

## Appendix 1.2

### Intervention studies of pain medication management for family carers of patients with advanced cancer

Author Date Country	Study population Sample size attrition	Evaluation design/method	Intervention control	Outcomes and measurement instruments		Findings		Quality score <sup>a</sup> Quality level <sup>b</sup>
				Carers	Patients	Carers	Patients	
Ferrell et al 1995 USA  Additional patient informa tion Ferrell et al 1994	Hospital clinic patients aged 60+ with cancer- related pain duration ≥3mo, prescribed opioids. Family caregiver identified by patient as person most involved in care/pain management. Recruited 66 patients, 50 family carers Number lost to follow up not reported	Single group pre/post design: carer assessment at baseline and 1 and 3 weeks post- intervention	Intervention 3-session pain education program delivered over two weeks by nurse specialist in patient's home. Caregivers instructed on supporting the patient. Total duration 3hrs, supported by printed and audio resources.	<i>Quality of life</i> Quality of Life Tool (QOL) <i>Knowledge</i> <i>/attitudes/</i> <i>experience</i> Family Pain Questionnaire (FPQ) <i>Caregiver</i> <i>burden</i> Caregiver Burden Tool (CB)	<i>Knowledge</i> Patient Pain Questionnaire (PPQ) <i>Pain</i> Self Care Log: pain intensity, distress and pain relief <i>Quality of life</i> QOL	Post-intervention data not reported. Authors report "significant improvements in psychological well-being and social well-being subscales and in total QOL score" at 1 week post intervention. Also report improvement in FPQ subscale scores.	Authors state patients reported 'increased use of medication' and provide data to demonstrate 'improvements in pain intensity, pain distress and pain relief across the points of evaluation'.	7 poor
Wells et al 2003  USA	Cancer centre patients 18+; cancer pain with onset or escalation in last 3mo, managed by analgesic; home telephone; primary caregiver willing to participate. Excluded if life expectancy < 6mo.  64 patient-carer dyads randomised No loss to follow up pre-post intervention measures (on same day). However, up to 50% attrition rates over 6mo follow up	Single group pre/post design to evaluate the pain education program. Dyads then randomised to 3 follow up treatments, compared at baseline and 1,2,3,4,5,6 months post-intervention	Brief, single session pain educational intervention, video presentation and discussion, duration 20- 30 minutes. Follow up with different types of access to pain information: <ul style="list-style-type: none"> <li>given number for pain telephone hotline + usual care</li> <li>provider-initiated telephone calls weekly for one month + usual care (duration of calls 20- 60 minutes)</li> <li>usual care</li> </ul>	<i>Knowledge/</i> <i>attitudes</i> FPQ (knowledge subscale only, revised)	<i>Beliefs</i> Barriers Questionnaire- revised (BQ-r) <i>Pain</i> Brief Pain Inventory (BPI- SF) <i>Adequacy of</i> <i>analgesics</i> <i>Pain</i> Management Index (PMI-r)	Carers' mean FPQ score improved from baseline (5.19) to immediately post-education (6.21), ie measured on same day (F (1,62)=18.2, p<0.001).  No other carer data reported.  There were no calls to the telephone hotline by patients or carers.	Patients' mean BQ-r score improved immediately post education, statistically significant for beliefs about communication of pain (F(1,62)=28.7, p<0.001) but nss for use of analgesics (F(1,62)=0.21, p>0.05). Change in beliefs on BQ-r had no effect on pain outcomes. Type of follow up had no effect on long term pain outcomes.	13 poor

Keefe et al 2005 USA	Hospice and clinic patients with advanced cancer diagnosis aged 18+; disease-related pain (worst >3 BPI); life expectancy < 6mo. Partners of patients: not stated how identified or defined.  82 patient-partner dyads recruited 78 dyads randomised 56 dyads completed follow up	RCT following baseline assessment. Intervention vs control compared at baseline and 0-31 days (mean 7.56) post-intervention.	<i>Partner-guided pain management training:</i> 3 x 45-60 minute education sessions delivered over 1-2 weeks by nurse educator in patient's home to patients and carers together. Total duration 2.25-3 hrs. Supported by written materials, videotapes and audiotapes.  Control = usual care	<i>Self-efficacy in pain management</i> Chronic Pain Self-Efficacy Scale (CPSES)  <i>Care-giver strain</i> Care-giver Strain Index (CSI)  <i>Mood</i> Profile of Mood States-B (POMS-B)	<i>Pain</i> BPI  <i>Quality of life</i> Functional Assessment of Cancer Therapy-General (FACT-G v4) subscales physical wellbeing; social/family wellbeing	Intervention group reported significantly higher levels of self-efficacy (CPSES) for helping patient to control pain (F(1,53)=8.14, p=0.006) and helping patient to control other symptoms (F(1,53), P=0.012). CSI scores improved (F(1,55)=3.67, p=0.061) No significant treatment effect on mood (POMS-B): positive mood (F(1,31)=0.883, p=0.355); negative mood (F(1,31)=1.44, p=0.24)	No significant treatment effects on BPI usual ratings of pain (F(1,54)=1.21, p=0.28) and worst pain (F(1,56)=0.81, p=0.37) or on quality of life (FACT-G)	20 good
Lin et al 2006 Taiwan	Patients of cancer outpatient clinic aged 18+, experiencing cancer pain and taking oral analgesics. Family carers identified by patients as the individual most involved carer in their lives, aged 18+.  61 patient-carer dyads randomised Loss to follow up not reported	RCT following baseline assessment. Intervention vs control compared at 2 and 4 weeks post initial education session.	Pain education intervention based on culturally specific booklet. Initial education session delivered in hospital outpatient clinic, duration 30-40 minutes. Copy of booklet provided. Two further 'interviews' 2 and 4 weeks later at which pain education information was reiterated. Control = usual care + 3 'interviews' in clinic with same pattern and duration as intervention group	<i>Beliefs</i> BQ Taiwan form (BQT)  <i>Pain</i> BPI Chinese version (BPI-C)  <i>Medication adherence</i> Self-Reporting Measure of Medication Adherence (SRMMA)	As for carers	At weeks 2 and 4 intervention group carers' BQT and SRMMA scores showed improvements that were statistically significant compared to control group.	At weeks 2 and 4 intervention group patients' BQT and SRMMA scores showed improvements that were statistically significant compared to control group. Also at week 4 intervention group pain intensity and pain interference scores (BPI-C) showed decreases that were statistically significant vs control.	12 poor
Ward et al 2009 USA	Oncology patients aged 18+, cancer diagnosis, reporting moderate to severe pain in last 2 weeks; performance status score indicating	RCT following baseline assessment: dyads randomised to three groups • Patient and SO	<i>RIDcancerPAIN+</i> Single education session delivered at convenient location, usually the patient's home. Duration 20-80 minutes.	<i>Beliefs</i> BQII (3 items on immune subscale not included)	<i>Beliefs</i> BQII (minus 3 items) <i>Pain</i> BPI-SF subscales Single item	There were no statistically significant changes in BQII from baseline to week 9 for either solo or dyad group compared to control	At 9 weeks patients in both solo group and dyad group showed decreases in BQII scores that were statistically significant compared to the control	20 good

	<p>out of bed &gt;50% of waking hours; and a significant other (SO) to participate in study. SOs were nominated by the patient as the person who had most influence on their illness and treatment.</p> <p>161 patient-SO dyads randomised: 124 completed 5 wk follow up; 109 completed 9 wk follow up</p>	<p>receive intervention together ('dyad')</p> <ul style="list-style-type: none"> <li>• Patient only receives intervention ('solo')</li> <li>• Control</li> </ul> <p>Compared at baseline and 5 and 9 weeks later.</p>	<p>Representations of symptoms were elicited before providing new information and developing strategies for behaviour change in a 7-step sequence.</p> <p>Two follow up telephone calls 2 and 4 weeks after education session, to review and revise pain management plan.</p> <p>Control = usual care</p>	<p><i>Influence of study on pain management</i> Study evaluation form</p>	<p>rating pain relief in past week.</p> <p><i>Global QOL</i> FACT-G, QLQ-C30</p> <p><i>Negative mood</i> Subscale of QLQ-C30</p> <p><i>Influence of study on pain management</i> Study evaluation form</p>	<p>group.</p> <p>Authors report "SOs in the dyad group had significantly higher scores on evaluation items concerning the way they think about cancer pain and pain management compared with SOs in the control groups. SOs in the solo group did not differ from those in the control group."</p>	<p>group.</p> <p>From baseline to 9 weeks no other patient measures showed changes for either solo or dyad group vs control group that were statistically significant.</p> <p>Authors report that patients in dyad and solo groups had higher scores on evaluation form than control group.</p>	
<p>Capewell et al 2010</p> <p>UK</p>	<p>Patients with cancer aged 18+ living at home; receiving palliative care services; experiencing pain from active cancer rated 3+ on 0-10 pain scale; able to complete assessments. Patients nominated carers.</p> <p>1<sup>st</sup> education session: 15 patients, 10 carers 2<sup>nd</sup> session : 12P, 8C completed 4 week follow up: 10P, 8C</p>	<p>Single group pre/post design: assessment at baseline; 1 and 4 weeks after first education session.</p>	<p>Brief structured educational intervention addressing cancer pain and use of strong opioids. 6-minute DVD of interviews with palliative care staff shown to patient alone or dyads in the hospital clinic on 2 occasions approx. 1 week apart by researcher who answered any questions. Copy of DVD and booklet provided.</p>	<p><i>Knowledge/attitudes/experience</i> FPQ</p> <p><i>Medication Adherence</i> Medication Adherence Questionnaire (modified) (MAQ)</p>	<p><i>Knowledge</i> PPQ</p> <p><i>Pain</i> BPI</p> <p><i>Psychological function</i> Coping Strategies Questionnaire (CSQ)</p> <p>Hospital Anxiety and Depression Scale (HADS)</p> <p><i>Medication Adherence</i> MAQ</p>	<p>No formal analysis of carer outcomes, or values reported. Authors state that pattern of change in carer FPQ scores (baseline to 4 weeks) mirrored PPQ scores: "experience subscale scores showed no significant change but the knowledge subscale scores improved by 42%". "Most improved items were beliefs about addiction to medication; saving medicine for when pain is worse; giving analgesics regularly."</p>	<p>From baseline to 1 week post-interv, authors report "total BPI and PPQ scores improved significantly by 9.6% (p=0.02) and 17% (p=0.04) respectively with no further improvements at 4 weeks." (Actual values not given.) BPI change due to items relating to pain interference but not pain intensity; PPQ change largely in knowledge subscale. No significant change observed in CSQ or HADS. MAQ scores represented good adherence.</p>	<p>10 poor</p>
<p>Vallerand et al 2010</p> <p>USA</p>	<p>Study based on 12 home care agencies with 232 nurses, Nurses caring for patients with cancer at home (not hospice nurses) identified eligible</p>	<p>Cluster RCT: home care agencies were randomised to one of four treatment groups A-D. Nurses in agencies A and B received nursing</p>	<p><i>Power Over Pain</i> consisted of: An educational program for nurses designed to improve management of pain and side effects in patients with cancer. 2</p>	<p><i>Knowledge/attitudes/experience</i> FPQ</p> <p><i>Barriers</i> BQ (17 items)</p>	<p><i>Knowledge</i> PPQ</p> <p><i>Pain</i> BPI</p> <p><i>Symptom distress</i> Symptom</p>	<p>Outcome data not reported in detail. Authors state "There was a significant effect of the nurse intervention on caregivers' perceived control (p=0.036).</p>	<p>Not reported in detail. Authors state "The patient intervention significantly reduced the number of perceived barriers (BQ) from 24.5 (SD 11.1) at T1 to 17.8</p>	<p>11 poor</p>

	<p>patients: aged 18+, cognitively intact, English speaking and experiencing cancer-related pain. Patients nominated caregivers.</p> <p>50 patients, 46 carers participated in the study. 4 carers reported as lost to follow up</p>	<p>intervention, C and D did not. Patients and carers in agencies A and C given patient/carer intervention (by research team); those in B and D did not get. Outcomes compared for effect of nurse training (AB vs CD) and effect of patient/carer education (AC vs BD).</p>	<p>teaching sessions over 6 weeks.</p> <p>Control = no additional education</p> <p>An educational intervention for patients and carers delivered by research team in the patient's home. Written materials provided on initial visit, followed one week later by 1hour education session. Control = usual care</p>	<p>only)</p> <p><i>Perceived control over pain</i></p> <p>Perceived Control Scale (PCS) - modified for cancer pain and carers</p>	<p>Distress Scale (SDS)</p> <p><i>Barriers BQ</i> (17 items only)</p> <p><i>Perceived control over pain</i></p> <p>PCS modified for cancer pain</p>	<p>Caregivers of patients with nurses who received the intervention improved PCS scores (3.87 [SD=.97] to 4.35 [SD=1.24]; n=28) relative to the control group (4.53 [SD=1.42] to 4.00 [SD=1.18]; n=180). No other significant changes were seen."</p>	<p>(SD 11.9) at T4".</p> <p>Knowledge and perceived control increased and pain and symptom distress decreased in groups where patients received the intervention and in those that did not.</p>	
<p>Valeberg et al 2013</p> <p>Norway</p> <p>Addition al patient informa tion</p> <p>Rustoen et al 2012</p>	<p>Oncology outpatients aged 18+ with bone metastasis; ; pain <math>\geq 2.5</math> on 1-10 scale; KPS<math>\geq 50</math></p> <p>Family carers identified by patients as the person most involved in their care.</p> <p>179 patients; 112 carers randomised</p> <p>Loss to follow up not reported</p>	<p>RCT following patient completion of 'enrolment questionnaire'.</p> <p>Intervention vs control groups compared at baseline and on completion (times unspecified).</p>	<p>Norwegian adaptation of the <i>PRO-SELF Pain Control Program</i>, developed in USA. 3 teaching sessions for patient alone or patient/carer together in the home by specially trained oncology nurse, interspersed with 3 telephone contacts. Delivered over 6 weeks.</p> <p>Control group received usual care + booklet about pain management; amount of contact same as interv group, but focusing on use of pain management diary.</p>	<p><i>Knowledge/ attitudes</i></p> <p>FPQ (Knowledge subscale only, modified, Norwegian transl)</p>	<p><i>Knowledge</i></p> <p>Pain Experience Scale (PES)</p> <p><i>Pain intensity</i></p> <p>Unnamed 1-10 scale</p>	<p>Mean score on FPQ knowledge subscale showed significantly greater pre-post increase for intervention group (5.53-7.60) than control (5.48-5.63) <math>p &lt; 0.001</math>. Statistically significant improvements intervention vs control found in mean scores on all knowledge items except 'cancer pain can be relieved'.</p>	<p>Statistically significant improvement in treatment group patients' knowledge about pain and management (PES score)</p>	<p>11 poor</p>

- Assessed using checklist of 27 items, total score possible =28. Downs SH, Black N (1998) The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. J Epidemiol Community Health 52:377-384.
- Based on Samoocha et al's classification of quality level: excellent (26-28); good (20-25); fair (15-19); poor ( $\leq 14$ ) Samoocha D, Bruinvels DJ, Elbers NA et al. Effectiveness of web-based interventions on patient empowerment: a systematic review and meta-analysis. J Med Internet Res. 2010;12:e23.