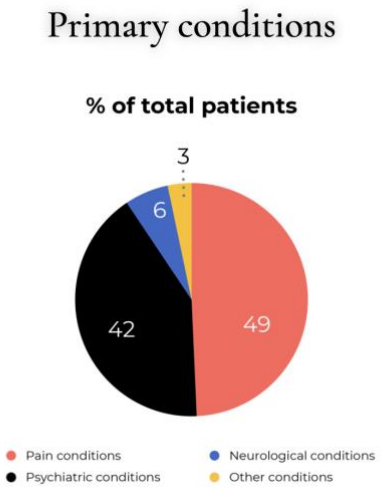
Cannabis-based medicinal products for treating chronic pain: Findings from T21

T21. Recognising the need for data on the safety and effectiveness of cannabis-based medicinal products (CBMPs) after they were legalised in November 2018, T21 was established by the charity Drug Science (https://www.drugscience.org.uk). T21 is an observational study collecting real world evidence. Patients receiving prescriptions from multiple clinics throughout the UK are invited to join the study and contribute data on their symptoms and well-being before starting treatment and at three monthly intervals. Participation is voluntary and T21 is entirely observational: Drug Science have no input into whether patients are prescribed CBMPs or what products they are prescribed.

Chronic pain in T21. To date, 3913 people have contributed data to T21. Broadly defined chronic pain, which encompasses nociceptive, neuropathic, inflammatory, and functional pain conditions, is the most common condition among T21 participants with 1929 people (49.3% of the sample) seeking treatment for some form of chronic pain. The other conditions being treated include psychiatric and neurological conditions.



Characteristics of chronic pain patients. The majority (57.6%) of chronic pain patients are male and their average age is 42.0 years, although there is wide variation in their ages (18-84 years). They report a number of comorbid health conditions and many are using multiple prescribed medications. Specifically, 91.7% reported experiencing one or more secondary conditions. Among those reporting secondary conditions: 34.2% reported 1–2 conditions; 31.5% reported 3–5 conditions and 34.4% reported 6 or more secondary conditions. The most commonly reported non-pain secondary conditions were: anxiety (41.9%), depression (29.9%), stress (23.7%) and insomnia (23.1%).

The majority (68.7%) of participants reported that they were using at least one prescribed medication while many reported using multiple medications: 19.0% reported one medication, 17.1% reported two, 39.0% reported three to five and 24.9% reported using six or more prescribed medications. Among individuals using prescribed medications the mean number of current medications prescribed was 4.2 (range = 1–23 medications).

The picture that emerges from this and from the self-report data, described below, is that these individuals have chronic, debilitating illness that has been unresponsive to multiple previous treatment regimens, including both medications (e.g. opioids) and other therapies.

Improvements in pain after 3 months. Self-reported pain is assessed using the Brief Pain Inventory, a widely used and well validated instrument which assesses two dimensions of pain: the severity of pain and the extent to which pains interferes with daily functioning. There were substantial and highly significant reductions in mean ratings of pain severity (from 5.8 to 4.8) and pain interference (7.0 to 5.6) after three months. The estimated effects sizes were 0.62-0.64, which would be classified as moderate to large reductions.

Improvements in well-being after three months. In addition to reporting on their pain, participants are asked to describe multiple aspects of well-being including sleep quality, mood/depression, general health and quality of life. There is a growing recognition of the

value and importance of assessments in quality of life, as well as more broader well-being, in healthcare and research. Quality of life measures provide insights into the impact of a treatment beyond specific symptom relief, reflecting daily functioning and the perceived ability to lead a fulfilling life. This is of particular importance in chronic pain due to the impact this has on daily functioning as well as mood (anxiety/depression) and sleep. Assessment of these measures at baseline confirmed that chronic pain patients were experiencing marked deficiencies across multiple components of well-being. For example, their mean rating of general health was 45.6, (on a scale of 0-100 with 100 representing perfect health) which is markedly lower than normative data for UK general population (mean = 85.7). However, there was considerable improvement across all these measures after three months of treatment. There were substantial reductions in sleep disturbance and depressed mood, as well as improvements in general health and quality of life with effect size estimates ranging from 0.38 to 0.63. For comparison, typical effect sizes reported for the effects of anti-depressant medications on depressed mood are typically in the region of 0.35.

Reduction in the use of opioids. Just over half (55.1%) of chronic pain patients reported using opioid medications at the start of treatment. At 3-month follow-up over half (59.9%) of those using opioids had stopped all use of these drugs. The mean dose (measured as Milligrams of Morphine Equivalents (MMEs)) reduced from 22.5 MMEs per day to a mean of 8.3 MMEs.

Prescribed medical cannabis. 53.8% of chronic pain patients received a prescription for a single CBMP, 35.6% received two products and 10.7% received three or more products: nearly half of all prescribed products were classified as high delta-9-tetrahydrocannabinol (THC) flower while nearly a quarter of all products were balanced oils. A further 10% of prescribed products were classified as high cannabidiol (CBD) oil while prescriptions for both high THC oil and high CBD flower were relatively uncommon.

Safety. Information on self-reported side effects of CBMPs from this sample indicate that adverse events were rare (reported by less than 3% of the sample) and were typically reported as mild or moderate: the most commonly reported adverse experiences were dry mouth, feeling drowsy and having red/sore eyes. It is notable that there have been no reports of psychosis in the entire sample.

Longer term health. Ongoing analyses of longer-term health and well-being indicate that the reductions in pain and improvements in well-being are maintained for up to 12 months.

Summary. Chronic pain is the most common primary condition for which people seek medicinal cannabis through the private health system in the UK. Those seeking treatment have a history of chronic, debilitating illness but experience substantial symptom relief, including in the severity of pain, when they commence using prescribed medical cannabis. Reductions in the severity of pain and the extent to which pain interferes with functioning are accompanied by substantial improvements across a range of measures of well-being including sleep, mood/depression, general health and quality of life. Importantly, a substantial proportion (59%) of those using prescribed opioids at the start of treatment were able to cease their use of these drugs after commencing treatment with prescribed cannabis. Side effects were reported by only a small minority of the sample and were typically mild in nature. Our findings are consistent with a growing body of evidence, both nationally and internationally, that prescribed cannabis is an effective and safe treatment for individuals with chronic pain.