What does taking part mean for me?

If you join the study, you will need to attend the study centre a minimum of **6 times** to have some tests and assessments, including:

- Routine medical tests
- Overall health checks
- Checking the signs and symptoms of your ulcerative colitis

As well as study centre visits, you will also be asked to complete a diary to document specific symptoms of your ulcerative colitis, any additional medications you have taken and any side-effects you may have experienced while taking the study medication.

How long will the study last?

The study will last for approximately **16 weeks** and will include a:

- **Screening period (up to 4 weeks):** to check your eligibility to take part
- **Treatment period (8 weeks):** you will be allocated to receive either **KBL697** or placebo
- **Follow-up period (4 weeks):** the study team will continue to monitor your health and well-being

Want to know more?

If you would like to learn more about the study, please contact:

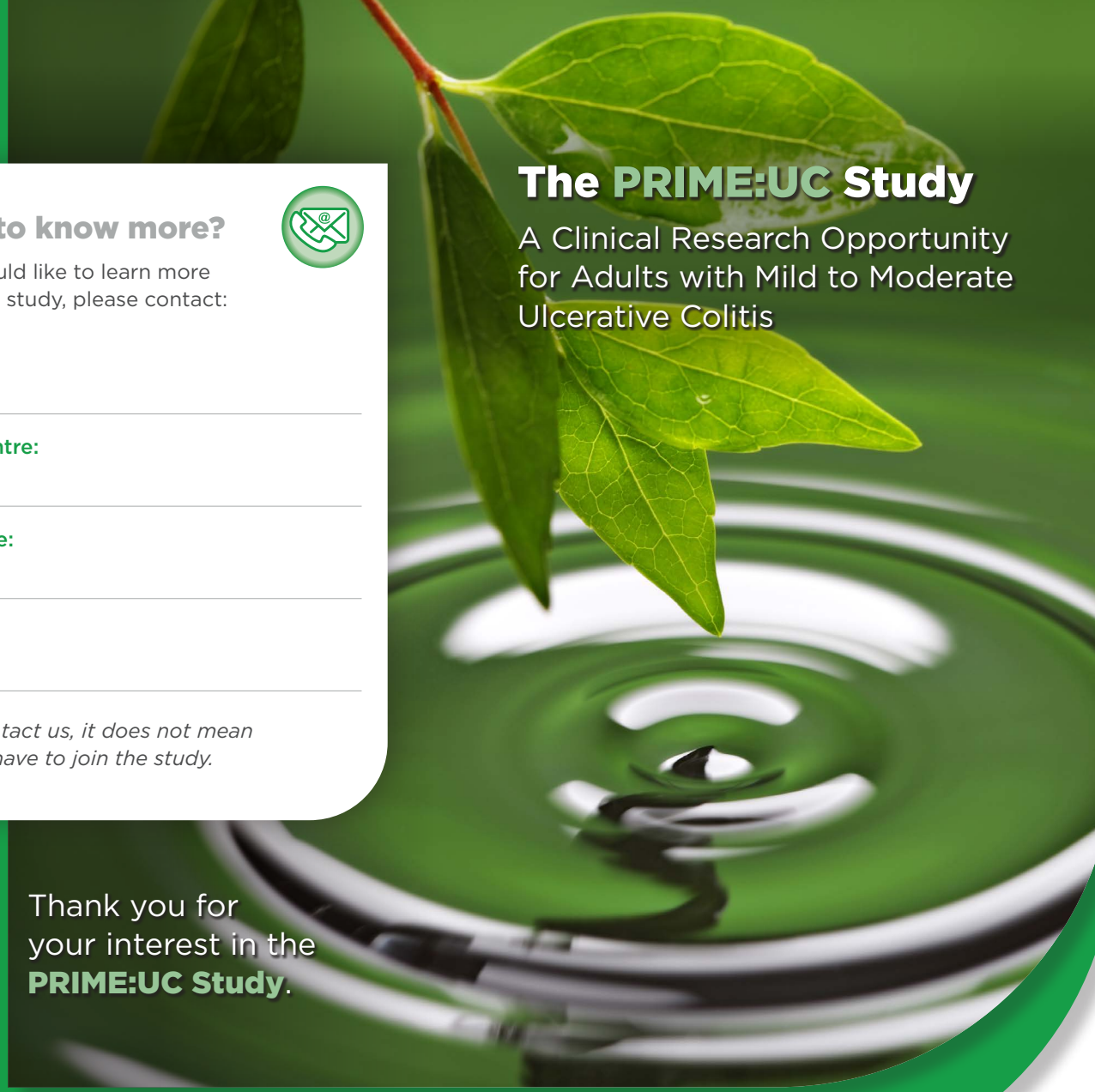
Name:

Study centre:

Telephone:

Email:

If you contact us, it does not mean that you have to join the study.



The PRIME:UC Study

A Clinical Research Opportunity for Adults with Mild to Moderate Ulcerative Colitis

Thank you for your interest in the **PRIME:UC Study**.

Participant Information Brochure

PRIME:UC

What is the PRIME:UC Study?

The **PRIME:UC Study** is a clinical research study evaluating the use of an investigational medication, called **KBL697**, in people with **mild to moderate ulcerative colitis**.

Ulcerative colitis is a long-lasting **autoimmune disease**. Most patients with **ulcerative colitis** have mild to moderate disease, where the disease is most active at diagnosis, followed by periods of time when the disease is less severe. In ulcerative colitis, the colon and rectum become inflamed, which can cause bleeding, diarrhoea, frequent urination, and abdominal pain.

'Investigational' means that KBL697 is still being tested and is not available for use outside of a clinical research study.

What will the PRIME:UC Study look at?

The **PRIME:UC Study** will assess the safety of **KBL697**, and also measure how the body responds to this investigational treatment.

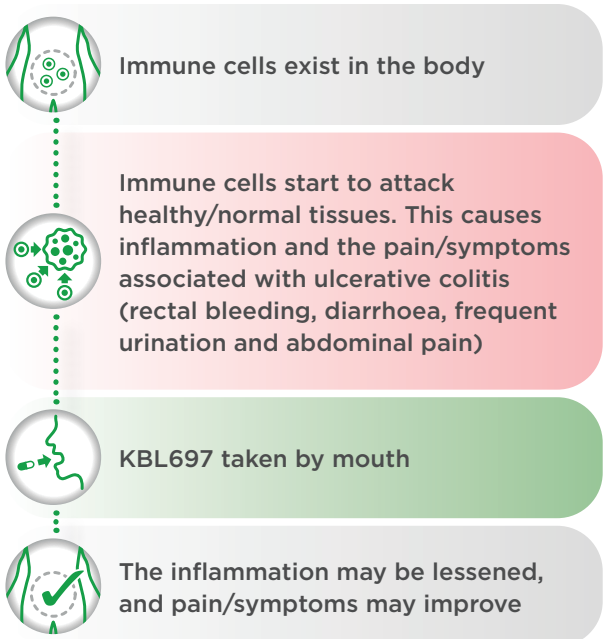
The **PRIME:UC Study** will enrol around **30 individuals** with mild to moderate ulcerative colitis in more than **10 centres in Australia and South Korea**.

What is the investigational medication?

Lots of different types of bacteria are found naturally in your body. The investigational medication, **KBL697**, is a particular strain of bacteria that has been taken from healthy volunteers.

Your body contains many immune cells. When these immune cells start attacking your own healthy tissues (called an autoimmune response), it can cause inflammation.

Some early studies in the laboratory have shown that **KBL697** can inhibit the inflammatory immune response occurring throughout your body. Lowering this immune response can reduce the inflammation in the colon and rectum, and therefore may improve the symptoms of your ulcerative colitis.



Can I take part in this study?

You may be able to take part in the **PRIME:UC Study** if you*:

- Are **aged 18 to 75 years**
- Have had **ulcerative colitis** for at least 3 months
- Are **taking oral (by mouth) medication** to manage your ulcerative colitis

*There are other criteria that you will need to meet to qualify for the **PRIME:UC Study**; the study team will discuss these with you.

Which study medication will I take?

If you decide to join the **PRIME:UC Study**, you will be randomly allocated to one of two groups as follows:

- **Group 1:** you will take 3 capsules (by mouth) of **KBL697** twice a day for a total of 8 weeks
- **Group 2:** you will take 3 capsules (by mouth) of **placebo** twice a day for a total of 8 weeks

The study is double-blind which means neither you nor your study doctor will know if you are receiving the investigational medication or placebo; this is to prevent any bias when the study results are analysed. In this study, 2 out of 3 participants will receive the investigational medication; the rest will receive placebo.

A placebo looks like the investigational medicine but contains no active ingredients.