Is implementing screening for distress an efficient means to recruit patients to a psychological intervention trial?

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Abstract

Objectives: Psychological interventions show greater efficacy when evaluated with distressed patients. We report on the feasibility of implementing screening for recruiting distressed cancer patients to a randomized controlled trial of problem-solving therapy (PST), characteristics associated with enrolment, and time investment and challenges of implementing screening.

Methods: Three medical settings implemented screening of patients, directly after cancer treatment (T1) and 2 months later (T2), using Hopkins Symptom Checklist-25 and one question about need for services. Distressed patients indicating need for services were interviewed. Eligible patients were offered the possibility to participate in the trial. Consenting patients were randomized to PST or waitlist.

Results: At T1, 366 of 970 screened patients (37%) scored above the cutoff and at T2, 208 of 689 screened patients (30%). At either or both T1 and T2, 423 patients reported distress, of whom 215 indicated need for services. Only 36 (4% of 970) patients consented to trial participation. Twenty-seven patients needed to be screened to recruit a single patient, with 17 h required for each patient recruited. Barriers to screening were time constraints and negative attitudes of oncology staff towards screening.

Conclusions: Implementing screening proved inefficient for recruiting distressed cancer patients post-treatment to a randomized controlled trial on PST, with need for services being much less than anticipated. Consecutively screening patients did not result in a sample representative of the larger pool of distressed patients, which may lower generalizability. An adequately powered intervention trial using screening requires a feasibility study establishing recruitment rates and dedicated, funded staff assistance.

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Introduction

Several meta-analyses and reviews concluded that there is still only weak evidence for the efficacy of psychological interventions to reduce distress among cancer patients [1–3]. Sheard and Maguire were among the first to comment that this could be due to most randomized controlled trials (RCTs) in psycho-oncology failing to select patients with significant distress [1]. Recent reviews and meta-analyses came to the same conclusion [4–6]. Psychological intervention RCTs that do not select distressed patients risk an underestimation of possible effects (floor effect). Interventions with significant distress as an inclusion criterion tend to show much stronger effects [7,8].

Investigators can choose several strategies to recruit distressed patients. One option is a convenience sample, based on physician or patient referrals, with screening for distress after referral. A convenience sample is 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]. An alternative is implementing systematic screening in a consecutive

sample of patients and to approach all patients with elevated distress for participation. This is considered to promote equal access to enrolment in trials and lead to a better representation of the patient population. This option is also consistent with national [10] and international clinical guidelines [11] recommending routine screening for distress in all patients and referral of distressed patients to services. However, if the resulting sample is biased by low recruitment, the sample may still be less representative, resulting in lower generalizability of findings [12].

Currently, still few psychological intervention RCTs screened cancer patients for distress as part of recruitment [4,7,13]. Yet, large-scale screening studies demonstrated that it is possible to have a considerable proportion of patients to complete screening [14–16]. Carlson *et al.* showed that, when using a dedicated screening team, 89% of patients consented to participate in screening [16]. However, it remains unclear how screening can be implemented in busy clinical settings that rely on regular staff. Second, there is little information about whether patients reporting elevated distress want services [14,17]. In distressed cancer patients post-

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treatment, Tuinman *et al.* found that only 14% *definitely* and an additional 29% *maybe* wanted to talk with a professional about their problems [18]. Thorsen *et al.* found that only 17% of those in need for psychological services had an unmet need [19].

Guided by current recommendations and clinical guidelines [4,5,11], we decided to recruit distressed cancer patients for an RCT of an 8- to 10-week problem-solving therapy (PST) intervention. It was our aim to replicate the study of Nezu et al. [8], which demonstrated strong effects of individual PST compared with waitlist control in a Dutch context. In general, several reviews and meta-analyses found that PST is a feasible and effective intervention for reducing psychological symptoms [20-23]. Whereas Nezu et al. [8] recruited a convenience sample during medical treatment, we screened a consecutive sample after ending treatment. We focus on this period, as research found that a considerable proportion of distress manifested early in the course of cancer treatment resolves within a few months [24–26]. The transition from active treatment to survivorship can itself be distressing, as patients may be confronted with long-term symptoms including persistent fatigue and fear of recurrence and decreased social support [27]. We hypothesized that PST could provide patients new coping strategies for dealing with these stressors and therefore reduce distress.

Yet, we encountered substantial challenges in implementing screening and recruitment, and we believe that our experience contains important lessons for others who might attempt such a study on the basis of current recommendations. In a forthcoming review, we conclude that many trials including screening for recruitment lack information about recruitment method and numbers of patients approached for screening, considered eligible, and randomized. Previously, we also reported preliminary findings from one third of the current screening data on the predictive value of distress level for need for services [28]. We had intended that the current paper would report results of a completed, adequately powered trial of PST. Instead, in the current paper, aside from being able to report on the full sample of 970 screened patients, we focus on recruitment rates and patients' characteristics associated with acceptance of enrolment in the trial. We also describe the time investment and difficulties posed by implementing screening for distress as recruitment method in settings where it was previously not established as routine clinical care.

Methods

Participants and procedure

Patient recruitment started December 2008 and ended May 2011. Four medical centers consented to participate and to newly implement screening for recruiting patients for the trial. One center was excluded, as we encountered

a large delay of 1.5 years in the use of their promised screening by touch screens. Participating sites were the following: University Medical Center Groningen, Martini Hospital, and Radiotherapy Institute Friesland. The study was approved by the Medical Ethical Committees of the hospitals.

Participating oncology nurses and radiation oncologists attended a 2-h presentation from the primary investigator (PI) to learn about the study and screening procedure. The main six persons responsible for screening at each participating site received weekly visits (main participating site) or monthly phone calls (other two centers) from the PI to monitor the screening process.

Patients were screened for distress immediately after completion of medical treatment (T1) and 2 months later (T2). Patients were screened twice in order to capture possible changes in their levels of distress and need for services. Patients were eligible for screening if they (i) had a curative cancer diagnosis, (ii) were ≥ 18 years old, and (iii) had recently completed medical treatment. Patients were eligible for the intervention study if they reported Hopkins Symptom Checklist-25 (HSCL-25) \geq 39 and need for services. Patients with severe psychiatric comorbidity, cognitive problems, insufficient ability to speak Dutch, or already receiving psychosocial services by a psychologist or psychiatrist were excluded.

At T1, a cancer nurse or radiation oncologist selected eligible patients for screening and handed out the screening questionnaire and an accompanying information letter. Patients were asked to return the questionnaire by post with their contact details to the PI. At T2, the questionnaire was sent to the patients by post or email, as patients preferred. In the letter, patients were informed that, within 1 week, they could receive a letter or a telephone interview to discuss their needs. Patients who did not want to be contacted could indicate this. At this stage, patients were not yet informed about the intervention trial. The study consent form, which entailed detailed information about the randomization procedure and the problem-solving intervention, was only provided to patients with elevated distress scores who indicated during the telephone interview that they were willing to participate in the study.

For ethical reasons, we called patients with low distress indicating a need for services and patients with elevated distress with or without a need for services at T1 and T2. Patients with low distress and no need for services received a letter. Interviews were held by the PI and a research assistant, both experienced in working with cancer patients. During the interviews, patients' psychological complaints and need for psychosocial services were explored, and eligibility was checked. Eligible distressed patients with an unmet need for services were informed about the RCT (i.e., that they could participate in a study and receive 8–10 individual sessions with a psychologist in the medical center). Patients were not informed about the

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content of PST. Those willing to participate were sent an informed consent form, baseline questionnaire, and preaddressed envelope. After consent, patients were randomized to PST or waiting list control (receiving PST after 10 weeks of waiting).

Sample size

We aimed to include at least 50 patients per group. With 50 patients per group, a power of 80%, and an alpha of 0.05 (tested one-sided), we would be able to detect an effect size of 0.6 according to Cohen (1992), which would be lower than the effects claimed by Nezu *et al.* [8]. Given possible dropout and non-response, a sample of 60 patients in each group (120 in total) was planned. We expected 30% of patients being distressed [29] and 25% of distressed patients willing to participate in our study [30]. We planned to approach 480 distressed patients, for which we would need to screen 1600 patients.

Problem-solving therapy

Our intervention was based on the PST book *Helping Cancer patients Cope* [31]. We developed a manualized treatment protocol, including session-by-session descriptions and homework assignments, and a patient workbook. At all sites, PST was provided during 8–10 weekly individual sessions of 45–60 min. After the first introductory session, each session was devoted to a specific problem-solving dimension (i.e., problem orientation, problem definition, generation of alternatives, decision making, and solution implementation).

Measures

Psychological distress was measured with the HSCL-25 [32]. It includes the anxiety and depressive subscales of the HSCL-58, developed by Derogatis *et al.* [33,34]. Test–retest reliability of the Brief Symptom Inventory 18, very closely related to HSCL-25, is moderate to good [35,36]. Instructions ask about symptoms in the previous week, on a scale from 1 (never) to 4 (always). A higher score indicates greater distress. Internal consistency for this study was excellent (Cronbach's alpha = 0.92). Separate studies have indicated scores of either \geq 39 or \geq 44 as optimal cutpoint for 'cases' [37,38]. Our study adopted the lower cutpoint \geq 39 to include also moderately distressed patients.

Need for services was measured with one question: 'Would you like to talk to a care provider about your situation?' answered with 'Yes', 'Maybe', or 'No'. We combined the answers Yes and Maybe, versus No.

In the questionnaire, we collected information regarding age, gender, marital status, education (with low referring to elementary school and lower levels of high school education and high referring to college/university), type of cancer diagnosis, and medical treatment.

In order to estimate time investment in screening, we made a list of all screening activities performed and then estimated the number of patients for each activity (based on numbers of patients approached, completing questionnaires, and their screening outcomes). During 1 week, we recorded the time needed for the different screening activities, and on the basis of these recordings, we calculated the total time.

Information on the problems in implementing screening was collected in the weekly visits or monthly phone calls, by interviewing the six persons responsible for screening about their experiences with screening implementation and problems encountered.

Data analysis

Standard descriptive statistics were generated to characterize the demographic and clinical variables. We used t-tests, chi-square analyses, and analyses of variance to examine patients' characteristics associated with elevated distress, need for services, and participation. As we found no significant differences in demographic and clinical variables between patients who were highly distressed on T1, T2, or both time-points, we combined these groups into one group (n = 423) for our analyses.

Results

Flow chart and patient characteristics

A total of 970 patients completed T1 and 689 patients completed T2 (Figure 1). At T1, 366 (38%) of 970 patients reported high distress, and 169 (46%) of these 366 distressed patients indicated a need for services. At T2, 208 (30%) of 689 patients reported high distress, and 99 (48%) of these 208 distressed patients indicated a need for services. On T1 and/or T2, 423 patients reported distress, of whom 215 patients reported a need for services (Table 1).

Efficiency of screening

During the interview, 41% (n=87) of 215 distressed patients with a need for services indicated that they had no need for psychosocial services, mainly because they felt better or thought that their problems would disappear naturally (Table 2). Another 17% (n=36) mentioned that they already received psychosocial services. 35% (n=74) reported an unmet need for psychosocial services. Of those 74 patients, 27 declined participation because they preferred a different type of services, nearer home, or less time consuming. Another seven patients were ineligible. Finally, 36 patients were eligible and willing to be randomized, representing 17% of 215 distressed patients with a need for services, 8% of all 423 distressed patients, and 4% of 970 screened patients.

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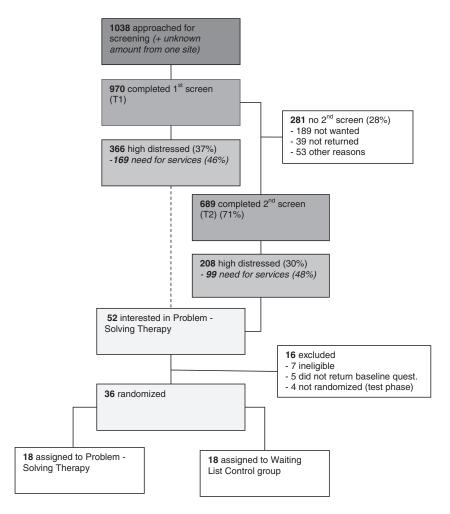


Figure 1. Flow diagram

Patient characteristics in relation to distress, need for services, and trial participation

Elevated distress was associated with being younger (t(956) = 5.8, p < 0.001), female $(\chi^2 = 21.3, p < 0.001)$, a diagnosis of breast cancer ($\chi^2 = 50.8$, p < 0.001), and type of treatment ($\chi^2 = 34.6$, p < 0.001) (Table 1). Among patients with high distress, need for services was associated with being younger (t(411) = 2.3, p < 0.05), more educated $(\chi^2 = 20.3, p < 0.001)$, and type of treatment $(\chi^2 = 14.5, p < 0.001)$ p < 0.05). Among the group of distressed patients with a need for services (n=215), those who were randomized and participated the trial (n=36) were significantly more educated than those not participating in the trial (n = 179) $(\chi^2 = 11.6, p < 0.01)$. Additional comparisons (not in the table) showed that patients randomized and participating in the trial (n=36) were younger than the other distressed patients (n = 423 - 36) (t(48) = 2.4, p < 0.05) and the rest of all screened patients (n = 970 - 36) (t(40.0) = 4.0, p < 0.001). Patients randomized and participating in the trial (n=36)were also more educated than the other distressed patients (n=423-36) $(\chi^2=20.6, p<0.001)$ and the rest of all screened patients (n = 970 - 36) $(\chi^2 = 16.5, p < 0.001)$.

Administrative time investment in screening

Table 3 shows the estimated amount of time invested in screening. A total of 601 h was invested to recruit 36 patients. Expressed differently, 17 h was needed to recruit one patient. The additional time investment of the distribution of the screening questionnaires by nurses and oncologists was not recorded. When also taking this into account, the time investment would have been considerably higher.

Challenges of implementing screening

In the main participating hospital, the number of questionnaires handed out and returned was recorded, showing a response rate of 87% (803 of 925). Yet, on the basis of estimates of number of patients yearly visiting the radiotherapy department at this hospital, we calculated that only 27% of patients fulfilling our eligibility criteria were approached for screening.

Interviews with the persons responsible for screening revealed several problems. At all sites, oncology nurses and radiation oncologists experienced significant time

Table 1. Patient characteristics for different subgroups of patients

Variable	Total (n = 970)	Total (n = 970)		Distress (n = 423)		Need for services (n = 215)	
		No Distress (n = 547)	Distress (n = 423)	No need for services $(n = 207)^{a}$	Need for services (n = 215)	No PST (n = 179)	PST (n=36)
Age, mean (SD)	61.6 (11.7)	63.5*** (11.4)	59.1*** (11.6)	60.5* (11.6)	57.8* (11.5)	58.2 (11.9)	55.7 (8.8)
Gender (%)							
Men	43.2	49.7**	34.8**	30.4	39.2	39.9	36.1
Women	56.8	50.3	65.2	69.6	60.8	60.1	63.9
Marital status (%)							
Partner	83.6	84.4	82.6	83.8	81.8	81.6	82.9
No partner	16.4	15.6	17.4	16.2	18.2	18.4	17.1
Educational level (%)							
Low	40.4	39.5	41.6	52.2***	31.1***	33.9**	17.1**
Average	37.5	37.I	38.0	33.2	42.9	44.6	34.3
High	22.1	23.4	20.3	14.6	25.9	21.5	48.6
Cancer diagnosis (%)							
Breast	37.0	33.6***	41.3***	39.4	42.8	40.8	52.8
Prostate	21.4	29.2	11.5	10.8	12.1	11.2	16.7
Gastrointestinal	14.4	14.4	14.3	14.3	14.4	14.0	16.7
Lung	8.1	5.4	11.5	12.3	10.7	12.3	2.8
Other	19.2	17.4	21.5	23.2	20.0	21.8	11.1
Type of treatment (%)						
RT	15.1	18.5***	10.2***	14.6*	6.1*	5.6	8.6
S + RT	25.6	27.7	23.3	19.5	27.1	24.0	42.9
S + RT + HT	7.9	8.4	7.1	8.3	6.1	6.7	2.9
S+CT	7.4	7.9	6.9	8.8	5.1	5.0	5.7
S + RT + CT	11.9	10.6	13.6	13.2	14.0	15.6	5.7
S + RT + CT + HT	7.7	4.4	11.9	9.8	14.0	14.5	11.4
Other	24.4	22.4	26.9	25.9	27.6	28.5	22.9

 $PST,\ problem-solving\ therapy;\ S,\ surgery;\ RT,\ radiotherapy;\ CT,\ chemotherapy;\ HT,\ hormone\ therapy.$

Table 2. Reasons of the 215 distressed patients with need for services to (not) participate in the randomized clinical trial

Need for services	n (%)	Main reasons	
Unmet need	36 (17%)	Wanted to participate in the intervention study (eligible)	
	7 (3%)	Wanted to participate in the intervention study (ineligible)	
	4 (2%)	Not randomized (test phase of the protocol)	
	27 (13%)	Desired other services than our intervention or services nearer home	
Met need	36 (17%)	Already received services from a psychologist, psychiatrist, or social worker	
No need	48 (22%)	Already feeling better or thought that problems would disappear naturall	
	19 (9%)	Sufficient social support from family and friends	
	20 (10%)	Maybe wanted services later in time	
Other reasons	13 (6%) 5 (2%)	Unreachable by phone Died/palliative care	

Table 3. Administrative time investment in screening

			Duration	Total
Activity		Amount	(min)	time (h)
Paperwork	Assembling screening questionnaires	2076	2	69
Coordination	Weekly visits to the main participating site	130	15	33
	Visits to other three sites	12	60	12
	Monthly phone calls to participating sites	90	15	23
Data management	Calculating scores and storing data	1659	5	138
Phone calls	Reminders to patients not returning the questionnaire	376	5	31
	Distressed patients (with or without need for services)	574	10 (5–15)	96
	Patients with low distress and a need for services	145	10 (5–15)	24
Letters	Patients with low distress and no need for services	927	5	77
Selection	Intake interviews	47	90	71
	Referrals to alternative psychosocial services	27	60	27
Total time				601

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^aOne value is missing.

^{*}p < 0.05. **p < 0.01.

^{***}p < 0.01. ****p < 0.001.

constraints when attempting to distribute the questionnaire in addition to their clinical tasks. In addition, at one site, the clinical staff implemented another research questionnaire during the study period, leading to mix-up of questionnaires and patients objecting to filling out multiple questionnaires. At another site, only a few oncologists were willing to adopt the systematic distribution of the screening questionnaire.

Discussion

The current literature strongly advocates to select patients with significant distress for a psychological intervention RCT, if a significant effect is to be obtained. However, our results indicate that implementing distress screening in a consecutive sample of cancer patients post-treatment did not prove an efficient means for recruiting patients in an RCT on PST. Although percentages of patients with elevated distress (30-40%) were comparable with what has been observed by others [29,39,40], only half of the distressed patients indicated a need for services. When this need was further explored, 41% of the distressed patients said that they had no need for psychosocial services, another 17% already received adequate psychosocial services, and 13% preferred other services. Only about half of the patients expressing an unmet need for psychological services were eligible and interested in trial participation. Consecutively screening patients did not result in a patient sample representative of the larger pool of distressed patients, and there was a tendency for younger and more educated patients to accept participation. Investment of time in screening was considerable, and several challenges in implementing screening were encountered.

A key finding is that only 17% of cancer patients reporting elevated distress and a need for services on a self-report screening questionnaire accepted participation and were randomized in our psychological intervention trial. To have reached a sufficiently powered sample, we should have needed to screen 3240 patients. Our results are consistent with an RCT in depressed cancer patients, screening more than 8000 patients for depression and finally recruiting 200 of them for the depression management program [41]. Difficulties with recruiting patients are found not only in psychological interventions but also in clinical cancer trials. Two meta-analyses reported on barriers for patients to participate in clinical trials, including preference for treatment and dislike of randomization, distance to the trial site, and a negative physicians' attitude towards the trial [42,43]. Our results add to the literature by showing that the main reason for the low efficiency of psychological screening for recruitment is that the majority of distressed patients indicated no need for services, with an additional group already receiving services or preferring other services. As patients being screened for distress were not yet informed about the

RCT and the content of the intervention (i.e., PST), the low need for services in distressed patients could be explained neither by no interest in participating in a trial nor by little interest in the PST approach. So far, few studies have examined these issues [19,44,45]. A screening study found that less than 30% of cancer patients post-treatment report a need for psychological services [19], with slightly higher percentages (43%) found in distressed cancer patients [18]. We also found that initially about half of distressed patients reported a need for services on the questionnaire. However, only a part of these patients appeared to have an unmet need and were willing to participate in the trial. These data stand in contrast to the yield in referrals and the initiation of treatment, anticipated by clinical guidelines recommending screening and treatment of all distressed patients [11], and highlight the need for better empirical documentation of the basis for these recommendations.

Given that 17% of distressed patients were already receiving services, it can be argued that screening during active treatment may have identified more distressed patients not yet receiving services. There is little literature concerning patients' need for psychological services throughout the illness trajectory. In patients receiving chemotherapy, 36% of patients reporting elevated distress indicated that they wanted help for psychological concerns, particularly from their nurse or family and friends, with much lower preference for psychological support [45]. These findings may suggest a preference for informal support, rather than formal psychological intervention, and not suggest that patients have a greater need and would be more willing to participate in a psychological intervention trial when receiving treatment. Our results call for more research on clarifying distressed patients' preferences and reasons for not accepting psychological interventions and how to effectively identify distressed patients with an unmet need for services.

Although a high percentage of patients approached for screening completed the questionnaire, in line with other studies [14–16], a considerable proportion of potentially eligible patients were not approached for screening. For our study, successful implementation of screening was critical for recruitment; it would have enabled us to have reached a sufficiently powered and possibly more representative sample of distressed patients. Our interview data suggest that the main barriers were time constraints and care professionals' negative attitudes regarding screening. We can learn from other studies evaluating screening that essential elements for success include centralized project management, a person dedicated and trained to implement screening at each site, and commitment of involved clinicians [46,47]. In addition, as our data management took up about 25% of the time for administrating screening, a shift to more automated data collection might reduce the investment of time [46]. Clark et al. reported that,

once implemented, the use of touch screens reduced the administrative costs of screening and improved recruit-

Low recruitment rates into RCTs not only limit power to detect meaningful treatment effects but may also threaten external validity. We found that younger and more highly educated patients were more likely to report a need for services and to participate in the trial. Thus, distress screening in a consecutive sample of patients for recruitment in an RCT may still involve selection bias, which may lower generalizability of findings. Given the small number of studies that screened a consecutive sample for recruitment as well as the poor quality of reporting on the recruitment process, still little is known about the extent to which results from consecutive samples are more representative than those of convenience samples, as assumed. The critical issue may not be whether a consecutive sample is approached, but whether the recruited sample is sufficiently large to be representative. It may be that other recruitment methods, emphasizing self-referral or staff referral, might more closely match to what would occur if the intervention were disseminated and implemented as routine care. Regardless, future trials need to be more transparent in reporting numbers of patients approached, eligible, interested, and consenting to participation in the trial. Such information may provide better insight into the likely uptake of psychological interventions by certain subgroups of cancer patients.

Limitations

Some limitations should be taken into account. First, we assessed need for services with one item, hereby not

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specifically referring to psychosocial services. Although it is common to assess such a general need for services or willingness to talk to a care provider, our assessment of need may be too broad and partly explain why some patients reporting a need for services indicated no need for psychosocial services. Second, findings regarding differences in characteristics between the 36 randomized patients and other subgroups of patients should be seen as preliminary, given the small number of randomized patients.

Conclusions

Implementing screening for distress in busy clinical practice without additional resources appeared an inefficient means to recruit cancer patients post-treatment into a psychological intervention trial. The use of screening for the realization of an adequately powered intervention trial will often require a multicenter approach and dedicated and funded staff assistance at each site. Using computerized data collection may prove to be a promising method for increasing the efficiency of screening. This could enable the screening of a large number of patients to detect those with elevated distress and an unmet need for psychosocial services, which is needed given that most distressed patients are not interested in these services or already receive services.

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