



# RESOLVE

## WHY the **RESOLVE** study?

For the proportion of people whose low back pain (LBP) persists beyond 3 months, obtaining pain relief and improving function becomes a significant concern. Unfortunately, chronic low back pain (CLBP) is difficult to treat.

Most available treatments have modest effects at best (**Table 1**), suggesting that alternative approaches to managing CLBP require investigation.

## WHAT is the **RESOLVE** study?

The RESOLVE study is a randomised controlled study in which we are comparing 2 new treatment programs that combine central nervous system-directed and traditional interventions.

Recently, interventions that are thought to target central nervous system function have been developed and tested in small studies, with promising results. Also, several preliminary investigations that have combined these central nervous system targeted treatments with traditional treatments suggest patients might obtain some additional benefit from a combined approach.

The aim of RESOLVE is to compare the effectiveness of these new treatment approaches at reducing pain intensity for people with CLBP.

Participants will be followed up at 18, 26 and 52 weeks post-randomisation.

Bagg, M et al The RESOLVE Trial for people with chronic low back pain: a protocol for a randomized clinical trial *Journal of Physiotherapy* 63 (2017) 47-48

**Table 1: Effects of interventions for persistent low back pain on short-term pain outcomes (less than 3 months post-randomisation)**

Pharmacological therapies	Clinically important?	Quality of Evidence
Tricyclic antidepressants vs placebo	N	High
Opioids vs placebo	?*	Moderate
NSAIDS vs placebo	N	Low
Skeletal muscle relaxants vs placebo	N	Very Low
Paracetamol vs placebo	N	Very Low
Non-pharmacological therapies		
Exercise vs no treatment, sham or placebo	?*	High
Acupuncture vs placebo	N	Moderate
TENS vs placebo	N	Moderate
Cognitive Behaviour Therapy vs waiting list control	?*	Moderate
Behaviour treatment vs usual care	N	Moderate
Ultrasound vs placebo	N	Low
Manual Therapy vs ineffective, sham, or inert control	?*	Very Low

\* Effect size 95% confidence interval includes the threshold for clinical meaningfulness (1/10 on 10 pt pain intensity scale)

Maher C, Underwood M, Buchbinder R. Non-specific low back pain *Lancet* 2017; 389: 736 - 747

## Why do people develop chronic low back pain?

Research evidence suggests that in people with persistent pain, the brain and nervous system is different compared to people without pain. These differences appear to be driven by two main neuroplastic processes:

- i. Facilitation
- ii. Imprecision
  - i. Facilitation leads to an increased sensitivity of the nervous system to stimuli and increased magnitude of responses.
  - ii. Imprecision is caused by dysfunction of brain cells; they do not simultaneously inhibit other nearby cells when they conduct impulses. This means that larger populations of brain cells activate in response to the same stimulus, or responses for a given stimulus generalise to other stimuli (an imprecise response).

Clinically, the current understanding is that these processes contribute to pain being felt during activities and movements that should not normally provoke pain; pain that is provoked by thoughts alone; or pain that spreads to other parts of the body.

Whilst the biological purpose of these neuroplastic differences is to prevent further injury and promote healing, they are not clearly helpful in the chronic stages of a condition.

It is not currently known if they may be one of the main reasons people develop chronic pain. That is, we do not know if they predispose people to develop chronic pain, or if they are the reason people do not recover from chronic pain.

The new treatment programs we are testing in the **RESOLVE** trial aim to retrain the brain to reduce chronic pain by targeting the fundamental processes (facilitation and imprecision) that underlie how the central nervous system produces low back pain.

### Participant Eligibility

- Patients with *non-specific* CHRONIC low back pain (this episode of LBP for greater than 3 months)
- No known or suspected serious spinal pathology
- Pain between 12<sup>th</sup> rib and buttock crease (with or without accompanying non-radicular leg pain)
- Age 18 – 70
- Live in the Sydney Metropolitan area and able to travel to Randwick for treatments

For new referrals please contact the RESOLVE research team:

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For further information, please visit our study homepage:

[www.neura.edu.au/resolve](http://www.neura.edu.au/resolve)