

Session 15

Clinical Research: Overview of Medicinal Cannabis Clinical Trials

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MCIA 
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Conference & Exhibition

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Crown Promenade, Melbourne**



**Session 15
Clinical Research: Overview of Medicinal Cannabis Clinical Trials**

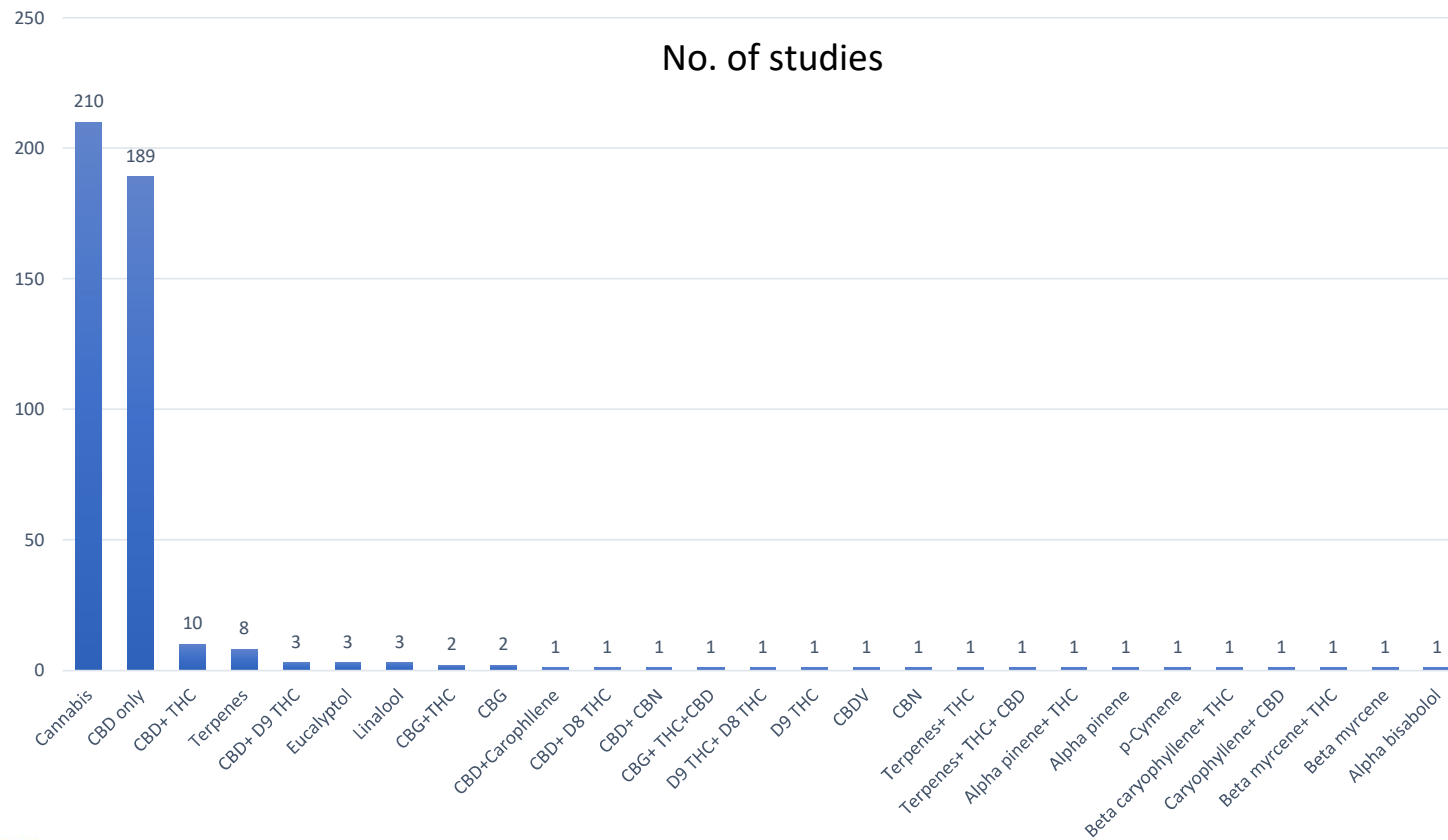
Mary Nteris, PhD

This presentation is a broad overview intended to solely intended to provide a general understanding of the subject matter. Your particular requirements may differ from those presented here. This presentation does not constitute regulatory advice.

Methodology

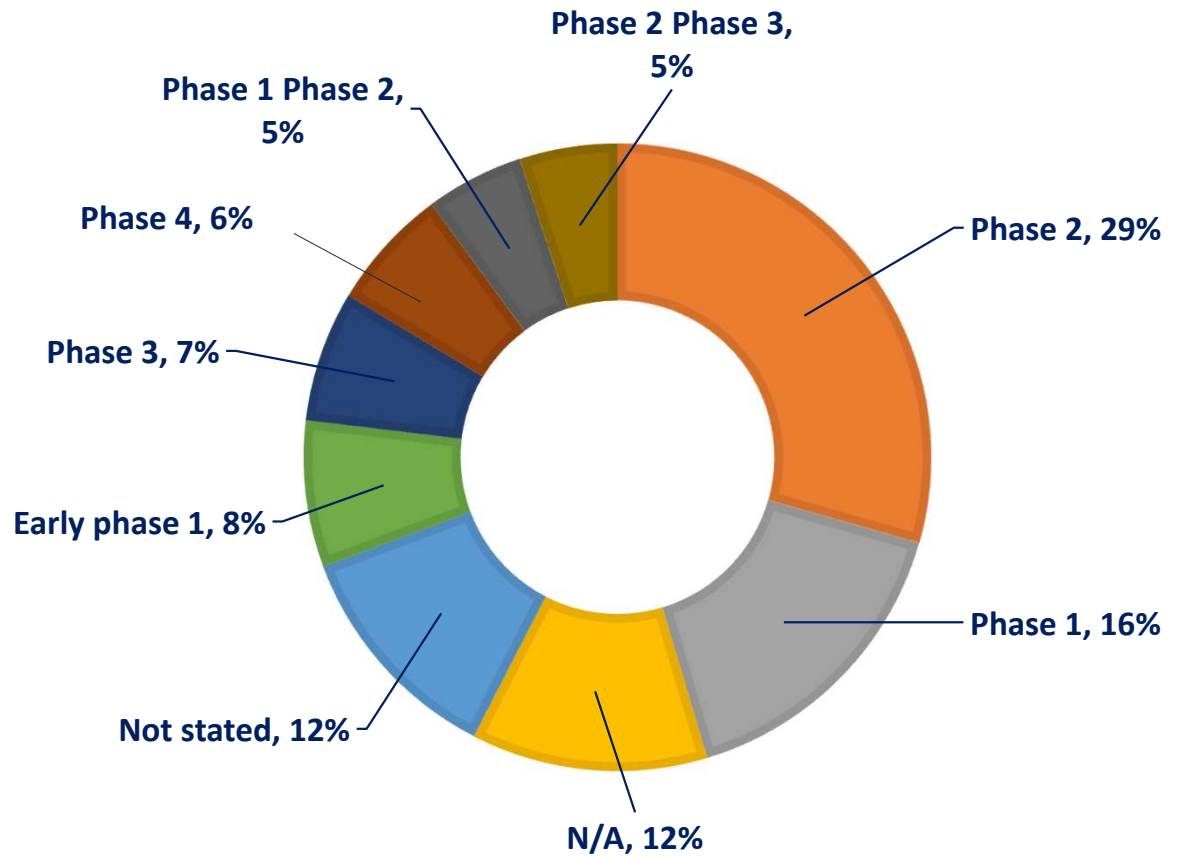
| | | |
|--------------|--------------------------------|---------------------------------|
| Databases | clinicaltrials.gov | australianclinicaltrials.gov.au |
| Search date | 28.02.2024 and 13.03.2024 | 06.03.2024 |
| Intervention | cannabis/cannabis derivative | |
| Filters | recruiting, not yet recruiting | |

By intervention



By phase

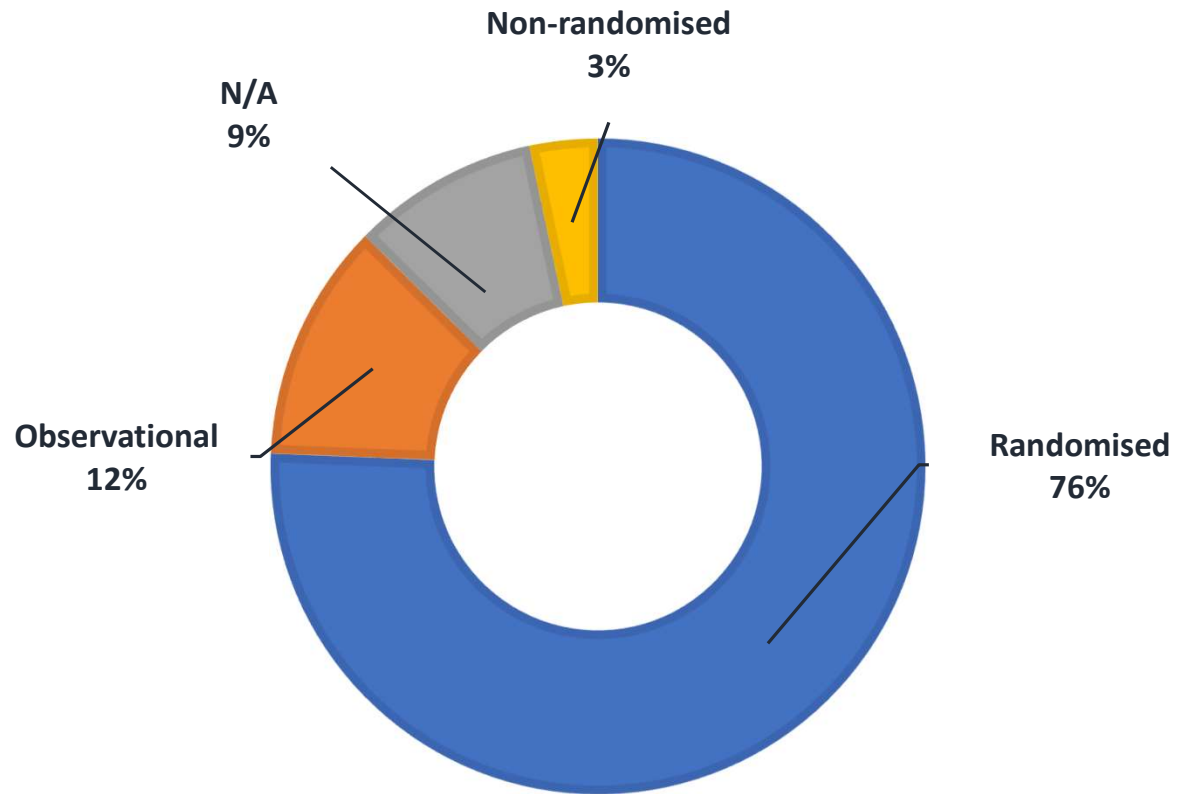
| By Phase | No. of studies |
|-----------------|----------------|
| Phase 2 | 70 |
| Phase 1 | 38 |
| NA | 29 |
| Not stated | 28 |
| Early phase 1 | 18 |
| Phase 3 | 16 |
| Phase 4 | 15 |
| Phase 1 Phase 2 | 12 |
| Phase 2 Phase 3 | 12 |
| Total | 238 |



clinicaltrials.gov

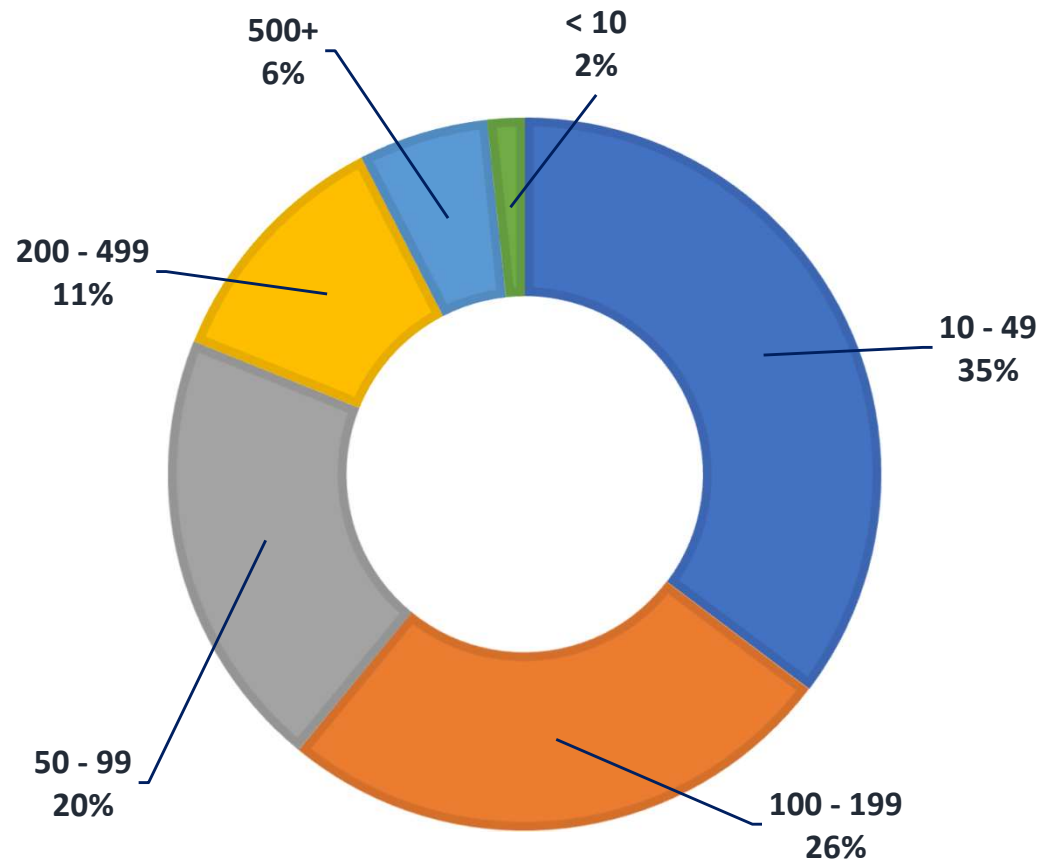
By trial design

| By design | No. of studies |
|----------------|----------------|
| Randomised | 180 |
| Observational | 28 |
| NA | 22 |
| Non-randomised | 8 |
| Total | 238 |



By no. enrolled

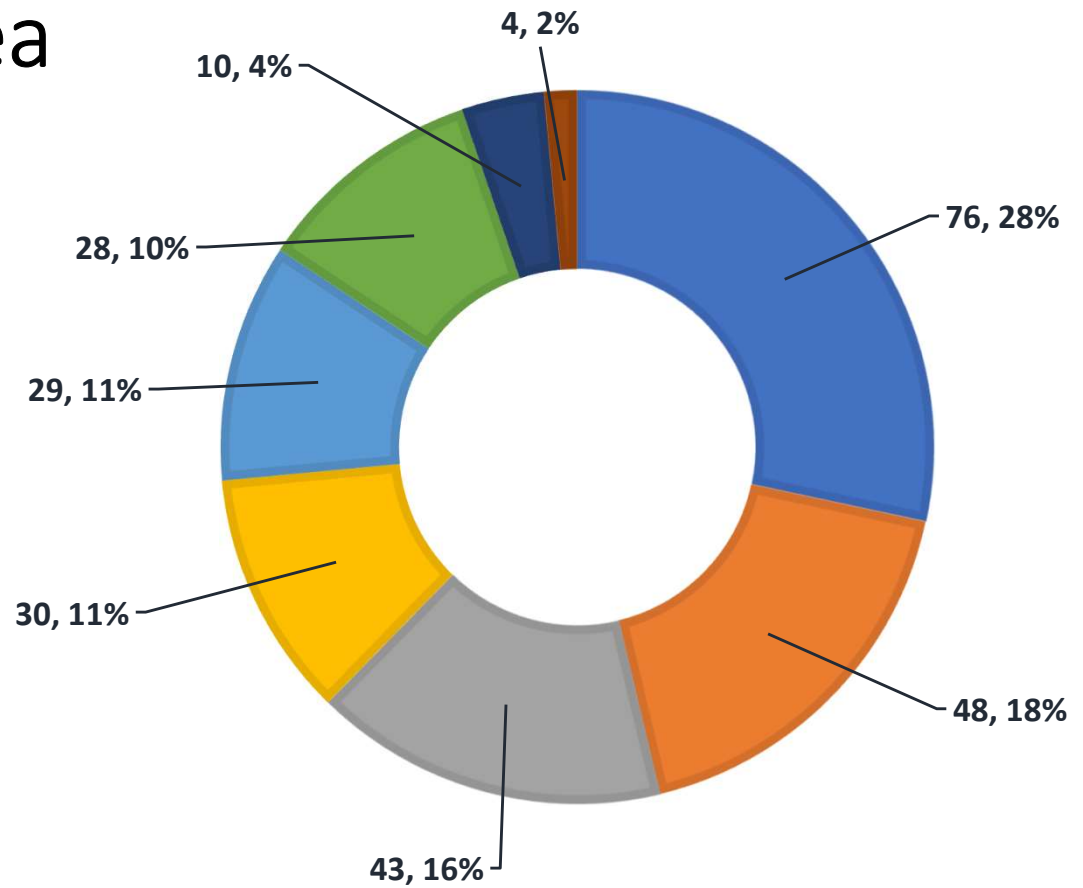
| By no. enrolled | No. of studies |
|-----------------|----------------|
| 10 - 49 | 84 |
| 100 - 199 | 61 |
| 50 - 99 | 48 |
| 200 - 499 | 27 |
| 500+ | 14 |
| < 10 | 4 |
| Total | 238 |



clinicaltrials.gov

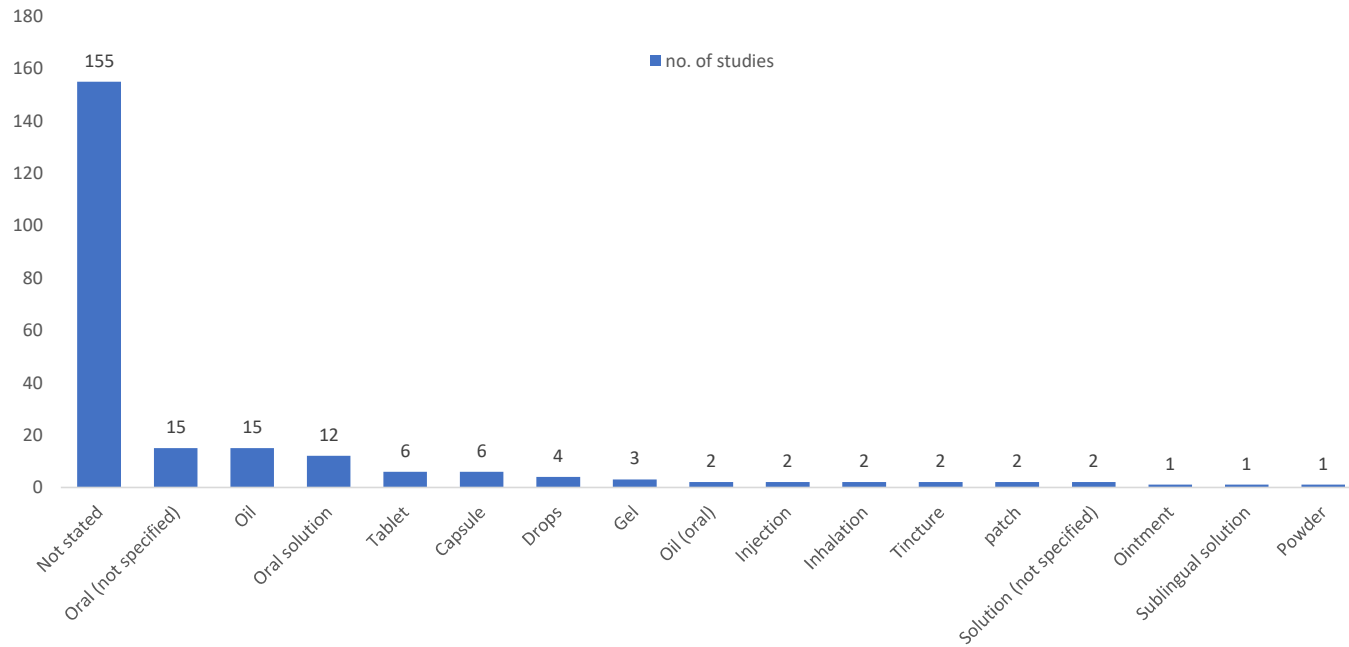
By therapeutic area

| By therapeutic area | No. of studies |
|-------------------------|----------------|
| Other | 76 |
| Neurological Disorders | 48 |
| Pain Management | 43 |
| Substance Use Disorders | 30 |
| Oncology | 29 |
| Mental Health | 28 |
| Healthy | 10 |
| Sleep Disorders | 4 |
| Total | 268 |



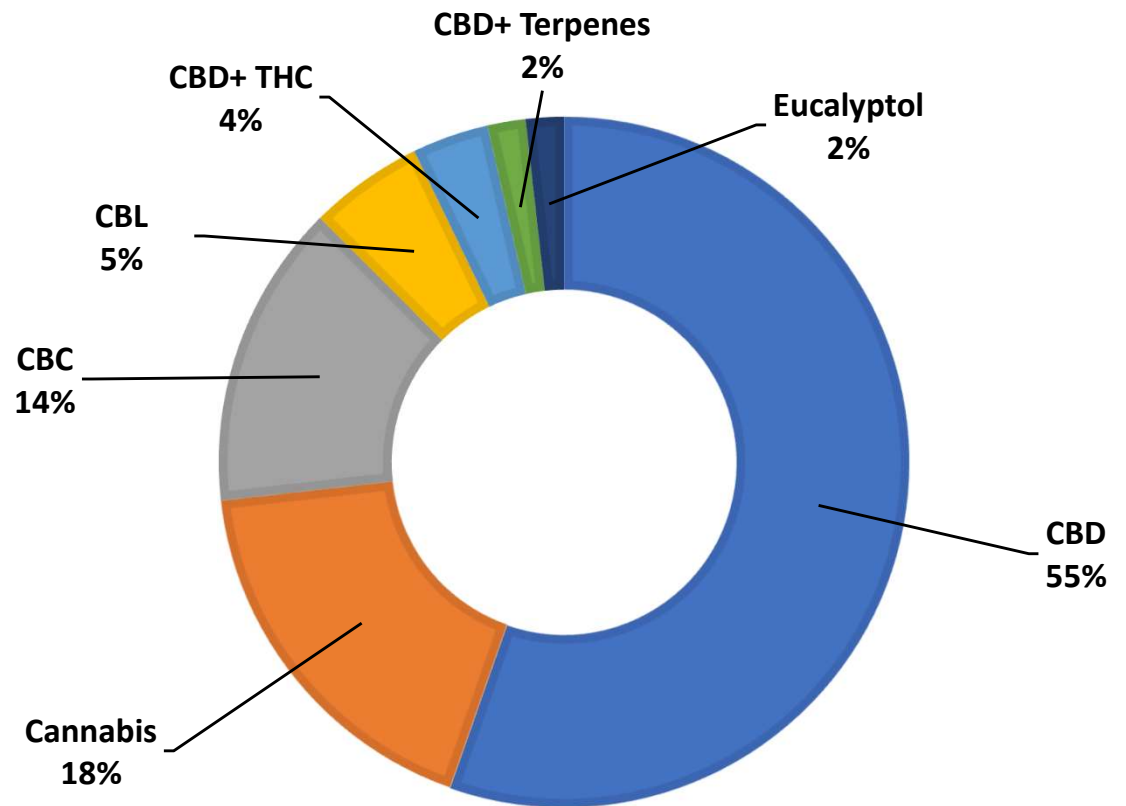
clinicaltrials.gov

By dosage form



By intervention

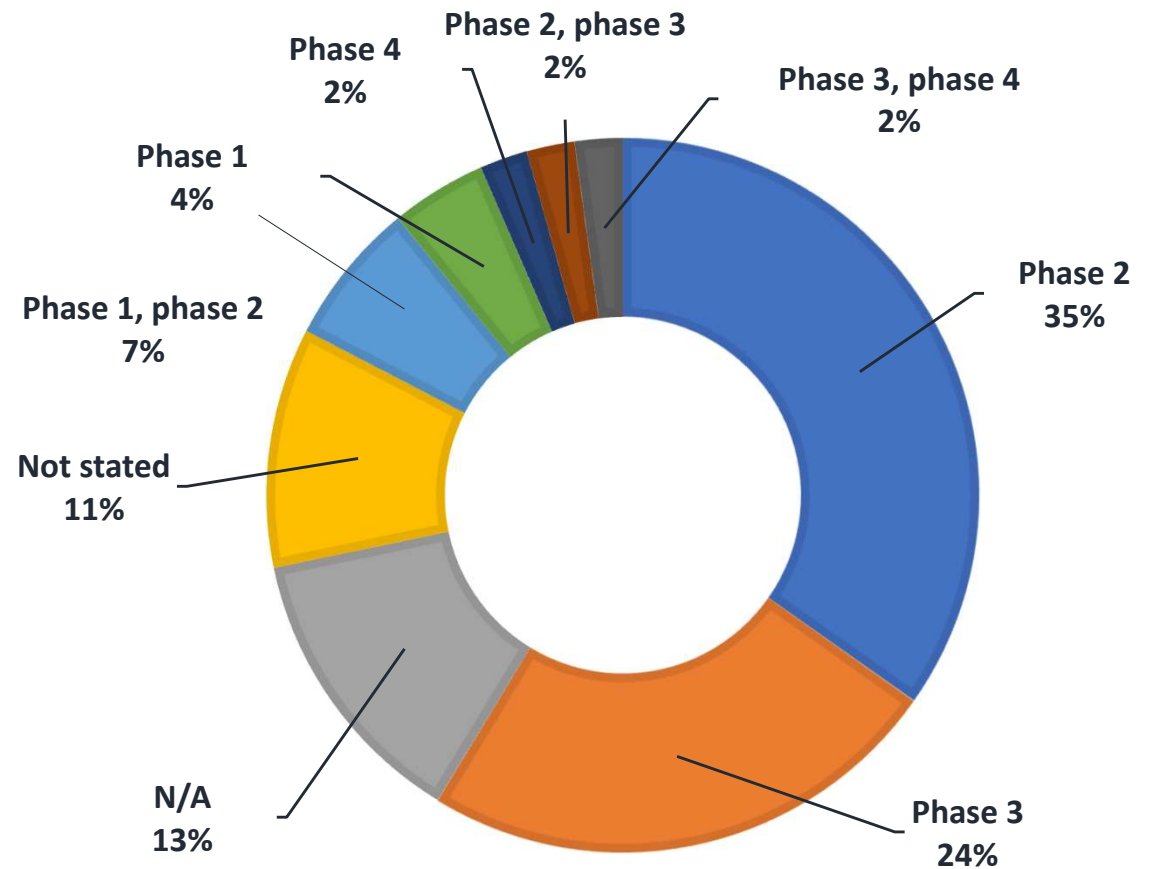
| By intervention | No. of studies |
|-----------------|----------------|
| CBD | 31 |
| Cannabis | 10 |
| CBC | 8 |
| CBL | 3 |
| CBD+ THC | 2 |
| CBD+ Terpenes | 1 |
| Eucalyptol | 1 |



australianclinicaltrials.gov.au

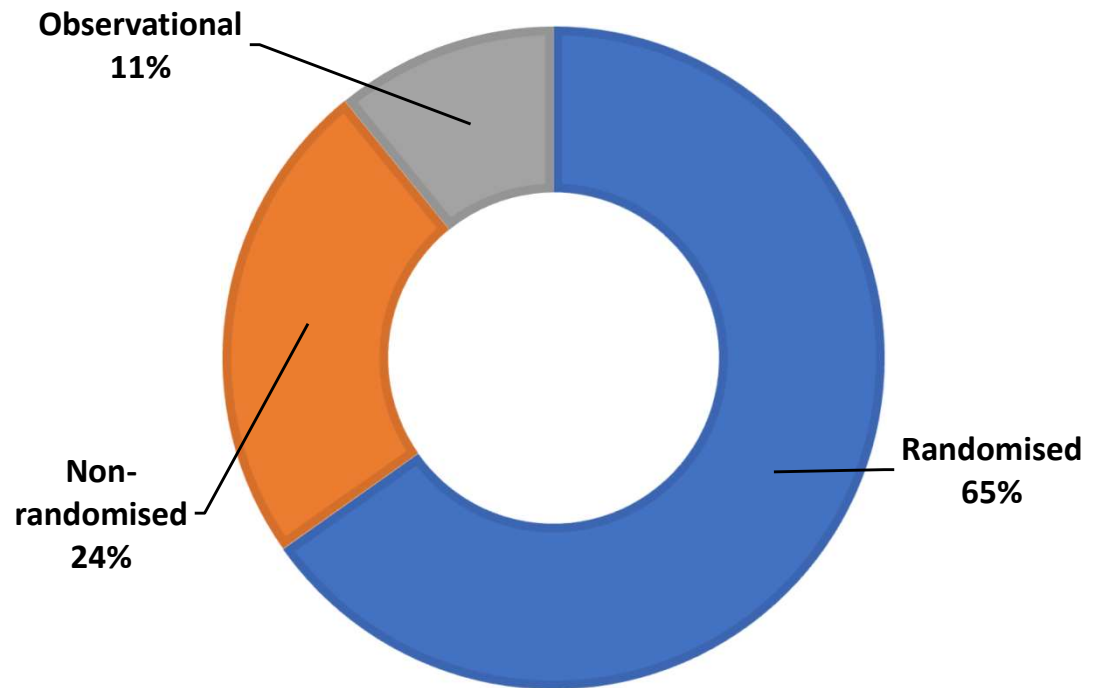
By phase

| By phase | No. of studies |
|------------------|----------------|
| Phase 2 | 16 |
| Phase 3 | 11 |
| N/A | 6 |
| Not stated | 5 |
| Phase 1, phase 2 | 3 |
| Phase 1 | 2 |
| Phase 4 | 1 |
| Phase 2, phase 3 | 1 |
| Phase 3, phase 4 | 1 |
| Total | 46 |



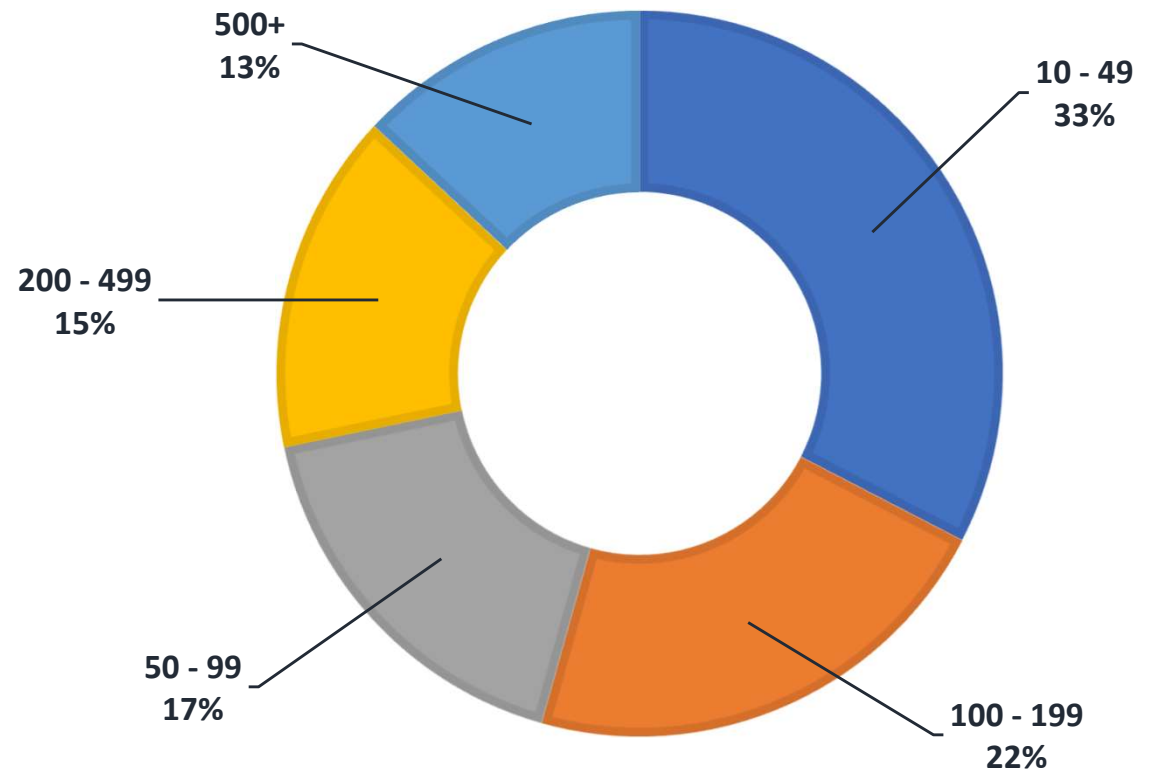
By design

| By design | No. of studies |
|----------------|----------------|
| Randomised | 30 |
| Non-randomised | 11 |
| Observational | 5 |
| Total | 46 |



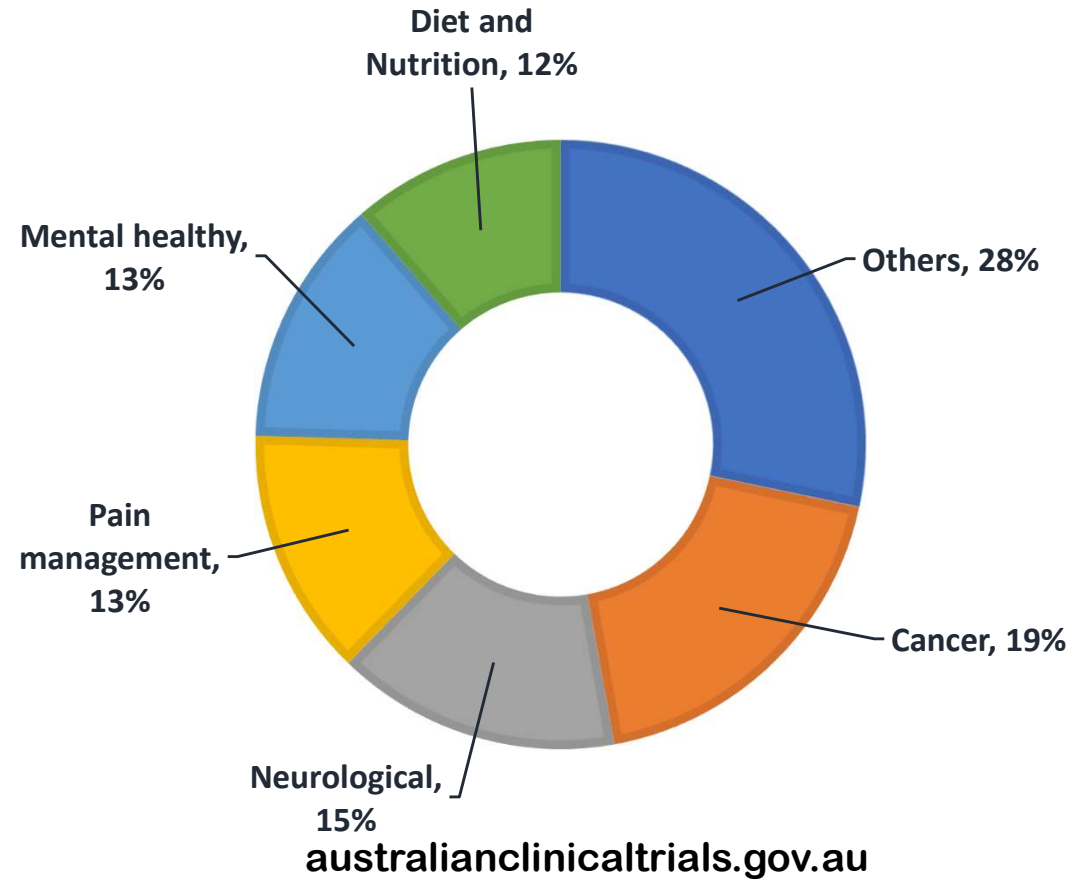
By no. enrolled

| By no. enrolled | No. of studies |
|-----------------|----------------|
| 10 - 49 | 15 |
| 100 - 199 | 10 |
| 50 - 99 | 8 |
| 200 - 499 | 7 |
| 500+ | 6 |
| <10 | 0 |
| Total | 46 |



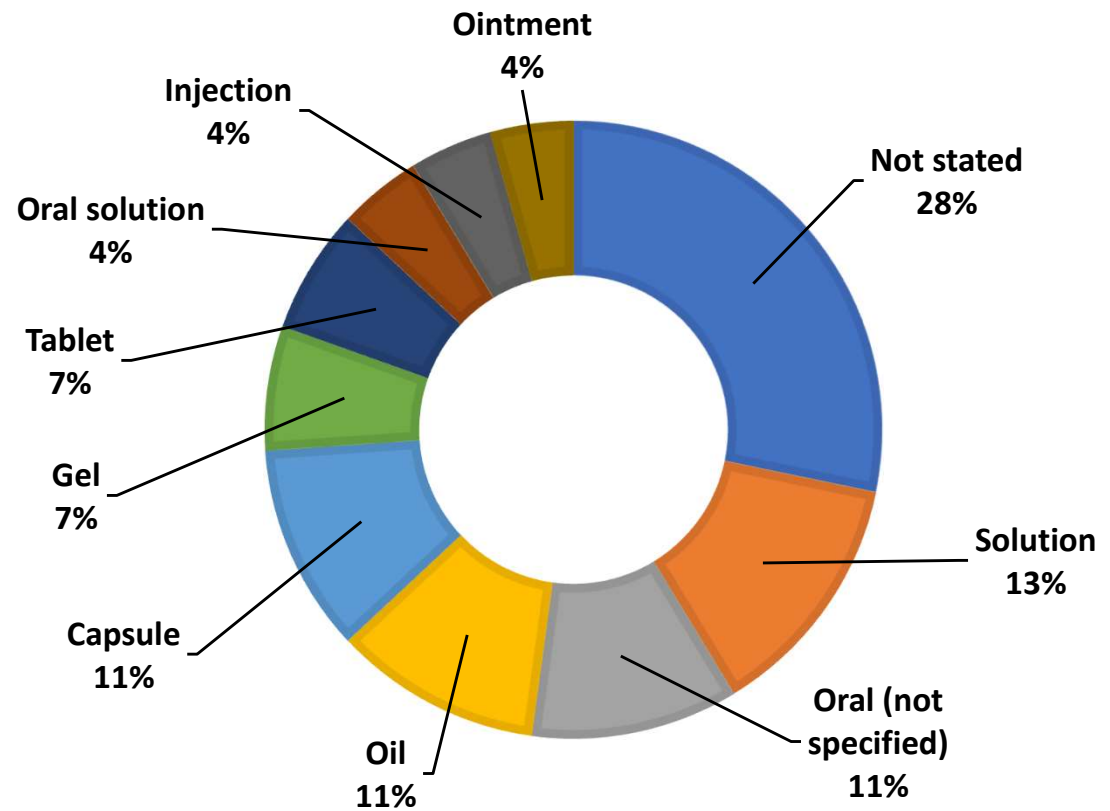
By therapeutic area

| By therapeutic area | No. of studies |
|---------------------|----------------|
| Others | 15 |
| Cancer | 10 |
| Neurological | 8 |
| Pain management | 7 |
| Mental health | 7 |
| Diet and Nutrition | 6 |
| Total | 53 |



By dosage form

| By dosage form | No. of studies |
|----------------------|----------------|
| Not stated | 13 |
| Solution | 6 |
| Oral (not specified) | 5 |
| Oil | 5 |
| Capsule | 5 |
| Gel | 3 |
| Tablet | 3 |
| Oral solution | 2 |
| Injection | 2 |
| Ointment | 2 |
| Total | 46 |



Summary

- Data limitations
- ~ 5x more trials via clinicaltrials.gov v australianclinicaltrials.gov.au
- *Cannabis and CBD* are studied more than other cannabis derivatives
- *Phase 2* more common than other phases
- *Randomised* is the most common trial design
- Relatively few 'large' (>200 enrolled) studies
- A range of therapeutic areas is studied



Acknowledgement

- Manjoban Buttar, Scientific Affairs Officer (student intern)