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Title: Supporting patients and carers affected by pancreatic cancer: a feasibility study of a counselling intervention

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VL Beesley, J Turner, RJ Chan, P Yates, LG Gordon, M Burge, MA Eastgate, DK Wyld and RE Neale conceived and designed the study; S Northfield and H Beebe delivered the intervention and curated data. AA Staneva conducted the interviews. V Beesley conducted the analyses and wrote the manuscript; all authors contributed to the data interpretation, reviewed the manuscript critically for important intellectual content and approved the final version.

Abstract

Purpose: Patients with pancreatic cancer have extremely high unmet psychological and physical needs. Family carers of these patients have even higher levels of distress than patients. Our purpose was to assess the feasibility and acceptability of a counselling intervention in patients diagnosed with pancreatic cancer and their carers.

Methods: We conducted a single-arm feasibily study of the PREPARES (Patients and RElatives affected by PAncreatic cancer: Referral, Education and Support) pilot intervention. Patient and carer participants received up to nine counselling sessions delivered by a trained nurse via telephone and/or telehealth technology. The intervention, informed by self-efficacy theory, involved components to assess and address care needs, and provide feedback to clinicians. Feasibility was measured using participation and retention rates. Participants completed semi-structured interviews at the end of the intervention about acceptability. These were analysed using thematic analysis.

Results: Twelve people participated: five patients and seven carers (38% and 50% participation rates respectively). Most participants (eight) completed all nine counselling sessions; two chose to receive fewer sessions and two were discontinued requiring more intensive psychiatric support. The intervention was highly acceptable. Participants unanimously preferred the telephone over video-conferencing and to receive counselling separately from their carer/patient. The main perceived benefits were emotional support, the nurse-counsellors' knowledge, care coordination and personalised care. Suggested improvements included a welcome pack about their nurse-counsellor and that sessions should continue beyond nine sessions if required.

Conclusions: The PREPARES intervention was feasible and highly acceptable. This low-cost intervention provided much-needed support to people affected by this devastating disease.

Key words: carers; feasibility study; pancreatic cancer; patients; supportive care intervention

Introduction

Pancreatic cancer has the worst survival statistics of any cancer, with 50% of deaths occurring within five months of diagnosis (Burmeister et al., 2015). Each year approximately 3,100 Australians are diagnosed with pancreatic cancer and 2,800 die (Australian Institute of Health and Welfare, 2017). The only curative treatment is surgical resection of the tumour, which improves five-year survival from less than five percent to over 20%, but for most patients (~85%) this is not possible due to locally advanced disease, metastases or comorbidities (Burmeister et al., 2015). The survival benefit of chemotherapy is increasing but remains modest, particularly in the metastatic setting, so a focus on optimal supportive care and quality of life is imperative.

Patients with pancreatic cancer are burdened with debilitating symptoms, including severe pain, diabetes, jaundice, fatigue, nausea and psychological distress (Gooden and White, 2013). In our previous study we found that among Australians with pancreatic cancer, 28% had anxiety, 31% had depression, and 32% had inadequately controlled pain (Beesley et al., 2016; Janda et al., 2017). The prevalence of pain (Lahoud et al., 2016) and distress (Hartung et al., 2017) was considerably higher in pancreatic cancer patients than in people with other cancer types. We also found that 70-75% of people with pancreatic cancer reported moderate-to-high unmet supportive care needs and that the proportion of patients with these unmet needs remained high over time (Beesley et al., 2016).

Our previous work also showed that carers were twice as likely to experience anxiety as the patients they cared for (53% vs 28%) (Janda et al., 2017) and they had frequent unmet needs for information about physical symptoms, having opportunities to discuss their concerns with health professionals, and addressing fears about the person with cancer (unpublished data).

While there has been debate over the effectiveness of psycho-oncologic interventions for distress

(Hersch et al., 2009), the most recent meta-analysis found that statistically significant small-to-medium effects were observed for individual and group psychotherapy and psychoeducation in patients (Faller et al., 2013). The key feature that determined the success of these interventions was delivery by experienced nurses or clinical psychologists, either in person or by telephone (Regan et al., 2012), and a duration of at least 2 months (Faller et al., 2013). However, the effects of such interventions in people with pancreatic cancer remain unknown. Evidence in carer populations is limited (Faller et al., 2013).

There is a clear need for a supportive care service to support patients and carers who are affected by pancreatic cancer. It is important that it is accessible to all families, irrespective of remoteness of location or mobility, and therefore telehealth (telephone and video-conferencing) is an attractive option (Dilworth et al., 2014). In this population in particular, high disease burden may limit capacity to attend face-to-face interventions. We therefore aimed to conduct a pilot study of feasibility and acceptability of a telehealth supportive care intervention. This will inform the later development of a large-scale appropriately powered randomised effectiveness trial.

The theoretical framework for the pilot intervention was based on promotion of self-efficacy. Self-efficacy refers to the person's belief in their ability to succeed at tasks and their willingness to persist despite challenges (Bandura, 1977). In the area of cancer and palliative care, self-efficacy theory has been applied in symptom management for patients and for caregivers providing assistance (Given et al., 2006; Kurtz et al., 2005). Further, self-efficacy strategies, including personal mastery, vicarious experiences, verbal persuasion, and physiologic feedback, have also been applied in psychosocial interventions to help cancer patients and caregivers foster perceptions of their capacity to cope with unpredictable and stressful situations (Lee et al., 2016; Leow et al., 2015; Merluzzi et al., 2019). This framework aligns clearly with the sense of helplessness patients experience when faced with this diagnosis which is associated with poor prognosis and high disease burden.

Methods

Study design and participants

We undertook a single-arm feasibility study of an intervention that included counselling and referral for patients at a tertiary cancer centre at the Royal Brisbane and Women's Hospital (RBWH, Brisbane, Queensland, Australia) and their carers. We aimed to assess: (i) the feasibility of the intervention (i.e. recruitment, eligibility, retention, adherence) using quantitative methods; and (ii) acceptability (i.e. recipient satisfaction) using qualitative methods. Human Research Ethics Committees of the RBWH (HREC/17/QRBW/422) and QIMR Berghofer Medical Research Institute (P2354) approved the study. To be eligible, patients had to have curative or locally advanced pancreatic cancer, or to have been diagnosed with metastatic pancreatic cancer less than three months prior to enrolling in the study. Carers were eligible if the patient they cared for met these criteria, and could be included even if the patient did not participate. There is no set sample size for feasibility studies (Polit and Beck, 2017; Thabane et al., 2010), but some authors have suggested approximately twelve participants is appropriate (Julious, 2005). Enrolment began in December 2017 and continued until August 2018 when twelve participants were recruited.

Recruitment

A member of the treating or clinical trials team at the RBWH provided eligible patients and their carers with a brief flyer about what the study would involve and asked for permission to release their details to the research nurse at QIMR Berghofer Medical Research Institute. The research nurse then telephoned the patient/carer to explain the study and confirm if either or both the patient and carer were interested in participating. The research nurse then mailed detailed information, a consent form, and a questionnaire to potential participants (patients and/or carers). When these were returned, a nurse-counsellor contacted the participant to initiate the counselling sessions.

The PREPARES (Patients and RElatives affected by PAncreatic cancer: Referral, Education and Support) intervention

Participants were offered up to nine sessions of counselling by telephone or video conference once per week for four weeks then fortnightly thereafter. Patients and carers who were both participating were able to receive their counselling separately or together.

The intervention was delivered by three oncology nurses (each with at least eight years of clinical experience in cancer care) who had undergone intensive specific training including completion of a self-directed 14 module training manual and two half-day education and role-play sessions with a consultant psychiatrist with expertise in psycho-oncology (JT). Nurses were trained to promote self-efficacy in the intervention by: (i) helping the patient and/or carer to define realistic achievable goals; (ii) giving explicit direct encouragement about the person's ability to achieve tasks; and (iii) giving insights into the success of others in similar circumstances. Allocation of participants to nurse-counsellors was random (subject to their availability and caseload). For consistency of care participants had the same nurse-counsellor throughout the intervention. During each session in the intervention nurse-counsellors assessed patient/carer distress and needs (using the distress thermometer (DT) and standard 39 item problem checklist (Donovan et al., 2014) plus 4 additional pancreatic-specific items: smelly greasy stools, vomiting, stomach cramping, muscle waste) and pain severity in patients using a 0-10 numeric analogue scale. The nurse-counsellors engaged in discussion with participants about how to address these specific patient/carer-nominated symptoms and needs with a focus on setting achievable and realistic goals. Progress in achieving specified goals was re-evaluated at each session. Details of the sessions and counselling components able to be delivered are provided in Figure 1. The counselling components were either specific to pancreatic cancer (such as education about management of pancreatic exocrine insufficiency) or known to be of high importance to this population (such as psychoeducation about the psychological impact of cancer, end-of-life decision-making and care planning). Nurse-counsellors provided feedback or referrals to other clinicians when their interactions with the participant suggested further expertise, intervention or support was warranted. After each session nurse-counsellors sent a brief email summary to participants of what was discussed. After the third session a care plan was sent to the participant and, with permission, their nominated clinician/s. The care plans detailed, for the patient, their diagnosis and treatment summary, and for all the participants, their clinician(s) contact details, priority issues, goals and strategies, recommended referrals and follow-up actions. The care plan was updated and resent at the end of the intervention. Nurse-counsellors were invited to participate in supervision and discuss cases with the lead investigator (VB) and/or psychiatrist investigator (JT) as necessary. All three nurse-counsellors maintained approximately fortnightly contact with VB. In addition, nurse counsellors had detailed discussion with JT on five occasions in relation to three participants with particularly difficult circumstances.

Questionnaire measures

To determine if participants would adhere to completing the outcome measures of the future randomised effectiveness trial, we asked them to complete questionnaires at baseline (enrolment), after the fourth and final counselling sessions, and then two months later. The questionnaires measured demographic characteristics (baseline only), and used validated tools to measure anxiety and depression (HADS) (Zigmond and Snaith, 1983), quality of life (EQ-5D-5L) (Janssen et al., 2013), supportive care needs for patients (SCNS-SF34) (Boyes et al., 2009) and carers (SCNS-P&C) (Girgis et al., 2011), and physical symptoms for patients only (ESAS) (Bruera et al., 1991).

Qualitative interviews

After completion of the intervention participants were invited to complete a telephone interview with an experienced qualitative interviewer, qualified in clinical psychology, who had no other involvement with the study. All participants except one patient who was very unwell completed the interview. The interviewer also interviewed the nurse-counsellors. The interviews were semi-structured to focus on the participants' and nurse-counsellors' experience of the intervention, including questions about how they found the mode and timing of the intervention delivery, the types of components and materials, helpful and unhelpful aspects of the intervention, and anything they would like to have changed (Figure 2). Participants were also asked about their experience of their nurse-counsellor, and nurse-counsellors were asked about any differences in delivery across carers and patients and aspects that were specific to pancreatic cancer versus generally applicable to people with cancer.

Quantitative analysis of feasibility, delivery and content requirements

The main measures of feasibility included (i) recruitment rate (enrolled/invited participants), (ii) retention rate (completed nine sessions/enrolled participants), (iii) fidelity to the intervention (completed session as per the planned schedule/enrolled participants), and (iv) fidelity to the four questionnaires (questionnaires completed/active participants). Using descriptive statistics, we additionally assessed preferences for mode of delivery (video conference versus telephone), and the timing and length of intervention sessions. We characterised content requirements by counting the frequency of supportive care needs reported and the intervention session components delivered as well as care plans and referrals sent.

Qualitative analysis of acceptability of the intervention

The interviews were transcribed, with pseudonyms used in place of real names. One investigator (VB) used a thematic approach to analyse the interviews, (Braun and Clarke, 2006) grouping emergent patterns of the data with common keywords and phrases to generate a set of codes. In discussion with AA, the codes were grouped together under general themes related to the questions asked around acceptability of delivery and content and then shared with other members of the research team for refinement and consensus.

Results

Participant recruitment

Overall 27 people were invited to take part in the study and 15 (56%) declined as they were not interested (Figure 3). An additional two potentially eligible patients died before they could be approached and two patients were not approached because of complex medical comorbidity and distress. Participants included five patients (38% participation rate) and seven carers (50% participation rate). This included three patient-carer dyads, one triad with one patient and two carers, one patient without a carer, and two carers who participated despite the patient they cared for not enrolling. All carers were spouses except in the triad where the carers were the mother and sister to a male patient and one carer who was the sister-in-law to a non-participating patient.

Participant characteristics

Participants were aged between 46 and 78 years (median 61). Most participants were female, with only high-school education, living with their partner only and living or caring for someone with metastatic disease receiving Folfirinox chemotherapy (Table 1). The patients were between one and ten months after diagnosis (median three months) at recruitment, and eight out of 12 participants had a HADS score consistent with subclinical-to-clinical symptoms of both anxiety and depression at baseline (Table 1).

Mode of intervention delivery

All participants chose to receive their counselling over the telephone and all participants in a dyad or triad chose to complete their sessions separately from the other family member(s).

Retention and fidelity to number, timing and length of intervention sessions

Eight of the twelve participants (three patients and five carers) completed all nine intervention sessions. Six of these (three patients and three carers) completed the sessions as per the planned schedule and two carers (of the same patient) were granted a request to space their nine sessions out as needed. One carer who completed seven sessions also requested to space their sessions out as needed, which was accommodated up until the end of the study period. Two participants (a dyad) were discontinued after three and four sessions respectively as their psychological needs exceeded the care and advice that the nurse-counsellor could safely provide. These two participants were referred to psychiatrists. One patient became uncontactable after four sessions over three months. The length of the sessions ranged from 20 to 99 minutes (median 57 minutes).

Distress, pain (patients only) and needs identified at each session

The distress and pain screening conducted by the nurse-counsellor at each intervention session showed no clear pattern of distress and pain levels over time and wide within-subject variation. The most prevalent supportive care needs over the 90 intervention sessions delivered were related to worry (count = 83), fears (count = 69), treatment decisions (count = 67), sadness (count = 57) and fatigue (count = 57) and were common to both patients and carers (Table 2).

Components delivered

In response to participant needs, the nurse-counsellors delivered the full range of available intervention components to both patients and carers (Table 3). The content most frequently delivered over the 90 sessions related to coping skills training (count=83), and psychoeducation about the psychological impact of cancer (count=81), enhancing relationships (count=68), and non-pharmacological approaches for symptom management (mindfulness, exercise, relaxation) (count=64).

Care plans and referrals

The priority issues included in the care plans for patients related to: feelings about death and dying; fear of pain; fatigue and being able to do usual daily activities; and end-of-life living arrangements. The main priority issues raised by carers were related to: their own mental health; concerns about the effect of the disease progression on the patient; feelings about death and dying; and maintaining their health while living with uncertainty. By the end of the intervention, two patients and five carers reported being referred to palliative care services by their oncologist and subsequently gave their nurse-counsellor permission to send their care plan to their palliative care team, and general practitioners if they were a carer. The nurse-counsellors sent a total of 30 referrals related to unmet needs across a range of issues for four patients and seven carers.

Questionnaire completion rates

All participants completed the quantitative baseline questionnaire. Follow-up questionnaires were completed at mid-intervention (after three-to-five sessions) by ten out of the twelve participants; of the ten participants who remained in the study, four and eight participants completed the questionnaires immediately and two months after the end of the intervention respectively.

Qualitative evaluation of acceptability

Overall, participants thought the PREPARES intervention was an excellent service that they would recommend to others. One participants said "*Yeah I would give it a ten out of ten. [...]. It's important for you. It's important for your family, yeah and especially for your partner or your carer because sometimes it's very difficult – it's harder for them sometimes I think." (Nicole, female patient)*

We identified four themes from the evaluation interviews. These included perceptions about the delivery of the counselling, benefits of the intervention, suggestions for improvement and contemplating delivery to people with other advanced cancers.

Theme 1: Delivery of the counselling

Participants were very positive and enthusiastic about the way the counselling was delivered. Participants preferred the telephone over video conferencing or face-to-face consultation as it was convenient and offered anonymity for participants and a safe space to open up. One participants explained *"By having it being anonymous in that you know you don't see them face-to-face, it's a lot easier to sort of share um some of your innermost thoughts" (Naomi, caregiving wife)*

In general, the allocated hour session length worked well and gave enough time to explore issues in depth. In some instances, the sessions went on a little longer, which was also appreciated. The participants also appreciated the flexibility to reschedule sessions. A patient said "*[Nurse-counsellor] made it quite apparent that if I wasn't feeling up for it that I could not take her calls and I could just send her a text and I probably did that a few times." (Luke, male patient)*

All participants in a patient-carer dyad or triad remarked that separate sessions were best for talking freely and directly without fear of upsetting the other's feelings. One carer explained "*You could be more direct and ask more personal things." (Barbara, caregiving mother)*

Theme 2: Perceived benefits of the intervention

There were four intervention cornerstones that were perceived as highly beneficial. Firstly, independent emotional support was perceived to be a key component. Being able to talk to someone independent of the treating team and family and friends was highly valued by participants. One patient said "*It was good to talk to someone outside, instead of talking to the same people all the time." (Garth, male patient)* Participants described this support as very comforting and reassuring. It was highlighted by one participant that this was particularly important for people with pancreatic cancer who said "*When you're suffering a different form of cancer yourself you just feel like there is no information really out there for you, like that makes sense, it's all about breast cancer, prostate cancer, those that are in the media, whereas pancreatic cancer is like I said it's almost like a taboo cancer that you don't talk about because it doesn't have a good risk recovery rate so um [nurse-counsellor] made that part of it just so much easier, you know just to have somebody who did care and answer questions was ah yeah again very comforting." (Nicole, female patient)*

Secondly, many participants commented that the nurse-counsellors were exceptional in their clinical expertise. Participants also said they were easy to talk to, thoughtful, caring, professional and particularly helpful in providing the information they needed. One participant confirmed "*Yes [nurse-counsellor's] pretty knowledgeable on chemo like she's worked with it before so she was good to bounce a few things off and um yeah she was a lovely person, really easy to talk to." (Casey, female patient)* This really helped to build trust.

Some participants reported looking forward to the sessions, although participants reported a range of feelings, from 'exhilarated' and 'better' to 'sad', immediately after the sessions. Participants shared that they managed to see these experiences positively as they encouraged them to reflect deeper and connect with their emotions better. One participant said "*I know that that whenever the session was over I didn't feel exhausted I kind of felt exhilarated so ah you know whatever we talked about made me feel better." (Laura, caregiving wife)*

Overall, the nurse-counsellors' expert knowledge and emotional support reportedly improved the participants' strength and confidence in their ability to cope. One carer recalls "*One day you're having your life, and then the next is the worst possible day you could ever have in your life. And then that goes into the worst possible week. And then the worst possible month. And so on. […] talking to [nurse-counsellor] um was extremely helpful." (Brad, caregiving husband) Another said "I found her quite a tower of strength." (Sue, caregiving wife)*

Thirdly, participants highly valued the nurse-counsellors' communication with their treating clinicians. One carer said "*The other thing which I think has been uhh so valuable is [nurse-counsellors'] communication that she has had with my brothers' management team at the hospital. She has been able to […] make sure they bring up some things that we need to address." (Kylie, caregiving sister)* Communication happened with participants' permission, either through the care plans being provided to clinicians or through advice/referrals to clinicians as needs arose throughout the intervention. This facilitated clinicians initiating difficult discussions about treatment and end-of-life. It also facilitated discussions between members of the treating team.

Fourthly, participants appreciated the personalised care. The nurse-counsellors identified the main issues, ascertained healthy coping mechanisms already being used and reinforced their value, and suggested new strategies. These were written into the goal-setting section of the care plans. Additionally a brief email summary of what was discussed in each session was sent to participants to document new emerging issues and strategies discussed. This approach was described as "amazing help". This participant describes the range of care options discussed "*Like she um suggested a meditation […] and to exercise because it had been proven to help people on chemotherapy […], trying to set goals like walk to the corner and back you know on the days that I didn't have energy […]. I suffered because I had terrible diarrhoea at one stage and a really bad haemorrhoid which was excruciatingly painful, so it was her that suggested something called the sitz bath, […] and both of those things where just an amazing help and relief for me and without [nurse-counsellor] I would never of thought of them." (Nicole, female patient)*

Theme 3: Participants' suggestions for improvement

When asked if there was anything that was not helpful or things that perhaps we could remove, all participants commented that nothing was unhelpful. However, two clear points were raised about the need to build rapport and to have ongoing support with suggestions for improvement provided. Participants commented that it takes a few sessions to build rapport. One participant raised the idea of a welcome pack to 'break the ice' more quickly. She said "*If we were just to get a welcome pack this is who I am about the counsellor, with a photo. […] because definitely the first session is where all trying to be very polite and not say too much but to have a little bit more of a personal connection with the counsellor I think would be an advantage." (Kylie, caregiving sister)*

Nine out of the 12 participants clearly indicated that they would have liked more sessions. Moving to once a month was suggested or one participants recommended an 'as needed' basis, saying "*If I'm really struggling um with something um you know could you ring and uh say look can you give me a call tomorrow or whenever you've got time […] You've already got that relationship and, and you know she's over all the information of what is going on you know?" (Janine, caregiving sister-in-law)*

Conversely, three participants who admitted to enrolling in the study because their participating partner/family member wanted them to or due to a motivation to help future patients said there was nothing that could help them and they were satisfied with the number of sessions received.

Concordant participant and nurse-counsellor feedback

Nurse-counsellors' feedback about the delivery of the intervention was concordant with participants' feedback. They preferred the telephone mode of delivery saying that it exceeded their expectations as it enabled them to deliver counselling and take notes simultaneously as well as facilitating open conversations. One nurse-counsellor gave an example "*One participant who wanted to talk about um having sex and things like that and I know that she um found it much easier having that conversation because she wasn't looking at someone face-to-face." (Tracey, nurse-counsellor)*

The nurse-counsellors thought the one hour session length was good and flexibility in scheduling was important. The nurse-counsellors also held a strong opinion that the intervention should be continued for longer saying "*I know that one of the aims of the study was to make them, to increase their self-efficacy so that they could better cope individually and feel like they have more confidence in their abilities but I think on another perspective they are living with something that is constantly changing all the time […] It would make more sense to just follow them through the entire process." (Sally, nurse-counsellor)*

They did observe some differences in delivering the intervention to patients versus carers. Carers often had to be reminded that the aim of the sessions were to support the carers themselves. One nurse-counsellor remembers "*I would say how is things going they would always talk about the patient and then I'd say no but how are you." (Tracey, nurse-counsellor)* The separate format was helpful in being able to reinforce this aim.

Regarding content, the nurse-counsellors felt all aspects were helpful but that emotional support was the most needed aspect.

Theme 4: Delivery to people with other advanced cancers.

The nurse-counsellors estimated that between 15-30% of the intervention they delivered covered content specific to pancreatic cancer. This included discussions about blood sugar levels and insulin, chemotherapy regimens, how having no curative options made them feel, and the acuteness of the disease process. They also added that a lot of their conversations with participants were general but with a palliative outlook and that the intervention could benefit people affected by other advanced cancers.

Discussion

Findings from this feasibility study suggest that the PREPARES intervention is feasible and highly acceptable, with perceived benefits reported by participants including: 1) the independent emotional support provided by the nurse-counsellors; 2) the self-efficacy participants gained from the nurse-counsellors' support and knowledge; 3) the coordination of care between the nurse-counsellors and treating team; and 4) the personalised care provided in the form of care plans, tailored strategies and email summaries. In particular, the experienced oncology nurse-counsellors were able to assess how best to support the inter-related psychosocial, spiritual and physical needs of participants by introducing tailored interventions, such as in the sitz baths example above. The carers reported that the value of the sessions was the focus on them 'specifically for me', tailored and customized towards their needs, something that is often overlooked in standard care.

While participants thought the PREPARES intervention was excellent, 56% (n=15) of those invited declined to participate, four patients were not approached due to death or complex medical comorbidity and distress, and two participants were enrolled and subsequently discontinued. In delivering an intervention such as PREPARES, it is important to consider personal preference (Clinical Oncology Society of Australia, 2016) and that not all patients and carers will have a desire for this type of support. Also, some people will require more intensive support than the nurse-counsellor is trained and has capacity to provide (Butow et al., 2015). It is possible, however, that some people did not participate as they did not want to complete the four study questionnaires. Participants were recruited from a tertiary metropolitan hospital, whereas people living in a location without access to specialist palliative care may be more likely to participate. There is sometimes the perception that adding a psychological intervention poses a burden or increases distress in those facing life-limiting illness, but participants were very prepared to talk with the nurse-counsellors and most actually wanted more counselling sessions.

There has been a burgeoning literature involving psychosocial interventions for cancer patients and their carers over the past two decades (Faller et al., 2013). These interventions were often delivered under different theoretical frameworks, through face-to-face methods and can be expensive and difficult to disseminate. This was the first psychoeducation intervention for patients with pancreatic cancer, in whom the frequently short survival leaves little time to create a true therapeutic alliance with the treating team, and to deal with existential crisis, practical considerations and advance care planning. In this setting, the theoretical framework of self-efficacy and telephone delivery worked very well. PREPARES participants' reported that being assisted to identify and set goals and actions and have these documented within a care plan was a cornerstone of their support, and that because of this their confidence in their ability to cope improved. Furthermore, the telephone-delivery worked well in this setting, where patients and carers experience significant fatigue. Their preference for telephone appears to reflect the flexibility and convenience as well as the anonymity it offered, providing a safe space for participants to open up about more personal things once rapport was established. Our findings are consistent with a previous report confirming that cancer patients preferred support from nurses and by telephone (Brebach et al., 2016). Telephone delivery is low cost with the potential for real-world delivery of accessible, equitable, high-quality person-centred care to all people affected by pancreatic cancer and potentially the broader population affected by all advanced cancers.

One limitation of this study was the enrolment of only five patients and seven carers. The small sample size did not allow us to compare patient and carer experiences of the intervention. Moving forward, it will be important that as part of a larger trial the sample is large enough to enable outcomes to be assessed for patients and carers separately. This pilot also showed that adherence to completing the end-intervention questionnaire was low and that the final outcome measures may need to be timed a month or two after the intervention, where adherence was good. Finally, it will also be important to consider implementation principles to ensure adoption of the intervention in routine clinical care.

In conclusion, PREPARES delivered by telephone in a flexible format is a low-cost feasible intervention that the overwhelming majority of participants would recommend to others faced with this devastatingly fast-progressing disease. A full-scale randomised controlled trial is needed to determine if the intervention is effective in improving carer and patient-reported outcomes, such as distress and quality of life and also whether it is cost-effective compared with usual care.

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Table 1. Participant characteristics

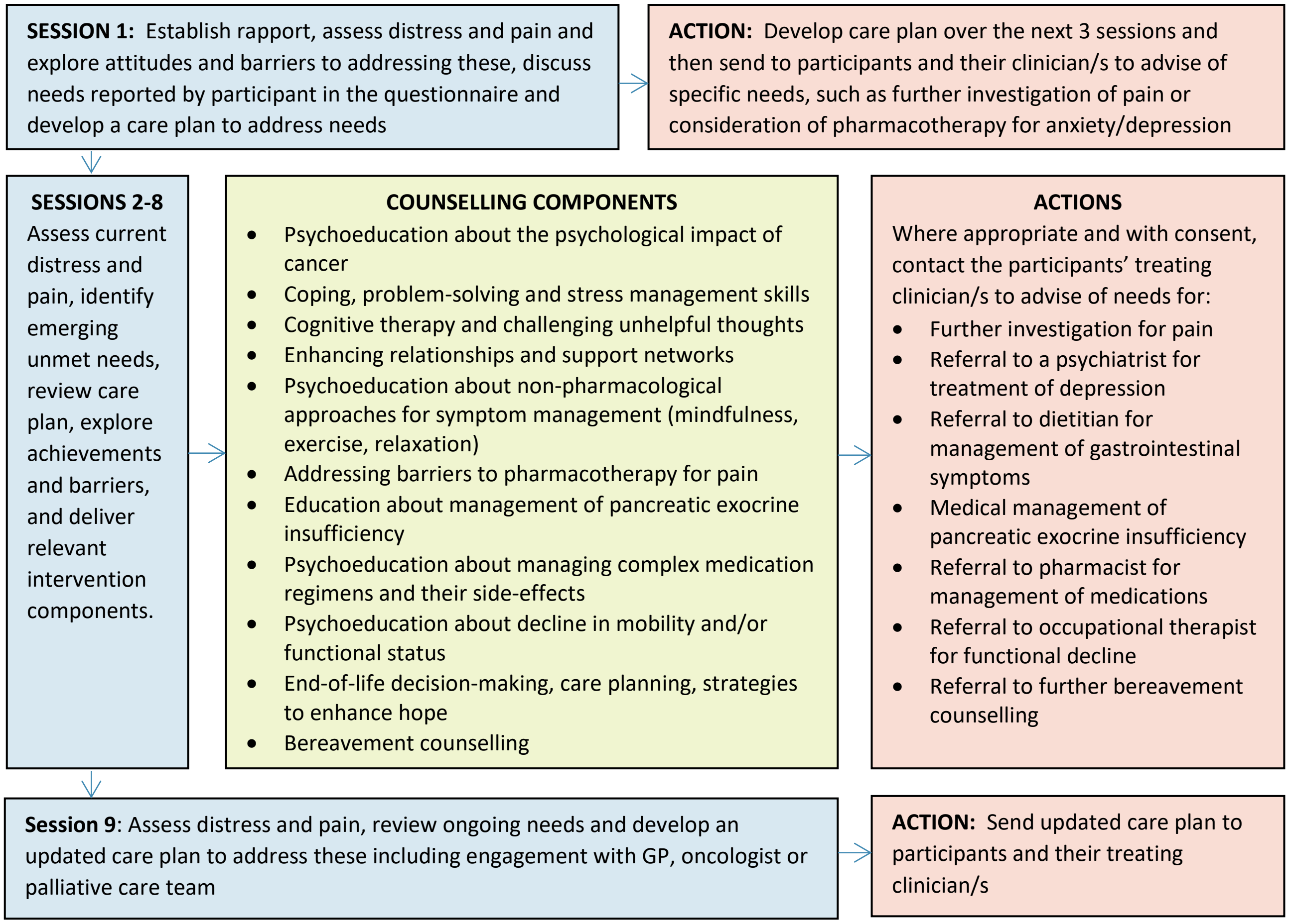
Characteristics	All participants	Patients	Carers
	n = 12	n = 5	n = 7
Age			
≤ 60 years	5	3	2
61-70 years	6	2	4
>70 years	1	0	1
Gender			
Male	4	3	1
Female	8	2	6
Highest level of education			
High school	6	3	3
Technical college/trade certificate	3	1	2
University	3	1	2
Living arrangement			
Living with partner only	8	4	4
Living with partner and children	1	0	1
Living with partner and parent	1	0	1
Living alone	2	1	1
Disease prognosis of the patient or patient being cared for			
Resection completed (curative)	-	0	0
Locally advanced disease	-	1	0
Metastatic disease	-	3	6
Unknown	-	1	1
Chemotherapy of the patient or patient being cared for			
Gemcitabine & Abraxane	-	1	2
Folfirinox	-	4	5
None	-	0	0
Months post-diagnosis at intervention start[a] (Median, Range)	-	3 (1-9)	3 (1-10)
Baseline distress (HADS measure)			
No anxiety or depression	3	0	3
Sub/clinical anxiety only	1	1	0
Sub/clinical depression only	0	0	0
Sub/clinical anxiety and depression	8	4	4

Table 2: Counts of needs identified from the Distress Thermometer Problem Checklist (top 12 needs for patients and carers, ordered by highest needs in all participants)

	Patients				Carers				All participants
	First session (N = 5)	Middle sessions (N = 24)	Last session (N = 5)	Total sessions (N = 34)	First session (N = 7)	Middle sessions (N = 42)	Last session (N = 7)	Total sessions (N = 56)	Total sessions (N = 90)
Worry	5	21	4	30	7	39	7	53	83
Fears	3	19	3	25	7	31	6	44	69
Treatment decisions	2	22	3	27	3	33	4	40	67
Fatigue	4	22	5	31	3	20	3	26	57
Sadness	4	16	3	23	5	23	6	34	57
Dealing with children	2	17	2	21	3	27	5	35	56
Dealing with partner	3	21	3	27	4	22	2	28	55
Family health issues	1	14	3	18	4	28	4	36	54
Pain	4	20	2	26	3	20	3	26	52
Sleep	1	17	2	20	2	20	3	25	45
Loss of interest in usual activities	4	13	1	18	2	13	3	18	36
Depression	4	12	2	18	4	11	2	17	35

Table 3: Counts of intervention components delivered

	Patients			Carers			All participants
	First session (N = 5)	Middle sessions (N = 24)	Last session (N = 5)	First sessions (N = 7)	Middle sessions (N = 42)	Last session (N = 7)	All sessions (N= 90)
Psychoeducation about psychological impact of cancer	5	23	4	6	38	5	81
Coping skills training	5	24	3	6	39	6	83
Cognitive therapy	2	8	1	0	2	0	13
Psychoeducation about enhancing relationships	4	22	4	5	28	5	68
Symptom management with mindfulness, exercise, relaxation	5	21	5	3	25	5	64
Addressing barriers to pharmacotherapy for pain	2	15	2	1	18	4	42
Education about management of pancreatic exocrine insufficiency	0	1	0	0	0	1	2
Psychoeducation about managing medication and side-effects	5	20	3	2	18	3	51
Psychoeducation about decline in functional status	2	13	3	1	9	2	30
End-of-life planning, strategies to enhance hope	2	7	1	3	23	5	41
Bereavement counselling	1	8	1	2	20	4	36



SESSION 1: Establish rapport, assess distress and pain and explore attitudes and barriers to addressing these, discuss needs reported by participant in the questionnaire and develop a care plan to address needs

ACTION: Develop care plan over the next 3 sessions and then send to participants and their clinician/s to advise of specific needs, such as further investigation of pain or consideration of pharmacotherapy for anxiety/depression

SESSIONS 2-8

Assess current distress and pain, identify emerging unmet needs, review care plan, explore achievements and barriers, and deliver relevant intervention components.

COUNSELLING COMPONENTS

- Psychoeducation about the psychological impact of cancer
- Coping, problem-solving and stress management skills
- Cognitive therapy and challenging unhelpful thoughts
- Enhancing relationships and support networks
- Psychoeducation about non-pharmacological approaches for symptom management (mindfulness, exercise, relaxation)
- Addressing barriers to pharmacotherapy for pain
- Education about management of pancreatic exocrine insufficiency
- Psychoeducation about managing complex medication regimens and their side-effects
- Psychoeducation about decline in mobility and/or functional status
- End-of-life decision-making, care planning, strategies to enhance hope
- Bereavement counselling

ACTIONS

Where appropriate and with consent, contact the participants' treating clinician/s to advise of needs for:

- Further investigation for pain
- Referral to a psychiatrist for treatment of depression
- Referral to dietitian for management of gastrointestinal symptoms
- Medical management of pancreatic exocrine insufficiency
- Referral to pharmacist for management of medications
- Referral to occupational therapist for functional decline
- Referral to further bereavement counselling

Session 9: Assess distress and pain, review ongoing needs and develop an updated care plan to address these including engagement with GP, oncologist or palliative care team

ACTION: Send updated care plan to participants and their treating clinician/s

Figure 1. Intervention Design

PATIENT CAREGIVER	NURSE
How did you find receiving care in the home via phone/video? • How did it feel to talk to the nurse via phone/video? • How did you find the timing of the sessions? • How did you find the number of sessions? • Did you complete the sessions together or separately from your loved one? • How did you find this worked?	How did you find delivering care via phone/video? • How did it feel to talk to the participant via phone/video? • How did you find the timing of the sessions? • How did you find the number of sessions? • Did you complete the sessions together or separately when there were multiple family members? • How did you find this worked? • Where there any differences in how you found the delivery for patients vs caregivers?
Do you feel that the nurse was able to help? • Do you feel that the nurse was able to help to identify key issues to develop your care plan? • Do you feel that the nurse was able to provide you with the information you needed? • Do you feel that the nurse was able to help you with strategies to cope? • How do you feel now that you have completed the intervention with the nurse? • Do you have any other comments about your experience with the nurse?	Do you feel that you were able to help the participants? • Do you feel that you were able to help to identify key issues to develop the care plan? • Do you feel that you were able to provide the information participants needed? • Do you feel that you were able to help teach strategies to cope? • How do you feel now that you have completed the intervention delivery? • Where there any differences in how patients vs caregivers responded to you? • Do you have any other comments about your experience with the participants?
Which sessions with the nurse did you find the most helpful? • What were these about? • Can you explain why these worked well? • Can you tell me if you feel that participation in the PREPARES study has had any impact on your confidence and thoughts?	Which sessions/intervention content did you find the most helpful for participants? • What were these about? • Can you explain why these worked well? • Did the content you delivered differ for patients vs caregivers? • Can you tell me if you feel there was any impact on the confidence and thoughts of participants in the PREPARES study?
Were there any sessions that were unhelpful? • What were these about? • Can you explain why they did not worked well? Do you have any suggestions about how the session(s) could be modified to help with this?	
	Did you discuss issues that were specific to pancreatic cancer (as appose to things that affect most people dealing with advanced cancer). • Can you tell me which pancreatic cancer-specific issues you covered? • What support or resources did you provide in relation to these? • Do you feel you were able to help meet these specific needs? • What proportion of care or how much time do you think you spent on pancreatic cancer-specific issues as appose to issues that are common to most people affected by advanced cancer?
Can we discuss how things have gone for you since you received your care plan? • Did you discuss the survivorship care plan with others (friends or family)? If so, what was their reaction? • Did you discuss the survivorship care plan with your doctor? If so, can you describe any assistance or support your doctor gave you regarding the plan? • What aspects of the care plan have been helpful? Can you explain why these have worked well? • What aspects of the care plan have not been helpful? Can you explain why this is the case? (For example too tired, lack motivation). Do you have any suggestions about how the plan could have been modified to help with this?	Can we discuss the care plans now? • Did you complete the survivorship care plans on schedule (i.e. after the first and last sessions)? If not, tell me what happened. • Did you send the survivorship care plans to participant's doctors as well? If so, do you know if any assistance or support came from this? • What aspects of the care plan did you think were helpful? Can you explain why these have worked well? • What aspects of the care plan have not been helpful? Can you explain why this is the case? (For example too tired, lack motivation). Do you have any suggestions about how the plan could have been modified to help with this? • Where there any differences in the usefulness of the care plans for patients vs caregivers?
If the nurse contacted your doctor to advise of any needs or issues that many need further investigation or referral, how did this work out for you? • Was the appropriate follow-up care coordinated in a timely manner to address your needs? • If not, what might have helped?	When/if you contacted the participants doctor to advise of any needs or issues that many need further investigation or referral, how did this work out? • Was the appropriate follow-up care coordinated in a timely manner to address the participant's needs? • If not, what might have helped?
What is your opinion about the approach to supportive care after a diagnosis of pancreatic cancer developed for the PREPARES trial? • Is this an approach which you think would be helpful for other patients and carers? • Can you see any advantages of this approach? • Do you think that there are any disadvantages of this approach? • Do you have any ideas about what would make it difficult to deliver more broadly?	
Do you have any other comments you would like to make about your involvement in the PREPARES study?	

Figure 2. Semi-structured interview prompts

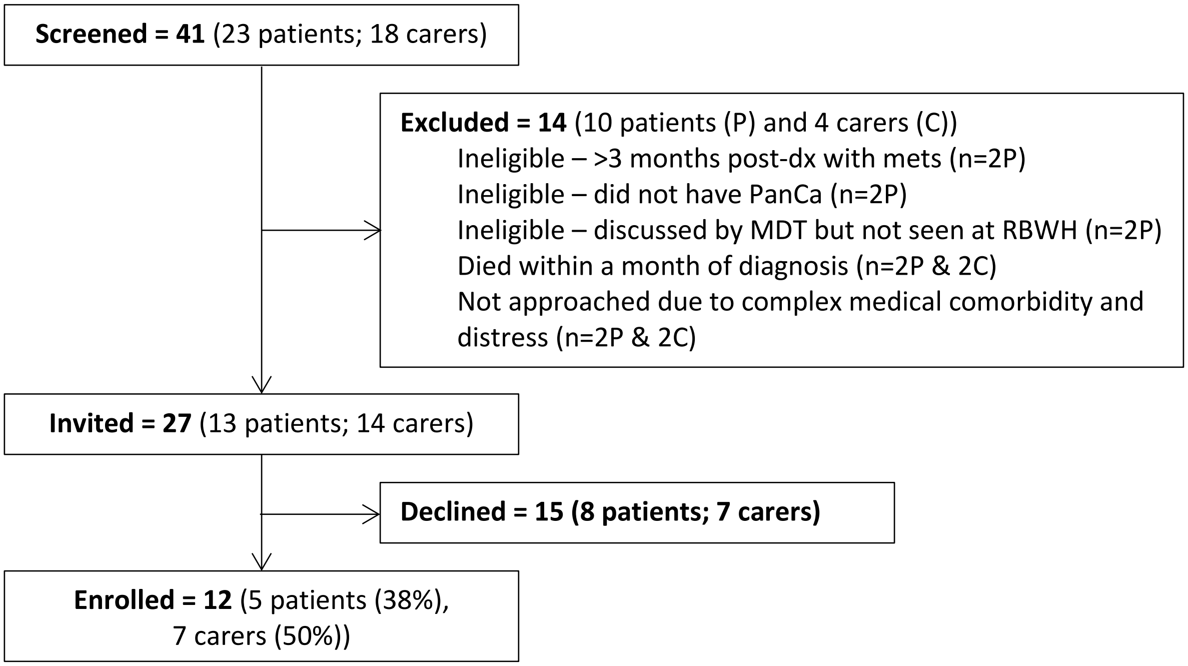


Figure 3. Flow of participant recruitment