



Letter of Information

Study Title:

U-Flourish Pilot Study:

Passively collected data to benefit university student mental health and academic outcomes

Principal Investigator:

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Student Health Services
Department of Psychiatry
Queen's University

Funder:

Canadian Institutes of Health Research (CIHR)

Background and purpose of the study

You are invited to participate in a research study investigating *the acceptability and utility of passively collected health data using a wearable device called the Oura Ring to support university student well-being*. This digital resource has been helpful in the general population collecting individual user health data and providing customized feedback helpful for understanding well-being. The purpose of this study is to collect preliminary data (i.e. a pilot study) to understand from students if this digital resource is acceptable and of possible benefit for improving and/or maintaining your well-being and academic performance. This study has received ethical approval by the Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board.

What will happen in the study?

Your participation in this pilot study is voluntary. Below is a brief summary of what will happen in this pilot study if you choose to take part. To read more about this pilot study and the U-Flourish research please go to our website: <https://www.queensu.ca/u-flourish/>.

For this pilot study, we are planning to recruit 60 eligible students from among those who completed at least one U-Flourish Survey and consented to be contacted by our research team to learn about related research opportunities. Students will be recruited into one of two study arms: (1) i-Spero Digital Well-Being Platform (n=40), or (2) i-Spero Digital Well-Being Platform + Oura Ring® (n=20). Recruitment for each study arm will occur separately. The arm that each eligible student is recruited to will be randomly determined. The students who respond first to the email invitations will be selected for participation until the quota for each study arm is met. The subset of students (n=20/60) recruited to use the Oura Ring in addition to the i-Spero Digital Well-Being Platform (PSIY-739-22) will allow us to study the added value of using the Oura Ring® in conjunction with the i-Spero Platform. The Oura Ring® (www.ouraring.com) passively collects health and well-being data including heart rate, temperature, sleep duration and calculates a "readiness score" for the day.

At study entry, the students who are using both i-Spero and the Oura Ring® will be asked to attend a research visit with one of our team members at the U-Flourish research office on campus in the Centre for Neurosciences (Room 242). At that time, after confirming that you have read and understood this Letter of Information and have had all your questions answered you will consent to take part. Then, you will be supported by our team to register for an Oura Ring® study account using an assigned unique study id and password. This study id and password will be linked to your student id and this linking information will be kept secure in a separate encrypted electronic file stored on a Queen's University desktop. At this visit, you

will also be fitted for the size of your Oura Ring® and then you will be supported to register for your research account. After registering, you will be sent the electronic baseline questionnaires to complete that ask about your current well-being, and level of common mental health symptoms. The questionnaires should take about 5 minutes to complete, but there is no time limit, and you can take as long as you need.

As mentioned above, you will be asked to repeat the brief electronic measures at 4 and 8-weeks, as well as a Student Experience Survey at 6 weeks after you start using the digital resource. The Experience survey asks you to rank ease and usefulness of the digital resources under study to understand the student user experience (ease, usefulness, visual display, content). The Student Experience Survey also asks if you accessed any university well-being or mental health services over the course of the study. For those students using both the i-Spero Digital Well-Being Platform and the Oura Ring®, you will be asked about any perceived added value of using both resources in terms of supporting your well-being.

The use of the Oura Ring®, like the i-Spero Digital Platform, is “self-guided” meaning that **your progress and responses will not be monitored by the research team and the research team cannot accept responsibility for your well-being or mental health care. If you have questions you can reach our study team via our research email at flourish@queensu.ca.**

As in other U-Flourish research studies, to understand the association between your use of this digital resource and your academic outcomes, your electronic measures 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 Oura Ring® and use of other student mental health resources, your questionnaire responses will also be linked to administrative data from your electronic medical record at Queen’s Student Wellness 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 or treatments. Further, if you have completed at least one of the [U-Flourish Surveys](#) your study data will be linked to survey data through your student number so that we can better understand who uses this digital resource and for whom it is helpful and not helpful.

Are there any risks to doing this study?

The Oura Ring® has been previously evaluated in the general population including young adults. We feel risks are minimal in this study. We have also followed all regulations in terms of safeguarding your data (see Confidentiality and research data section below). While every effort will be made to protect the privacy of your information, absolute confidentiality cannot be guaranteed. This does not limit the duty of the researchers and others to protect your privacy. Some of the questions in electronic measures may cause upset or bring up painful memories. If you experience any distress from participating in this study, you may stop completing the measure at any time or skip any upsetting questions. If your distress continues after completing the measure, we have provided a list of supportive services that can be helpful at the end of this Letter. These resources are also listed on the QSW website (<https://www.queensu.ca/studentwellness/resources>) and on the i-Spero Well-Being platform.

Are there any benefits to doing this study?

There may be benefits to your well-being and mental health through use of this digital technology. The feedback such as the Readiness Score based on your own entries might be helpful to you in assessing your well-being. We also hope that the study findings will help us together with students improve resources available to support student well-being and academic success moving forward.

Payment or reimbursement

Access to an Oura Ring® is offered free of charge during the study for consenting students through an in-kind contribution by research collaborators and through CIHR research grant funding. As a thank you for your participation in this research, you will be offered a Starbucks e-gift card worth \$5 for completing all study measures up to 8-weeks including the Student Experience Survey at 6-weeks. Starbucks e-gift cards will be sent on May 15th for participants who have completed all study measures between November 1st and May 1st and on November 15th for those that have completed all surveys between May 2nd and October 31st.

Further, students who participated in the current research study using only i-Spero will be offered 8 weeks of use following study completion, as a thank you for their participation.

Confidentiality and use of research data

Please be assured that your study data will be kept strictly confidential. Participants confidentiality will be protected to the extent permitted by the applicable laws. For this study, we are collaborating with researchers affiliated with the University of Toronto. Specifically, co-investigator Dr Pham and her research team at UHN Centre for Digital Therapeutics will collaborate with Dr Bhat and his research team at St Michael's Hospital Interventional Psychiatry Program who specialize in this digital technology research to analyze the de-identified Oura Ring® data. In this pilot study, the collection of personal identifiable information is minimal (i.e. student id). To protect your personal information, a set of study identifiers will be used as your username when you create your Oura Ring® study account to de-identify the data the Oura ring collects. The Oura Ring® connects to your smartphone via Bluetooth. It will collect raw data locally in the ring and send to the app when synchronized. Once the Oura app detects internet access, encrypted data will be securely transferred and stored on the secure Oura server (data processor). It is important to note your Oura Ring® account will only have your study id, and so Oura will not have access to your direct identifiers. At the end of the study, your Oura account will be deleted, at which point your data will also be deleted from Oura Ring®. You can read more about Oura's privacy policy here: <https://ouraring.com/en/privacy-policy-oura-health>. Please note that Oura does track and share how you browse their website with third parties through tracking cookies.

The data you provide will be held securely on Oura processor servers during the study. At the end of the study, encrypted data files will be securely transferred for analysis. Oura will store data only up until deletion is requested by our research team, after all relevant data has been safely transferred to us. If you wish to have any data collected from the Oura Ring®, you can request this by emailing the U-Flourish email at: flourish@queensu.ca. We will aim to process your request within 30 days. 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 health and academic data through your student number. Specifically, your Oura Ring® data will be linked to administrative health data from your electronic medical record (EMR) at Queen's Student Wellness Services. This will allow us to evaluate the transition to mental health care for students in the study who try to access mental health care. Extracted data will be strictly limited to routinely collected health administrative data needed to estimate wait times and pathways to and through mental health related appointments (e.g. time to see family doctor, counsellor or mental health consultant). The research team will not extract any personal health data such as diagnoses or treatment. 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. We may also link your Well-Being Platform data with your [U-Flourish Survey](#) data if you have completed at least one U-Flourish Survey.

Encrypted password protected data files will be stored on password-protected university computers. Data will be stored separately from student id and email addresses provided. Study data will be assigned a unique identifier so that individuals cannot be identified in any analysis. Reports of this study will use group data

and will not discuss individual information. Only members of the research team at Queen's University will have access to the data following data transfer. There are organizations and their representatives that may look at or receive copies of some of the information in your study records and in some cases, your medical records, for data analysis and quality assurance for monitoring, control, safety, and security. These may include, members of the study team, as delegated by the study doctor/principal investigator, and authorized representatives of Queen's University, its hospitals and/or Queen's University Health Sciences and Affiliated Teaching Hospitals Research Ethics Board (HSREB).

Data 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 study 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 the Oura Ring® 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. In addition, you can decline to participate in any aspect of the research without impact on your academic standing. You just need to tell us by emailing us at: flourish@queensu.ca. Furthermore, you can delete your i-spero account and/or Oura Ring® account at any time. Your decision whether or not to be part of the study will not affect your access to other university supports or your academic standing.

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

This sub-study is expected to complete by April 30th 2025 unless additional funding is secured. 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/u-flourish>

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 - Dr. Dean A. Tripp, Chair of the 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

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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).

SEXUAL ASSAULT AND VIOLENCE

Queen's University has an office of Sexual Violence Prevention and Response Services. If you are unsure or have experienced any form of sexual assault or violence you can connect with them through: <https://www.queensu.ca/sexualviolencesupport/>

Queen's SWS has a counsellor who specializes in sexual assault. To make an appointment, call 613-533-2506.

Sexual Assault Centre Kingston (SACK) has crisis & support services available 24/7 by phone 1-877-544-6424. [Chat and text support](#) is also available.

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>