



Letter of Information

Study Title: **University student mental health and well-being research:**
Digital Well-Being Resources

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Background and purpose of the study

You are invited to participate in a study investigating *the acceptability and utility of digital resources to support university student well-being*. These resources have proven effectiveness in the general population of young adults and provide support for common well-being and mental health-related difficulties. The purpose of this study is to understand if these resources are acceptable and of benefit in supporting university student well-being and academic performance. This study is funded by the Mach-Gaensslen Foundation and has been reviewed for ethical compliance by Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

What will happen in the study?

Your participation in this study is voluntary. For the duration of the academic year, as part of this research all consenting undergraduate and graduate students at Queen's University will have free access to effective digitalized well-being resources. Specifically, these digital resources offer support for improving sleep quality, managing stress and anxiety, and binge eating symptoms. All resources have been tested in clinical research. Please [inset hyperlink click here] for detailed information about each digital resource.

If you would like to access any of the well-being resources, you can do so by creating a secure account in i-spero® [inset URL to i-spero®] using your Queen's University email address (ending in @queensu.ca). i-spero® is a new digital technology that provides access to the well-being resources and administers electronic study measures. After registering and providing consent to take part, you will be provided with a brief set of electronic questionnaires to complete that ask about your demographics (i.e. age, gender, ethnicity), lifetime mental health history, current level of well-being, and symptoms of common mental health problems. These questionnaires should take about 10 minutes to complete, but there is no time limit and you can take as long as you need. You will then be invited to select the digital app of your choosing (note that you may only select one). Depending on the app you select, you may be asked some additional screening questions to determine whether the app is suitable for you.

Once you have selected the resource you wish to use, i-spero® will provide a secure URL link to access the digital resource of your choice. As part of the research, i-spero® will ask you to complete additional brief electronic questionnaires at 4, 8, and 12 weeks after you start using a digital resource. The questions will ask about your experience of using the resource, in addition to reviewing your well-being and mental health. The resources we offer are "self-guided" meaning that your progress and responses **will not** be monitored by the research team.

Once you have completed a resource, or feel that you no longer require it, you are able to select and work through one of the other digital resources on offer. This will involve completing the same set of initial electronic questionnaires. It is only possible to work through one digital resource at a time.

To understand the association between your use of the resources and your academic outcomes, your survey responses will be linked via your student number to university administrative (e.g. program and year of study) and academic data (e.g. course grades, withdrawal, academic sanctions). To understand the association between use of the digital resources and use of other mental health resources, your questionnaire responses will also be linked to administrative data from your electronic medical record at student health services (should you have accessed help for a mental health problem) via your student number. Extracted data will be strictly limited to routinely collected administrative service use data to estimate wait times and number of visits by provider type (e.g. family doctor, counsellor or mental health consultant). The research team will not extract any personal health data such as diagnoses.

Are there any risks to doing this study?

All of the digital resources have been tested in clinical research. We feel risks are minimal in this study. Some of the questions in electronic surveys may cause upset or bring up painful memories. If your distress continues please share this with a member of your care team. We have also followed all regulations in terms of safeguarding your data (see Confidentiality and research data section below).

At the end of this letter, we have provided a list of mental health services that you might consider contacting. These resources are also listed at the end of each survey and on our website [insert website link].

Are there any benefits to doing this study?

There may be benefits to your well-being and mental health through use of the available digital resources. We also hope that the study findings will help us to improve resources and services available to support university students' well-being and academic success moving forward.

Payment or reimbursement

Access to our resources is offered free of charge for all Queen's University students through an in-kind contribution by the resource developers and through research grant funding. However, you will not be paid or provided with any reimbursement for taking part in this study.

Confidentiality and use of research data

Please be assured that your research data will be held securely and handled in strict confidence. For this study, we are collaborating with several external groups (data processors) including Big Health, Global Initiative, and P1vital Products, who host the digital resources we are making available and will process the data you input. The collection of your personal identifiable information will be minimized. The data you provide will be held securely on their servers during the study. At the end of the study, encrypted data files will be securely transferred for analysis. These external groups will store data only up until deletion is requested by our research team, after all relevant data has been safely transferred to us. Our collaborators acknowledge their requirement to: (i) comply with the applicable privacy legislation and (ii) maintain adequate safeguards and inform us if there is a breach of these safeguards.

The information you input will be linked to administrative and academic data through your student number. Academic outcome data linked in this study will include course grades, overall grade percentage, rate of failed courses, and any instance of academic probation or suspension.

Study data will be stored electronically on secure university computers. Encrypted password protected data files will be stored on password-protected university computers. Study data will be assigned a unique identifier so that individuals cannot be identified in any analysis. Only the research team at Queen's University will have access to these files. However, the HSREB may require access to study records to monitor the ethical conduct of the research.

Identifiable data (ie email addresses) will be securely stored on university servers for a minimum of 5 years after study close and de-identified data will be stored in a secure university research data repository indefinitely. We may collaborate with other researchers at other institutions to analyze de-identified data. Researchers from inside and outside of Canada can apply to access this de-identified information for research purposes only.

What if I change my mind about being in the study?

Your participation is voluntary and you are free to withdraw at any time. You can stop using our digital resources at any point. Even if you choose to take part, you can withdraw from the study and have all your data removed without penalty and without giving a reason at any time until the point of publication. You just need to tell us by emailing flourish@queensu.ca. Furthermore, you can delete your i-spero® account at any time, which will permanently delete any personally identifiable data from i-spero®. Your decision whether or not to be part of the study will not affect your access to other university support.

How do I find out what was learned in this study?

This study is expected to complete by September 2023. If you would like a brief summary of the results, please write to us by email to request information. We will share findings in manuscripts and through the Queen's Journal, social media and our website:

<https://www.queensu.ca/studentwellness/health-promotion/u-flourish-student-health-project>.

Questions about the study?

Any questions about study participation may be directed to the investigators and their research team through the study email: flourish@queensu.ca. Alternatively you could contact the lead investigator Dr. Anne Duffy at 613-533-2508 directly. If you have any concerns about your rights as a research participant please contact - Queen's University HSREB at 1-844-535-2988 (toll free in North America) or email HSREB@queensu.ca.

We want to thank you for considering taking part in this research! The responses you and other students provide will identify areas where we can improve education and health promotion resources to support well-being and academic success among university students.

IMPORTANT MENTAL HEALTH SERVICES INFORMATION

IN A LIFE OR DEATH EMERGENCY

If you are experiencing suicidal thoughts and think that you might be unable to keep yourself safe, visit your nearest hospital emergency department or call 911.

IF YOU ARE IN CRISIS

If you are in crisis and cannot wait to receive medical attention or are unsure what to do, call Addiction and Mental Health Services KFL&A at 613-544-4229 (local) or Crisis Services Canada at 1-833-456-4566 (Canada-wide).

IF YOU ARE IN NEED OF NON-URGENT CARE

If you are concerned about your mental health and are in need of non-urgent care, there are several options you might consider.

Your family doctor

Book an appointment with your family doctor. They can offer advice or refer you to other more specific services to get help.

Queens University Student Wellness Services.

If you do not have a family doctor, Student Wellness Services can offer a range of services, including counselling and medical assessment and treatment. The Counselling Service can help you address personal or emotional problems that are getting in the way of having a positive experience at Queen's University and realising your full academic and personal potential. Services are free and confidential. It is important to know that the Counselling Service is not just for those with a diagnosis: you can contact them for any reason. To make an appointment, call 613-533-2506.

For further information about the services provided by Queen's Student Wellness Services please visit:

<http://queensu.ca/studentwellness/health-services>

Appendix

Description of Resources

Daylight (anxiety): Daylight is a fully automated digital worry and anxiety improvement program based on cognitive behavioral therapy (CBT) for Generalized Anxiety Disorder. While often initially triggered by a stressful life event, Generalized Anxiety Disorder is maintained by unhelpful behaviors and thoughts. Daylight targets these unhelpful behaviors and thoughts using evidence-based cognitive and behavioral interventions. Reducing these unhelpful behaviors and thoughts leads to a reduction in Generalized Anxiety Disorder symptoms.

Common behaviors maintaining Generalized Anxiety Disorder include avoiding situations and/or thoughts that are anxiety-provoking (e.g., procrastinating or trying not to think about a feared outcome), and/or engaging excessively in activities to try to reduce acute anxiety (e.g., seeking reassurance from others, “checking” things excessively, overplanning, etc.). Psychoeducation about the impact of these behaviors on anxiety (i.e., that these unhelpful behaviors may seem helpful but can actually maintain or worsen anxiety) is provided in Daylight, as well as techniques to target unhelpful behaviors, such as stimulus control (i.e., limiting worrying to a specific time and place) and imaginal exposure (i.e., facing, or not avoiding, worrisome thoughts and fears).

GAD involves excessive worrying, often with unhelpful thinking patterns that can involve catastrophizing, overgeneralizing, all-or-nothing thinking, jumping to conclusions, and emotional reasoning. Daylight addresses unhelpful thinking patterns using a cognitive technique called cognitive restructuring (i.e., identifying and challenging unhelpful thoughts), as well as introducing a physiological technique (applied relaxation) to help reduce tension and focus mental attention which can in turn relax the mind.

Digital CBTe (binge eating): Digital CBTe is an entirely automated online self-help programme for adults with binge eating symptoms. Recurrent binge eating responds well to a specific psychological treatment, a form of cognitive behavior therapy for eating disorders called enhanced cognitive behaviour therapy. This treatment has been converted into an online self-help programme called “Digital CBTe”. It consists of 12 sessions over 8 weeks. Each session takes approximately 20 minutes to complete. Users can complete these sessions wherever they want but need to be in a private place and where there is internet access. At the end of each Digital CBTe session there is a "To Do List" in which the action points from the session are summarised. In order the benefit from the programme, users are asked to complete the action points between sessions.

Users are initially asked to fill in questionnaires about the severity of their eating difficulty and mood. These questionnaires will be asked again at the end of Digital CBTe (after 8 weeks) and 6 months after completion, in order to review progress.

Sleepio (sleep): Sleepio is a fully automated digital sleep improvement program based on cognitive behavioral therapy for insomnia (CBT-I). While typically triggered by a stressful life event, insomnia is maintained by unhelpful behaviors and thoughts. Over the course of six sessions, your virtual sleep expert -- The Prof -- teaches you evidence-based cognitive and behavioral interventions, sleep hygiene education, and relaxation exercises to target these unhelpful behaviors

and thoughts. Reducing these unhelpful behaviors and thoughts leads to a reduction in insomnia symptoms.

Common behaviors maintaining insomnia include spending an excessive amount of time awake in bed, sleeping in on the weekends, taking daytime naps, and drinking excessive caffeine. Sleep restriction (i.e., establishing a regular sleep window based on the actual amount of time spent asleep), stimulus control (i.e., reducing the amount of time awake in bed to reassociate the bed with sleep), and sleep hygiene (i.e., education about behaviors that interfere with sleep) are introduced in Sleepio to target unhelpful behaviors.

Common thoughts maintaining insomnia include excessive worries about sleep, dysfunctional beliefs about sleep, and bed-related tension and anxiety. Sleepio identifies, challenges, and addresses thoughts and worries that contribute to difficulty sleeping using cognitive therapy such as cognitive restructuring (i.e., identifying and challenging unhelpful thoughts) and paradoxical intention (i.e., instead of focusing on trying to sleep, focus on trying to stay awake). Relaxation techniques such as progressive muscle relaxation are also introduced to help reduce bed-related anxiety and tension.