21,353 Adults not receiving palliative care, with ≥2 prescriptions for strong opioids in six months identified from 191 clinics (computer search)¹

18680 Did not respond to invitation
453 Not invited²

2220 Replied to invitation

2087 Interested and approached for eligibility assessment

133 Replied and not interested

546 Did not respond

1541 Assessed for eligibility

491 Ineligible
264 Unable to attend group session*
115 Haven’t used opioids for last 3 months
26 Younger than 18 years old
25 Unknown
22 Not using opioids for chronic non-malignant pain
14 Not fluent in written and spoken English
8 Serious mental health problems*
8 Participated in a clinical trial in the last 90 days
6 Reported chronic headache as dominant pain
3 Not happy to inform GP of participation
*One person listed both reasons

442 Eligible but not randomised
293 Consent not received
102 Not interested
19 Unknown
12 Unable to contact
8 Consent received too late
5 Too late to contact
2 Ineligible

1050 Eligible

608 Randomised ¹, ²

305 Randomised to receive education and support intervention

303 Randomised to receive usual care

76 Without follow-up at 12 months⁵
43 Withdrew completely
29 Lost to follow-up
4 Died

229 Included in the primary analysis for pain interference (PROMIS-8A) ²
76 Without follow-up

225 Included in the primary analysis for opioid use ⁷
76 Without follow-up
4 Missing primary outcome

210 Included in the primary analysis for pain interference (PROMIS-8A) ²
92 Without follow-up
1 Missing primary outcome

208 Included in the primary analysis for opioid use ⁷
92 Without follow-up
3 Missing primary outcome

1: 9 Self-referrals, 5 Secondary care referrals.
2: GP practice felt it inappropriate to approach. Reasons including malignant pain, short life expectancy, care home resident/housebound, severe mental illness, active cancer causing pain.
3: 2 Self-referrals, 2 Secondary care referrals.
4: Randomisation stratified by geographical locality, baseline pain severity (low/high) and baseline morphine equivalent dose of opioids.
5: See eTable 11 in Supplement 2 for follow-up rates and availability for secondary outcomes at 4 and 8 months. See eTable 10, 12-14 in Supplement 2 for information on withdrawals.
6: Patient-reported Outcomes Measurement Information System (PROMIS) Pain interference Short Form (8A)
7: Opioid use calculated as morphine equivalent dose (MED) per day in the four weeks prior to 12-month follow-up. NOTE