



UNSW
AUSTRALIA

ONLINE PARTICIPANT INFORMATION STATEMENT

The springboardD project: Trial of a self-help intervention to improve functioning and emotional well-being in people with type 2 diabetes
A/Professor Judy Proudfoot

The research study is being carried out by the following researchers:		
Role	Name	Organisation
Chief Investigator	A/Professor Judy Proudfoot	UNSW Australia
Co-Investigator/s	Professor Kay Wilhelm Professor Lesley Campbell Professor Nicholas Zwar Mr Dusan Hadzi-Pavlovic Professor Jane Gunn Professor Helen Christensen Professor Helen Lapsley Dr Janine Clarke Dr Susie Fletcher Professor Mark Harris	UNSW Australia Garvan Institute UNSW Australia UNSW Australia University of Melbourne UNSW Australia UNSW Australia UNSW Australia University of Melbourne UNSW Australia
Research Funder	This research is being funded by National Health and Medical Research Council.	

What is the research study about?

You are invited to take part in this research study which is conducted online. You have been invited to take part because you are aged between 18 and 75 years and have diabetes.

To participate in this research study you need to:

- Have type 2 diabetes (diagnosed by a GP or endocrinologist)
- Be 18 to 75 years of age
- Experience fatigue or sleep difficulties, or problems with concentration or motivation, or low mood or sadness, or irritability from time-to-time, or any other mild-to-moderately severe symptoms of depression or distress
- Have access to the Internet
- Have a valid email address

We are looking for 650 people with Type 2 diabetes to take part in the study. You will not be able to take part in the study if you have Type 1 diabetes or are currently receiving face-to-face care for depression or have changed anti-depressant medication within the previous two months.

The research study is aiming to learn whether an online and fully-automated self-help program that is available 24/7 on Internet-enabled devices (computers, tablets, and mobile phones) is effective for improving mental wellbeing and daily functioning in people with type 2 diabetes.

This is the first Australian study to test whether it is possible to provide wellbeing support to people with type 2 diabetes using easily accessible every day tools, without human support.

Do I have to take part in this research study?

Participation in this research is voluntary. If you don't wish to take part, you don't have to. Your decision will not affect your relationship with UNSW Australia, the Black Dog Institute, the University of Melbourne, the Sax Institute or your General Practitioner.



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This Participant Information Statement tells you about the research study. It explains the research tasks involved. Knowing what is involved will help you decide if you want to take part.

Please read this information carefully. Before deciding whether or not to take part, you might want to talk about it with a relative or friend.

What does participation in this research require, and are there any risks involved?

If you are interested in taking part in the research study, you will be asked to complete a short online survey to see if the study is suitable for you. This will take about 10 minutes. If the study is not suitable for you, you will be notified immediately of some other possible options.

If the study is suitable and you agree to take part, you will be asked to complete an online questionnaire that has questions about your diabetes and diabetes treatment, mental health history, use of health services and a range of emotional and functioning issues that people with type 2 diabetes might deal with. This will take you about 25 minutes.

You will then be given full access to one of two online self-help programs to use wherever and whenever you want for 8 weeks. The program you are given will be decided by chance (i.e., at random). We recommend you use the program at least once a week, and more if possible.

At the end of 12 weeks, and again 6, and 12 later, you will complete more online surveys. Because we are interested to learn what changes take place over the course of the study, each survey will ask the same questions as the one you fill out at the start of the research study.

When you enrol in the research study, we will ask you to give us contact details for the general practice where you receive your diabetes treatment and your GP's name. This is because around the time you complete each survey, a member of the research team will contact your general practice to collect your latest HbA1c test result. This is the test measures your blood glucose level for the previous two-to-three months.

If we become concerned about your emotional well-being during the program, we may contact both you and your GP to recommend that you receive support. We will notify you before we contact your nominated GP.

Will I be paid to participate in this project?

Taking part in this study will not cost you anything, nor will you be paid.

As compensation for time spent, and as a token of our appreciation, you will receive a shopping voucher to the value of \$30 every time you complete a follow-up survey at 3, 6, and 12 months. At 24 months, participants who complete the survey will be entered into a prize draw for a chance to win a mobile tablet device or one of ten \$100 shopping vouchers.



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What are the possible benefits from taking part?

Currently there are not enough services to meet the emotional health care needs of people with diabetes, putting them at increased risk of a range of negative diabetes outcomes. An online tool that is completely self-guided could assist people with type 2 diabetes to better manage their mental well-being, daily functioning and diabetes health outcomes.

What will happen to information about me?

By clicking on the 'I agree' button you consent to the research team collecting and using information from the questionnaires you complete in the research study. We will keep your data securely for 15 years and then we will destroy it. If you are also taking part in the 45 and Up Study, the information you provide will be combined with information you have already allowed the 45 and Up Study to access securely, which means it can be used for research into the future.

Any information obtained in connection with this research study that can identify you will remain confidential, and will be de-identified as soon as possible. This means that we will replace the identifying information (e.g., your name, date of birth) with a code. A link that matches you to your coded information will be kept in a separate password-protected computer file that will be kept safe and available only to members of the research team.

All information collected from you over the course of the study will be stored in password protected computer files on a secure server at UNSW Australia.

Information about your HbA1c may be obtained from your medical records. By signing the consent form, you agree to the research team accessing your HbA1c data from your general practice.

It is anticipated that the results of this research study will be published and/or presented at conferences and other forums. You will not be identified in any publication or presentation.

How and when will I find out what the results of the research study are?

You have a right to receive feedback about the overall results of this study. You can tell us that you wish to receive feedback by answering "yes" to the question that asks about your interest in study feedback in the last online questionnaire. Feedback will be provided by email. This feedback will be in the form of a one-page lay summary of the overall aims and outcomes of the study.

What if I want to withdraw from the research study?

By clicking on the button "I agree", you consent to take part in the study. If you change your mind, you can withdraw at any time, up to the point that we have analysed and published the results. You can do this by sending an email to the research team at myCompass@blackdog.org.au.

What should I do if I have further questions about my involvement in the research study?



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Feel free to contact us using the details below. The person you should contact will depend on the nature of your query.

If you want any further information about this project or if you have any problems relating to your involvement in the project, please contact:

Research Team Contact

Name	Dr Janine Clarke
Position	Research Officer/Trial Manager
Telephone	+61 2 9382 3767
Email	Janine.clarke@unsw.edu.au

If at any stage during the project you become distressed or require additional support from someone not involved in the research please call:

Contact for feelings of distress

Name/Organisation	Lifeline
Telephone	13 11 14
Website	www.lifeline.org.au

If taking part in the research is causing you distress, you can also contact your GP for support and advice.

What if I have a complaint or any concerns about the research study?

If you have any complaints about any aspect of the project, the way it is being conducted, then you may contact:

Complaints Contact

Position	Human Research Ethics Coordinator
Telephone	+ 61 2 9385 6222
Email	humanethics@unsw.edu.au
HC Reference Number	15090