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**Information Sheet**

**A validation trial of the IBS.Mindovergut.com resilience program**

**for Irritable Bowel Syndrome (IBS)**

**Project title:**

A validation trial of the IBSclinic.org.au online assessment and psychological support program.

**Principal investigator:**

Conducted by Dr Simon Knowles, Clinical Psychologist and Senior Lecturer, Swinburne University of Technology. Melbourne Australia.

**What this project is about and why it is being undertaken?**

Irritable Bowel Syndrome (IBS) is a chronic gastrointestinal illness that affects around 1 in 11 Australians. Common symptoms include: Abdominal pain (sometimes relieved in part/entirely with bowel movements or passing gas), flatulence, bloating or distension, diarrhoea, constipation or alternating diarrhoea and constipation (i.e. IBS with mixed bowel habits), mucus in stool and nausea. Individuals with IBS commonly identify experiencing psychological distress. Psychological distress is also known to exacerbate the physical symptoms of IBS.

Reflecting this interaction between the brain and the gastrointestinal tract, is the evidence indicates that IBS is due to the dysfunction of the brain-gut axis (BGA; the pathways by which the brain and the gastrointestinal tract communicate). Research indicates that focused BGA psychological interventions can reduce IBS and associated psychological distress. eHealth (or online) focused BGA psychological interventions have also shown to reduce IBS symptoms and psychological distress.

In 2013, IBSclinic.org.au was established by the principal investigator (SK) as the first freely available eHealth intervention for IBS. IBSclinic.org.au provided free evidence-based peer-reviewed information about IBS and a CBT-based (12 modules; 1 module per week) psychological intervention for IBS. Until its closure in 2019, the website was used by over 50,000 individuals. IBSclinic.org.au has recently been updated and now found at IBS.Mindovergut.com, including the development of a revised BGA focused psychological intervention for IBS, [hencefort](https://www.wordhippo.com/what-is/another-word-for/henceforth.html)h referred to as the IBS.Mindovergut.com resilience program of IBS.

*About the new IBS.Mindovergut.com resilience program of IBS*

Based on participant feedback from the original IBSclinic.org.au intervention and recent evidence for the efficacy of transdiagnostic interventions (targets common processes that underpin most psychological disorders) for IBS and psychological distress a new IBS-focused resilience intervention has been developed. The 5-module transdiagnostic intervention (1 module per week; 5th module is optional) has been designed to help facilitate resilience and promote optimal health in relation to living with IBS. The IBS.mindovergut.com resilience program will help you identify and target stress, illness-related thoughts and beliefs, maladaptive illness-related coping patterns, psychological distress all of which have been identified in the research as facilitating IBS and psychological distress.

IBS.mindovergut.com resilience program is based on a combination of Stress Management (SM), Cognitive Behaviour Therapy (CBT), and Acceptance and Commitment Therapy (ACT). SM strategies, such as relaxed breathing, will be utilised to reduce stress and the physiological impact that stress has on the body (e.g. increased muscle tension around the gastrointestinal tract). CBT strategies such as cognitive flexibility (identify and challenge unhelpful thinking patterns that promote stress and IBS symptoms e.g. ‘My IBS is getting worse’) and exposure work (a planned activity where individuals confront a situation which they currently avoid due to unwanted distress). ACT strategies (e.g. Mindfulness and Cognitive defusion) aim to change the negative cycle of distress associated with illness.

*Why it is being undertaken?*

Now that we have developed the IBS.mindovergut.com resilience program, we are seeking your help to volunteer and complete the program and provide feedback from a consumer’s perspective. We aim to recruit a total of 80 participants.

**Who can participate?**

You are welcome to participate if you are (1) aged over aged 18 or older, (2) have a diagnosis of IBS by a medical professional (e.g. general practitioner, gastroenterologist), (3) experience normal to moderate levels of distress (as confirmed via the Mindovergut.com brief psychological distress assessment tool), and (4) not currently seeing a mental health professional (e.g. psychologist, psychiatrist) for mental health concerns.

**What participation will involve – time, effort, resources, costs, compensatory payments, etc?**

Both prior to starting the program and before accessing the optional 5th module, we will ask you to answer a questionnaire taking approximately 45 minutes to complete. The questionnaires will involve answering anonymous demographic questions and then completing questions relating to your IBS symptoms (e.g. “1. Over the past week how often have you had loose or watery bowel motions?”), illness perceptions (e.g. “How much does your illness affect your life?”), visceral sensitivity (e.g. “I worry that whenever I eat during the day, bloating and distension in my belly will get worse”), pain catastrophizing (e.g. “I worry all the time about whether the pain will end.”), thinking patterns (e.g. how much do you agree with the following statements “You have a list of ironclad rules about how you and other people should act”), psychological well-being (e.g. “I found it hard to wind down”, “I found it difficult to relax”), personality (e.g. “I feel like I act totally on impulse.”), and quality of life (e.g. “How would you rate your quality of life?”). The questionnaires will also ask you to develop a unique ID (i.e. First 3 letters of your best friend’s surname and First 3 letters Mother’s maiden name) so we can match your pre- and post- IBS.mindovergut.com resilience program results. In the final questionnaire (completed prior to the 5th module), we will also ask you to prove you feedback about the resilience program. Your feedback is essential so that we can continue to improve this free service.

In relation to the questionnaires, there are no right or wrong answers. We are interested in your views and experiences, whatever they are. Consent will be implied by completion of the online questionnaires.

In relation to the IBS.mindovergut.com resilience program, each module (4 modules; 1 module per week; with an optional 5th module) is designed to provide a step-by-step therapeutic program which aims to help you develop strategies to reduce your symptoms. Modules will include a combination of education about the psychological distress as well as targeted behavioural and psychological strategies (e.g. identifying and challenging thoughts that contribute to your distress, relaxation and breathing retaining), to help you overcome your psychological distress. Access to the optional 5th module will be attained though completing a post-intervention questionnaire taking approximately 45 minutes. Your involvement in completing the post-intervention questionnaire is important as it will help us better understand how the intervention worked for you and how we can improve this free online service.

*Each of the 4 core modules (1 module per week) of the IBS.Mindovergut.com resilience program will take approximately 45 minutes to complete and homework activities taking around 20-40 minutes per day.*

**Participant rights and interests – Risks & Benefits/Contingencies/Back-up Support:**

As this study explore issues relating to mental health, please do not participate if you believe doing so may cause undue distress. If you feel concerned about any of your answers to this questionnaire and how it relates to your physical and/or mental health, please do not hesitate to contact the primary investigator supervisor (Dr. Simon Knowles, sknowles@swin.edu.au Tel: +61 03 9214 8206). Alternatively, if participating in the study has given rise to any concerns, you may want to consider contacting your local health professional. If you are experiencing a crisis and need help urgently, phone Lifeline on 131 114 or Suicide Line on 1300 651 251 (Australia), or your local area emergency service. If you are overseas, please search for local mental health services near you; one website that may be of help is <http://www.befrienders.org/>

# Participant rights and interests – Free Consent/Withdrawal from Participation:

Your participation is completely voluntary, and you are free to discontinue participation at any stage during the study without question. We respect your beliefs, customs and cultural heritage, and local laws. Given this, if you believe providing personal non-identifiable information (including about your physical and psychological well-well-being) and/or participating in the online resilience program may be inconsistent with your beliefs, customs and cultural heritage, and/or local laws we would recommend that you do not participate. If you have any questions or concerns relating to these matters, please feel free to contact the principal investigator.

# Participant rights and interests – Privacy & Confidentiality:

At no point in the questionnaire is any information asked that can identify you as an individual. Information from all participants will be held in strict confidence to ensure that no participant can be identified from their responses. All of your provided answers will be stored anonymously with many other participant responses and only the above researchers will have access to the data. All non-identifying data will be retained for at least 5 years post publication on a password-protected computer only accessible by the researchers. The grouped and averaged results obtained will be presented in the form of a research publication. The non-identified data may also be used in future research projects, including those being conducted by students. At the end of the pre-intervention questionnaire, you will be asked if you would like to provide contact details to take part in other research being conducted by the principal investigator. Any identifying information will be stored independently from the data provided in the pre-intervention questionnaire. This will ensure your responses and personal information will not be connected or able to be connected.

# Research output:

The research group conducting the study plan to write a report, which will be made available to anyone who is interested. The report will be available via IBS.Mindovergut.com. The results will also be written for publication in a scientific medical journal.

**Further information about the project – Who to contact:**

If you have any questions or feel any level of distress associated with this study, please feel free to ask at any stage by contacting the principal investigator: Dr. Simon Knowles, Swinburne University, Hawthorn (sknowles@swin.edu.au Tel: +61 03 9214 8206).

**Concerns/complaints about the project – Who to contact:**

This project has been approved by or on behalf of Swinburne’s Human Research Ethics Committee (SUHREC) in line with the *National Statement on Ethical Conduct in Human Research*. If you have any concerns or complaints about the conduct of this project, you can contact:

Research Ethics Officer, Swinburne Research (H68),

Swinburne University of Technology, P O Box 218, HAWTHORN VIC 3122 Australia.

Tel (03) 9214 3845 or +61 3 9214 3845 or resethics@swin.edu.au

Consent

I have read, or have had read to me in a language that I understand,this document and I understand the purposes, procedures and risks of this research project as described within it*.*

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described.

I understand that I can print off or contact the primary investigator to attain a copy of the information and consent form.

If you have read and agree to participant, please click on the button below.