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The HypoPAST study: evaluation of an online program for Hypoglycaemia Prevention, Awareness of Symptoms and Treatment among adults with type 1 diabetes

Study Information

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Project Title: The HypoPAST study: evaluation of an online program for Hypoglycaemia Prevention, Awareness of Symptoms and Treatment among adults with type 1 diabetes

Project number: DUHREC 2023-132

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You may like to save a copy of this Study Information on your computer for future use. Or you can download a copy from the ACBRD website (www.acbrd.org.au) or email the HypoPAST team for a copy (hypopast@deakin.edu.au).

What is the study about?

The aim of this study is to find out whether a new online program can help adults with type 1 diabetes to feel less worried about hypoglycaemia (low blood glucose), also known as 'hypos'. The program is called HypoPAST.

HypoPAST is short for Hypoglycaemia Prevention, Awareness of Symptoms, and Treatment. You can access HypoPAST on your computer, tablet device, or smartphone. It includes information, activities, and videos which you may find useful to help you prevent and manage severe hypos, and your worries about hypos.

Who can take part?

You can take part if you:

- are an adult, aged 18 years or older, and
- have been diagnosed with type 1 diabetes, and
- have concerns or worries about hypos, and
- live in Australia, and
- have access to the internet via a computer, tablet device, and/or smartphone.

What will I need to do?

This is a 6-month study with several steps.

In brief:

People who take part will be put randomly into one of two groups.

- Group 1 (*HypoPAST now*) will be able to access the program on their computer or tablet device straight away.
- Group 2 (*HypoPAST wait-list*) will need to wait 24 weeks before they can access the program.

Everyone will be asked to fill-in some surveys and to use an 'app'. Some people will be asked to take part in a telephone interview at the end of the study. The data (information) from these will help the researchers to find out how well the program works.

In more detail:

Step 1: Agree to take part (2-3 minutes)

Visit the study registration website https://hypopast.org.au

You will be asked to tick a box to tell the researchers that you have read this Study Information and agree to take part in the study. This is called giving 'informed consent'.

Step 2: Check your eligibility and register your details (5 minutes)

You will be asked to answer a few quick questions to check that you meet the study criteria (see "Who can take part?" above). If you are eligible, you will also be asked to write your name, email address, and phone number. This is only so we know how to reach you about the study.

Step 3: Fill-in the first survey (about 45 minutes)

If you meet the study criteria, you will be asked some more survey questions. This is likely to take around 45 minutes. So, please make sure you allow enough time. The questions are not a 'test', there are no 'right' or 'wrong' answers.

The survey will ask you questions about:

- you, such as: your age, gender, education, and the language you speak at home
- your diabetes, such as: how old you were when you were diagnosed with diabetes, your most recent HbA1c, whether you use an insulin pump or injections, and how you monitor your glucose levels
- your hypos, such as: what worries you about hypos, how often you have hypos, are you always aware of your hypo symptoms, and how hypos affect your quality of life
- your emotional health e.g. how often you feel anxious (in general), how living with diabetes makes you feel, and have you ever been diagnosed with a mental health problem
- your general physical health, any complications you have related to diabetes, and your use of health services.
- the name and contact details of your diabetes doctor (the person you see most often for your diabetes care), so we can write to tell them that you are taking part in this study.

This may seem like a lot of information. But it is important to help us understand how well HypoPAST works for adults with type 1 diabetes. If it works, we will be able to offer it to more people with diabetes in the future.

Step 4: Use an 'app' to tell us about your daily hypos (about 5-10 minutes, twice a day for two weeks)

In this step, you will use an 'app' twice a day for two weeks to tell us about your experiences of hypos each day, and your worries about having hypos later that day. The app is called uMotif. You will need to download the app to your smartphone or tablet device and register an account. We will email you a unique invite code so you can access the 'app'. You will 'check-in' about your hypos two times each day: in the morning (at a time of your choice between 06:00am to 12:00pm) and in the evening (at a time of your choice between 6:00pm to midnight). The 'app' will send you a notification to remind you for each check-in. If you don't have a smartphone or tablet device, you can skip this step.

Step 5: Randomisation (1-2 minutes)

Once you have finished the using the 'app' for two weeks, our computer will randomly put you into one of two groups: *HypoPAST now* or *HypoPAST wait-list*. You have an equal chance of being put into each group, like flipping a coin. We will send you an email to let you know your group.

- If you are in the *HypoPAST now* group: You will be able to start using HypoPAST straight away. You will receive instructions in an email about how to access the program. You will need to log-in with your email address and a password. You will be advised to use the HypoPAST program over the next 4 to 8 weeks. You will be able to use the HypoPAST program as much as you like, for a maximum of 24 weeks (about 6 months). There is more information below about HypoPAST.
- If you are in the *HypoPAST wait-list* group: You will be able to use HypoPAST after the final survey at 24 weeks (about 6 months later). In the meantime, you will continue with your usual diabetes management. We will email you at the end of the study about how you can access HypoPAST. We need to ask some people to delay their use of the program so that we can compare the two groups. This will tell us whether HypoPAST has changed anything for the people who used HypoPAST.

Step 6: Fill-in the second survey (about 45 minutes)

Twelve weeks (about 3 months) after randomisation, we will invite everyone to complete a second survey (same questions as before). The *HypoPAST now* group participants will receive a few extra questions about their experience of using the HypoPAST program.

Step 7: Fill-in the third survey (about 45 minutes)

At week 24, we will invite you to complete a third survey (same questions as before).

Step 8: Use the 'app' for a second time (about 5-10 minutes, twice a day for two weeks)

At week 24, we will email you to ask you to start using the HypoPAST (uMotif) 'app' again (same questions) every day for another 2-week period. The 'app' will also send you a notification as a reminder. If you don't have a smartphone or tablet device, you can skip this step. After the two weeks, the *HypoPAST wait-list group* will receive an email with instructions about how to access HypoPAST.

Step 9: Interviews (about 30-45 minutes)

Some people from the *HypoPAST now group* will be invited (by phone or email) to talk on the telephone with one of our researchers about:

1) how you applied the HypoPAST program to your diabetes management and life, and
2) your thoughts about the future of HypoPAST, so we can help people to get the most out of the program.

We will not interview everyone. We will interview about 25 people (about a quarter of the *HypoPAST now group)*. The interviews are optional, which means you can say 'no' if you do not want to take part. We will audio-record the interviews to help the researcher remember what you said.

Will I have any other contact with the study team?

The study is fully online. You will not need to visit our research office or meet anyone from the research team in-person.

If you have any questions about the HypoPAST program or study, you can contact us via email or phone. Our contact information is on page 6.

The 'app' will remind you when it is time to 'check-in'. We will send you two email reminders to complete each survey. If you are in the *HypoPAST now group,* we will send you two email reminders to use the program in the first six weeks. If you are in the *HypoPAST now* group and have not used the program after 6 weeks, a HypoPAST researcher will phone you to support you to access the program. We will also email you one week before your program access ends.

If you share with us (via survey, app, or by e-mail or phone) that you had a severe hypo or mental health crisis during the study, a HypoPAST researcher will contact you about it. In this case, 'severe' means that you needed emergency services (e.g. ambulance or CATT) or to go to hospital. We will contact you once by email, and once by phone to ask you about what happened. You can choose not to answer the questions. This will not affect your participation in the study. We are required by law to report the episode to Deakin University's Human Research Ethics Committee and to the Australian Therapeutic Goods Administration.

How will my information be kept private?

Your name and contact details will only be known to some of the research team. The rest of the research team will not know who you are or that you are taking part in the study. We will not share your name or contact details with people who are not part of the research team, except if required by law.

Every person in the study will have a unique participant number. It will be used to protect your identity. Only some of the research team will know which participant has which number. The number will replace any information that could be used to identify you (e.g. your name or email address) once data collection is finished.

All the study data (information) will be saved, as electronic files, on the Deakin University password-protected secure network.

Your responses to the survey and 'app' questions, and your personal information (name and contact details) will be kept confidential (only known to the research team). The only exception would be where disclosure is required by law or as described in this study information. This is very unlikely.

How will the study findings be used?

Once we have collected the study data (survey responses and interviews) we will combine the responses of all the people who took part and analyse the findings. The analyses will be done by trained researchers employed by Deakin University or Monash University.

Other researchers may also want to do extra analyses using the data we collect for HypoPAST. They will be allowed to request a copy of the study data from us for their analyses. If the HypoPAST study team agrees that they have a good reason to use the data, we will share a copy with them. A good reason would be if they have an important research question that our study data can help them to answer. We will only share the data if we don't already have plans or resources to answer that question ourselves. We will only share the data if we are confident that

they will use and store it appropriately. We will not share your personal data (name or contact details) or data that could be used to identify you.

How can I, and others, access the study findings?

We will publish our findings in scientific journal articles. We may also report findings at scientific conferences. When we do this, we will summarise the findings on our research centre's website (acbrd.org.au) and post them on social media. We will add them to the *HypoPAST* website and promotion materials. No-one will be able to identify you or know that you took part.

If you would like us to email you a summary of the findings, you will be able to let us know in the first survey by ticking a box. The study findings will be available after the study ends, in late 2024.

How long will you keep my information?

We must keep your information for at least fifteen (15) years after the study findings are published. Then, it will be destroyed by erasing the electronic files under direction of the Deakin University IT Manager. This is required by law.

Are there any benefits for me personally?

If you access the HypoPAST program, you may learn something new, refresh your knowledge about hypos, or learn to think in different ways about your hypos. This is because HypoPAST has been designed to support you to worry less about hypos. But as we have not yet tested the program, we cannot guarantee you will experience these benefits.

As a token of thanks, we will send e-Gift vouchers to all people who take part after they complete:

1. Survey 2 (study midpoint: week 12): $50 voucher (all participants)
2. Survey 3 and HypoPAST (uMotif) app (study end: week 24-26): $50 voucher (all participants)
3. A telephone interview (after study end): $50 voucher (about 25 people in the *HypoPAST now* group)

The project research assistant will get in touch with you to arrange to send you your vouchers via email.

Does HypoPAST replace the advice of my diabetes doctor?

No. HypoPAST is not designed to replace the advice of your usual diabetes health professional(s). This means you should continue with your usual diabetes management during the study. If you have a severe hypo or another diabetes-related issue during the study, you should contact your diabetes health professional for advice. If you have a severe hypo or another health-related issue during the study your medical expenses will not be paid/reimbursed by the research team or the organisations involved with the study.

Are there any risks to me?

The HypoPAST program and data collection (survey, 'app', interviews) include topics related to your diabetes and your emotional well-being. It is possible these questions may cause some people to feel uncomfortable or distressed. That is not our intention.

You choose what you complete. We advise everyone to complete the whole HypoPAST program. But it is your choice. You may skip any topics in the HypoPAST program that you don't want to complete. You may skip any questions in the survey, 'app', or interview that you don't want to answer. You may stop taking part in the study at any time.

If you do feel discomfort or distress, you don't have to go through this alone. Please contact your GP, diabetes health professional, or BeyondBlue (Telephone: 1300 224 636). For diabetes-related information and support, you can also contact the National Diabetes Services Scheme Helpline

(Telephone: 1800 637 700). You can also contact our research team. Our contact details are on page 6.

What if I don't want to take part anymore?

Taking part is voluntary. You can change your mind if you no longer want to take part.

If you no longer want to take part, you can email us to ask us to remove you from the study (hypopast@deakin.edu.au). You may like to sign a 'Withdraw Consent' form. Email us for a copy of the form (hypopast@deakin.edu.au).

If you no longer want to take part, it will not affect your relationship with the *HypoPAST* staff, researchers, partners, or funders. We will not be able to delete the data you have already given us, as we are required to keep all data, by law, for 15 years or more. Your data may be used in analyses, unless you request that we don't use it before we finish data collection.

Has this study been approved by an Ethics Committee?

Yes. This study is approved by Deakin University Human Research Ethics Committee (Project Number: 2023-132).

Who is running the study?

HypoPAST is led by the Australian Centre for Behavioural Research in Diabetes (ACBRD). The ACBRD is a partnership for better health between Deakin University and Diabetes Victoria. We are supported by our colleagues at the following organisations: Australian Diabetes Educators Association, Australian Diabetes Society, Diabetes Australia, La Trobe University, Monash University, and Newcastle University (UK).

The lead researcher is Professor Jane Speight (Director, ACBRD). Professor Speight takes responsibility for the HypoPAST study and is the data custodian.

How is the study funded?

The study is funded by the Medical Research Future Fund (MRFF) Targeted Translation Research Accelerator (TTRA), with in-kind support from our partners, Diabetes Australia, Australian Diabetes Educators Association, Australian Diabetes Society, La Trobe University, Monash University, and Newcastle University. In-kind support means that our partners are providing their time and/or expertise to the project without charge. The 2-year funding from the TTRA is $749,764. With the in-kind support, the value of the HypoPAST funding is $1.16 million.

Who can I contact for more information about this study?

Jennifer Halliday (HypoPAST project manager)

Email: j.halliday@deakin.edu.au Telephone: 03 9244 5278

or

Professor Jane Speight (HypoPAST study lead and Director, ACBRD)

Email: jane.speight@deakin.edu.au Telephone: 03 5227 8415.

Who do I contact if I have a complaint about the study?

If you have any complaints about the way the project is run or questions about your rights as a research participant, contact: The Human Research Ethics Office, Deakin University, 221 Burwood Highway, Burwood Victoria 3125, Telephone: 9251 7129, research-ethics@deakin.edu.au

Please quote project number [2023-132].