## Supplementary Material 1: Statistical Tables and Figures

Table 14 IMPACCT RCT Milestones - recruitment period, follow up period, and data cut-off point

|  |  |  |
| --- | --- | --- |
| **Milestone** | **Original** | ***Extension* / Actual** |
| **Overall Duration** | 31/05/2014 – 31/05/2017 (3 years)  | *31/10/2018 (4 years, 5 months)* |
| **Set-up** | 31/05/2014 – 31/07/2015 |  |
| **Training** | 01/07/2015 – 30/09/2015 |  |
| **Recruitment**  | 01/10/2015 – 30/09/2016 (1 year) | *Extension:* *28/02/2018 (2 years, 5 months)*Actual: 16/01/2018 |
| **Follow-up** | 01/10/2016 – 31/12/2016 | 16/01/2018– 16/04/2018 |
| **Analysis** | 01/01/2017 – 31/05/2017 | Data cleaning and final follow-up: 16/04/2018 - 11/06/2016Analysis: 11/06/2016 – 31/08/2018Dissemination/write up: 01/09/2016 – 31/10/2018 |

**Screening and recruitment**

Table 15 Screening and recruitment by Hospital

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Site - Detailed** | **Site** | **Intervention site / community palliative care team base** | **Opened to recruitment** | **First recruit** | **N** |
| St James’ University Hospital, Leeds | Leeds | St Gemma’s, Leeds | 07/10/2015 | 22/10/2015 | 43 |
| Wheatfield’s (Sue Ryder), Leeds | 59 |
| Mid Yorkshire NHS Palliative Care, Wakefield | 10/11/2016 | 5 |
| Kirkwood, Huddersfield\* | *Leeds referrals accepted >Dec 16* |  | *4* |
| Marie Curie, Bradford\* |  | *3* |
| Scarborough General Hospital | Scarborough | St Catherine’s  | 13/10/2015 | 09/11/2015 | 4 |
| MacMillan CNS Team, Humber NHSFT | 01/09/2016 | 0 |
| Huddersfield Royal Infirmary | Huddersfield | Kirkwood, Huddersfield | 22/10/2015 | 23/02/2016 | 9 |
| Bradford Royal Infirmary | Bradford | Marie Curie, Bradford | 10/12/2015 | 20/04/2016 | 2 |
| York Hospital\* | York | St Leonard’s, York | 09/02/2016 | 14/03/2016 | 15 |
| Nottingham City Hospital | Nottingham | CityCare | 04/04/2016 | 31/08/2016 | 8 |
| Diana, Princess of Wales Hospital, Grimsby | Grimsby | Care Plus | 01/09/2016 | 03/10/2016 | 6 |
| Churchill Hospital, Oxford | Oxford | Sobell House | 11/10/2017 | 10/11/2017 | 3 |

*\*York ceased recruitment in Oct 2016; the local community palliative care team no longer had capacity to deliver the study.*

Figure 16 Screening and recruitment graph

Table 16 Consent, number and reasons for eligibility violation

|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
| **Protocol participant randomised under** |  |  |  |
| Version 3 – pre amendment | 7 (8.8%) | 6 (7.4%) | 13 (8.1%) |
| Version 4 – post amendment | 73 (91.3%) | 75 (92.6%) | 148 (91.9%) |
| **Eligibility violators** |  |  |  |
| **Have inclusion criteria been breached** |  |  |  |
| No | 80 (100.0%) | 81 (100.0%) | 161 (100.0%) |
| **Have exclusion criteria been breached** |  |  |  |
| Yes – Exclusion criteria 1, previous palliative care | 1 (1.3%) | 1 (1.2%) | 2 (1.2%) |
| No | 79 (98.8%) | 80 (98.8%) | 159 (98.8%) |

Table 17 Characteristics of Screened, Eligible, and Randomised populations

|  | **Screened (n=2395)** | **Eligible (n=274)** | **Randomised (n=161)** |
| --- | --- | --- | --- |
| **Gender** |  |  |  |
| Male | 1125 (47.2%) | 141 (51.5%) | 89 (55.3%) |
| Female | 1260 (52.8%) | 133 (48.5%) | 72 (44.7%) |
| Missing | 10 | 0 | 0 |
| **Age - Screening** |  |  |  |
| N | 2393 | 274 | 161 |
| Mean (SD) | 66.5 (11.70) | 65.6 (11.77) | 64.1 (11.59) |
| Median (Range) | 68.0 (1.0, 95.0) | 67.0 (19.0, 88.0) | 66.0 (19.0, 85.0) |
| **Ethnicity** |  |  |  |
| White British | 2166 (94.0%) | 247 (93.6%) | 150 (96.2%) |
| Non-white British | 139 (6.0%) | 17 (6.4%) | 6 (3.8%) |
| Missing | 90 | 10 | 5 |
| **Type of advanced disease** |  |  |  |
| Breast cancer | 569 (24.0%) | 66 (24.4%) | 36 (22.4%) |
| Colon or rectal cancer | 313 (13.2%) | 31 (11.4%) | 21 (13.0%) |
| Non-small cell lung cancer | 197 (8.3%) | 33 (12.2%) | 13 (8.1%) |
| Lung (other/not specified) | 255 (10.8%) | 13 (4.8%) | 9 (5.6%) |
| Prostate cancer | 354 (15.0%) | 46 (17.0%) | 27 (16.8%) |
| Urological (other/not prostate) | 97 (4.1%) | 14 (5.2%) | 10 (6.2%) |
| Upper GI cancer | 373 (15.8%) | 34 (12.5%) | 19 (11.8%) |
| Gynaecological | 78 (3.3%) | 5 (1.8%) | 2 (1.2%) |
| Haematological | 50 (2.1%) | 17 (6.3%) | 15 (9.3%) |
| Skin | 12 (0.5%) | 0 (0.0%) | 0 (0.0%) |
| Soft and connective tissue | 6 (0.3%) | 3 (1.1%) | 2 (1.2%) |
| Head and neck | 7 (0.3%) | 1 (0.4%) | 0 (0.0%) |
| Other | 24 (1.0%) | 0 (0.0%) | 0 (0.0%) |
| Unknown | 32 (1.4%) | 8 (3.0%) | 7 (4.3%) |
| Missing | 28 | 3 | 0 |
| **Stage of disease** |  |  |  |
| Locally advanced | 26 (9.6%) | 26 (9.6%) | 12 (7.5%) |
| Metastatic | 245 (90.1%) | 245 (90.1%) | 149 (92.5%) |
| Locally advanced and Metastatic | 1 (0.4%) | 1 (0.4%) | 0 (0.0%) |
| Missing | 2123 | 2 | 0 |
| **Time since original diagnosis (years to screening)** |  |  |  |
| N | NA | 255 | 161 |
| Mean (SD) |  | 3.5 (4.60) | 3.8 (4.92) |
| Median (Range) |  | 1.4 (0.0, 21.4) | 1.8 (0.0, 21.4) |

Table 18 Randomisation strata: Summary of treatment allocations at randomisation for stratification factors provided, and true values

|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
| **Randomisation factors** |  |  |  |
| **Site** |  |  |  |
| Diana Princess of Wales Hospital, Grimsby | 3 (3.8%) | 3 (3.7%) | 6 (3.7%) |
| Nottingham City Hospital | 4 (5.0%) | 4 (4.9%) | 8 (5.0%) |
| St James University Hospital | 56 (70.0%) | 58 (71.6%) | 114 (70.8%) |
| York Hospital | 8 (10.0%) | 7 (8.6%) | 15 (9.3%) |
| Bradford Royal Infirmary | 1 (1.3%) | 1 (1.2%) | 2 (1.2%) |
| Huddersfield Royal Infirmary | 4 (5.0%) | 5 (6.2%) | 9 (5.6%) |
| Churchill Hospital | 2 (2.5%) | 1 (1.2%) | 3 (1.9%) |
| Scarborough General Hospital | 2 (2.5%) | 2 (2.5%) | 4 (2.5%) |
| **Average pain item on the BPI** |  |  |  |
| 4-6 | 60 (75.0%) | 61 (75.3%) | 121 (75.2%) |
| 7-10a | 20 (25.0%) | 20 (24.7%) | 40 (24.8%) |
| **Consistency of the Average pain item on the BPI at randomisation** |  |  |  |
| **Average pain as randomised and patient reported pain consistent?** b |  |  |  |
| Yes | 75 (93.8%) | 75 (92.6%) | 150 (93.2%) |
| No | 5 (6.3%) | 6 (7.4%) | 11 (6.8%) |
| **Discrepancy** b |  |  |  |
| Randomised 4-6, patient BPI<4 | 1 (1.3%) | 2 (2.5%) | 3 (1.9%) |
| Randomised 4-6, patient BPI>6 | 0 (0.0%) | 1 (1.2%) | 1 (0.6%) |
| Randomised 7-10, missing patient BPI | 1 (1.3%) | 0 (0.0%) | 1 (0.6%) |
| Randomised 7-10, patient BPI<7 | 3 (3.8%) | 3 (3.7%) | 6 (3.7%) |
| **Average pain as recorded by the researcher for randomisation** |  |  |  |
| Missing | 0 | 0 | 0 |
| Mean (SD) | 5.7 (1.34) | 5.5 (1.40) | 5.6 (1.37) |
| Median (Range) | 5 (4, 10) | 5 (4, 10) | 5 (4, 10) |
| **Average pain as reported in the patient completed BPI** |  |  |  |
| Missing | 1 | 0 | 1 |
| Mean (SD) | 5.6 (1.36) | 5.3 (1.48) | 5.5 (1.42) |
| Median (Range) | 5 (2, 10) | 5 (2, 10) | 5 (2, 10) |
| **Average pain as reported in the patient completed BPI** |  |  |  |
| 0-3 | 1 (1.3%) | 2 (2.5%) | 3 (1.9%) |
| 4-6 | 62 (77.5%) | 61 (75.3%) | 123 (76.4%) |
| 7-10 | 16 (20.0%) | 18 (22.2%) | 34 (21.1%) |
| Missing | 1 (1.3%) | 0 (0.0%) | 1 (0.6%) |

a Average pain as recorded by the researcher for randomisation was entered incorrectly on the randomisation system for two participants (one in each arm) who were randomised with average pain 7-10, not 4-10.

b Discrepancies in average pain reported for randomisation and by the patient are due to differences in when the individual average pain BPI item was asked for screening/randomisation and when the patient completed baseline questionnaires including the BPI.

There were a number of discrepancies in average pain reported by the participant to inform screening and randomisation, and average pain reported by the participant on completion of their full baseline BPI questionnaire. Inconsistency in reporting of average pain, and two errors in entry at randomisation, resulted in a different average pain categorisation than that used in the randomisation for 11 (6.8%) participants.

Table 19 Further disease characteristics, and previous palliative care

|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
| **Stage of disease** |  |  |  |
| Locally advanced | 5 (6.3%) | 7 (8.6%) | 12 (7.5%) |
| Metastatic | 75 (93.8%) | 74 (91.4%) | 149 (92.5%) |
| **Disease progressive or incurable at diagnosis** |  |  |  |
| Yes | 43 (53.8%) | 58 (71.6%) | 101 (62.7%) |
| *Locally advanced* | *8 (10.0%)* | *13 (16.0%)* | *21 (13.0%)* |
| *Metastatic* | *35 (43.8%)* | *45 (55.6%)* | *80 (49.7%)* |
| No | 37 (46.3%) | 23 (28.4%) | 60 (37.3%) |
| **Years since advanced diagnosis (to randomisation)** |  |  |  |
| N | 33 | 22 | 55 |
| Missing | 47 | 59 | 106 |
| Mean (SD) | 1.5 (1.63) | 3.1 (3.85) | 2.1 (2.83) |
| Median (Range) | 1 (0, 5.6) | 1.7 (0.1, 14.4) | 1 (0, 14.4) |
| **Participant currently receiving pain medication** |  |  |  |
| Yes | 80 (100.0%) | 80 (98.8%) | 160 (99.4%) |
| *Strong opioid* | *48 (60.0%)* | *47 (58.0%)* | *95 (59.0%)* |
| *Weak opioid* | *37 (46.3%)* | *41 (50.6%)* | *78 (48.4%)* |
| *Non-opioid* | *56 (70.0%)* | *56 (69.1%)* | *112 (69.6%)* |
| *Adjuvant* | *18 (22.5%)* | *19 (23.5%)* | *37 (23.0%)* |
| No | 0 (0.0%) | 1 (1.2%) | 1 (0.6%) |
| **Referral to palliative care discussed previously** |  |  |  |
| Yes | 4 (5.0%) | 2 (2.5%) | 6 (3.7%) |
| *Patient declined previous input*  | *1 (1.3%)* | *1 (1.2%)* | *2 (1.2%)* |
| *Patient previously referred to palliative care and discharged prior to screening* | *3 (3.8%)* | *1 (1.2%)* | *4 (2.5%)* |
| No | 76 (95.0%) | 79 (97.5%) | 155 (96.3%) |
| **Identified for referral prior to screening** |  |  |  |
| Yes | 15 (18.8%) | 20 (24.7%) | 35 (21.7%) |
| No | 58 (72.5%) | 55 (67.9%) | 113 (70.2%) |
| NA (recruited to original protocol) a | 7 (8.8%) | 6 (7.4%) | 13 (8.1%) |

a After recruitment of the first 13 participants the trial protocol was amended to enable the recruitment of patients who had been identified for referral to palliative care prior to trial screening if palliative care contact had not yet been made. Prior to this amendment patients were not eligible if a referral had been made to palliative care; this question is therefore NA for the first 13 participants recruited however based on the eligibility criteria in place at the time of their recruitment no referral would have been made prior to screening.

##

**Participant Follow-up**

Table 20 Withdrawals

|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
| **Participant requested withdrawal**  |  |  |  |
| Yes | 4 (5.0%) | 5 (6.2%) | 9 (5.6%) |
| No | 76 (95.0%) | 76 (93.8%) | 152 (94.4%) |
| **Withdrawn from postal questionnaire completion** |  |  |  |
| Yes | 4 (5.0%) | 4 (4.9%) | 8 (5.0%) |
| No | 76 (95.0%) | 77 (95.1%) | 153 (95.0%) |
| **Participant withdrawn questionnaire completion via researcher contact** |  |  |  |
| Yes | 4 (5.0%) | 5 (6.2%) | 9 (5.6%) |
| No | 76 (95.0%) | 76 (93.8%) | 152 (94.4%) |
| **Participant willing further data to be collected** |  |  |  |
| Yes | 80 (100.0%) | 81 (100.0%) | 161 (100.0%) |
| **Withdrawal coincided with follow-up at** |  |  |  |
| 6-weeks post randomisation | 2 (50.0%) | 4 (80.0%) | 6 (66.7%) |
| 12-weeks post randomisationa | 2 (50.0%) | 1 (20.0%) | 3 (33.3%) |
| **Time to withdrawal (weeks)** |  |  |  |
| N | 4 | 5 | 9 |
| Mean (SD) | 11.9 (3.09) | 7.4 (2.70) | 9.4 (3.58) |
| Median (Range) | 12.4 (8.0, 14.7) | 6.4 (5.1, 12.0) | 8.0 (5.1, 14.7) |
| **Reason for withdrawal** |  |  |  |
| Does not want to focus on pain | 1 (1.3%) | 0 (0.0%) | 1 (0.6%) |
| Not in pain does not want to continue | 0 (0.0%) | 1 (1.2%) | 1 (0.6%) |
| Too unwell | 3 (3.8%) | 4 (4.9%) | 7 (4.3%) |

aTwo participants (one in each arm) who withdrew at the 12 week time point from both post and researcher questionnaire completion did complete their 6 week questionnaires; all other participants with a withdrawal completed no follow-up questionnaires.

Table 21 Overall questionnaire completion

| **Any questionnaire follow-up?** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
|  |  |  |  |
| **Yes** | **56 (70.0%)** | **59 (72.8%)** | **115 (71.4%)** |
| BL, 6 weeks, 12 weeks | *36 (45.0%)* | *43 (53.1%)* | *79 (49.1%)* |
| BL, 6 weeks | *15 (18.8%)* | *13 (16.0%)* | *28 (17.4%)* |
| BL, 12 weeks | *5 (6.3%)* | *3 (3.7%)* | *8 (5.0%)* |
| **No** | **24 (30.0%)** | **22 (27.2%)** | **46 (28.6%)** |
| BL only | *23 (28.8%)* | *22 (27.2%)* | *45 (28.0%)* |
| No BL or follow-up | *1 (1.3%)* | *0 (0.0%)* | *1 (0.6%)* |

Figure 17 Time between randomisation and questionnaire completion\*



\* Baseline questionnaires were to be completed prior to randomisation, however one baseline questionnaire was completed 2.4 weeks post randomisation, whilst the earliest questionnaire was completed ~ 2 weeks prior to randomisation. The latest questionnaires were completed at 9.4 weeks and 18.1 weeks for 6 and 12 week follow-up respectively.

Table 22 Help received for follow-up questionnaire completion

|  | **6 Week Follow up** | **12 Week Follow up** |
| --- | --- | --- |
|  | **SSM (n=51)** | **UC (n=56)** | **Total (n=107)** | **SSM (n=41)** | **UC (n=46)** | **Total (n=87)** |
| **Anyone help you complete this questionnaire** |  |  |  |  |  |  |
| Yes | 14 (27.5%) | 14 (25.0%) | 28 (26.2%) | 9 (22.0%) | 6 (13.0%) | 15 (17.2%) |
| No | 37 (72.5%) | 42 (75.0%) | 79 (73.8%) | 31 (75.6%) | 39 (84.8%) | 70 (80.5%) |
| Missing |  |  |  | 1 (2.4%) | 1 (2.2%) | 2 (2.3%) |
| **The person who helped you is** |  |  |  |  |  |  |
| Partner | 9 (64.3%) | 5 (35.7%) | 14 (50.0%) | 6 (66.7%) | 3 (50.0%) | 9 (60.0%) |
| Daughter/Son | 2 (14.3%) | 7 (50.0%) | 9 (32.1%) | 1 (11.1%) | 2 (33.3%) | 3 (20.0%) |
| Friend/Neighbour | 1 (7.1%) | 0 (0.0%) | 1 (3.6%) | 1 (11.1%) | 0 (0.0%) | 1 (6.7%) |
| Nurse | 1 (7.1%) | 0 (0.0%) | 1 (3.6%) | 1 (11.1%) | 1 (16.7%) | 2 (13.3%) |
| Grandchild | 0 (0.0%) | 1 (7.1%) | 1 (3.6%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Researcher | 1 (7.1%) | 1 (7.1%) | 2 (7.1%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| **Helped how (not mutually exclusive)** |  |  |  |  |  |  |
| Someone discussed the questions with you | 9 (64.3%) | 11 (78.6%) | 20 (71.4%) | 6 (66.7%) | 4 (66.7%) | 10 (66.7%) |
| Someone read out the questions | 8 (57.1%) | 12 (85.7%) | 20 (71.4%) | 7 (77.8%) | 4 (66.7%) | 11 (73.3%) |
| Someone ticked the boxes | 9 (64.3%) | 11 (78.6%) | 20 (71.4%) | 7 (77.8%) | 5 (83.3%) | 12 (80.0%) |
| Whole questionnaire completed on participant's behalf | 1 (7.1%) | 0 (0.0%) | 1 (3.6%) | 1 (11.1%) | 0 (0.0%) | 1 (6.7%) |
| Had to explain when the question was not clear | 1 (7.1%) | 0 (0.0%) | 1 (3.6%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |

Table 23 Participant baseline characteristics by 6 and 12 week primary outcome completion

|  | **6 week outcome** | **12 week outcome** |
| --- | --- | --- |
| **Characteristic** | **Not missing (n=107)** | **Missing** **(n=54)** | **Total** **(n=161)** | **P-valuea** | **Not missing (n=86)** | **Missing** **(n=75)** | **Total** **(n=161)** | **Association** **p-valuea** |
| **Randomisation Allocation** |  |  |  | 0.4692 |  |  |  | 0.3878 |
| Supported self-management | 51 (47.7%) | 29 (53.7%) | 80 (49.7%) |  | 40 (46.5%) | 40 (53.3%) | 80 (49.7%) |  |
| Usual Care | 56 (52.3%) | 25 (46.3%) | 81 (50.3%) |  | 46 (53.5%) | 35 (46.7%) | 81 (50.3%) |  |
| **Site** |  |  |  | *0.073* |  |  |  | *0.0847* |
| Grimsby | 4 (3.7%) | 2 (3.7%) | 6 (3.7%) |  | 3 (3.5%) | 3 (4.0%) | 6 (3.7%) |  |
| Nottingham  | 6 (5.6%) | 2 (3.7%) | 8 (5.0%) |  | 8 (9.3%) | 0 (0.0%) | 8 (5.0%) |  |
| Leeds | 80 (74.8%) | 34 (63.0%) | 114 (70.8%) |  | 58 (67.4%) | 56 (74.7%) | 114 (70.8%) |  |
| York  | 10 (9.3%) | 5 (9.3%) | 15 (9.3%) |  | 8 (9.3%) | 7 (9.3%) | 15 (9.3%) |  |
| Bradford  | 2 (1.9%) | 0 (0.0%) | 2 (1.2%) |  | 2 (2.3%) | 0 (0.0%) | 2 (1.2%) |  |
| Huddersfield  | 4 (3.7%) | 5 (9.3%) | 9 (5.6%) |  | 5 (5.8%) | 4 (5.3%) | 9 (5.6%) |  |
| Oxford | 0 (0.0%) | 3 (5.6%) | 3 (1.9%) |  | 0 (0.0%) | 3 (4.0%) | 3 (1.9%) |  |
| Scarborough  | 1 (0.9%) | 3 (5.6%) | 4 (2.5%) |  | 2 (2.3%) | 2 (2.7%) | 4 (2.5%) |  |
| **Gender** |  |  |  | 0.1636 |  |  |  | ***0.0377*** |
| Male | 55 (51.4%) | 34 (63.0%) | 89 (55.3%) |  | 41 (47.7%) | 48 (64.0%) | 89 (55.3%) |  |
| Female | 52 (48.6%) | 20 (37.0%) | 72 (44.7%) |  | 45 (52.3%) | 27 (36.0%) | 72 (44.7%) |  |
| **Patient has access to computer** |  |  |  | 0.1409 |  |  |  | 0.6291 |
| Yes | 78 (72.9%) | 45 (83.3%) | 123 (76.4%) |  | 67 (77.9%) | 56 (74.7%) | 123 (76.4%) |  |
| No | 29 (27.1%) | 9 (16.7%) | 38 (23.6%) |  | 19 (22.1%) | 19 (25.3%) | 38 (23.6%) |  |
| **ECOG Performance status** |  |  |  | ***0.0204*** b |  |  |  | *0.0897* b |
| 0 | 1 (0.9%) | 2 (3.7%) | 3 (1.9%) |  | 1 (1.2%) | 2 (2.7%) | 3 (1.9%) |  |
| 1 | 71 (66.4%) | 22 (40.7%) | 93 (57.8%) |  | 57 (66.3%) | 36 (48.0%) | 93 (57.8%) |  |
| 2 | 28 (26.2%) | 24 (44.4%) | 52 (32.3%) |  | 23 (26.7%) | 29 (38.7%) | 52 (32.3%) |  |
| 3 | 7 (6.5%) | 6 (11.1%) | 13 (8.1%) |  | 5 (5.8%) | 8 (10.7%) | 13 (8.1%) |  |
| **Type of advanced disease** |  |  |  | 0.1575 |  |  |  | 0.2067 |
| Breast cancer | 27 (25.2%) | 9 (16.7%) | 36 (22.4%) |  | 22 (25.6%) | 14 (18.7%) | 36 (22.4%) |  |
| olon or rectal cancer | 14 (13.1%) | 7 (13.0%) | 21 (13.0%) |  | 10 (11.6%) | 11 (14.7%) | 21 (13.0%) |  |
| Non-small cell lung cancer | 8 (7.5%) | 5 (9.3%) | 13 (8.1%) |  | 8 (9.3%) | 5 (6.7%) | 13 (8.1%) |  |
| Prostate cancer | 22 (20.6%) | 5 (9.3%) | 27 (16.8%) |  | 19 (22.1%) | 8 (10.7%) | 27 (16.8%) |  |
| Upper GI cancer | 9 (8.4%) | 10 (18.5%) | 19 (11.8%) |  | 8 (9.3%) | 11 (14.7%) | 19 (11.8%) |  |
| Lung (other/not specified) | 4 (3.7%) | 5 (9.3%) | 9 (5.6%) |  | 2 (2.3%) | 7 (9.3%) |  (5.6%) |  |
| Urological (other/not prostate) | 6 (5.6%) | 4 (7.4%) | 10 (6.2%) |  | 4 (4.7%) | 6 (8.0%) | 10 (6.2%) |  |
| Gynaecological | 2 (1.9%) | 0 (0.0%) | 2 (1.2%) |  | 1 (1.2%) | 1 (1.3%) | 2 (1.2%) |  |
| Haematological | 10 (9.3%) | 5 (9.3%) | 15 (9.3%) |  | 7 (8.1%) | 8 (10.7%) | 15 (9.3%) |  |
| Soft and connective tissue | 0 (0.0%) | 2 (3.7%) | 2 (1.2%) |  | 0 (0.0%) | 2 (2.7%) | 2 (1.2%) |  |
| Unknown | 5 (4.7%) | 2 (3.7%) | 7 (4.3%) |  | 5 (5.8%) | 2 (2.7%) | 7 (4.3%) |  |
| **Stage of disease** |  |  |  | 0.9874 |  |  |  | 0.7226 |
| Locally advanced | 8 (7.5%) | 4 (7.4%) | 12 (7.5%) |  | 7 (8.1%) | 5 (6.7%) | 12 (7.5%) |  |
| Metastatic | 99 (92.5%) | 50 (92.6%) | 149 (92.5%) |  | 79 (91.9%) | 70 (93.3%) | 149 (92.5%) |  |
| **Disease progressive/incurable at diagnosis** |  |  |  | *0.0769* |  |  |  | 0.1058 |
| Yes | 62 (57.9%) | 39 (72.2%) | 101 (62.7%) |  | 49 (57.0%) | 52 (69.3%) | 101 (62.7%) |  |
| No | 45 (42.1%) | 15 (27.8%) | 60 (37.3%) |  | 37 (43.0%) | 23 (30.7%) | 60 (37.3%) |  |
| **Patient on an opioid?** |  |  |  | ***0.0116*** |  |  |  | ***0.008*** |
| Strong opioid | 55 (51.4%) | 40 (74.1%) | 95 (59.0%) |  | 44 (51.2%) | 51 (68.0%) | 95 (59.0%) |  |
| Weak opioid | 39 (36.4%) | 8 (14.8%) | 47 (29.2%) |  | 34 (39.5%) | 13 (17.3%) | 47 (29.2%) |  |
| Non-opioid | 13 (12.1%) | 6 (11.1%) | 19 (11.8%) |  | 8 (9.3%) | 11 (14.7%) | 19 (11.8%) |  |
| **Receiving current treatment or within past month** |  |  |  | 0.7483 |  |  |  | 0.1497 |
| Yes | 74 (69.2%) | 36 (66.7%) | 110 (68.3%) |  | 63 (73.3%) | 47 (62.7%) | 110 (68.3%) |  |
| No | 33 (30.8%) | 18 (33.3%) | 51 (31.7%) |  | 23 (26.7%) | 28 (37.3%) | 51 (31.7%) |  |
| **Rand strata: average pain – correct values** |  |  |  | 0.3602 |  |  |  | 0.3018 |
| ≤6 | 86 (80.4%) | 40 (74.1%) | 126 (78.3%) |  | 70 (81.4%) | 56 (74.7%) | 126 (78.3%) |  |
| ≥7 | 21 (19.6%) | 14 (25.9%) | 35 (21.7%) |  | 16 (18.6%) | 19 (25.3%) | 35 (21.7%) |  |
| **Age** |  |  |  | ***0.0396*** |  |  |  | 0.1669 |
| Mean (SD) | 65.4 (10.77) | 61.4 (12.76) | 64.1 (11.59) |  | 65.3 (10.21) | 62.7 (12.92) | 64.1 (11.59) |  |
| Median (Range) | 67.0 (33.0, 85.0) | 63.0 (19.0, 84.0) | 66.0 (19.0, 85.0) |  | 66.5 (33.0, 85.0) | 65.0 (19.0, 84.0) | 66.0 (19.0, 85.0) |  |
| **Log transformed years since original diagnosis** |  |  |  | ***0.02*** |  |  |  | *0.0687* |
| Mean (SD) | 0.5 (1.79) | -0.2 (1.54) | 0.3 (1.74) |  | 0.5 (1.85) | 0.0 (1.57) | 0.3 (1.74) |  |
| Median (Range) | 1.1 (-3.3, 3.1) | 0.0 (-3.3, 2.9) | 0.6 (-3.3, 3.1) |  | 1.0 (-3.3, 3.1) | 0.3 (-3.3, 2.9) | 0.6 (-3.3, 3.1) |  |
| **BPI Worst pain - BL** |  |  |  | ***0.0003*** |  |  |  | ***0.0101*** |
| Mean (SD) | 7.3 (1.75) | 8.4 (1.58) | 7.7 (1.76) |  | 7.3 (1.83) | 8.1 (1.61) | 7.7 (1.76) |  |
| Median (Range) | 7.0 (0.0, 10.0) | 9.0 (5.0, 10.0) | 8.0 (0.0, 10.0) |  | 7.0 (0.0, 10.0) | 8.0 (5.0, 10.0) | 8.0 (0.0, 10.0) |  |
| **BPI Worst pain – 6 weeks** |  |  |  |  |  |  |  |  |
| N |  |  | NA |  | 78 | 29 | 107 |  |
| Missing |  |  |  |  | 8 | 46 | 54 |  |
| Mean (SD) |  |  |  |  | 5.6 (2.43) | 6.4 (2.06) | 5.8 (2.35) |  |
| Median (Range) |  |  |  |  | 6.0 (0.0, 10.0) | 7.0 (2.0, 10.0) | 6.0 (0.0, 10.0) |  |
| **BPI Pain severity score** |  |  |  | ***0.0006*** |  |  |  | *0.0953* |
| Mean (SD) | 4.7 (1.38) | 5.5 (1.51) | 5.0 (1.47) |  | 4.8 (1.42) | 5.2 (1.52) | 5.0 (1.47) |  |
| Median (Range) | 4.5 (2.0, 9.3) | 5.5 (3.0, 10.0) | 4.8 (2.0, 10.0) |  | 4.5 (2.0, 9.3) | 4.9 (2.8, 10.0) | 4.8 (2.0, 10.0) |  |
| **BPI Pain interference score** |  |  |  | ***0.0117*** |  |  |  | 0.1608 |
| Mean (SD) | 5.1 (2.36) | 6.1 (2.28) | 5.5 (2.37) |  | 5.2 (2.34) | 5.8 (2.39) | 5.5 (2.37) |  |
| Median (Range) | 5.1 (0.0, 10.0) | 6.4 (1.4, 10.0) | 5.6 (0.0, 10.0) |  | 5.4 (0.0, 10.0) | 6.0 (1.0, 10.0) | 5.6 (0.0, 10.0) |  |
| **PPQ Knowledge subscale** |  |  |  | 0.4742 |  |  |  | 0.5156 |
| Mean (SD) | 38.8 (15.57) | 36.9 (14.80) | 38.2 (15.30) |  | 38.9 (14.81) | 37.3 (15.91) | 38.2 (15.30) |  |
| Median (Range) | 38.0 (5.0, 80.0) | 35.0 (6.0, 70.0) | 37.0 (5.0, 80.0) |  | 38.0 (5.0, 69.0) | 35.0 (5.0, 80.0) | 37.0 (5.0, 80.0) |  |
| **PPQ Experience subscale** |  |  |  | ***0.0011*** |  |  |  | *0.0832* |
| Mean (SD) | 39.8 (8.97) | 44.9 (9.11) | 41.5 (9.30) |  | 40.3 (8.87) | 42.9 (9.67) | 41.5 (9.30) |  |
| Median (Range) | 39.0 (18.0, 61.0) | 45.0 (27.0, 61.0) | 40.5 (18.0, 61.0) |  | 39.5 (18.0, 61.0) | 42.5 (21.0, 61.0) | 40.5 (18.0, 61.0) |  |
| **PPQ Total score** |  |  |  | 0.2944 |  |  |  | 0.7376 |
| Mean (SD) | 78.6 (18.99) | 81.8 (17.18) | 79.7 (18.42) |  | 79.2 (18.06) | 80.2 (18.94) | 79.7 (18.42) |  |
| Median (Range) | 78.0 (36.0, 124.0) | 84.0 (34.0, 118.0) | 80.0 (34.0, 124.0) |  | 75.5 (36.0, 123.0) | 82.4 (34.0, 124.0) | 80.0 (34.0, 124.0) |  |
| **QLQc30 Global health status** |  |  |  | ***0.0498*** |  |  |  | 0.3994 |
| Mean (SD) | 48.8 (18.20) | 42.6 (19.04) | 46.7 (18.65) |  | 47.9 (19.10) | 45.4 (18.15) | 46.7 (18.65) |  |
| Median (Range) | 50.0 (8.3, 83.3) | 41.7 (0.0, 83.3) | 50.0 (0.0, 83.3) |  | 50.0 (0.0, 83.3) | 50.0 (0.0, 83.3) | 50.0 (0.0, 83.3) |  |
| **QLQc30 Physical functioning** |  |  |  | ***0.0026*** |  |  |  | ***0.0015*** |
| Mean (SD) | 52.8 (22.18) | 41.3 (22.04) | 49.0 (22.73) |  | 54.3 (21.52) | 42.8 (22.68) | 49.0 (22.73) |  |
| Median (Range) | 53.3 (6.7, 100.0) | 40.0 (6.7, 100.0) | 46.7 (6.7, 100.0) |  | 53.3 (13.3, 100.0) | 40.0 (6.7, 100.0) | 46.7 (6.7, 100.0) |  |
| **QLQc30 Role functioning** |  |  |  | ***0.0115*** |  |  |  | ***0.0102*** |
| Mean (SD) | 41.4 (27.79) | 28.9 (31.21) | 37.3 (29.47) |  | 42.8 (28.30) | 30.9 (29.67) | 37.3 (29.47) |  |
| Median (Range) | 33.3 (0.0, 100.0) | 33.3 (0.0, 100.0) | 33.3 (0.0, 100.0) |  | 50.0 (0.0, 100.0) | 33.3 (0.0, 100.0) | 33.3 (0.0, 100.0) |  |
| **QLQc30 Emotional functioning** |  |  |  | 0.6951 |  |  |  | 0.2901 |
| Mean (SD) | 60.8 (29.92) | 58.8 (30.11) | 60.1 (29.90) |  | 62.4 (29.95) | 57.4 (29.83) | 60.1 (29.90) |  |
| Median (Range) | 66.7 (0.0, 100.0) | 58.3 (0.0, 100.0) | 66.7 (0.0, 100.0) |  | 66.7 (0.0, 100.0) | 62.5 (0.0, 100.0) | 66.7 (0.0, 100.0) |  |
| **QLQc30 Cognitive functioning** |  |  |  | 0.7523 |  |  |  | 0.8795 |
| Mean (SD) | 66.4 (31.14) | 64.8 (26.89) | 65.8 (29.72) |  | 65.5 (30.01) | 66.2 (29.58) | 65.8 (29.72) |  |
| Median (Range) | 66.7 (0.0, 100.0) | 66.7 (0.0, 100.0) | 66.7 (0.0, 100.0) |  | 66.7 (0.0, 100.0) | 66.7 (0.0, 100.0) | 66.7 (0.0, 100.0) |  |
| **QLQc30 Social functioning** |  |  |  | *0.0564* |  |  |  | ***0.0499*** |
| Mean (SD) | 47.5 (30.70) | 37.7 (29.26) | 44.3 (30.49) |  | 48.6 (30.81) | 39.2 (29.51) | 44.3 (30.49) |  |
| Median (Range) | 50.0 (0.0, 100.0) | 33.3 (0.0, 100.0) | 33.3 (0.0, 100.0) |  | 50.0 (0.0, 100.0) | 33.3 (0.0, 100.0) | 33.3 (0.0, 100.0) |  |
| **EQ5D-3L QoL** |  |  |  | ***0.0058*** |  |  |  | ***0.0011*** |
| Mean (SD) | 0.6 (0.23) | 0.5 (0.27) | 0.6 (0.25) |  | 0.6 (0.23) | 0.5 (0.26) | 0.6 (0.25) |  |
| Median (Range) | 0.7 (-0.1, 1.0) | 0.5 (-0.2, 1.0) | 0.6 (-0.2, 1.0) |  | 0.7 (-0.1, 1.0) | 0.5 (-0.2, 1.0) | 0.6 (-0.2, 1.0) |  |
| **EQ5D-3L Your health today** |  |  |  | ***0.0072*** |  |  |  | ***0.0227*** |
| Mean (SD) | 56.0 (17.86) | 47.6 (18.92) | 53.2 (18.59) |  | 56.3 (18.86) | 49.6 (17.73) | 53.2 (18.59) |  |
| Median (Range) | 55.0 (10.0, 90.0) | 50.0 (10.0, 90.0) | 50.0 (10.0, 90.0) |  | 55.0 (10.0, 90.0) | 50.0 (10.0, 90.0) | 50.0 (10.0, 90.0) |  |
| **EORTC-8D QoL** |  |  |  | ***0.0366*** |  |  |  | ***0.0341*** |
| Mean (SD) | 0.6 (0.12) | 0.6 (0.13) | 0.6 (0.12) |  | 0.6 (0.12) | 0.6 (0.12) | 0.6 (0.12) |  |
| Median (Range) | 0.6 (0.3, 0.9) | 0.6 (0.3, 0.9) | 0.6 (0.3, 0.9) |  | 0.6 (0.3, 0.9) | 0.6 (0.3, 0.9) | 0.6 (0.3, 0.9) |  |

**a** Univariable association between the baseline participant characteristic and missing outcome - p-value from the univariable logistic regression model. Italics represent characteristics significant at the 10% level, bold represent characteristics significant at the 5% level.

b ECOG Performance status (0/1, 2, 3)

**Completeness of questionnaire data**

Completed questionnaire packs contained missing questionnaires, or pages of questionnaires for four (3.7%) participants at 6 weeks, and five (5.7%) participants at 12 weeks.

Over all time points, missing item level data were present for up to 2.8% of participants for an item on the BPI, 6.9% on the PPQ, 3.4% on the EORTC QLQ-c30, and 2.3% on the global rating of change (Table 24). Missing item level data resulted in the primary outcome, worst pain on the BPI, missing for one participant at 12 weeks. Missing item level data also resulted in the following missing scores: BPI pain severity for three participants at 6 weeks, BPI pain interference for one participant at 6 weeks, PPQ experience subscale for one participant at 12 weeks, PPQ knowledge subscale and PPQ total score for one participant at 6 weeks and three participants at 12 weeks, QLQ-c30 summary score for four participants at baseline, and three participants at 6 and 12 weeks.

Missing item level data also resulted in missing scores for: BPI pain severity, three participants at 6 weeks; BPI pain interference, one participant at 6 weeks; PPQ experience subscale, one participant at 12 weeks; PPQ knowledge subscale and PPQ total score, one participant at 6 weeks and three participants at 12 weeks; and QLQ-c30 summary score, four participants at baseline, and three participants at 6 and 12 weeks.

More than one response to the worst pain item on the BPI were recorded for one (0.6%), two (1.9%), and one (1.1%) participants at baseline, 6 and 12 weeks respectively; multiple responses to questions on the PPQ were recorded for five participants across time points, relating to 9 responses overall; and multiple responses to the Global change in pain question were recorded for two participants at 6 and 12 weeks. Primary analysis imputed the ‘worst’ response in each case. Multiple responses to the EORTC QLQ-c30 were excluded from analysis as per the scoring instructions.

Table 24 *Missing data and multiple responses for completed questionnaires*

|  | **Baseline (n=160)** | **6 weeks (n=107)** | **12 weeks (n=87)** |
| --- | --- | --- | --- |
| **Brief Pain Inventory** a |  |  |  |
| **Missing BPI pain severity or intensity item/s** | 2 (1.3%) | 5 (4.7%) | 3 (3.4%) |
| **Missing BPI pain severity item/s (and score)** | 0 (0.0%) | 0 (0.0%) | 3 (3.4%) |
| **Worst pain**  |  |  |  |
| More than one response a | 1 (0.6%) | 2 (1.9%) | 1 (1.1%) |
| Missing | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) |
| **Least pain**  |  |  |  |
| More than one response a | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) |
| **Average pain** |  |  |  |
| More than one response a | 1 (0.6%) | 3 (2.8%) | 0 (0.0%) |
| Missing | 0 (0.0%) | 0 (0.0%) | 2 (2.3%) |
| **Pain right now**  |  |  |  |
| More than one response a | 0 (0.0%) | 0 (0.0%) | 2 (2.3%) |
| **Missing BPI pain intensity item/s** | 2 (1.3%) | 5 (4.7%) | 0 (0.0%) |
| **General activity**  |  |  |  |
| More than one response a | 1 (0.6%) | 0 (0.0%) | 0 (0.0%) |
| Missing | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| **Mood**  |  |  |  |
| More than one response a | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| Missing | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| **Walking ability**  |  |  |  |
| More than one response a | 0 (0.0%) | 2 (1.9%) | 0 (0.0%) |
| Missing | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| **Normal work** |  |  |  |
| Missing | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| **Relations**  |  |  |  |
| Missing | 2 (1.3%) | 3 (2.8%) | 0 (0.0%) |
| **Sleep** |  |  |  |
| Missing | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| **Enjoyment of life** |  |  |  |
| More than one response a | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| Missing | 0 (0.0%) | 2 (1.9%) | 0 (0.0%) |
| **Patient Pain Questionnairea** |  |  |  |
| **PPQ Total score missing** | 0 (0.0%) | 1 (0.9%) | 3 (3.4%) |
| **PPQ Knowledge subscale missing** | 0 (0.0%) | 1 (0.9%) | 3 (3.4%) |
| **PPQ Experience subscale missing** | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) |
| **Q1 -** Missing | 1 (0.6%) | 3 (2.8%) | 3 (3.4%) |
| ***Q1 -*** *More than one response* | *0 (0.0%)* | *1 (0.9%)* | *1 (1.1%)* |
| **Q2 -** Missing | 0 (0.0%) | 2 (1.9%) | 3 (3.4%) |
| **Q3 -** Missing | 0 (0.0%) | 3 (2.8%) | 5 (5.7%) |
| **Q4 -** Missing | 1 (0.6%) | 3 (2.8%) | 3 (3.4%) |
| **Q5 -** Missing | 0 (0.0%) | 2 (1.9%) | 3 (3.4%) |
| **Q6 -** Missing | 1 (0.6%) | 3 (2.8%) | 4 (4.6%) |
| **Q7 -** Missing | 1 (0.6%) | 5 (4.7%) | 6 (6.9%) |
| **Q8 -** Missing | 1 (0.6%) | 2 (1.9%) | 4 (4.6%) |
| **Q9 -** Missing | 0 (0.0%) | 3 (2.8%) | 4 (4.6%) |
| **Q10 -** Missing | 0 (0.0%) | 1 (0.9%) | 1 (1.1%) |
| ***Q10 -*** *More than one response* | *1 (0.6%)* | *0 (0.0%)* | *0 (0.0%)* |
| **Q11 -** Missing | 0 (0.0%) | 1 (0.9%) | 1 (1.1%) |
| ***Q11 -*** *More than one response* | *0 (0.0%)* | *0 (0.0%)* | *2 (2.3%)* |
| **Q12 -** Missing | 0 (0.0%) | 2 (1.9%) | 3 (3.4%) |
| **Q13 -** Missing | 0 (0.0%) | 1 (0.9%) | 2 (2.3%) |
| ***Q13*** *- More than one response* | *0 (0.0%)* | *1 (0.9%)* | *0 (0.0%)* |
| **Q14 -** Missing | 2 (1.3%) | 1 (0.9%) | 3 (3.4%) |
| **Q15 -** Missing | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) |
| ***Q15 -*** *More than one response* | *0 (0.0%)* | *2 (1.9%)* | *0 (0.0%)* |
| **Q16 -** Missing | 0 (0.0%) | 3 (2.8%) | 5 (5.7%) |
| ***Q16 -*** *More than one response* | *0 (0.0%)* | *0 (0.0%)* | *1 (1.1%)* |
| **EORTC-QLQ c30 – Items missing** |  |  |  |
| Summary score missing | 4 (2.5%) | 3 (2.8%) | 3 (3.4%) |
| Q1 **-** Missing | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| Q2 **-** Missing | 1 (0.6%) | 1 (0.9%) | 0 (0.0%) |
| Q3 **-** Missing | 0 (0.0%) | 2 (1.9%) | 1 (1.1%) |
| Q4 **-** Missing | 1 (0.6%) | 1 (0.9%) | 1 (1.1%) |
| Q5 **-** Missing | 1 (0.6%) | 0 (0.0%) | 0 (0.0%) |
| Q6 **-** Missing | 0 (0.0%) | 2 (1.9%) | 2 (2.3%) |
| Q7 **-** Missing | 2 (1.3%) | 0 (0.0%) | 1 (1.1%) |
| Q8 **-** Missing | 2 (1.3%) | 2 (1.9%) | 1 (1.1%) |
| Q9 **-** Missing | 4 (2.5%) | 0 (0.0%) | 2 (2.3%) |
| Q10 **-** Missing | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) |
| Q11 **-** Missing | 1 (0.6%) | 0 (0.0%) | 0 (0.0%) |
| Q12 **-** Missing | 1 (0.6%) | 0 (0.0%) | 0 (0.0%) |
| Q13 **-** Missing | 0 (0.0%) | 1 (0.9%) | 1 (1.1%) |
| Q14 **-** Missing | 2 (1.3%) | 1 (0.9%) | 0 (0.0%) |
| Q15 **-** Missing | 0 (0.0%) | 1 (0.9%) | 0 (0.0%) |
| Q16 **-** Missing | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) |
| Q17 **-** Missing | 1 (0.6%) | 0 (0.0%) | 1 (1.1%) |
| Q18 **-** Missing | 1 (0.6%) | 0 (0.0%) | 1 (1.1%) |
| Q19 **-** Missing | 0 (0.0%) | 2 (1.9%) | 1 (1.1%) |
| Q20 **-** Missing | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) |
| Q21 **-** Missing | 1 (0.6%) | 0 (0.0%) | 1 (1.1%) |
| Q22 **-** Missing | 0 (0.0%) | 0 (0.0%) | 1 (1.1%) |
| Q23 **-** Missing | 0 (0.0%) | 1 (0.9%) | 2 (2.3%) |
| Q24 **-** Missing | 1 (0.6%) | 0 (0.0%) | 2 (2.3%) |
| Q25 **-** Missing | 1 (0.6%) | 1 (0.9%) | 1 (1.1%) |
| Q26 **-** Missing | 1 (0.6%) | 1 (0.9%) | 3 (3.4%) |
| Q27 **-** Missing | 1 (0.6%) | 0 (0.0%) | 1 (1.1%) |
| Q28 **-** Missing | 0 (0.0%) | 0 (0.0%) | 3 (3.4%) |
| Q29 **-** Missing | 0 (0.0%) | 1 (0.9%) | 1 (1.1%) |
| Q30 **-** Missing | 1 (0.6%) | 1 (0.9%) | 1 (1.1%) |
| **Global change in paina** |  |  |  |
| More than one response |  | 2 (1.9%) | 1 (1.1%) |
| Missing |  | 2 (1.9%) | 2 (2.3%) |

aPrimary analysis imputes the worst pain score where more than one response was provided

Inconsistencies were present across the four pain severity items (worst, least, average, current pain) for over 10% of participants at each time point (Table 25). Inconsistencies were largely due to participants reporting least pain as more than current pain, and further inconsistencies comprised worst pain less than least pain or current pain. Inconsistencies question the internal validity of the BPI pain severity items within our sample, however as questionnaire data could not be further queried with participants the responses as recorded are used within the analysis.

Table 25 Number of completed questionnaires with inconsistency within the BPI severity items

|  | **Baseline (n=160)** | **6 weeks (n=107)** | **12 weeks (n=87)** |
| --- | --- | --- | --- |
| **Inconsistency reported pain severity?** |  |  |  |
| Yes | 17 (10.6%) | 18 (16.8%) | 12 (13.8%) |
| *Worst pain less than least pain* | *0 (0.0%)* | *2 (1.9%)* | *4 (4.6%)* |
| *Worst pain less than current pain* | *2 (1.3%)* | *5 (4.7%)* | *3 (3.4%)* |
| *Least pain more than current pain* | *15 (9.4%)* | *13 (12.1%)* | *9 (10.3%)* |
| No | 143 (89.4%) | 89 (83.2%) | 75 (86.2%) |

**Safety**

Table 26 Number, timing and place of death

|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
| **Patient known to have died?** |  |  |  |
| Yes\* | 45 (56.3%) | 47 (58.0%) | 92 (57.1%) |
| No | 35 (43.8%) | 34 (42.0%) | 69 (42.9%) |
|  |  |  |  |
| **Place of death** |  |  |  |
| Home | 14 (31.1%) | 12 (25.5%) | 26 (28.3%) |
| Hospice | 22 (48.9%) | 19 (40.4%) | 41 (44.6%) |
| Hospital | 6 (13.3%) | 14 (29.8%) | 20 (21.7%) |
| Nursing home | 2 (4.4%) | 1 (2.1%) | 3 (3.3%) |
| Unknown | 1 (2.2%) | 1 (2.1%) | 2 (2.2%) |
|  |  |  |  |
| **Median survival (weeks, 95% CI)** | 52.4 ( 32.1, 67.3) | 53.3 ( 34.3, 59.4) | 53.3 ( 40.9, 59.6) |
|  |  |  |  |
| **6 week post randomisation** |  |  |  |
| Number died | 5 | 3 | 8 |
| Number alive | 75 | 78 | 153 |
| Death rate, % (95% CI) | 6.2% (0.9%, 11.6%) | 3.7% (0.0%, 7.8%) | 5.0% (1.6%, 8.3%) |
| Survival estimate, % (95% CI) | 93.8% (88.4%, 99.1%) | 96.3% (92.2%, 100.0%) | 95.0% (91.7%, 98.4%) |
|  |  |  |  |
| **12 week post randomisation** |  |  |  |
| Number died | 14 | 11 | 25 |
| Number alive | 66 | 70 | 136 |
| Death rate % (95% CI) | 17.5% (9.2%, 25.8%) | 13.6% (6.1%, 21.0%) | 15.5% (9.9%, 21.1%) |
| Survival estimate, % (95% CI) | 82.5% (74.2%, 90.8%) | 86.4% (79.0%, 93.9%) | 84.5% (78.9%, 90.1%) |

\*Almost all were cancer related however one was detailed as due to Cerebro-vascular accident, two Pneumonia, and one Sepsis.

**Intervention delivery**

Table 27 Intervention training

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Recruiting Hospital Site** | **Intervention site / community palliative care team base** | **N participants recruited** | **Training dates** | **N total staff trained** | **N staff delivering the initial palliative care visit to participants** |
| **Supported self-management** | **Usual care** | **Total** |
| Leeds | St Gemma’s, Leeds | 43 | 28/09/2015 (90 mins)08/10/2015 (85 mins)20/04/2016 (25 mins)10/07/2017 (30 mins)24/07/2017 (30 mins)+ follow-up visits (x3) | 16 | 12 | 9 | 14 |
| Wheatfield’s (Sue Ryder), Leeds | 59 | 15/09/2015 (55 mins)07/04/2016 (15 mins)12/04/2016 (30 mins)follow up phone call (x1) | 15 | 12 | 9 | 12 |
| Mid Yorkshire NHS Palliative Care, Wakefield | 5 | 07/09/2016 (70 mins) | 7 | 2\* | 3\* | 3\* |
| Leeds / Huddersfield | Kirkwood, Huddersfield | *13* | *23/09/2015 (missing)**14/04/2016 (60 mins)**16/05/2017 (50 mins)* | *8* | *3* | *4* | *5* |
| Leeds / Bradford | Marie Curie, Bradford | *5* | *24/09/2015 (80 mins)**08/04/2016 (10 mins)* | *6* | *3\** | *1* | *3* |
| Scarborough | St Catherine’s | 4 | 18/09/2015 (115 mins) | 8 | 2\* | 1 | 2\* |
| MacMillan CNS Team, Humber NHSFT | 0 | 18/08/2016 (65 mins) | 1 |  |  |  |
| York | St Leonard’s, York | 15 | 12/01/2016 (105 mins)22/04/2016 (80 mins) | 16 | 6 | 6\* | 10\* |
| Nottingham | CityCare | 8 | 05/05/2016 (20 mins, TC)follow up phone call (x1) | 5 | 2 | 2 | 2 |
| Grimsby | Care Plus | 6 | 04/08/2016 (60 mins) | 9 | 2\* | 2 | 4 |
| Oxford | Sobell House | 3 | 20/09/2017 (140mins inc. recruitment process) | 16 | 2 | 1\* | 3\* |

\*The following personnel were detailed as delivering the initial visit but were not detailed within the training logs: #128 Mid Yorkshire NHS Palliative Care, Wakefield; #114 Marie Curie, Bradford; #34 St Leonard’s, York; #65 Care Plus, Grimsby; #106 St Catherine’s Hospice, Scarborough; #140 Sobell House Hospice, Oxford

Table 28 Participants initial palliative care visit – location, duration, and timing

|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
| **Participant happy to receive care in community** |  |  |  |
| Yes | 78 (97.5%) | 71 (87.7%) | 149 (92.5%) |
| Noa | 2 (2.5%) | 4 (4.9%) | 6 (3.7%) |
| NAb | 0 (0.0%) | 6 (7.4%) | 6 (3.7%) |
| **Location of visit** |  |  |  |
| In clinic/hospice | 1 (1.3%) | 3 (4.2%) | 4 (2.7%) |
| Participants home | 74 (94.9%) | 68 (95.8%) | 142 (95.3%) |
| Workplace | 1 (1.3%) | 0 (0.0%) | 1 (0.7%) |
| Telephone | 2 (2.6%) | 0 (0.0%) | 2 (1.3%) |
| **Visit duration (minutes)** |  |  |  |
| N | 69 | 64 | 133 |
| Missing | 9 | 7 | 16 |
| Mean (SD) | 75.6 (23.26) | 79.1 (21.96) | 77.3 (22.63) |
| Median (Range) | 75.0 (15, 130) | 75.0 (30, 120) | 75.0 (15, 130) |
| **Weeks to first palliative care visit** |  |  |  |
| N | 78 | 71 | 149 |
| Mean (SD) | 1.4 (1.36) | 1.4 (1.63) | 1.4 (1.49) |
| Median (Range) | 1.0 (0.1, 8.7) | 1.0 (0.0, 11.0) | 1.0 (0.0, 11.0) |
| **Initial palliative care visit within one week of randomisation?** |  |  |  |
| Yes | 45 (57.7%) | 40 (56.3%) | 85 (57.0%) |
| No | 33 (42.3%) | 31 (43.7%) | 64 (43.0%) |
| **Reason visit late**  |  |  |  |
| Participant busy / holiday / convenience | 15 (45.5%) | 10 (32.3%) | 25 (39.1%) |
| Participant in hospital | 11 (33.3%) | 7 (22.6%) | 18 (28.1%) |
| CNS annual leave/logistics | 2 (6.1%) | 7 (22.6%) | 9 (14.1%) |
| Difficulty making contact | 1 (3.0%) | 2 (6.5%) | 3 (4.7%) |
| Unknown | 3 (9.1%) | 3 (9.7%) | 6 (9.4%) |
| Otherc | 1 (3.0%) | 2 (6.5%) | 3 (4.7%) |

aReasons participants did not receive care in the community:

* *Initial delay contacting patient, patient then in hospital for knee replacement and CNS did not feel appropriate by time of discharge.*
* *Too much going on with hospital visits*
* *Patient well and working full time. Stated they will contact Oncologist if further intervention required.*
* *Patient declined home visits as pain was very well controlled after radiotherapy.*
* *Feels that pain is well controlled and does not want intervention*
* *Declined input from community team and district nurses. Disease progressed - admitted to hospital. On discharge contact made again form symptom management; this support was accepted.*

bThe six usual care participants NA to receive care in the community were randomised to the first part of the study where care in the community was not on offer.

cOther reasons for late visits: patient did not initially want care in the community - one in each arm (8.7 weeks SSM and 11 weeks UC), and in order to allow granddaughter to be present.

Table 29 Participants initial palliative care visit – palliative care needs and medications (in those happy to receive care in the community with a visit)

|  | **SSM (n=78)** | **UC (n=71)** | **Total (n=149)** |
| --- | --- | --- | --- |
| **Palliative care needs addressed /established** |  |  |  |
| Yes | 77 (98.7%) | 71 (100.0%) | 148 (99.3%) |
| No | 1 (1.3%) | 0 (0.0%) | 1 (0.7%) |
| **Which palliative care needs addressed (not mutually exclusive)** |  |  |  |
| None | 1 (1.3%) | 0 (0.0%) | 1 (0.7%) |
| Pain | 72 (92.3%) | 69 (97.2%) | 141 (94.6%) |
| Additional symptoms | 41 (52.6%) | 45 (63.4%) | 86 (57.7%) |
| Carer concerns | 15 (19.2%) | 15 (21.1%) | 30 (20.1%) |
| Psychological needs | 37 (47.4%) | 34 (47.9%) | 71 (47.7%) |
| Othera | 8 (10.3%) | 13 (18.3%) | 21 (14.1%) |
| **Recommend change to medication** |  |  |  |
| Yes | 51 (65.4%) | 49 (69.0%) | 100 (67.1%) |
| No | 27 (34.6%) | 22 (31.0%) | 49 (32.9%) |
| **Recommend change to medication according to strongest baseline medication** |  |  |  |
| Strong opioid | 33 (71.7%) | 28 (66.7%) | 61 (69.3%) |
| Weak opioid | 14 (60.9%) | 17 (77.3%) | 31 (68.9%) |
| Non-opioid | 4 (44.4%) | 3 (50.0%) | 7 (46.7%) |
| No medication | 0 (0.0%) | 1 (100.0%) | 1 (100.0%) |

a Other care needs established included: anxiety (2), benefits (3), future/end of life care (3), family support (1), finances (6), housing (1), further/other symptoms (2), physio/referrals (3)

Table 30 Health care professional Pain Check uptake

|  | **SSM participants with PainCheck log on (n=32)** |
| --- | --- |
| **Health care professional Pain Check use (per participant)** |  |
| HCP logged onto pain check | 21 (65.6%) |
| *Same HCP who conducted the initial visit* | *11* |
| *Same HCP who conducted the initial visit + another HCP* | *5* |
| *Different HCP* | *5* |
| No HCP pain check log on | 11 (34.4%) |
| **Number of HCPs using pain Check (per participant)** |  |
| 0 | 11 (34.4%) |
| 1 | 16 (50.0%) |
| 2 | 5 (15.6) |
| **HCP Total times Pain Check accessed** |  |
| N | 32 |
| Missing | 0 |
| Mean (SD) | 4.2 (10.57) |
| Median (Range) | 1 (0, 55) |
| **HCP Total time on Pain Check (mins)** |  |
| N | 19 |
| Missinga | 13 |
| Mean (SD) | 56.4 (94.07) |
| Median (Range) | 25.7 (3.1, 423.3) |
| **HCP engaged with PainCheck (3+)?** |  |
| Yes | 9 (28.1%) |
| No | 23 (71.9%) |

a Missing for two HCPs who did log on due to single log in with no log off

**Effectiveness analysis**

**Missing data**

Table 31 Summary of variables identified and selected as predictive of missing data (P<0.10 for inclusion in forward selection)

|  |  |
| --- | --- |
|  | **Selected as predictive of missing** |
|  | **6 weeks** | **12 weeks** |
| **Pre-specified variables for MI** |
| BL BPI Worst pain | x |  |
| Gender |  | x |
| Rand strata: average pain |  |  |
| Age | x |  |
| Site |  | x |
| Randomisation Allocation |  |  |
| **Identified additional variables for MI**  |
| Patient on an opioid | x | x |
| EQ5D-3L Your health today | x |  |
| EQ5D-3L QoL |  | x |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Significant at selection step |  | P-value<0.05 |  | P-value<0.1 |

Table 32 Summary of univariable effects, effects entered at each selection step, and final multivariable associations for selected baseline variables with missing worst pain outcome at 6 and 12 weeks (P<0.10 for inclusion in forward selection)

|  | **Step** | **Effect Entered** | **DF** | **Univariable p-value** | **Selection step P-value** | **Final multivariable P-value** |
| --- | --- | --- | --- | --- | --- | --- |
| **6 weeks** | 1 | Worst pain | 1 | 0.0003 | 0.0003 | 0.0028 |
| 2 | **Patient on an opioid?** | 2 | 0.0116 | 0.0148 | 0.0212 |
| 3 | EQ5D-3L Your health today | 1 | 0.0072 | 0.0352 | 0.0384 |
| 4 | Age  | 1 | 0.0396 | 0.0605 | 0.0640 |
| **12 weeks** | 1 | EQ5D-3L QoL | 1 | 0.0011 | 0.0011 | 0.0008 |
| 2 | **Patient on an opioid?** | 2 | 0.008 | 0.0044 | 0.0026 |
| 3 | Gender | 1 | 0.0377 | 0.0294 | 0.0480 |
| 4 | Site | 7 | 0.0847 | 0.0537 | 0.9952 |

\*Bold= effects selected at both 6 and 12 weeks.

**Primary outcome**

Figure 18 BPI pain severity items with unadjusted 95% CIs



Table 33 Summary statistics for the BPI pain severity items and scores at baseline and follow-up

| **BPI Pain Severity Outcome** *(score 0-10;* *higher score = increased pain)* | **Baseline** | **6 weeks** | **12 weeks** |
| --- | --- | --- | --- |
| **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| **Worst pain** |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 56 | 107 | 40 | 46 | 86 |
| Mean (SD) | 7.7 (1.84) | 7.6 (1.70) | 7.7 (1.76) | 6.1 (2.29) | 5.6 (2.40) | 5.8 (2.35) | 4.9 (3.10) | 4.5 (3.10) | 4.7 (3.09) |
| Median (Range) | 8 (0, 10) | 8 (4, 10) | 8 (0, 10) | 6 (2, 10) | 6 (0, 10) | 6 (0, 10) | 5 (0, 10) | 4 (0, 10) | 5 (0, 10) |
| **Worst pain category** |  |  |  |  |  |  |  |  |  |
| No pain | 1 (1.3%) | 0 (0.0%) | 1 (0.6%) | 0 (0.0%) | 2 (3.6%) | 2 (1.9%) | 6 (15.0%) | 9 (19.6%) | 15 (17.4%) |
| Mild pain (1-4) | 1 (1.3%) | 1 (1.2%) | 2 (1.3%) | 14 (27.5%) | 16 (28.6%) | 30 (28.0%) | 8 (20.0%) | 15 (32.6%) | 23 (26.7%) |
| Moderate pain (5-6) | 15 (19.0%) | 22 (27.2%) | 37 (23.1%) | 12 (23.5%) | 17 (30.4%) | 29 (27.1%) | 11 (27.5%) | 8 (17.4%) | 19 (22.1%) |
| Severe pain (7-10) | 62 (78.5%) | 58 (71.6%) | 120 (75.0%) | 25 (49.0%) | 21 (37.5%) | 46 (43.0%) | 15 (37.5%) | 14 (30.4%) | 29 (33.7%) |
| **Least pain** |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 56 | 107 | 41 | 46 | 87 |
| Mean (SD) | 2.5 (1.97) | 2.8 (1.94) | 2.6 (1.95) | 2.9 (2.32) | 2.6 (1.96) | 2.7 (2.13) | 2.5 (2.43) | 2.3 (2.41) | 2.4 (2.41) |
| Median (Range) | 2 (0, 9) | 2 (0, 10) | 2 (0, 10) | 2 (0, 9) | 3 (0, 9) | 2 (0, 9) | 2 (0, 8) | 2 (0, 10) | 2 (0, 10) |
| **Average pain** |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 56 | 107 | 40 | 45 | 85 |
| Mean (SD) | 5.6 (1.36) | 5.4 (1.47) | 5.5 (1.42) | 4.6 (2.00) | 4.1 (1.97) | 4.3 (1.99) | 3.8 (2.09) | 3.7 (2.56) | 3.7 (2.34) |
| Median (Range) | 5 (2, 10) | 5 (2, 10) | 5 (2, 10) | 5 (1, 9) | 4 (0, 10) | 4 (0, 10) | 4 (0, 8) | 4 (0, 10) | 4 (0, 10) |
| **Pain right now** |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 56 | 107 | 41 | 46 | 87 |
| Mean (SD) | 4.0 (2.33) | 4.2 (2.41) | 4.1 (2.37) | 3.7 (2.46) | 3.8 (2.56) | 3.7 (2.50) | 3.1 (2.75) | 3.2 (2.88) | 3.2 (2.80) |
| Median (Range) | 4 (0, 10) | 4 (0, 10) | 4 (0, 10) | 3 (0, 9) | 4 (0, 10) | 4 (0, 10) | 3 (0, 8) | 3 (0, 10) | 3 (0, 10) |
| **Overall pain severity score** |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 56 | 107 | 39 | 45 | 84 |
| Mean (SD) | 4.9 (1.39) | 5.0 (1.56) | 5.0 (1.47) | 4.3 (1.95) | 4.0 (1.99) | 4.2 (1.97) | 3.6 (2.29) | 3.4 (2.61) | 3.5 (2.45) |
| Median (Range) | 4.8 (2, 8.8) | 4.5 (2, 10) | 4.8 (2, 10) | 4 (0.8, 9.0) | 4.3 (0, 9.8) | 4.0 (0, 9.8) | 3.8 (0, 8.3) | 2.8 (0, 10.0) | 3.4 (0, 10) |

Table 34 Summary statistics for the change in the primary outcome compared to baseline

|  | **6 weeks** | **12 weeks** |
| --- | --- | --- |
|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| **Change in worst pain since baseline (- indicates reduction)** |  |  |  |  |  |  |
| N | 51 | 56 | 107 | 40 | 46 | 86 |
| Mean (SD) | -1.2 (2.62) | -1.8 (2.61) | -1.5 (2.62) | -2.3 (3.74) | -3.0 (3.37) | -2.7 (3.54) |
| Median (Range) | -1 (-7, 8) | -1 (-8, 3) | -1 (-8, 8) | -2.0 (-10, 10) | -2 (-10, 2) | -2 (-10, 10) |
| **Percentage change in worst pain since baseline (- indicates reduction)** |  |  |  |  |  |  |
| N | 50 | 56 | 106 | 39 | 46 | 85 |
| Mean (SD) | -17.0 (32.96) | -21.8 (34.68) | -19.5 (33.80) | -33.5 (44.36) | -38.0 (41.79) | -35.9 (42.79) |
| Median (Range) | -12.5 (-71.4, 60) | -15.5 (-100, 50) | -14.3 (-100, 60) | -28.6 (-100, 40) | -33.3 (-100, 40) | -28.6 (-100, 40) |
| **Responder - reduction in worst pain by 2+ points or ≥30%** |  |  |  |  |  |  |
| Yes | 20 (39.2%) | 24 (42.9%) | 44 (41.1%)a | 23 (57.5%) | 26 (56.5%) | 49 (57.0%)b |
| No | 31 (60.8%) | 32 (57.1%) | 63 (58.9%) | 17 (42.5%) | 20 (43.5%) | 37 (43.0%) |
| Missing | 29 | 25 | 54 | 40 | 35 | 75 |
| **Change in worst pain from baseline** |  |  |  |  |  |  |
| Reduction | 31 (60.8%) | 37 (66.1%) | 68 (63.6%) | 28 (70.0%) | 33 (71.7%) | 61 (70.9%) |
| No change | 11 (21.6%) | 7 (12.5%) | 18 (16.8%) | 4 (10.0%) | 8 (17.4%) | 12 (14.0%) |
| Increase | 9 (17.6%) | 12 (21.4%) | 21 (19.6%) | 8 (20.0%) | 5 (10.9%) | 13 (15.1%) |
| Missing | 29 | 25 | 54 | 40 | 35 | 75 |

a At 6 weeks, of the 44 responders, all but two had both a >=2 point and a >=30% reduction, the two remaining had a reduction of 2 points corresponding to a 25% (8 to 6 point) reduction and a 22.2% (9 to 7 point) reduction.

b At 12 weeks, of the 49 responders, all but seven had both a >=2 point and a >=30% reduction, the seven remaining had a reduction of 2 points corresponding to a 28.6% (8 to 6 point) reduction for five participants, and a 28.6% (7 to 5 point) reduction for two participants.

Table 35 Adjusted mean scores with 95% CIs for pain severity outcomes on the BPI (Sensitivity analysis to availability of data, adjusted for baseline score and covariates)

| **BPI Pain Severity Outcome** *(score 0-10;* *higher score = increased pain)* | **6 weeks** | **12 Weeks** |
| --- | --- | --- |
| **N** | **SSM, Mean (95% CI), SE** | **UC, Mean (95% CI), SE** | **Difference a, Mean** **(95% CI), SE, p-value** | **N** | **SSM, Mean (95% CI), SE** | **UC, Mean (95% CI), SE** | **Difference a, Mean** **(95% CI), SE, p-value** |
|  |  |  |  |  |  |  |  |  |
| **Primary outcome: Worst Pain** | 107 | 7.1 (6.1, 8.1), SE=0.51 | 6.6 (5.6, 7.6), SE=0.50 | 0.4 (-0.4, 1.3), SE=0.44, p=0.3292 | 86 | 5.9 (4.7, 7.1), SE=0.61 | 5.6 (4.4, 6.7), SE=0.58 | 0.3 (-0.9, 1.6), SE=0.64, p=0.6099 |
|  |  |  |  |  |  |  |  |  |
| **Secondary Pain severity outcomes:** |  |  |  |  |  |  |  |  |
| **Least Pain** | 107 | 3.8 (2.9, 4.7), SE=0.46 | 3.7 (2.8, 4.6), SE=0.46 | 0.1 (-0.7, 0.8), SE=0.39, p=0.8784 | 87 | 3.6 (2.6, 4.5), SE=0.50 | 3.3 (2.3, 4.2), SE=0.48 | 0.3 (-0.6, 1.2), SE=0.47, p=0.5094 |
|  |  |  |  |  |  |  |  |  |
| **Average pain** | 107 | 4.8 (3.9, 5.7), SE=0.46 | 4.7 (3.8, 5.5), SE=0.42 | 0.1 (-0.6, 0.9), SE=0.37, p=0.6900 | 85 | 4.2 (3.2, 5.2), SE=0.51 | 4.3 (3.3, 5.2), SE=0.47 | -0.1 (-1.0, 0.9), SE=0.49, p=0.9067 |
|  |  |  |  |  |  |  |  |  |
| **Pain right now** | 107 | 4.3 (3.2, 5.3), SE=0.53 | 4.6 (3.5, 5.6), SE=0.52 | -0.3 (-1.2, 0.7), SE=0.48, p=0.5649 | 87 | 3.7 (2.6, 4.9), SE=0.57 | 3.9 (2.9, 5.0), SE=0.54 | -0.2 (-1.3, 0.9), SE=0.57, p=0.7173 |
|  |  |  |  |  |  |  |  |  |
| **Overall pain severity score** | 107 | 4.9 (4.0, 5.7), SE=0.42 | 4.8 (3.9, 5.6), SE=0.41 | 0.1 (-0.6, 0.8), SE=0.36, p=0.7753 | 84 | 4.3 (3.3, 5.2), SE=0.49 | 4.1 (3.2, 5.0), SE=0.46 | 0.2 (-0.8, 1.1), SE=0.49, p=0.7566 |
|  |  |  |  |  |  |  |  |  |

a Difference: SSM - UC

Table 36 Adjusted mean proportions, Odds and Odds Ratios with 95% CIs for response (≥30% or ≥2 point reduction) on the primary outcome (Sensitivity analysis to availability of data, adjusted for baseline score and covariates)

| **Time point** |  | **Mean proportion (95% CI), SE** | **Odds (95% CI)** | **Odds Ratio (95% CI), p-value** |
| --- | --- | --- | --- | --- |
| **N** | **SSM** | **UC** | **SSM** | **UC** | **SSM vs UC** |
|  |  |  |  |  |  |  |
| **6 weeks** | 107 | 0.32 (0.19, 0.48), SE=0.08 | 0.36 (0.23, 0.52), SE=0.07 | 0.47 (0.23, 0.94) | 0.57 (0.30, 1.07) | 0.82 (0.36, 1.85), p=0.6287 |
|  |  |  |  |  |  |  |
| **12 weeks** | 86 | 0.51 (0.33, 0.69), SE=0.10 | 0.50 (0.34, 0.66), SE=0.09 | 1.06 (0.50, 2.22) | 0.99 (0.50, 1.96) | 1.06 (0.43, 2.59), p=0.8959 |

Figure 19 BPI worst pain with unadjusted 95% CIs by treatment group and intervention engagement

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**Secondary outcomes**

Figure 20 BPI pain severity and interference index with unadjusted 95% CIs1



Figure 21 PPQ pain knowledge and experience scales with unadjusted 95% CIs



Figure 22 Cancer specific quality of life - EORTC QLQ-c30 summary score with unadjusted 95% CIs

**

Table 37 Secondary outcomes at baseline and follow-up

|  | **Baseline** | **6 weeks** | **12 weeks** |
| --- | --- | --- | --- |
|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| **BPI Pain interference score***(scores 0-10; higher score = increased pain)* |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 50 | 56 | 106 | 41 | 46 | 87 |
| Mean (SD) | 5.2 (2.48) | 5.7 (2.25) | 5.5 (2.37) | 4.4 (2.42) | 4.6 (2.26) | 4.5 (2.33) | 3.3 (2.51) | 3.8 (2.74) | 3.5 (2.63) |
| Median (Range) | 5.3 (0, 10) | 5.9 (1.4, 10) | 5.6 (0, 10) | 4.4 (0, 9) | 4.9 (0, 9.1) | 4.7 (0, 9.1) | 3 (0, 8.4) | 3.2 (0, 9) | 3.1 (0, 9) |
|  |  |  |  |  |  |  |  |  |  |
| **PPQ** *(higher score = poorer experience of pain)* |  |  |  |  |  |  |  |  |  |
| **PPQ Knowledge subscale***(scores 0-90)* |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 55 | 106 | 39 | 45 | 84 |
| Mean (SD) | 38.2 (13.52) | 38.1 (16.94) | 38.2 (15.30) | 36.3 (16.80) | 33.6 (16.60) | 34.9 (16.67) | 35.4 (12.62) | 33.1 (19.37) | 34.1 (16.53) |
| Median (Range) | 35 (10, 80) | 38 (5, 70) | 37 (5, 80) | 37 (2, 75) | 34 (0, 67) | 34.5 (0, 75) | 38 (5, 66) | 37 (0, 66) | 37 (0, 66) |
| **PPQ Experience subscale***(scores 0-70)* |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 56 | 107 | 41 | 45 | 86 |
| Mean (SD) | 41.3 (9.70) | 41.7 (8.96) | 41.5 (9.30) | 36.6 (11.85) | 35.2 (11.86) | 35.9 (11.81) | 32.8 (13.53) | 31.2 (14.99) | 32.0 (14.25) |
| Median (Range) | 40 (18, 61) | 42 (27, 61) | 40.5 (18, 61) | 37 (8, 67) | 35 (8, 65.8) | 37 (8, 67) | 36 (2.3, 59) | 30 (7, 70) | 32 (2.3, 70) |
| **PPQ Total score***(scores 0-160)* |  |  |  |  |  |  |  |  |  |
| N | 79 | 81 | 160 | 51 | 55 | 106 | 39 | 45 | 84 |
| Mean (SD) | 79.4 (16.50) | 79.9 (20.22) | 79.7 (18.42) | 72.9 (22.35) | 68.8 (23.81) | 70.8 (23.10) | 68.9 (20.90) | 64.3 (27.99) | 66.4 (24.92) |
| Median (Range) | 79 (43, 124) | 81 (34, 123) | 80 (34, 124) | 74 (20, 118) | 69 (23.5, 119.8) | 71.5 (20, 119.8) | 72 (22, 109) | 64 (13, 131) | 67.5 (13, 131) |
|  |  |  |  |  |  |  |  |  |  |
| **EORTC QLQ-C30 Summary Score**(*scores 0-100; higher score = high QoL and functioning)* |  |  |  |  |  |  |  |  |  |
| N | 77 | 79 | 156 | 51 | 53 | 104 | 39 | 45 | 84 |
| Mean (SD) | 57.4 (17.20) | 54.1 (16.53) | 55.7 (16.89) | 61.4 (16.73) | 57.0 (15.80) | 59.1 (16.33) | 65.6 (17.11) | 62.4 (17.16) | 63.9 (17.11) |
| Median (Range) | 58.9 (20, 91.6) | 53.7 (13.6, 91.3) | 56.2 (13.6, 91.6) | 64.6 (24.5, 94.8) | 56.5 (21.3, 89.7) | 61.6 (21.3, 94.8) | 69.1 (25.6, 99.5) | 61.6 (25.4, 87.1) | 68.4 (25.4, 99.5) |

Table 38 Mean scores with 95% CIs for secondary outcomes adjusted for baseline score and covariates – Sensitivity analysis to availability of data

|  | **6 weeks** | **12 Weeks** |
| --- | --- | --- |
| **Analysis** | **SSM, Mean (95% CI), SE** | **UC, Mean (95% CI), SE** | **Difference a, Mean** **(95% CI), SE, p-value** | **SSM, Mean (95% CI), SE** | **UC, Mean (95% CI), SE** | **Difference a, Mean** **(95% CI), SE, p-value** |
|  |  |  |  |  |  |  |
| **BPI Pain Interference***(scores 0-10; higher score = increased pain)* | 5.3 (4.3, 6.2), SE=0.49 | 5.5 (4.5, 6.4), SE=0.48 | -0.2 (-1.1, 0.7), SE=0.45, p=0.6402 | 4.2 (3.2, 5.3), SE=0.51 | 4.6 (3.6, 5.5), SE=0.50 | -0.3 (-1.3, 0.7), SE=0.51, p=0.5197 |
|  |  |  |  |  |  |  |
| **PPQ Pain knowledge subscale***(scores 0-90; higher score = poorer experience of pain)* | 39.6 (32.8, 46.4), SE=3.42 | 38.2 (31.6, 44.9), SE=3.34 | 1.3 (-4.9, 7.5), SE=3.13, p=0.6698 | 37.7 (30.7, 44.8), SE=3.56 | 36.6 (29.9, 43.3), SE=3.36 | 1.1 (-5.7, 8.0), SE=3.43, p=0.7387 |
|  |  |  |  |  |  |  |
| **PPQ Pain experience subscale***(scores 0-70; higher score = poorer experience of pain)* | 40.6 (35.9, 45.3), SE=2.36 | 39.6 (35.1, 44.2), SE=2.31 | 1.0 (-3.1, 5.0), SE=2.05, p=0.6391 | 36.2 (31.0, 41.5), SE=2.66 | 35.4 (30.4, 40.5), SE=2.54 | 0.8 (-4.5, 6.2), SE=2.68, p=0.7560 |
|  |  |  |  |  |  |  |
| **PPQ Total score***(scores 0-160; higher score = poorer experience of pain)* | 80.3 (71.2, 89.3), SE=4.58 | 78.3 (69.5, 87.2), SE=4.46 | 1.9 (-6.3, 10.1), SE=4.13, p=0.6436 | 74.4 (64.9, 84.0), SE=4.82 | 72.4 (63.4, 81.4), SE=4.56 | 2.0 (-7.2, 11.2), SE=4.65, p=0.6665 |
|  |  |  |  |  |  |  |
| **EORTC QLQ-C30 Summary Score**(*scores 0-100; higher score = high QoL and functioning)* | 54.4 (48.7, 60.1), SE=2.89 | 53.2 (47.6, 58.8), SE=2.82 | 1.2 (-4.0, 6.3), SE=2.58, p=0.6535 | 58.1 (51.8, 64.5), SE=3.20 | 58.4 (52.5, 64.4), SE=3.01 | -0.3 (-6.7, 6.0), SE=3.20, p=0.9164 |
|  |  |  |  |  |  |  |

Table 39 Global change in pain scores at follow-up

|  | **6 weeks** | **12 weeks** |
| --- | --- | --- |
|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| **Change in pain a** |  |  |  |  |  |  |
| Increase | 20 (40.8%) | 11 (19.6%) | 31 (29.5%) | 13 (33.3%) | 14 (30.4%) | 27 (31.8%) |
| *-3 very much worse* |  |  |  | *0 (0.0%)* | *1 (2.2%)* | *1 (1.2%)* |
| *-2 much worse* | *7 (14.3%)* | *4 (7.1%)* | *11 (10.5%)* | *4 (10.3%)* | *2 (4.3%)* | *6 (7.1%)* |
| *-1 minimally worse* | *13 (26.5%)* | *7 (12.5%)* | *20 (19.0%)* | *9 (23.1%)* | *11 (23.9%)* | *20 (23.5%)* |
| No change (0) | 4 (8.2%) | 11 (19.6%) | 15 (14.3%) | 4 (10.3%) | 11 (23.9%) | 15 (17.6%) |
| Reduction | 25 (51.0%) | 34 (60.7%) | 59 (56.2%) | 22 (56.4%) | 21 (45.7%) | 43 (50.6%) |
| *+1 minimally improved* | *12 (24.5%)* | *15 (26.8%)* | *27 (25.7%)* | *11 (28.2%)* | *10 (21.7%)* | *21 (24.7%)* |
| *+2 much improved* | *10 (20.4%)* | *16 (28.6%)* | *26 (24.8%)* | *11 (28.2%)* | *7 (15.2%)* | *18 (21.2%)* |
| *+3 very much improved* | *3 (6.1%)* | *3 (5.4%)* | *6 (5.7%)* | *0 (0.0%)* | *4 (8.7%)* | *4 (4.7%)* |
| Missing | 31 | 25 | 56 | 41 | 35 | 76 |

**a** Based on imputation of the 'worst' response whether multiple responses were provided'

**Health care use**

Table 40 Palliative care contact during the 12 week trial period

|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| --- | --- | --- | --- |
| **Palliative care contact?** |  |  |  |
| Yes | 80 (100.0%) | 75 (92.6%) | 155 (96.3%) |
| No | 0 (0.0%) | 6 (7.4%) | 6 (3.7%) |
| **Palliative care status at end of 12 week trial period**  |  |  |  |
| Continuing in palliative care  | 50 (62.5%) | 43 (53.1%) | 93 (57.8%) |
| Discharged at end of trial period | 14 (17.5%) | 18 (22.2%) | 32 (19.9%) |
| Discharged before 12 weeks | 16 (20.0%) | 14 (17.3%) | 30 (18.6%) |
| No palliative care contact | 0 (0.0%) | 6 (7.4%) | 6 (3.7%) |
| **Reason for early discharge before 12 weeks** |  |  |  |
| Participant death | 14 (87.5%) | 10 (71.4%) | 24 (80.0%) |
| Participant choice | 0 (0.0%) | 3 (21.4%) | 3 (10.0%) |
| Discharged on review - improvement in pain and tumour | 1 (6.3%) | 0 (0.0%) | 1 (3.3%) |
| Discharged to palliative care consultant and chemotherapy team | 1 (6.3%) | 0 (0.0%) | 1 (3.3%) |
| Participant admitted to hospital for a prolonged period of time | 0 (0.0%) | 1 (7.1%) | 1 (3.3%) |

Table 41 Pain medication at baseline, 6 and 12 weeks

|  | **Baseline** | **6 weeks** | **12 weeks** |
| --- | --- | --- | --- |
|  | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** | **SSM (n=80)** | **UC (n=81)** | **Total (n=161)** |
| **Participant receiving pain medication** |  |  |  |  |  |  |  |  |  |
| Yes | 80 (100.0%) | 80 (98.8%) | 160 (99.4%) | 71 (98.6%) | 70 (95.9%) | 141 (97.2%) | 63 (98.4%) | 64 (95.5%) | 127 (96.9%) |
| *Strong opioid* | *48 (60.0%)* | *47 (58.0%)* | *95 (59.0%)* | *53 (73.6%)* | *52 (71.2%)* | *105 (72.4%)* | *47 (73.4%)* | *47 (70.1%)* | *94 (71.8%)* |
| *Weak opioid* | *37 (46.3%)* | *41 (50.6%)* | *78 (48.4%)* | *19 (26.4%)* | *12 (16.4%)* | *31 (21.4%)* | *17 (26.6%)* | *12 (17.9%)* | *29 (22.1%)* |
| *Non-opioid* | *56 (70.0%)* | *56 (69.1%)* | *112 (69.6%)* | *50 (69.4%)* | *49 (67.1%)* | *99 (68.3%)* | *49 (76.6%)* | *44 (65.7%)* | *93 (71.0%)* |
| *Adjuvant* | *18 (22.5%)* | *19 (23.5%)* | *37 (23.0%)* | *26 (36.1%)* | *23 (31.5%)* | *49 (33.8%)* | *27 (42.2%)* | *25 (37.3%)* | *52 (39.7%)* |
| No | 0 (0.0%) | 1 (1.2%) | 1 (0.6%) | 1 (1.4%) | 3 (4.1%) | 4 (2.8%) | 1 (1.6%) | 3 (4.5%) | 4 (3.1%) |
| Missing a | 0 | 0 | 0 | 8 | 8 | 16 | 16 | 14 | 30 |
|  |  |  |  |  |  |  |  |  |  |
| **Strongest pain medication** |  |  |  |  |  |  |  |  |  |
| Strong opioid | 48 (60.0%) | 47 (58.0%) | 95 (59.0%) | 53 (73.6%) | 52 (71.2%) | 105 (72.4%) | 47 (73.4%) | 47 (70.1%) | 94 (71.8%) |
| Weak opioid | 23 (28.8%) | 24 (29.6%) | 47 (29.2%) | 12 (16.7%) | 8 (11.0%) | 20 (13.8%) | 10 (15.6%) | 8 (11.9%) | 18 (13.7%) |
| Non-opioid | 9 (11.3%) | 9 (11.1%) | 18 (11.2%) | 6 (8.3%) | 10 (13.7%) | 16 (11.0%) | 6 (9.4%) | 8 (11.9%) | 14 (10.7%) |
| Adjuvant | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 0 (0.0%) | 1 (1.5%) | 1 (0.8%) |
| No medication | 0 (0.0%) | 1 (1.2%) | 1 (0.6%) | 1 (1.4%) | 3 (4.1%) | 4 (2.8%) | 1 (1.6%) | 3 (4.5%) | 4 (3.1%) |
| Missing | 0 | 0 | 0 | 8 | 8 | 16 | 16 | 14 | 30 |
|  |  |  |  |  |  |  |  |  |  |
| **Number of pain medications** |  |  |  |  |  |  |  |  |  |
| N | 80 | 81 | 161 | 72 | 73 | 145 | 64 | 67 | 131 |
| Missing | 0 | 0 | 0 | 8 | 8 | 16 | 16 | 14 | 30 |
| Mean (SD) | 2.4 (0.82) | 2.4 (0.98) | 2.4 (0.90) | 2.8 (1.11) | 2.7 (1.33) | 2.8 (1.22) | 3.1 (1.21) | 2.7 (1.31) | 2.9 (1.27) |
| Median (Range) | 2 (1, 4) | 2 (0, 5) | 2 (0, 5) | 3 (0, 7) | 3 (0, 6) | 3 (0, 7) | 3 (0, 7) | 3 (0, 5) | 3 (0, 7) |

*a Missing due to data not available and/or participant death*