it was freely available, and therefore easy to use for replication studies (34). The HSCL-25 is closely related to the Brief Symptom Inventory-18, which is a widely used screening instrument among cancer patients (9,35). As the BSI-18 is not freely available we decided to use the HSCL-25 instead. We considered the HSCL-25 a more appropriate instrument for research aims than a short (5-20 items) or ultra-short (1-4 items) measure of distress (9). A recent review showed that most screening tools have approximately the same accuracy and that a choice can be based on acceptability or cost-effectiveness (36).

In addition, we were able to conduct a large systematic review into the reporting of the recruitment process of psychosocial intervention RCTs for cancer patients, including thirteen years of research, which delivered valuable insight in which aspect of this reporting need improvement. Another strength was that we contacted several authors by email for additional information on recruitment items that were inexplicable or missing in their paper. Although the response rate to our emails was low (about 20%), the replies of the authors enabled us to complete some of the incomplete flow charts of the studies included in our review.

7.7.2. Limitations

Our screening questionnaire was provided at two time-points to patients; directly after they completed medical treatment and two months later. Instead of only providing support to those patients with high distress at both time-points, we also offered the intervention to patients with high distress at only one of these measurements. It appeared ethically difficult to let patients with high distress wait for psychosocial
services for two months when they just expressed a need for it. A drawback of this approach was that it may have led to the inclusion of some patients who could have recovered from their distress by themselves after a few weeks. This appeared to occur in some patients in the waiting list control condition. However, including only those patients with high distress at two time-points would have reduced the number of eligible and participating patients even more.

‘I think that, almost four months after diagnosis, the psychological support is not necessary anymore. I am in peace now with the things that were happening then’.

(Women, breast cancer, drop-out from the waiting-list group)

In addition, we used a rather simple means to measure need for psychosocial services, instead of a validated questionnaire, such as for example the Supportive Care Needs Survey (SCNS), which is widely used in cancer patients (37). Phone calls to patients indicating a need on the screening questionnaire revealed that their need for services sometimes differed from what they indicated on the questionnaire. This shows that interviewing patients about their needs, instead of using a simple, or even a validated questionnaire, could be a better option to gain insight in patients’ actual need for psychosocial services.

At one setting, it appeared too complex to implement the screening with their recently implemented touch screen technology. After several months, we decided to give up collaboration. This decision unfortunately reduced the amount of patients that could have been screened when we could have been able to continue collaboration.

Due to the small sample size of the PST trial, we were unable to draw conclusions about the efficacy of PST and the mechanisms of change of the intervention, which was the original aim of our study. Instead, it offered us the opportunity to write down the many difficulties that we encountered in our project in order to support other researchers planning to conduct a similar trial.

7.8 General conclusions

It is of great value to pay attention to not only the medical, but also to the emotional wellbeing of patients after cancer treatment. Also, it is necessary to develop and monitor scientific designs for psychosocial screening and intervention studies to evaluate the effectiveness of such interventions according to scientific standards. The papers in this thesis show that it is of great importance to remain critical and creative on the road to the development and execution of such studies, as many of our results raised questions about the state of the art concerning screening and the RCT-design as ‘gold standard’ in psychosocial intervention research. We acknowledge that the discussion of ‘whether or not screening for distress’ for both scientific reasons and clinical practice has not come to an end with this thesis, and recommend that it will be continued in future research
and practice. We hope that the current thesis increases insight in the possibilities and pitfalls in the development and execution of psychosocial intervention studies, and that researchers feel supported in the difficult task to recruit a sufficiently powered sample of patients, retain them in the study, and evaluate and report the intervention process in a way that others get insight in all the steps that are taken to finally improve the quality of psycho-oncological care.
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